

# ***e*IRB**

## **Electronic Institutional Review Board**

### **Medical University of South Carolina**

### **User Guide**



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# About this Manual

The Health Sciences South Carolina (HSSC) is a statewide biomedical research collaboration with a goal to improve the health of South Carolinians by advancing and streamlining research efforts, as well as health education and training.

The HSSC eIRB is a web-based system for IRB submissions and management. It is a paperless, electronic method to submit, track, and route all submission types through the approval process and provides a means to obtain and store information required for the safe conduct of human subject research. Seven (7) of HSSC member sites' IRBs use the eIRB system – AnMed Health Medical Center, Greenville Health System, Medical University of SC, Palmetto Health, Self Regional Healthcare, Spartanburg Regional Healthcare System and University of SC.

The **purpose** of this manual is to provide you with the skills to create, submit and track initial protocols, modifications, continuing reviews and reportable events at MUSC. In addition, you will learn how to navigate through the system and to become familiar with all application tools.

To advance throughout the system, a response must be included for questions labeled with a red asterisk. This manual will also help to identify the additional questions in the system that do not include a red asterisk but that require a response for an adequate MUSC IRB submission and review.

**\*\*As additional resources, including printable and recorded demonstrations of system functions, are available in the eIRB [Education & Training](#) section and the [MUSC eIRB Training and Guidance](#) website.\*\***

## Objectives

To familiarize yourself with eIRB environment, you will

- Access the HSSC eIRB
- Navigate through the workspaces
- Use the SmartForms to enter protocol information

## In using this manual you will learn to:

- Log on to eIRB
- Become familiar with the components of the eIRB environment
- Navigate through the workspace
- Create and edit, submit and track all activities in accordance with MUSC IRB review for all study types:
  - Full Board Review
  - Expedited Review
  - Exempt Review
  - Not Human Subjects Research Review
  - Multi-Site Research Reviews (MUSC IRB Centralized Review, Facilitated Review, NCI CIRB Independent Review, External IRB Review)
- Respond to review comments
- Access IRB review documents

**\*\*italicized NOTES and text boxes are designed to give you helpful hints as you use eIRB\*\***

*Disclaimer: the content in this manual is subject to routine updates as the system is refined*

# GETTING STARTED

## Logging in to eIRB

For additional assistance, view the recorded demonstration 'Getting Started' in the eIRB [Education & Training](#) section.

To begin utilizing the system, assess the internet site by clicking [HERE](#).

From the drop down list, select Medical University of South Carolina as your Organization.

*If you are an External Affiliate member of MUSC (e.g., not an MUSC employee), select 'MUSC External Affiliate')*

Click Continue.



Enter in your MUSC netID and password and click Login.

*\*\*Note: This is the same as your MUSC systems account log on information. \*\**



First time users of the system will get a registration screen to begin using the system. Completely fill out the information, and select 'Register'.

*\*\*Note: If you are a student and will be the PI of a project, you must respond 'Yes' to the question about Student/Trainee. \*\**

An e-mail will be sent to MUSC's eIRB administrator to activate your account, and you will receive an e-mail confirming that your registration is complete.

**Registration**

A valid user account is required to use the eIRB system. If you are a first time user, please complete the following information for registration. Personnel involved in conducting human subjects research are required to complete the CITI web-based course on protection of human research subjects.

All eIRB Users should login to CITI and complete the following:  
a. Ensure First and Last Name match eIRB registration  
b. Ensure the Preferred Email in CITI matches your Primary Email in eIRB

Honorific: -- Select One --

\*First Name:   
Middle:   
\*Last Name:   
Suffix:  (For example PhD, MD, RN, MS, BA, etc.)

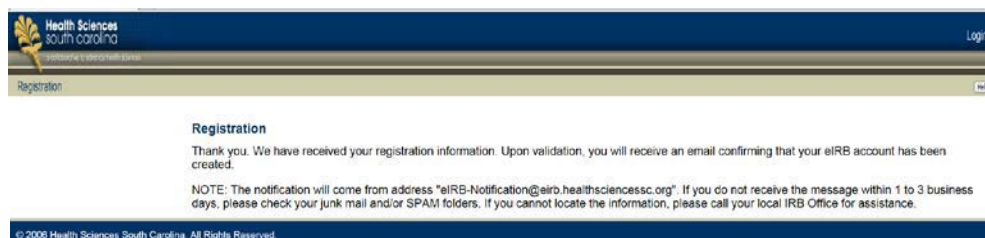
Position Title:   
\*Department/Affiliation Name:

\*Student/Trainee?: ☐ Yes ☐ No

\*Business Phone:   
Mobile Phone:   
Home Phone:   
Fax:   
\*Primary Email:

Business Address  
\*Line 1:   
Line 2:   
Line 3:   
\*City:   
\*State: -- Select -- \*Zip:   
Country: -- Select One --

\* Required



After logging in the eIRB main page with access to MUSC guidance material becomes available. This can be accessed throughout the system by selecting the eIRB tab.

*System Education and Training Material, including recorded demonstrations of system functions and resource documents are also available at login by selecting the Education and Training tab.*

**eIRB** Education and Training Studies

**Welcome to the Health Sciences South Carolina (HSSC) electronic Institutional Review Board (eIRB), the application to manage the IRB research process.**

Access eIRB educational material in the [Education and Training](#) section, **located in the top navigation pane.**

**System outages:**

**eIRB will be unavailable during all scheduled times listed below. Users will not be able to log in:**

- DAILY System Maintenance:** Beginning at 12:30 am each morning, system maintenance is performed on the eIRB system. This process takes up to 2 hours to complete.
- System Updates:** the next system changes are scheduled for Wednesday May 18, 2016 from 5:00 am - 6:00 am.

**To ensure content remains in the system, users should save their work before these outages begin.**

**Navigation Links:**

- AnMed Health Medical Center
- Greenville Health System
- Medical University of South Carolina
- Palmetto Health
- Self Regional Healthcare
- Spartanburg Regional Healthcare System
- University of South Carolina
- Announcements
- Code of Federal Regulation/Ethical Principles

## My Home

For additional assistance, view the recorded demonstration 'Getting Started' in the eIRB [Education & Training](#) section.

The eIRB 'My Home' page is home page for your personal workspace. From this screen, you can access all your IRB approved studies and view those studies awaiting approval.

After logging into the system, the eIRB main log in page appears.

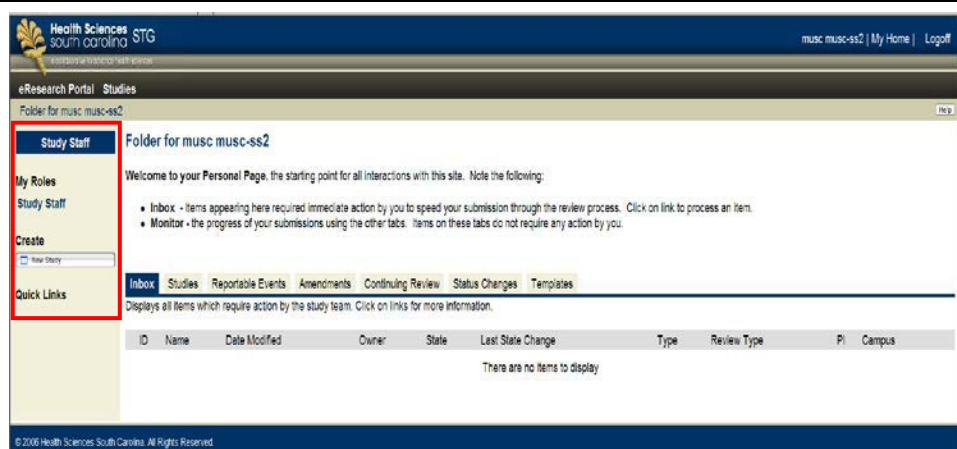
Select 'My Home' to view your personal workspace.



This screen is your Personal Workspace or 'My Home'.

The left Navigation column lists the 'Roles' assigned to you, allows you to create new studies, includes any system quick links and lists all your projects' activities.

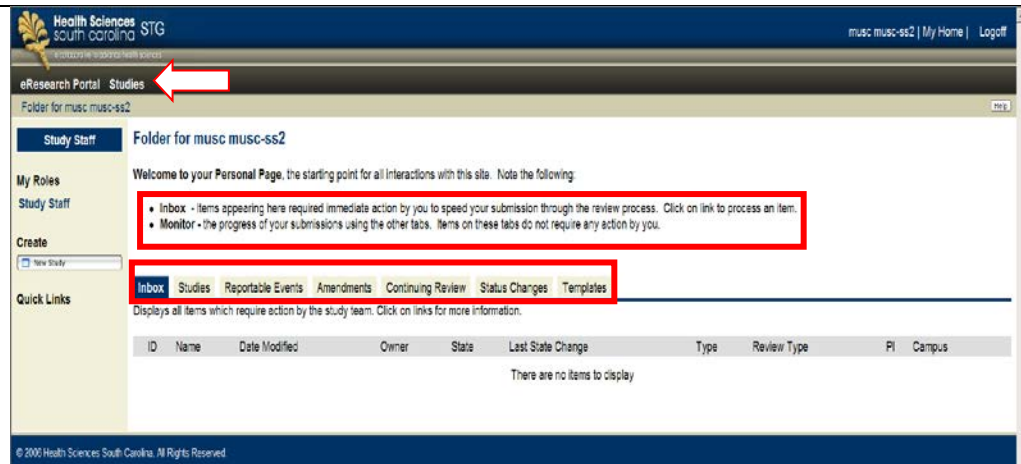
*\*\*Note: click 'My Home' from any page to bring you back to your personal workspace to access studies and items that require action\*\**



Your active research Roles are identified in the left navigation column. At log in, these roles have been defined by institutional administrators. Roles include:

- Study Staff – includes all research staff (Principal Investigator (PI), Co-Investigators (Co-I), coordinators, and other study staff). Users with this role are able to create and modify study applications, amendments, continuing reviews and reportable events, if they have been granted those study rights. *(Note: The PI role is included in the study staff role. If institutional administrators have defined one of your roles as a PI, you will have additional options to submit study applications.)*
- Mentor – the role for review and approval of mentored IRB application. *(Note: Mentees may be students (medical, dental, graduate or nursing), post-doctoral fellows, residents, interns and any others as determined by the advising department.)*
- Department/Division/Ancillary Approvers – the role for review and approval of IRB applications within the colleges, often prior to receipt by the IRB.
- IRB Staff – the role for the IRB office to process and manage submissions.
- IRB Member – the role for IRB members to review submitted study applications.
- IRB Chair – the role for IRB chairs to complete activities at the IRB Chair level.

At 'My Home' you can go to the eIRB homepage or your study listings.



'My Home' includes brief instructions for the tabs on the screen. From these tabs, you can access action items relative to IRB submissions and view progress of an IRB submission. Tabs on 'My Home' include:

- The 'Inbox' tab contains activities that require some action on your part (for instance, new studies or amendments to finish that have not yet been submitted to IRB).
- The 'Studies' tab will show all studies of which you are associated. You can click on the 'Name' of a particular study to view the details of the study and perform tasks. *You can also see all of your studies by clicking the 'Studies' link at the top of the page.*
- The 'Reportable Events' tab contains the reported safety events, deviations and safety committee reports completed within the system.
- The 'Amendments' tab contains all changes in process or completed within the system for all studies.
- The 'Continuing Review' tab contains the continuing reviews entered into the system for all studies.
- The 'Status Changes' tab contains the changes to a study's enrollment status as entered into the system.
- The 'Templates' tab contains study templates you have created as a non-editable copy to model future submissions.

# CREATING NEW APPLICATIONS

For additional assistance, view the recorded demonstration “Created and Submitting New Studies” in the [eIRB Education & Training](#) section.

## Beginning all application types

On your Personal Workspace screen, click New Study on the left Navigation column.

*\*\*Note: If you don't see the option to create a new study, you may have multiple roles assigned in the system. If so, click on the 'Study Staff' role.* \*\*

The top screenshot shows the 'Health Sciences South Carolina STG' interface. In the left navigation column, the 'New Study' button is highlighted with a red rectangle. The main content area shows a 'Folder for shyam musc-surgery-ss' with a 'Welcome to your Personal Page' message and a list of items in the 'Inbox'.

The bottom screenshot shows the same interface but with the 'Study Staff' role selected in the 'My Roles' section. A red arrow points to the 'Study Staff' role. The main content area shows a 'Folder for musc musc-radiology-dept2' with a 'Welcome to your Personal Folder' message and a list of items in the 'My Inbox'.

eIRB SmartForms will begin. The SmartForm is designed to guide you through the process. Depending upon your answers, eIRB will select applicable forms that you should complete for a successful submission. To ensure that this occurs, it is important to use the Continue button, particularly after completing the first page of a form. After saving the first page, you may use the Continue button or 'Jump To' another section feature to save information entered in on the rest of the form.



Enter the Study Identification Information.

Click Continue.

***\*\*Note: all fields marked with an asterisk (\*) must be completed\*\****

The screenshot shows the 'Study Identification Information' form. It includes sections for: 1.0 Full Title (with a text input field), 2.0 Short Title (with a text input field and a character count), 3.0 Briefly describe the scientific or scholarly rationale (with a text input field), 4.0 Brief Study Summary (with a text input field and a note about its use for recruitment), and 5.0 Is this a pilot study? (with radio buttons for Yes, No, and Clear).

Select MUSC on the Institution page to request review by MUSC IRB.

Click Continue.

***\*\*Note: throughout each type of submission, you will have the option at the top of the page to Save, Exit, Hide/Show errors in your application, or Print\*\****

The screenshot shows the 'Institution' page. It features a section titled '1.0 \* Select the appropriate Institutional Review Board (IRB) for review:' with a list of radio button options: AnMed Health Medical Center, Greenville Health System, Medical University of South Carolina (which is selected), Palmetto Health, Self Regional Healthcare, Spartanburg Regional Healthcare System, and University of South Carolina. There is also a 'Clear' link. At the bottom, there is a navigation bar with buttons for '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', and a dropdown menu currently showing '- Study Identification - Institutional Review Board'.

<h2>IRB Review Request</h2> <p>Select whether study requests a different IRB Review process if it is a multi-site study.</p> <p><i>**See SmartForm descriptions of these types of reviews. **</i></p> <p>Only one type can be selected. If you select yes to any of these reviews, you will be routed to the appropriate SmartForm pages.</p> <p><i>*Click one of the links below to go to the section of this document that describes a review process on this page.</i></p> <p><i>Otherwise, continue within this section*</i></p> <p><a href="#">Central Review</a>  <a href="#">Facilitated Review</a>  <a href="#">NCI CIRB Independent</a>  <a href="#">External Review</a></p>	<p><b>IRB Review Request for Multi-site Studies</b></p> <p>The <b>IRB of Record</b> is the IRB with the primary responsibility for reviewing a study. For a multi-site study, the internal IRB may serve as the IRB of Record for other sites as well, or they may defer review to another IRB. <b>If you are requesting one of these IRB reviews, indicate the type below. Otherwise, click Continue on this page.</b></p> <p><b>IRB OF RECORD IS YOUR INTERNAL IRB</b></p> <p><b>Central Review</b></p> <p>1.0 The review model where your internal IRB has agreed to serve as the single, central IRB of Record for other sites involved in a multi-site study. Be sure to contact your local IRB to assure that appropriate authorization agreements have been or will be executed.</p> <p><i>The institutions that allow this in eIRB are MUSC.</i></p> <p>* Is this a Central Review?</p> <p><input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p><b>IRB OF RECORD IS ANOTHER IRB</b></p> <p><b>Facilitated Review</b></p> <p>2.0 The review process used by your local, internal IRB as they make the determination whether or not to accept another IRB's review of a study.</p> <p><i>All institutions allow this review in eIRB.</i></p> <p>* Is this a Facilitated Review (non-HSSC IRB, non-NCI CIRB, non-contracted IRB)?</p> <p><input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p><b>Independent Review Model</b></p> <p>3.0 The review model where the NCI CIRB is the sole IRB of Record responsible for both study review as well as review of local content considerations for enrolled institutions.</p> <p><i>The institutions that allow this review in eIRB are MUSC, GHS, SHS, PH, AnMed and Self Regional.</i></p> <p>* Is this an Independent Review (NCI CIRB)?</p> <p><input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p><b>External IRB Review</b></p> <p>4.0 The review process used by your local, internal IRB where they defer IRB review to a contracted IRB. The external IRB becomes the IRB of record for all aspects of the study.</p> <p><i>The institutions that allow this review in eIRB are MUSC, GHS, SHS, AnMed and Self Regional.</i></p> <p>* Is this an External IRB Review (e.g., WRB, etc.)?</p> <p><input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p>
<p>Select the appropriate IRB Committee (IRB I, II or III). This selection of the appropriate board is the same as the current system.</p> <p>Click Continue.</p>	<p><b>MUSC Institutional Review Board Selection</b></p> <p>1.0 * Select the appropriate committee:</p> <p><input type="radio"/> IRB-I - Medical    Cell Biology and Anatomy, Cell and Molecular Pharmacology &amp; Experimental Therapeutics, Clinical Services, College of Health Professions, College of Nursing, College of Pharmacy, Dermatology, Harper Student Life Center, Medical Lab Sciences, Otolaryngology, Pathology and Laboratory Medicine, Pediatrics, Pharmaceutical Sciences, Pharmacy Practice, Physical Therapy, Psychiatry and Behavioral Sciences, Radiology, Urology</p> <p><input checked="" type="radio"/> IRB-II - Medical    Anesthesiology, Biochemistry and Molecular Biology, Center For Health Care Research, Experimental Oncology, Family Medicine, General Dentistry, Graduate Studies, Medicine, Microbiology and Immunology, Molecular and Structural Biology, Neurosciences, Obstetrics and Gynecology, Ophthalmology, Oral &amp; Maxillofacial Surgery, Orthopedic Surgery, Pediatric Dentistry/Orthodontics, Physical Medicine &amp; Rehabilitation, Prosthodontics, Public Health Sciences, Radiation Oncology, Stomatology, Surgery</p> <p><input type="radio"/> IRB-III - Medical    Industry Sponsored Trials</p> <p><a href="#">Clear</a></p>



## Adding Study Personnel

Indicate whether or not all study personnel are affiliated with MUSC.

Click Continue.

**\*\*Note:** Those affiliated with MUSC include faculty, employees, students & personnel required to obtain an MUSC netID to participate in this study. This question is asking if other [HSSC](#) sites are also participating in this study. If the answer is no, the next list of personnel will include those from all HSSC institutions. \*\*

**\*\*Note:** To be located in eIRB, personnel must have an MUSC netID assigned. If the name is not found, contact an [eIRB systems administrator](#) for assistance with adding the personnel to the system. \*\*

Begin typing in a name or use 'Select' button to choose the Principal Investigator and Study Coordinator. These two roles will receive e-mail notification from eIRB when changes are required or an IRB review is complete.

Do the same when choosing Co-Investigators, other Study Staff and guests.

PIs, Co-Is and study coordinators have automatic read/edit access. This type of access will need to be indicated for other study personnel as they are added.

Guests may be added to view the details of the study. Guests must also have MUSC netIDs and will have read-only access. After a study has been approved by the IRB, the guest list may be revised at any time from the main protocol workspace *without* an amendment to the protocol.

**\*\*The PI and study coordinator roles are automatically defaulted to whoever is initially logged in (depending on the role assigned by the system). You may need to change this to the correct personnel.**

**If you are changing your name from one personnel role to another, FIRST add your name to the new role and THEN delete yourself from the old role. This will let you to continue preparing the IRB application without being removed from the study.**

**Only one PI and study coordinator can be indicated, per study. You can select more than one Co-Investigator, other personnel and guests. \*\***

Multiple Co-Is can be chosen at a time by searching for the name & selecting the check box next to the Co-Is name. The next Co-I can be added by following this step.

Click Ok when done adding all Co-Is.

**\*\*Note:** To search for the name you may type in the whole name or filter criteria. To filter, you may use the percent sign (%) as a wild card search function for partial names. Click Go to begin the search. \*\*

Select One or More Persons

Filter by: Last [Go] [Clear] [Advanced]

First	Last	Organization
<input type="checkbox"/>	Aaronson	UROLOGY - MUSC
<input type="checkbox"/>	Abdallah	Medical University of South Carolina
<input type="checkbox"/>	Abdel-Hafez	OPHTHALMOLOGY - MUSC
<input type="checkbox"/>	Abennethy	ANESTHESIA AND PERIOPERATIVE MED - MUSC
<input type="checkbox"/>	Abou-Fayssal	Medical University of South Carolina
<input type="checkbox"/>	Abraham	Medical University of South Carolina
<input type="checkbox"/>	Acerno	NATIONAL CRIME VICTIMS CENTER - MUSC
<input type="checkbox"/>	Ackerman	RADIOLOGY - MUSC
<input type="checkbox"/>	Accell	ANESTHESIA FOR NURSES - MUSC
<input type="checkbox"/>	Adams	GENERAL SURGERY - MUSC
<input type="checkbox"/>	Adams	Medical University of South Carolina
<input type="checkbox"/>	Adams	Medical University of South Carolina
<input type="checkbox"/>	Alfin	HEMATOLOGY/ONCOLOGY - MUSC
<input type="checkbox"/>	Aguero	RADIATION ONCOLOGY - MUSC
<input type="checkbox"/>	Ahlsstrom	Medical University of South Carolina
<input type="checkbox"/>	Ahn	Medical University of South Carolina
<input type="checkbox"/>	Alenzy	OB/GYN GROUP - MUSC
<input type="checkbox"/>	Alkayubi	PHARMACOLOGY - MUSC
<input type="checkbox"/>	Alonesius	STOMATOLOGY - MUSC
<input type="checkbox"/>	Alberg	BIOSTATISTICS AND EPIDEMIOLOGY - MUSC
<input type="checkbox"/>	Aiele	ENDOCRINOLOGY - MUSC
<input type="checkbox"/>	Allen	HPCC - MUSC
<input type="checkbox"/>	Allison	GENERAL SURGERY - MUSC
<input type="checkbox"/>	Alpert	ANESTHESIA AND PERIOPERATIVE MED - MUSC
<input type="checkbox"/>	Amells	HPCC - MUSC

OK Cancel

Other study team members must be added one at a time so that study roles can be identified.

**\*\*Note:** Other study team members must have role descriptions included and study edit access rights identified. \*\*

Instructions:

- Use this form to add additional personnel to the team.
- Do not add Co-Investigators or the primary Study Coordinator here.
- You may add multiple people by clicking the 'OK Add Another' button.

Other Study Team Member

Press on the Select button, find the person you want to add:

[None] [Select]

Role On Study

Enter a description of the role this person will be performing on this:

Allow team member to maintain(edit) study application:

Yes No Clear

Required

OK OK and Add Another Cancel

Select the person's name from the pick list.

A description of the personnel's study function is required for MUSC IRB review.

**\*\*Note:** To search for the name you may type in the whole name or filter criteria. To filter, you may use the percent sign (%) as a wild card search function for partial names. Click Go to begin the search.

Instructions:

- Use this form to add additional personnel to the team.
- Do not add Co-Investigators or the primary Study Coordinator here.
- You may add multiple people by clicking the 'OK Add Another' button.

Other Study Team Member

Press on the Select button, find the person you want to add:

[None] [Select]

Role On Study

Enter a description of the role this person will be performing on this:

Allow team member to maintain(edit) study application:

Yes No Clear

Required

Select Person

Filter by: Last [Go] [Clear] [Advanced]

First	Last	Organization
<input type="checkbox"/>	Nadour	Alaa Greenville Hospital System
<input type="checkbox"/>	Aamir	Sayed Internal Medicine - USC
<input type="checkbox"/>	Abennethy	Jason Linguistics Program - USC
<input type="checkbox"/>	Ables	Adrienne Spartanburg Regional
<input type="checkbox"/>	Aboulan	Kal Greenville Hospital System
<input type="checkbox"/>	Abrams	Randel Greenville Hospital System
<input type="checkbox"/>	Absher	John Greenville Hospital System
<input type="checkbox"/>	Account Manager	Clemson University
<input type="checkbox"/>	Ackard	Trudy Self Registration
<input type="checkbox"/>	Ackard	Trudy Greenville Hospital System
<input type="checkbox"/>	Ackerman	Mary Hematology-Oncology - PHR
<input type="checkbox"/>	Adams	Samuel Greenville Hospital System
<input type="checkbox"/>	Swann	Cancer Prevention Control Program - USC
<input type="checkbox"/>	Adcock	David Radiology - USC
<input type="checkbox"/>	Addonizio	Frank Social Work College of - USC

OK Cancel

"Clear" removes radio button/selection only.

Indicate eIRB communication coordinator(s) for the study.

In addition to the PI and study coordinator, the person(s) indicated here will receive e-mail correspondences from IRB when actions are required or reviews have been completed for the study.

*\*\*Note: Only personnel who have been granted study edit rights are able to serve as an eIRB communication coordinator, which can be changed at any time from the main protocol workspace and without an amendment.\*\**

Click Continue.

## Study Locations

Identify study sites.

Click Continue.

*\*\*Note: When indicating the use of centers, such as VAMC, SCTR Research Nexus, HCC and IDS, a notice will be sent to the center that a project may be forthcoming. While the center will be given automatic guest access to view study details in eIRB, project submission through the routine process for that center is still required.\*\**

*\*\*Note: if completing a Not Human Research Review application, click [here](#) to go to that section of this guide to finish completing the application\*\**

"Affiliated" sites include MUSC, its affiliates & non-MUSC sites for which an off-campus form is required (see below).

If the project involves MUSC as the lead investigative site & is using off campus non-MUSC sites (other than HSSC institutions using eIRB), responses are required for MUSC IRB review. You will be prompted to upload an off campus form for each site.

The answer to this question should be 'yes' if there are multiple sites involved in the study.

## Off-Campus

### 1.0 Click the link below to access the Off Campus Form

<http://academicdepartments.musc.edu/research/oir/irb/IRB%20Forms/Off-Campus%20Study%20Site%20Form.doc>

\* Upload a completed Off Campus Form for each external site:

Add

Upload Revision

Upload Revision

If the project involves MUSC as the lead investigative site & is using off campus non-MUSC sites (other than HSSC institutions using eIRB), upload off campus forms and supporting documents (i.e., letter of support, etc.) for each site. See guidance.

Created	Last Modified
9:52 AM 2/27/2013	9:51 AM 2/27/2013

If multiple HSSC institutions are involved, include responses.

*\*\*Note: Clemson University is not participating as an HSSC eIRB site. If Clemson is used in this study, an off-campus site form must be completed and the Clemson personnel must obtain an MUSC netID. See notes within eIRB.\*\**

Answers within this section will initiate cooperative IRB review (i.e., reciprocal review) among HSSC institutions.

*\*\*Note: The collaborating institution's IRB reserves the right to its own full IRB review instead of a cooperative review. This would require a new study to be submitted & reviewed by that IRB and may require an amendment to the original study to exclude the collaborating institution from the study.\*\**

*Please reference the [eIRB Study Sites and Multiple Sites guidance](#) document for additional assistance with responding to questions in these sections.*

**Multiple Study Sites**

1.0 Cooperative Review is a process where collaborating Health Sciences South Carolina (HSSC) institutions are requested to accept one of the IRB's review of a single study.

\* Is this project requesting review by other HSSC sites' IRB(s) through the cooperative review process? ☒ Yes ☐ No [Clear](#)

If the research study will be conducted at other HSSC site(s), check all that apply:

Name
<input type="checkbox"/> AnMed Health Medical Center
<input type="checkbox"/> Greenville Health System
<input type="checkbox"/> Palmetto Health
<input type="checkbox"/> Self Regional Healthcare
<input type="checkbox"/> Spartanburg Regional Healthcare System
<input type="checkbox"/> University of South Carolina

Identify a PI at each collaborating institution for an HSSC Cooperative Review submission:

Name	Organization
Christine Turley	Pediatrics - USC

Upload the site specific document(s) required with an HSSC Cooperative Review submission:

AnMed Health Medical Center  
Greenville Health System  
Medical University of South Carolina  
Palmetto Health  
Self Regional Healthcare  
Spartanburg Regional Healthcare System  
University of South Carolina

Collaborating Institutions Documents:

Name	Version	Orig. Author	Orig. Created
There are no items to display			

☐ Clemson University (Clemson University researchers collaborating with other HSSC institutions must contact the Clemson IRB (irb@clemson.edu, 864-656-3100). University IRB is not possible within the eIRB system.)

2.0 If the research study will be conducted at other local or U.S. sites/institutions, list all of the non-HSSC sites at which the Principal Investigator will conduct the study.

3.0 Will you or your research personnel conduct this research study at other institutions/sites outside of the US?  
☐ Yes ☒ No [Clear](#)

If yes, list the institutions and countries below.

4.0 **Lead Investigator of a Multi-Site Study**  
If you are the lead investigator of this multi-site study, briefly describe how the lead investigator will manage information that is relevant to the protection of participants.

- Unanticipated problems involving risks to participants or others
- Interim results
- Amendments/Revisions

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Study Identification - Multiple Study Sites - v2.0

A 'yes' response will initiate a collaborative review among HSSC IRBs.

Include a collaborating site investigator and collaborating site documents if this is an HSSC cooperative review study.



## Human Research Requirements

Indicate if the study meets Human Subjects Research requirements.

Click Continue.

*\*\*Note: if conducting a Humanitarian Use Device (HUD) study, indicate 'Yes' for question 3 to ensure proper IRB review. Please contact your IRB for additional information and requirements for Humanitarian Use Device (HUD) submissions\*\**

### Human Subjects Research

The following questions will assist you in determining whether this project meets the federal requirements for Human Subjects Research.

1.0 \* Is this project a systematic investigation, including research development, testing, and evaluation, designed to develop or to contribute to generalizable knowledge?

☒ Yes ☐ No [Clear](#)

Note: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>

2.0 \* Does this project involve the investigator obtaining data about living individuals through 1) intervention or interaction with the individual; or 2) identifiable private information?

☒ Yes ☐ No [Clear](#)

Note: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>

3.0 Does this project involve a Humanitarian Use Device (HUD)? A HUD is a device intended to benefit patients in the treatment or diagnosis of a disease or condition affecting fewer than 4,000 individuals in the US per year. See additional guidance on HUD Designations.

☐ Yes ☒ No [Clear](#)

## CITI Training Records

This form assists the research team in verifying listed PI, Study Coordinator, Co-Investigators and Other Study Staff members' research training required for initial and continued study approval.

*In order for personnel training to display in eIRB, the study staff members: Names and preferred email addresses must be the same in eIRB and CITI and that required research training for the affiliated research site must be complete and appear in the matched CITI account.*

For additional guidance for this feature is located in the [Education & Training](#) section of eIRB.

### CITI Training Records

VIEWR02232F2A5CA06F

Review this information when considering if human subjects research education/training is complete for all investigators and study staff. Personnel training displayed are the current and historical records required by the institution associated with the team member's eIRB user account.

**NOTE: All study team members must be in compliance with training requirements prior to beginning any role in the study.**

If training is missing or expired:

1. Instructions for completing research education requirements can be found at [www.musc.edu/citi](http://www.musc.edu/citi).
2. Verify this institution's affiliation has been added to the CITI user profile and complete the required training.
3. Verify the first name, last name and preferred email of the CITI user profile matches the eIRB user profile.

The content on this page is provided as a tool to display research training records in real time. These data are routinely updated and are, therefore, current at the present viewing of this content.

#### 1.0 Principal Investigator CITI Completion Records

Name	Organization	Completed CITI Training			
		Curriculum	Group	Stage	Date Earned
					Date Expires

#### 2.0 Study Coordinator CITI Completion Records

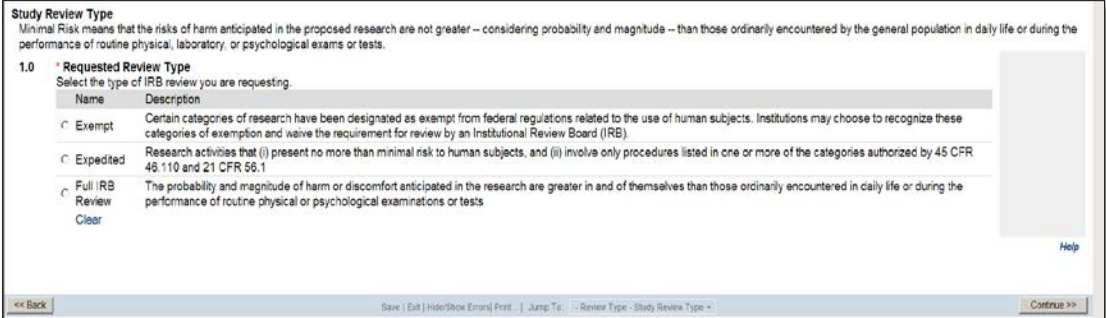
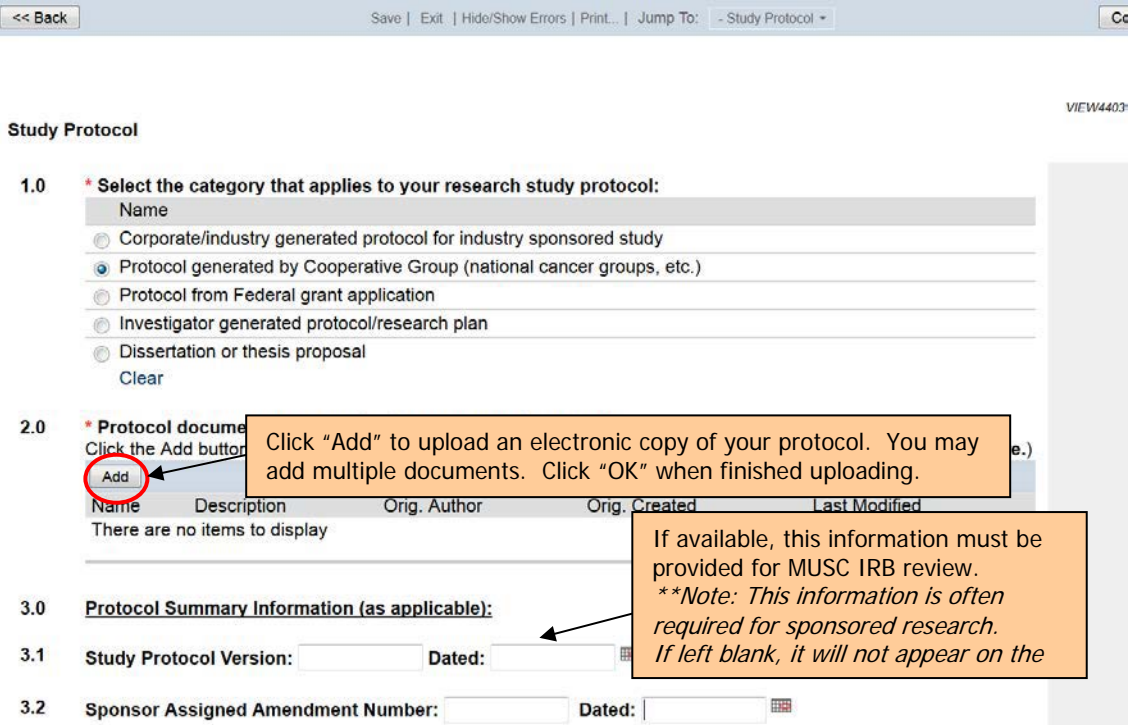
Name	Organization	Completed CITI Training			
		Curriculum	Group	Stage	Date Earned
					Date Expires

Click on the appropriate study review type below for guidance to finish completing the application:

- [Full Board Review](#)
- [Expedited Review](#)
  - [Category 5 Retrospective Only Review](#)
- [Central Review](#) (MUSC serves as the Single IRB for a multi-site study)
- [Facilitated Review](#)
- [NCI CIRB Independent Review](#)
- [External Review](#)
- [Exempt Review](#)
- [Not Human Research Review](#)

## Request for Full Board Review

If not already completed, follow the steps in the [‘Beginning the Application’](#) section.

<p>Indicate Study Review Type as “Full IRB Review”.</p> <p>Click Continue.</p>																	
<p><b>Protocol Information</b></p> <p>Enter Study Protocol Information.</p> <p>Click Continue.</p> <p><i>**Note: a scientific protocol template is available at the <a href="#">IRB's website</a> <a href="#">here</a>**</i></p>	 <p><b>Study Protocol</b></p> <p>1.0 * Select the category that applies to your research study protocol:</p> <table border="1"> <thead> <tr> <th>Name</th> </tr> </thead> <tbody> <tr> <td><input type="radio"/> Corporate/industry generated protocol for industry sponsored study</td> </tr> <tr> <td><input checked="" type="radio"/> Protocol generated by Cooperative Group (national cancer groups, etc.)</td> </tr> <tr> <td><input type="radio"/> Protocol from Federal grant application</td> </tr> <tr> <td><input type="radio"/> Investigator generated protocol/research plan</td> </tr> <tr> <td><input type="radio"/> Dissertation or thesis proposal</td> </tr> </tbody> </table> <p>2.0 * Protocol documents Click the Add button</p> <p><b>Add</b></p> <p>Click “Add” to upload an electronic copy of your protocol. You may add multiple documents. Click “OK” when finished uploading.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Description</th> <th>Orig. Author</th> <th>Orig. Created</th> <th>Last Modified</th> </tr> </thead> <tbody> <tr> <td colspan="5">There are no items to display</td> </tr> </tbody> </table> <p>3.0 <b>Protocol Summary Information (as applicable):</b></p> <p>3.1 Study Protocol Version: <input type="text"/> Dated: <input type="text"/></p> <p>3.2 Sponsor Assigned Amendment Number: <input type="text"/> Dated: <input type="text"/></p> <p>If available, this information must be provided for MUSC IRB review.  <i>**Note: This information is often required for sponsored research. If left blank, it will not appear on the</i></p>	Name	<input type="radio"/> Corporate/industry generated protocol for industry sponsored study	<input checked="" type="radio"/> Protocol generated by Cooperative Group (national cancer groups, etc.)	<input type="radio"/> Protocol from Federal grant application	<input type="radio"/> Investigator generated protocol/research plan	<input type="radio"/> Dissertation or thesis proposal	Name	Description	Orig. Author	Orig. Created	Last Modified	There are no items to display				
Name																	
<input type="radio"/> Corporate/industry generated protocol for industry sponsored study																	
<input checked="" type="radio"/> Protocol generated by Cooperative Group (national cancer groups, etc.)																	
<input type="radio"/> Protocol from Federal grant application																	
<input type="radio"/> Investigator generated protocol/research plan																	
<input type="radio"/> Dissertation or thesis proposal																	
Name	Description	Orig. Author	Orig. Created	Last Modified													
There are no items to display																	

Study Subjects  
Enter information regarding the subjects you will include in the study.

Check all subject populations that are involved in this study.

*\*\*Note: the system will prompt you to answer questions regarding vulnerable populations if they are a part of your study or if there is no intent to include set groups\*\**

Describe the population, inclusion/exclusion & recruitment procedures.

Click Continue.

#### Study Subjects

1.0 \* Estimated Local Enrollment Goal

Enter the anticipated number of subjects to be enrolled at local site:

2.0 Estimated Study-Wide Enrollment Goal

Enter the anticipated number of subjects to be enrolled at all sites:

3.0 \* Briefly describe the setting in which the research will be conducted.

4.0 \* Participant Remuneration (Payment/Academic Credit)

Will subject(s) receive remuneration?

☒ Yes ☐ No [Clear](#)

5.0 \* Will prospective participants be vulnerable to coercion or undue influence?

☐ Yes ☒ No [Clear](#)

If yes, briefly describe additional safeguards included in the protocol to protect the rights and welfare of participants likely to be vulnerable.

A 'Yes' response indicates your population may be considered to be a vulnerable one (i.e., pregnant women, children, prisoners, cognitively impaired or another category for specialized research). Information must also be included in the text box.

6.0 \* Identify targeted subject population(s) involved in this research study (Note: The purpose of this question is to determine equitable selection of subjects and to identify vulnerable populations.)

Select all that apply:

- ☐ Adults (18+)
- ☐ Males
- ☐ Females
- ☐ Pregnant Women
- ☐ Human Fetuses or Neonates
- ☐ Minorities
- ☐ Children (<18 years of age)
- ☐ Prisoners
- ☐ Comatose persons
- ☐ Cognitively Impaired persons
- ☐ Terminally Ill persons
- ☐ Employees of the principal investigator's institution
- ☐ Students enrolled at the principal investigator's institution
- ☐ Non-English speaking persons
- ☐ Socially/Economically disadvantaged persons
- ☐ Caregivers
- ☐ Elderly/Aged persons
- ☐ Institutionalized Individuals

7.0 \* Study Population

Briefly describe the study population? (e.g. healthy volunteers, adults with Type II Diabetes, children with Asthma):

8.0 \* Describe the selection criteria (inclusion/exclusion criteria):

9.0 \* Describe recruitment procedures, including how subjects will be contacted, by whom, and how eligibility will be determined.

## Study Funding

Indicate study funding sources.

**\*\*Note:** if the 'Federal Government' is the funding source, a [Favorable Funding Score](#) Letter must be included.

*PIs (not including students) with internally or non-funded studies may be prompted to include details from the Intra-Institutional Transfer (IIT) form for an IRB review fee.*

Click Continue.

The screenshot shows the 'Study Funding Information' form in the Health Sciences Training system. The form is titled 'Study Funding Information' and includes a section for '1.0 Primary Funding Source (Active or Pending)'. Below this, there is a list of funding sources with checkboxes: Federal Government, Private Industry, Private Not-for-Profit Organization, State or Local Government, Internal Funding, Non-US Funding, Other, and No Funding. The 'Federal Government' checkbox is selected. The form also includes navigation buttons like 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', 'Funding and Sponsorship - Study Funding Info', and 'Continue'.

Indicate details of study sponsorship.

**\*\*Note:** if the sponsor information is omitted, it will not appear on the IRB review letter\*\*

Click Continue.

The screenshot shows the 'Study Sponsorship' form in the Health Sciences Training system. The form is titled 'Study Sponsorship' and includes sections for '1.0 Sponsor(s)', '2.0 Other Sponsor(s)', '3.0 External Identifier (if applicable)', and '4.0 Internal Identifier (if applicable)'. An annotation box is overlaid on the form, stating: 'At minimum, sponsor name must be provided for MUSC IRB review.' The form also includes navigation buttons like 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', 'Funding and Sponsorship - Study Sponsorship', and 'Continue'.

The Intra-Institutional Transfer (IIT) Smartform is required for faculty researchers of unfunded or internally funded (non-exempt) IRB studies.

*Please continue to consult with your business administrators to obtain the information required for IRB submission.*

Click Continue.

The screenshot shows the 'Internally Sponsored or Un-sponsored Research' form. The form is titled 'Internally Sponsored or Un-sponsored Research' and includes sections for '1.0 PAYING UDAK' and '2.0 IIT Number'. The '1.0 PAYING UDAK' section includes a text box for 'Please enter the paying UDAK for the \$100 IRB fee.' and a table with columns for 'Entity', 'Account', 'Unit', 'Project', and 'Reporting'. The 'Entity' column has a dropdown menu with 'MUC' selected. The 'Account' column has the value '50228'. The 'Unit', 'Project', and 'Reporting' columns have text boxes. The '2.0 IIT Number' section includes a text box for 'An IIT is not necessary; however, you may enter an IIT number along with the UDAK.' The form also includes a note: 'If Entity is MUCR, Enter Project Year (a sequential number representing the current grant year [i.e., 01, 02, etc.]).' The form also includes navigation buttons like 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', 'Funding and Sponsorship - Study Sponsorship', and 'Continue'.



Indicate the costs associated with the study.

Click Continue.

## Subject Remuneration

Describe Participant Remuneration.

*\*\*Note: this form is required if you indicated you will be giving remuneration to subjects \*\**

Click Continue.

## Application Checklist

Check all applicable items for this project.

*\*\*Note: the program will prompt you for additional information depending on your responses (i.e. if you have a DSMP are using drugs/devices, advertisements, radioactive substances, HSSC Clinical Data Warehouse (CDW), etc.).*

*You will also be prompted to upload a copy of all forms you'll use (i.e., advertisements, surveys/questionnaires, consents, etc.). \*\**

Click Continue.

### Application Checklist

#### 1.0 Will the following be involved in the research study?

Select all that apply

- ☒ Informed consent document(s)
- ☐ Waiver of the Requirement to Obtain Written and Recorded Informed Consent
- ☐ Waiver of Informed Consent of Subjects or Alteration of Requirements
- ☐ Clinical trials
- ☐ Data Safety Monitoring Plan is used in this research study.
- ☐ Medical Record/Chart Review
- ☐ Vaccine Trials
- ☐ Human Genetic Research
- ☐ Human In Vitro Fertilization
- ☐ Transplantation
- ☐ Alcohol and Drug Abuse Research
- ☐ Use of survey, questionnaire, focus group/interview questions
- ☐ Healthy, normal volunteers as research subjects
- ☐ Individuals with HIV/AIDS as research subjects
- ☐ Cancer-related research ?
- ☐ Drugs will be used in this research study
- ☐ Chemicals, metabolites, nutritional substances, biological agents or other substances whether regulated or not that will be administered to subjects
- ☐ Use of Placebos
- ☒ Investigation of medical device, instrument, machine, computer program or other device, FDA approved or not
- ☐ Specimens (blood, urine, tissue and other human products)
- ☐ The storage of biological specimens (e.g. biological material, tissue, blood, etc.) or Data (e.g. subject level data) for potential future, yet undesignated, research
- ☐ Recombinant or synthetic nucleic acid molecules, gene transfer, infectious agents, select agents or microorganisms
- ☐ Botulinum toxins exposure to human subjects
- ☐ The use of diagnostic or therapeutic ionizing radiation, or radioactive isotopes that are not part of clinical trials as part of this research study
- ☐ Advertisements or recruiting materials
- ☐ Data from the statewide Health Sciences South Carolina (HSSC) Clinical Data Warehouse ?

A clinical trial is a prospective biomedical or behavioral human subject research study that is designed to answer specific questions about biomedical or behavioral interventions or lab test evaluations and determine whether these are safe, efficacious and effective. These trials often require Data and Safety Monitoring Plans (DSMPs).

All relevant study activities must be indicated for MUSC IRB review.

## Data and Safety Monitoring Plan

If the study utilizes a data and safety monitoring plan (DSMP), provide descriptions and details of a Data Safety Review Board (if applicable).

Click Continue.

### Data and Safety Monitoring Plan (DSMP)

#### 1.0 Provide a general description of the data and safety monitoring plan:

#### 2.0 Is there a data and safety monitoring board/committee (DSMB/DSMC) to review for safety and adherence to the study protocol?

☒ Yes ☐ No [Clear](#)

#### 3.0 If yes, describe the composition of the board/committee and their qualifications:

#### 4.0 Describe the frequency of DSMB/DSMC reviews and reports, planned interim analysis, etc.

#### 5.0 Describe plans for assuring compliance with requirements regarding the reporting of Unanticipated Problems Involving Risks to Participants or Others and/or Adverse Events to the IRB and appropriate regulatory agencies.

<h3>Clinical Trials</h3> <p>Indicate the type of clinical trial applicable for the project.</p> <p>Click Continue.</p>	<div> <div> <h4>Clinical Trials</h4> <p>1.0 * What is the phase of the clinical trial?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Phase I clinical trial</li> <li><input type="checkbox"/> Phase II clinical trial</li> <li><input type="checkbox"/> Phase III clinical trial</li> <li><input type="checkbox"/> Phase IV clinical trial</li> <li><input type="checkbox"/> Symptom Management</li> <li><input type="checkbox"/> Prevention Trial</li> <li><input type="checkbox"/> Observational</li> <li><input type="checkbox"/> Interventional</li> <li><input type="checkbox"/> Other</li> <li><input type="checkbox"/> This study does not involve a clinical trial</li> <li><input type="checkbox"/> Open-Label Extension Study</li> </ul> <p>2.0 If OTHER, describe:</p> <div></div> </div> <div> <p><b>Visit ClinicalTrials.gov for descriptions of trial <a href="#">Phases</a>. Additional descriptions are below:</b></p> <p><b>Symptom Management trials</b> improve comfort and the quality of life for individuals with a serious or life-threatening illness.</p> <p><b>Prevention trials</b> look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals or lifestyle changes.</p> <p><b>Observational trials</b> assess outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine clinical care, but participants are not assigned to specific intervention by the investigator.</p> <p><b>Interventional trials</b> involve participants receiving specific interventions according to a research plan or protocol. These trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.</p> <p><b>Open-Label Extension Studies</b> are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.</p> <p><a href="#">ClinicalTrials.gov</a></p> </div> </div>
<h3>Study Procedures</h3> <p>Describe all procedures, those used solely for research and those performed as standard of care.</p> <p>Click Continue.</p>	<div> <h4>Study Procedures</h4> <p>(Blood draw, Imaging, Lab Tests, Physical Exam, Medical History)</p> <p>1.0 * Briefly describe the procedures to be performed solely as part of this research study.</p> <div></div> <p>2.0 * Briefly describe the procedures being performed already for diagnostic or treatment purposes (standard of care).</p> <div></div> </div>
<h3>Risks</h3> <p>Describe all potential risks and discomforts and precautions to minimize risks.</p> <p>Click Continue.</p>	<div> <h4>Study Risks and Precautions</h4> <p>1.0 * Risks, Discomforts and Potential Harms</p> <p>Briefly describe the risks associated with all aspects of the study. Include consideration of physical, psychological, social, financial, and other factors, as applicable.</p> <div></div> <p>2.0 * Describe the safety precautions that will be taken to minimize risks/harms. This should include your data protection management plan:</p> <div></div> </div>

## Potential Benefit

Select the potential benefit category and explain potential benefits to the subject and/or society.

Click Continue.

Health Sciences  
south carolina  
STG

Edit: Study - Pro00005028

VIEW443B0AE2F6000

**Potential Benefits**  
Benefits - A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation is generally not considered to be a research benefit.

1.0 **Benefit Category**  
Select a benefit Category:  
☐ This research study is not expected to directly benefit individual subjects, but is likely to yield generalizable knowledge which contributes to the field.  
☐ This research study involves the prospect of direct benefit to the individual subject.  
Clear

2.0 **What are the potential benefits of the research study to the subject and/or to society?**  
Explain:

Back Continue

## Conflict of Interest

Indicate potential Conflict of Interest.

Click Continue.

*\*\*Note: A 'Yes' response or privately funded studies will require responses on the next screens in the system to disclose the interest. In addition, conflicts of interest must be verified at the time of continuing review. \*\**

VIEW443B0CF00F0000

**Conflict of Interest**

**Definition - Conflict of Interest:** conflict of interest means that because of activities or relationships with other persons or organizations, an individual is unable, or potentially unable, to remain impartial, that the individual's objectivity is, or might be otherwise impaired, or that the individual has, or might acquire, an unfair competitive advantage. Information that is relevant to a conflict of interest determination includes stock holdings and investments of the individual, the individual's spouse or dependent children, current positions held or under negotiation, any other sources of income, involvement in the design, conduct, or reporting of the research and any other relevant information that may have a bearing on the individual's proposed participation.

**Definition- Financial Interest Related to the Research:** means financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.

1.0 **Do any of the participating study investigators or other research personnel (or their immediate family) have a financial and/or intellectual property interest in the sponsor or products used with this research study?**  
☐ Yes ☐ No Clear

Back Continue

## Consent Process

Describe Consent Process and upload consent form(s).

*\*\*Note: A watermark approval stamp template must be included in consenting documents. Access to the consent template & watermark stamp is available at the IRB's website [here](#).*

*If the HIPAA form is separate, it will be uploaded later in the application. \*\**

Click Continue.

The screenshot shows the 'Consent Process' form in a web browser. The form has several sections with numbered questions:

- 1.0 Will the consent be obtained from the subject? (Yes/No/Clear)
- 2.0 Will the consent be obtained from the subject's legally authorized representative? (Yes/No/Clear)
- 3.0 Describe any waiting period between informing the prospective participant and obtaining consent: (Text area)
- 4.0 Who will obtain consent? Please list Research Personnel Authorized and Qualified to obtain Informed Consent (Text area)
- 5.0 Describe the process (where, when and how) for obtaining consent. (Text area)
- 6.0 Consent Forms: To allow for documentation of IRB approval and electronic watermarking, please use the following link to access your institution's Informed Consent Form Template. (Link field)

Below section 6.0, there is a 'NOTE' and an instruction: 'Click the Add button to upload a copy of the consent form(s), including translated versions for this research study.' The 'Add' button is circled in red. Below this is a table with columns: Name, Version, Orig. Author, Orig. Created, and Last Modified. The table is currently empty, with the text 'There are no items to display' below it.

Annotations on the screenshot:

- An orange box with the text 'Responses must be provided for MUSC IRB review.' has arrows pointing to questions 2.0 and 3.0.
- Another orange box at the bottom with the text 'Click "Add" to upload the first electronic version of your consent form(s). You may add multiple documents. Click "OK" when finished uploading.' has an arrow pointing to the 'Add' button.

## Privacy and Confidentiality

Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

Select where study records and data collected will be stored. If "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)" is selected then explain how this device will be protected.

Indicate whether or not this project will use a federal Certificate of Confidentiality.

Click Continue.

***\*\*Note: A NIH Certificate of Confidentiality protects investigators and institutions from being forced to disclose research participants' identity in research projects with 'sensitive' topics (studies in which disclosure can have adverse consequences for the participant). \*\****

The screenshot shows the "Privacy and Confidentiality" section of the eIRB form. The form is titled "Health Sciences south carolina" and includes a "Save" button. The section is divided into three parts: 1.0, 2.0, and 3.0. Part 1.0 asks for a description of procedures and safeguards to protect privacy and confidentiality. Part 2.0 asks where study records and data will be stored, with options for "in a locked office", "in a locked cabinet", "Password protected network storage", "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)", and "Other". Part 3.0 asks if the study will use a National Institutes of Health (NIH) Certificate of Confidentiality, with options for "Yes", "No", and "Clear".

1.0 Describe the procedures and safeguards that will be implemented to protect the privacy and confidentiality of the participants' data. Include details, as applicable to the study, such as: privacy of interview site; procedures for coding/de-identifying data; provisions to avoid public identification/embarrassment of participants; persons with access to private identifiable data, etc.

2.0 Where will study records and data collected at this site be stored? Select all that apply:

- ☐ In a locked office
- ☐ In a locked cabinet
- ☐ Password protected network storage
- ☐ Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)
- ☐ Other

If OTHER, describe:

If information will be stored on an end-user/portable device, describe the security on the end-user/portable device that will be used:

3.0 Will the study use a National Institutes of Health (NIH) Certificate of Confidentiality?

☐ Yes ☐ No

If YES, what is the NIH Certificate of Confidentiality status?

☐ The NIH Certificate of Confidentiality has been approved

☐ Will apply for a NIH Certificate of Confidentiality for this study

Annotations on the form:

- An orange box with the text: "If 'Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)' is selected then explain how this device will be protected." with an arrow pointing to the "Password protected end-user/portable device" option.
- An orange box with the text: "As applicable, responses must be provided for MUSC IRB review." with arrows pointing to the "If information will be stored on an end-user/portable device, describe the security on the end-user/portable device that will be used:" and "If YES, what is the NIH Certificate of Confidentiality status?" sections.



## Protected Health Information (PHI)

Indicate if the study will access (view, obtain or use) participant protected health data.

Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI).

Click Continue.

**Protected Health Information (PHI) for Research**

Protected Health Information (PHI) is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future physical or mental health or conditions of an individual.

Covered Entity - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form.

1.0 \* To determine if this research study is using/disclosing PHI, select any of the following 18 elements that your study will require access to, as defined by the Health Insurance Portability and Accountability Act (HIPAA), as identifiers. If none of these 18 identifiers will be used/disclosed, then select the final option.

- ☐ Names
- ☐ All geographic subdivision smaller than a state including street address, city, county, precinct, zip code, and/or equivalent geocodes
- ☐ All elements of date (except year) for dates directly related to an individual (DOB, admission date, discharge date, date of death)
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ Social security numbers
- ☐ Medical record number
- ☐ Health plan Beneficiary number
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Any other unique identifying number, characteristic or code
- ☐ None of the above 18 identifiers will be used/disclosed for this research study

**Checking the last option means **no access to protected health information** is needed for the study.**

**However, if the study **has to access any of these identifiers** in order to obtain or associate health information, you must check all applicable identifiers on this page. *See notes on this Smartform***

*If the study requires access to any of the 18 identifiers but will not be linked to PHI, please select those that are applicable to the left. On the next screen, you will be able to select "Study where health information is not linked to identifiers".*

If indicating that PHI is accessed, check all the sources of health information and how the project is requesting access to it.

Click Continue.

**Health Sciences South Carolina**

Access to Protected Health Information (PHI) for Research

1.0 Indicate the sources of health information to be used. Select all that apply.

- ☐ Medical Records/Physician Notes/Hospital Discharge Records
- ☐ Psychotherapy Notes
- ☐ Medical Test Results
- ☐ Payment/Billing Insurance records
- ☐ Biological samples obtained from subjects for non research purposes
- ☐ Databases/Registers
- ☐ Tissue Repositories
- ☐ Other

**IF OTHER, indicate any other source(s) of health information to be collected/used:**

2.0 How will PHI be accessed for the research study? (Check all those that apply)

- ☐ HIPAA Research Authorization
- ☐ HIPAA Waiver of Authorization for Research
- ☐ Accessing Information for Preparatory Work for Research
- ☐ Accessing Information Through Limited Data Sets
- ☐ Accessing Deceased Persons' Information
- ☐ Access Information through De-identification
- ☐ Study where health information is not linked to identifiers

**Responses to all questions must be provided for MUSC IRB review.**

If the study will use a HIPAA authorization, upload the HIPAA document and summarize the procedures for obtaining authorization.

***\*\*Note: The HIPAA document must include a stamped watermark template. This template is different than the watermark for the consent form.***

***The HIPAA template & watermark can be accessed from the IRB website [here](#). \*\****

Click Continue.

Health Sciences south carolina MUSC

Edit: Study - Pro00005409

VIEW4459E5247600

**HIPAA Research Authorization**  
An authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the authorization for the purpose(s) and to the recipient (s) stated in the authorization. A valid authorization for research must contain core elements and required statements as specified by 45 CFR 164.508(c)(1) & (2).

1.0 Click on the following link to access the HIPAA Research Authorization Form.  
There are no items to display

Upload HIPAA Research Authorization Form:

Name	Description	Orig. Author
There are no items to display		

2.0 Summarize the procedures to be used when obtaining authorization:

There are no items to display

Responses and HIPAA document must be provided for MUSC IRB review.

Indicate whether de-identified information will be accessed (viewed, obtained or used) for this study.

***\*\*Note: The intent of this question is to document whether study data is received through a de-identification method (i.e., via a de-identified database warehouse). \*\****

Click Continue.

Health Sciences south carolina MUSC

Edit: Study - Pro00024043

VIEW44750E5222000

**Use of De-Identification to Access Protected Health Information (PHI)**

1.0 The Privacy Rule permits a covered entity to assign to, and retain with, the health information a code or other means of record identification if that code is not derived from or related to the information about the individual and could not be translated to identify the individual. The covered entity may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

The Privacy Rule permits a covered entity to assign to, and retain with, the health information a code or other means of record identification if that code is not derived from or related to the information about the individual and could not be translated to identify the individual. The covered entity may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

Will you be receiving de-identified information from a covered entity for the purpose of this project?

☐ Yes ☐ No ☐ Clear

If the answer is "yes" to the question above, indicate how the data will be de-identified.

Click Continue.

Health Sciences south carolina MUSC

Edit: Study - Pro00005345

VIEW44570E4C27C00

**Accessing Protected Health Information (PHI) Through De-Identification**

1.0 Select one below:

☐ The research dataset will contain none of the 18 elements defined by HIPAA as identifiers.

☐ The research dataset has been reviewed by a statistician, or other qualified expert, de-identified PHI of re-identifying the information is very small.

Clear

2.0 If applicable, attach the recommendation from the statistician along with documentation of the methods and analysis used for justification.  
Click on the Add button to upload the document(s):

Add

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

A response must be provided for MUSC IRB review.



For VA studies, indicate medical record flagging waiver requests.

Click Continue.

VIEW400000020400

**VA Medical Record Flagging**  
Per VA regulations, medical records must be flagged if the subjects' participation in the study involves

- Any invasive research procedure (e.g. muscle biopsy or bronchoscopy);
- Interventions that will be used in the medical care of the subjects, or that could interfere with other care the subject is receiving or may receive (e.g., administration of a medication, treatment, or use of an investigational device);
- Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as a part of the study), or that could interfere with other care the subject is receiving or may receive; or
- The use of a survey or questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interests of the subject (e.g., an interview study of victims of sexual assault).

Under Certain circumstances, flagging may be waived. Examples include

- Retrospective chart audit studies
- Studies involving only one encounter
- Participation in the study involves the use of a questionnaire or previously collected biological specimens; and/or
- Studies where identification of the patient as a subject in the study would place the subject at greater than minimal risk.

**1.0 Waiver of Medical Record Flagging Requested:**  
☐ Yes ☐ No ☐ Clear

If yes, please provide the rationale for waiver request:

## Drugs

If you indicated that drugs are used for the study, complete the drug information section.

*\*\*Note: Depending on your responses, you will be required to answer questions specific to investigational drugs, marketed drugs or other types of drugs. \*\**

Click Continue.

Health Sciences South Carolina STG Edit: Study - Pro00005028

VIEW45C21E06C800

**Drugs**

**1.0** Indicate which of the following will be involved in this research study. Select all that apply:

☐ Investigational drugs will be used in this study

☐ Marketed drugs will be used in this research study

☐ Chemicals, metabolites, nutritional substances, biological agents or other substances will be used in this study

**2.0** Applicable forms (ie, 1571, 1572, and/or 310)  
Click on the Add button to upload applicable document(s).

Add

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

## Devices

If you indicated you would be using a device, begin the series of questions related to the device activities on your study, such as IDE application, IDE exemption, 510K letters, risk determinations, HUDs and storage & dispensing.

Click Continue.

### Medical Devices - Exempt from IDE Regulations Determination - Device #1

All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulation.

21 CFR 812.2(c) describes investigations that are exempt. Studies are exempt from the IDE regulations if they meet any of the following criteria. Select any that apply to your study:

- ☐ A legally marketed device used in accordance with its labeling
- ☐ A diagnostic device and the sponsor complies with labeling requirements in 809.10(c)
- ☐ A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices, if all such devices are legally marketed devices
- ☐ A custom device as defined in 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution
- ☐ A 510K/Pre-market Notification device (a device that is substantially equivalent to a legally marketed device), as described in 21 CFR 807 Subpart E.
- ☐ No, none of the above are applicable

## General Comments

Include any General Comments and upload any additional documents that may assist with the review of the study.

*\*\*Note: Upload a CV here if the study is privately funded, requires an IND or IDE application to FDA, or as requested by IRB.\*\**

Click Continue.

### General Comments

VIEW44AFF21C4E00

1.0 Add any additional comments to assist in the review of this research study.

2.0 Add any miscellaneous documents that do not fit in other sections of the study application.

**Palmetto Health IRB applications ONLY:** please upload the completed PHARR Documentation.

Click Add to upload document(s)

Add				
Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - General Comments -

Continue >>

## S.C. Research Studies Directory Online Posting

The study will be included on [SCResearch.org](http://SCResearch.org), a state-wide online directory of studies actively recruiting subjects.

*\*\*Note: if you DO NOT want your study included in this directory, you must remove the checkbox\*\**

Continue to the next screen to enter in the recruitment coordinator's name, phone & e-mail and select from a list of keywords to associate with the study.

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - SCResearch.org Directory -

Continue >>

VIEW44AFF21C4E00

SCResearch.org Directory

SCResearch.org is a web based research studies directory designed to promote research opportunities available within the HSSC Consortium. Use of this directory is appropriate for any research study currently recruiting human subjects. Specific information from this eIRB application will be used to populate the directory.

This study will automatically be included in the directory unless you un-check the box below.

☒ INCLUDE this study on the SCResearch.org website

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - SCResearch.org Directory -

Continue >>

### SCResearch.org Directory

**Recruitment Contact and Keywords:** The following information is required to populate SCResearch.org and can be edited at any time without requiring IRB review.

1.0 **Recruitment Coordinator:**

Click the Select button and choose the person who should be contacted by potential volunteers.

If name is not found, enter it here:

2.0 **\* Recruitment Coordinator Phone:**

3.0 **\* Recruitment Coordinator Email:**

4.0 **\* Keyword(s):**

Click the Add button and select as many keywords that apply to this study:

Review a preview of how the study will appear on [SCResearch.org](http://SCResearch.org).

Follow the instructions on this screen to make changes and finalize the study application.

Posting the study on the registry & the information in this section can be revised at any point by accessing the 'Edit SC Research Studies Directory Posting' option on the protocol's main page.

**SCResearch.org Directory**

Below is a preview of how your study will appear on SCResearch.org.

In addition to other study details (Study Title, PI Name, etc.), your Brief Study Summary will be displayed for public view. To change this language, Jump To the Study Identification Smartform page and edit the textbox *Brief Study Summary*. Once IRB approved, an amendment will be required to change this language as well as other study details (with the exception of the recruitment contact information and Keywords).

Click "Continue" if no edits are required.

The Use of Acamprostate in Alcohol Dependent Individuals with Comorbid Anxiety and Depressive Disorders		
<b>Date Added</b>	<b>Keywords</b> Psychiatry, Mental Health	<b>Institution</b> Medical University of South Carolina
<b>PRO Number</b> Pro00011713	<b>Summary</b> This study is being conducted to see if the drug Campral® (also called acamprostate) is safe and effective in treating adults who are alcohol dependent and who are also experiencing anxiety disorder or depression. This study will be conducted at three sites across the country and will involve approximately 90 volunteers between the ages of 18-60.	<b>Recruitment Contact</b> Stephanie Gentlin 843-792-8300 success@musc.edu
<b>Researcher</b> musc-surgery-pi musc		

**Health Sciences south carolina**  
a consortium to advance health

**eIRB Studies**  
Studies > Acamprostate in Alcohol

**Current State**  
Approved  
View Study  
Printer Version  
View Differences

**My Activities**  
55 Edit Guest Access  
55 PI Suspend  
55 Copy Study  
55 Edit Communication Leads  
55 Edit SC Research Studies Directory Posting

**Edit SC Research Studies Directory Posting**

Post Study online in S.C. Research Studies Directory:  
☒ INCLUDE study in S.C. Research Studies Directory.

**Recruitment Coordinator:**  
Clare Tyson | Select... | Clear

if name is not found, enter it here:

\* **Recruitment Coordinator Phone:**  
843-792-1534

\* **Recruitment Coordinator Email:**  
tysonc@musc.edu

\* **Edit/Add Keyword(s):**  
Add

Alcohol Remove  
Anxiety Remove  
Depression Remove  
Mental Health Remove  
Psychiatry Remove

## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#).

[Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Enter the study's Research Master ID.

Click Continue.

Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for study applications and is created on the [MUSC Research Master ID website](#), which also includes details about this process.

Enter the Research Master ID (RMID) associated with this study. If the study's RMID is not known, [CLICK HERE](#) to go to the RMID website to search or create one. Then, return here to add the RMID to this study application.

\* Research Master ID:

## End of Application

Click "Finish" to close the forms and return to the Application workspace.

***\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the application to IRB. \*\****

Final Page

This is the end of the application. Click the Finish button to close the forms and return to the Application workspace. Click Edit Application Forms in the Application workspace to return to the forms at any time.

NOTE: Clicking Finish does not submit the application for review; this activity can only be executed in the Application workspace by the PI.

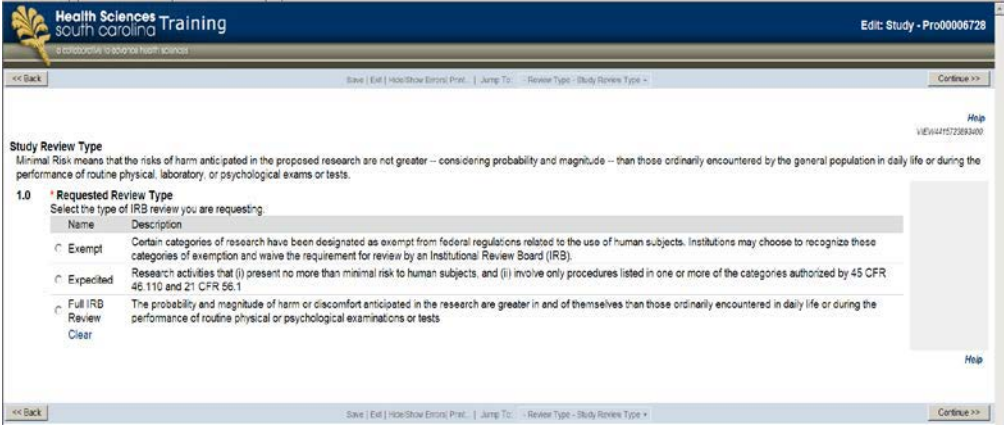
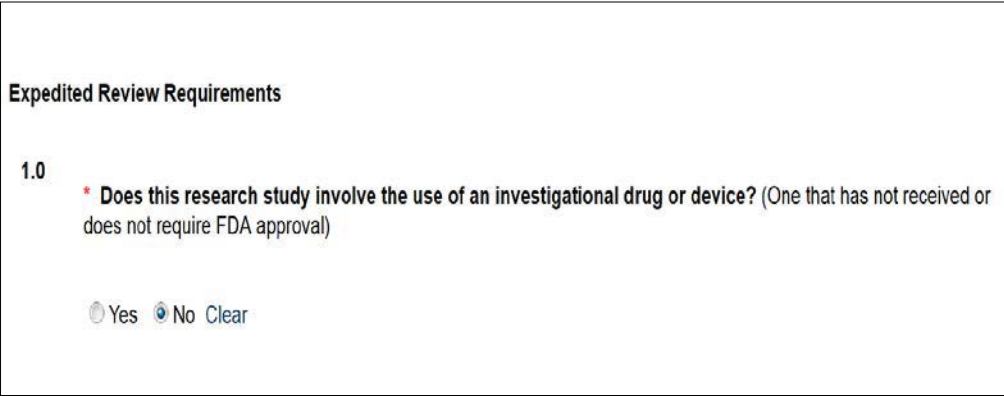
The system will return to the protocol workspace.

***\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.***

To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document. \*\*

## Request for Expedited Review

If not already done, complete steps in the [‘Beginning the Application’](#) section.

<p><b>Study Review Type</b></p> <p>Indicate Study Review Type as “Expedited”.</p> <p>Click Continue.</p>	
<p><b>Expedited Review Requirements</b></p> <p>You will be routed to the Expedited Review Requirements page.</p> <p>Indicate if the study uses an investigational drug or device.</p> <p><i>**Note: An investigational drug can include one that is marketed but changes the risk of the drug (change in dose, population, etc.). An investigational device can include one that is not being used according to its approved labeling. If your study involves the use of an investigational drug or device, it will not qualify for expedited review and you must submit a request for “full board” review. **</i></p> <p>Click Continue.</p>	



## Expedited Review Categories

Select the expedited review category that applies to your study.

Choose one or more categories that are applicable to the study.

Click Continue.

*\*\*Note: If these categories do not apply to all project activities, your project is not eligible for an expedited review. \*\**

The screenshot shows the 'Expedited Review Categories' form in the Health Sciences South Carolina system. The form is titled 'Expedited Review Categories' and includes a 'Reviewer Notes' section. The 'Expedited Review Categories' section contains a list of categories with checkboxes for selection. The categories are:

- 1.0 \* Indicate the Expedited Review Category(s) that apply to this research study. Note: In order to qualify for expedited review, one or more categories must be selected.
  - 1 - Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
    - (a) Research on drugs for which an investigational new drug application is not required.
    - NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
    - (b) Research on medical devices for which 1) an investigational device exemption application is not required or 2) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
  - 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    - (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    - (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
  - 3 - Prospective collection of biological specimens for research purposes by noninvasive means.
    - Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) unannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
  - 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
    - Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroradiography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
  - 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
  - 6 - Collection of voice, video, digital, or image recordings made for research purposes
  - 7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

## Retrospective Review Study

If you selected **only** Expedited Category 5 on the previous page, you will be asked to verify the research activities.

*If you select "yes", you are conducting only a retrospective data review. Follow the instructions in the Expedited Category 5 studies section.*

*If you select "no", then continue with the instructions below.*

The screenshot shows the 'Retrospective Review Study' form in the Health Sciences South Carolina system. The form is titled 'Review Type - Retrospective Review Study' and includes a question for verification. The question is:

1.0 \* Do research activities involve **only** the collection or study of currently existing data, documents, records or specimens (i.e., is this a retrospective study)?

The form has radio buttons for 'Yes' and 'No Clear'.

The system will confirm your response based on what you selected on the previous page.

***\*\*Note: This is NOT an IRB approval via an expedited review method. The system is only recognizing that you have selected one of the applicable expedited review categories. You must still proceed with completing & submitting the application to IRB. \*\****

Click Continue.

The screenshot shows the 'Expedited Review Status Confirmed' page in the Health Sciences South Carolina STG system. The page header includes the logo and 'Edit: Study - Pro00009028'. The main content area states: 'Based on the information provided, it appears this research study qualifies for an IRB Expedited review. Click the Continue button.' There are navigation buttons at the top and bottom: '<< Back', 'Save | Edit | Hide/Show Errors | Print...', 'Jump To: Expedited Review Status Confirmed', and 'Continue >>'.

## Protocol Information

Select the type of study category that applies to your protocol and upload an electronic copy of your protocol within the system.

***\*\*Note: a scientific protocol template is available at the IRB's website [here](#) \*\****

Click Continue.

The screenshot shows the 'Study Protocol' form in the Health Sciences South Carolina STG system. The page header includes the logo and 'Edit: Study - Pro000037164'. The form has several sections:
 

- 1.0 Select the category that applies to your research study protocol:** Includes radio buttons for 'Corporate/industry generated protocol for industry sponsored study', 'Protocol generated by Cooperative Group (national cancer groups, etc.)', 'Protocol from Federal grant application', 'Investigator generated protocol/research plan', and 'Dissertation or thesis proposal'. There is a 'Clear' button.
- 2.0 Protocol document, grant application, or research proposal:** Includes a sub-header 'Click the Add button to upload these document(s) (Note: Do NOT upload consent or any other documents here.)'. Below this is a table with columns 'Name' and 'Description'. An arrow points to the 'Add' button in the top left of this section.
- 3.0 Protocol Summary Information (as applicable):** Includes fields for 'Study Protocol Version:' and 'Dated:', and 'Sponsor Assigned Amendment Number:' and 'Dated:'.

 Annotations include:
 

- An orange box with text: 'Click "Add" to upload an electronic copy of your protocol. You may add multiple documents. Click "OK" when finished uploading.' with an arrow pointing to the 'Add' button.
- Another orange box with text: 'If available, this information must be provided for MUSC IRB review. \*\*Note: This information is often required for sponsored research. If left blank, it will not appear on the IRB review letter. \*\*' with an arrow pointing to the 'Study Protocol Version:' field.

 Navigation buttons at the top and bottom include '<< Back', 'Save | Edit | Hide/Show Errors | Print...', 'Jump To: Study Protocol', and 'Continue >>'.

## Study Subjects

Enter information regarding the subjects you will include in the study.

Check all subject populations that are involved in this study.

*\*\*Note: the system will prompt you to answer questions regarding vulnerable populations if they are a part of your study or if there is no intent to include set groups\*\**

Describe the population, inclusion/exclusion & recruitment procedures.

Click Continue.

### Study Subjects

**1.0 \* Estimated Local Enrollment Goal**

Enter the anticipated number of subjects to be enrolled at local site:

**2.0 Estimated Study-Wide Enrollment Goal**

Enter the anticipated number of subjects to be enrolled at all sites:

**3.0 \* Briefly describe the setting in which the research will be conducted.**

**4.0 \* Participant Remuneration (Payment/Academic Credit)**

Will subject(s) receive remuneration?

☒ Yes ☐ No [Clear](#)

**5.0 \* Will prospective participants be vulnerable to coercion or undue influence?**

☐ Yes ☒ No [Clear](#)

If yes, briefly describe additional safeguards included in the protocol to protect the rights and welfare of participants likely to be vulnerable.

A 'Yes' response indicates your population may be considered to be a vulnerable one (i.e., pregnant women, children, prisoners, cognitively impaired or another category for specialized research). Information must also be included in the text box.

**6.0 \* Identify targeted subject population(s) involved in this research study (Note: The purpose of this question is to determine equitable selection of subjects and to identify vulnerable populations.)**

Select all that apply:

- ☐ Adults (18+)
- ☐ Males
- ☐ Females
- ☐ Pregnant Women
- ☐ Human Fetuses or Neonates
- ☐ Minorities
- ☐ Children (<18 years of age)
- ☐ Prisoners
- ☐ Comatose persons
- ☐ Cognitively Impaired persons
- ☐ Terminally ill persons
- ☐ Employees of the principal investigator's institution
- ☐ Students enrolled at the principal investigator's institution
- ☐ Non-English speaking persons
- ☐ Socially/Economically disadvantaged persons
- ☐ Caregivers
- ☐ Elderly/Aged persons
- ☐ Institutionalized Individuals

**8.0 \* Describe the selection criteria (inclusion/exclusion criteria):**

**9.0 \* Describe recruitment procedures, including how subjects will be contacted, by whom, and how eligibility will be determined.**



## Study Funding

Indicate study funding sources.

***\*\*Note: If the 'Federal Government' is the funding source, a Favorable Funding Score Letter must be included.***

***PIs (not including students) with internally or non-funded studies may be prompted to include details from the Intra-Institutional Transfer (IIT) form for an IRB review fee.***

Click Continue.

The screenshot shows the 'Study Funding Information' section of a web form. It includes a 'Primary Funding Source (Active or Pending)' dropdown menu with options: Federal Government, Private Industry, Private Not-for-Profit Organization, State or Local Government, Internal Funding, Non-US Funding, Other, and No Funding. There are 'Back' and 'Continue' buttons at the top and bottom of the section.

Indicate details of study sponsorship.

***\*\*Note: if any of this information is omitted, it will not appear on the IRB review letter\*\****

Click Continue.

The screenshot shows the 'Study Sponsorship' section of a web form. It includes a 'Sponsor(s)' dropdown menu with a 'Name' field and a 'Click the Add button and select the sponsor(s)' instruction. There are also fields for 'Other Sponsor(s)', 'External Identifier (if applicable)', and 'Internal Identifier (if applicable)'. An orange callout box states: 'At minimum, sponsor name must be provided for MUSC IRB review.' There are 'Back' and 'Continue' buttons at the top and bottom of the section.

The Intra-Institutional Transfer (IIT) Smartform is required for faculty researchers of unfunded or internally funded (non-exempt) IRB studies.

***Please continue to consult with your business administrators to obtain the information required for IRB submission.***

Click Continue.

The screenshot shows the 'Internally Sponsored or Un-sponsored Research' section of a web form. It includes a 'Paying UDAK' section with a 'Please enter the paying UDAK for the \$100 IRB fee.' instruction. There are fields for 'Entity', 'Account', 'Unit', 'Project', and 'Reporting'. A note states: 'If Entity is MUCR, Enter Project Year (a sequential number representing the current grant year [i.e., 01, 02, etc.]):'. There is also a 'UDAK' field. Below this is a '2.0 IIT Number' section with a note: 'An IIT is not necessary; however, you may enter an IIT number along with the UDAK.' There are 'Back' and 'Continue' buttons at the top and bottom of the section.

Indicate the costs associated with the study.

Click Continue.

## Subject Remuneration

Describe Participant Remuneration.

*\*\*Note: this form is required if you indicated you would give remuneration to subjects\*\**

Click Continue.

## Application Checklist

Check all applicable items for this project.

*\*\*Note: The program will prompt you for additional information depending on your responses (i.e. if you have a DSMP or are using drugs/devices, advertisements, radioactive substances, HSSC Clinical Data Warehouse (CDW), etc.).*

*You will also be prompted to upload a copy of all forms you'll use (i.e., advertisements, surveys/questionnaires, consents, etc.). \*\*\**

Click Continue.

## Application Checklist

### 1.0 Will the following be involved in the research study?

Select all that apply

- ☐ Informed consent document(s)
- ☐ Waiver of the Requirement to Obtain Written and Signed Informed Consent
- ☐ Waiver of Informed Consent of Subjects or Alteration of Requirements
- ☐ Clinical trials
- ☐ Data Safety Monitoring Plan is used in this research
- ☐ Medical Record/Chart Review
- ☐ Vaccine Trials
- ☐ Human Genetic Research
- ☐ Human In Vitro Fertilization
- ☐ Transplantation
- ☐ Alcohol and Drug Abuse Research
- ☐ Use of survey, questionnaire, focus group/interview questions
- ☐ Healthy, normal volunteers as research subjects
- ☐ Individuals with HIV/AIDS as research subjects
- ☐ Cancer-related research
- ☐ Drugs will be used in this research study
- ☐ Chemicals, metabolites, nutritional substances, biological agents or other substances whether regulated or not that will be administered to subjects
- ☐ Use of Placebos
- ☒ Investigation of medical device, instrument, machine, computer program or other device, FDA approved
- ☐ Specimens (blood, urine, tissue and other human products)
- ☐ The storage of biological specimens (e.g. biological material, tissue, blood, etc.) or Data (e.g. subject level data) for potential future, yet undesignated, research
- ☐ Recombinant or synthetic nucleic acid molecules, gene transfer, infectious agents, select agents or microrganisms (e.g. Botulinum toxins) exposure to human subjects
- ☐ The use of diagnostic or therapeutic ionizing radiation, or radioactive isotopes that are not part of clinical practice as part of this research study
- ☐ Advertisements or recruiting materials
- ☐ Data from the statewide Health Sciences South Carolina (HSSC) Clinical Data Warehouse

A clinical trial is a prospective biomedical or behavioral human subject research study that is designed to answer specific questions about biomedical or behavioral interventions or lab test evaluations and determine whether these are safe, efficacious and effective. These trials often require Data and Safety Monitoring Plans (DSMPs).

All study activities must be indicated for MUSC IRB review.

## Data and Safety Monitoring Plan

If the study utilizes a data and safety monitoring plan (DSMP), provide descriptions and details of a Data Safety Review Board (if applicable).

Click Continue.

### Data and Safety Monitoring Plan (DSMP)

#### 1.0 \* Provide a general description of the data and safety monitoring plan:

#### 2.0 \* Is there a data and safety monitoring board/committee (DSMB/DSMC) to review for safety and adherence to the study protocol?

☐ Yes ☐ No

#### 3.0 If yes, describe the composition of the board/committee and their qualifications:

#### 4.0 Describe the frequency of DSMB/DSMC reviews and reports, planned interim analysis, etc.

#### 5.0 Describe plans for assuring compliance with requirements regarding the reporting of Unanticipated Problems Involving Risks to Participants or Others and/or Adverse Events to the IRB and appropriate regulatory agencies.

<h3>Clinical Trials</h3> <p>Indicate the type of clinical trial applicable for the project.</p> <p>Click Continue.</p>	<div data-bbox="467 226 544 247">Clinical Trials</div> <div data-bbox="475 279 760 537"> <p>1.0 *What is the phase of the clinical trial?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Phase I clinical trial</li> <li><input type="checkbox"/> Phase II clinical trial</li> <li><input type="checkbox"/> Phase III clinical trial</li> <li><input type="checkbox"/> Phase IV clinical trial</li> <li><input type="checkbox"/> Symptom Management</li> <li><input type="checkbox"/> Prevention Trial</li> <li><input type="checkbox"/> Observational</li> <li><input type="checkbox"/> Interventional</li> <li><input type="checkbox"/> Other</li> <li><input type="checkbox"/> This study does not involve a clinical trial</li> <li><input type="checkbox"/> Open-Label Extension Study</li> </ul> </div> <div data-bbox="475 558 760 680"> <p>2.0 If OTHER, describe:</p> <div style="border: 1px solid #ccc; height: 40px;"></div> </div> <div data-bbox="776 174 1448 800" style="border: 1px solid #ccc; padding: 10px;"> <p>Visit <a href="https://clinicaltrials.gov">ClinicalTrials.gov</a> for descriptions of trial <a href="#">Phases</a>. Additional descriptions are below:</p> <p><b>Symptom Management trials</b> improve comfort and the quality of life for individuals with a serious or life-threatening illness.</p> <p><b>Prevention trials</b> look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals or lifestyle changes.</p> <p><b>Observational trials</b> assess outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine clinical care, but participants are not assigned to specific intervention by the investigator.</p> <p><b>Interventional trials</b> involve participants receiving specific interventions according to a research plan or protocol. These trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.</p> <p><b>Open-Label Extension Studies</b> are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.</p> <p><a href="https://clinicaltrials.gov">ClinicalTrials.gov</a></p> </div>
<h3>Study Procedures</h3> <p>Describe all procedures, those used solely for research and those performed as standard of care.</p> <p>Click Continue.</p>	<div data-bbox="537 995 1398 1367" style="border: 1px solid #ccc; padding: 10px;"> <p><b>Study Procedures</b> (Blood draw, Imaging, Lab Tests, Physical Exam, Medical History)</p> <p>1.0 * Briefly describe the procedures to be performed solely as part of this research study.</p> <div style="border: 1px solid #ccc; height: 40px;"></div> <p>2.0 * Briefly describe the procedures being performed already for diagnostic or treatment purposes (standard of care).</p> <div style="border: 1px solid #ccc; height: 40px;"></div> </div>
<h3>Risks</h3> <p>Describe all potential risks and discomforts and precautions to minimize risks.</p> <p>Click Continue.</p>	<div data-bbox="480 1507 1411 1839" style="border: 1px solid #ccc; padding: 10px;"> <p><b>Study Risks and Precautions</b></p> <p>1.0 * <b>Risks, Discomforts and Potential Harms</b> Briefly describe the risks associated with all aspects of the study. Include consideration of physical, psychological, social, financial, and other factors, as applicable.</p> <div style="border: 1px solid #ccc; height: 40px;"></div> <p>2.0 * Describe the safety precautions that will be taken to minimize risks/harms. This should include your data protection management plan:</p> <div style="border: 1px solid #ccc; height: 20px;"></div> </div>

## Potential Benefit

Select the potential benefit category and explain potential benefits to the subject and/or society.

Click Continue.

The screenshot shows the 'Potential Benefits' section of the Health Sciences South Carolina STG system. The header includes the logo and 'STG' text. The page title is 'Edit: Study - Pro00005028'. The form contains a definition of 'Benefit' and a section for selecting a benefit category. Under '1.0 \*Benefit Category', there are two radio button options: 'This research study is not expected to directly benefit individual subjects, but is likely to yield generalizable knowledge which contributes to the field.' and 'This research study involves the prospect of direct benefit to the individual subject.' Below this is a 'Clear' link. Section '2.0 \*What are the potential benefits of the research study to the subject and/or to society?' has a text area labeled 'Explain:'. Navigation buttons at the bottom include '<< Back', 'Save | Exit | View/Show/Errors/Print...', 'Jump To: >> Other Study Specifics > Potential Benefits >', and 'Continue >>'.

## Conflict of Interest

Indicate potential Conflict of Interest.

Click Continue.

***\*\*Note: A 'Yes' response or privately funded studies will require responses on the next screen in the system to disclose the interest. In addition, conflicts of interest must be verified at the time of continuing review. \*\****

The screenshot shows the 'Conflict of Interest' section of the Health Sciences South Carolina STG system. The header includes the logo and 'STG' text. The page title is 'Edit: Study - Pro00005028'. The form contains a definition of 'Conflict of Interest' and a section for indicating potential conflict. Under '1.0 \*Do any of the participating study investigators or other research personnel (or their immediate family) have a financial and/or intellectual property interest in the sponsor or products used with this research study?', there are radio button options for 'Yes' and 'No', and a 'Clear' link. Navigation buttons at the bottom include '<< Back', 'Save | Exit | View/Show/Errors/Print...', 'Jump To: >> Conflict of Interest >', and 'Continue >>'.

## Consent Process

Describe Consent Process and upload consent form(s).

*\*\*Note: A watermark approval stamp template must be included in consenting documents. Access to the consent template & watermark stamp is available at the IRB's website [here](#).*

*If the HIPAA form is separate, it will be uploaded later in the application. \*\**

Click Continue.

The screenshot shows a web browser window with the URL "http://www.musc.edu/irb/consentprocess". The page title is "Consent Process". The form contains several sections:

- 1.0** \*Will the consent be obtained from the subject?  
☐ Yes ☐ No Clear
- 2.0** Will the consent be obtained from the subject's legally authorized representative?  
☐ Yes ☐ No Clear
- 3.0** Describe any waiting period between informing the prospective participant and obtaining consent:
- 4.0** \*Who will obtain consent?  
Please list Research Personnel Authorized and Qualified to obtain Informed Consent:
- 5.0** \*Describe the process (where, when and how) for obtaining consent.
- 6.0** **Consent Forms**  
To allow for documentation of IRB approval and electronic watermarking, please use the following link to access your institution's Informed Consent Form Template:  
link url:  
  
No template or form available  
If no template is available, please leave at least a one inch margin at the bottom of each page of the final "clean" version of the consent document(s).  
**NOTE:** When revising a consent document associated with an amendment or continuing review, Click "Upload Revision" to upload the revised version of the consent document. Use ADD only when uploading a new consent document.  
\* Click the Add button to upload a copy of the consent form(s), including translated versions for this research study.  
Add  
Name Version Orig. Author Orig. Created Last Modified  
There are no items to display

At the bottom of the form, there is a "Back" button and a "Continue" button.

Responses must be provided for MUSC IRB review.

Click "Add" to upload an electronic copy of your consent form(s). You may add multiple documents. Click "OK" when finished uploading.



## Privacy and Confidentiality

Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

Select where study records and data collected will be stored. If "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)" is selected then explain how this device will be protected.

Indicate whether or not this project will use a federal Certificate of Confidentiality.

Click Continue.

***\*\*Note: A NIH Certificate of Confidentiality protects investigators and institutions from being forced to disclose research participants' identifying information in research projects with 'sensitive' topics (studies in which disclosure can have adverse consequences for the participant). \*\****

The screenshot shows the 'Privacy and Confidentiality' section of the eIRB form. It includes a header for 'Health Sciences south carolina' and a navigation bar. The main content area is titled 'Privacy and Confidentiality' and contains several sections:

- 1.0** Describe the procedures and safeguards that will be implemented to protect the privacy and confidentiality of the participants' data. Include details, as applicable to the study, such as: privacy of interview site, procedures for coding/identifying data, provisions to avoid public identification/embarrassment of participants, persons with access to private identifiable data, etc. This section has a large text input area.
- 2.0** Where will study records and data collected at this site be stored? Select all that apply:
  - ☐ In a locked office
  - ☐ In a locked cabinet
  - ☐ Password protected network storage
  - ☐ Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)
  - ☐ OtherIf OTHER, describe: [Text input area]
- If information will be stored on an end-user/portable device, describe the security on the end-user/portable device that [Text input area]
- 3.0** Will the study use a National Institutes of Health (NIH) Certificate of Confidentiality?
  - ☐ Yes ☐ No ☐ ClearIf YES, what is the NIH Certificate of Confidentiality status?
  - ☐ The NIH Certificate of Confidentiality has been approved
  - ☐ Will apply for a NIH Certificate of Confidentiality for this study
  - ☐ Clear

Three orange callout boxes with arrows pointing to specific parts of the form:

- Box 1: "If 'Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)' is selected then explain how this device will be protected." (Points to the 'Password protected end-user/portable device' checkbox in section 2.0)
- Box 2: "As applicable, responses must be provided for MUSC IRB review." (Points to the 'If OTHER, describe:' text input area in section 2.0)
- Box 3: "device is lost or stolen:" (Points to the text input area for describing security on the device in section 2.0)

## Protected Health Information (PHI)

Indicate if the study will access (view, obtain or use) participant protected health data.

Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI).

Click Continue.

**Protected Health Information (PHI) for Research**  
Protected Health Information (PHI) is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future physical or mental health or conditions of an individual.

Covered Entity - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form.

1.0 \* To determine if this research study is using/disclosing PHI, select any of the following 18 elements that your study will require access to, as defined by the Health Insurance Portability and Accountability Act (HIPAA), as identifiers. If none of these 18 identifiers are used, select the last option.

- ☐ Names
- ☐ All geographic subdivisions smaller than a state including street address, city, county, precinct, zip code, or a unique post office box
- ☐ All elements of date (except year) for dates directly related to an individual (DOB, admission dates, discharge dates, death dates, etc.)
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ Social security numbers
- ☐ Medical record number
- ☐ Health plan beneficiary number
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Any other unique identifying number, characteristic or code
- ☐ None of the above 18 identifiers will be used/disclosed for this research study

If the study requires access to any of the 18 identifiers but will not be linked to PHI, please select those that are applicable to the left. On the next screen, you will be able to select "Study where health information is not linked to identifiers".

Checking the last option means **no access to protected health information** is needed for the study.

However, if the study **has to access any of these identifiers** in order to obtain or associate health information, you must check all applicable identifiers on this page. *See notes on this Smartform page.*

If indicating that PHI is accessed, check all the sources of health information and how the project is requesting access to it.

Click Continue.

**Health Sciences South Carolina**  
Access to Protected Health Information (PHI) for Research

1.0 Indicate the sources of health information to be used. Select all that apply.

- ☐ Medical Records/Physician Notes/Hospital Discharge Records
- ☐ Psychotherapy Notes
- ☐ Medical Test Results
- ☐ Payment/Billing/Insurance records
- ☐ Ecological samples obtained from subjects for non-research purposes
- ☐ Databases/Registries
- ☐ Tissue Repositories
- ☐ Other

If OTHER, indicate any other source(s) of health information to be collected/used:

2.0 How will PHI be accessed for the research study? (Check all those that apply)

- ☐ HIPAA Research Authorization
- ☐ HIPAA Waiver of Authorization for Research
- ☐ Accessing Information for Preparatory Work for Research
- ☐ Accessing Information Through Limited Data Sets
- ☐ Accessing Deceased Persons Information
- ☐ Access Information through De-identification
- ☐ Study where health information is not linked to identifiers

Responses to all questions must be provided for MUSC IRB review.

If the study will use a HIPAA authorization, upload the HIPAA document and summarize the procedures for obtaining authorization.

***\*\*Note: The HIPAA document must include a stamped watermark template. This template is different than the watermark for the consent form.***

***The HIPAA template & watermark can be accessed from the IRB website [here](#).***

Click Continue.

Health Sciences south carolina MUSC

Edit: Study - Pro00005409

VIEW445652474800

**HIPAA Research Authorization**  
An authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the authorization for the purpose(s) and to the recipient (s) stated in the authorization. A valid authorization for research must contain core elements and required statements as specified by 45 CFR 164.508(c)(1) & (2).

1.0 Click on the following link to access the HIPAA Research Authorization Form.  
There are no items to display.

Upload HIPAA Research Authorization Form:  
Add

Name	Description	Orig. Author
There are no items to display.		

2.0 Summarize the procedures to be used when obtaining authorization:  
[Text Area]

Responses must be provided for MUSC IRB review.

Indicate whether de-identified information will be accessed (viewed, obtained or used) for this study.

***\*\*Note: The intent of this question is to document whether the study data is received through a de-identification method (i.e., via a de-identified database warehouse).***

Click Continue.

Health Sciences south carolina MUSC

Edit: Study - Pro00024043

VIEW447506522200

**Use of De-identification to Access Protected Health Information (PHI)**

1.0 The Privacy Rule permits covered entities, depending on IRB approval, to use and disclose data that have been de-identified without obtaining an authorization. The Principal Investigator must receive the data from the covered entity in a de-identified format. A covered entity may de-identify PHI in one of two ways. The first method requires the removal of every one of 18 identifiers enumerated at section 164.514(b)(2) of the Privacy Rule. Data that are stripped of these 18 identifiers are regarded as de-identified. The second way to de-identify PHI is to have a qualified statistician determine, using generally accepted statistical and scientific principles and methods, that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the anticipated recipient to identify the subject of the information.

The Privacy Rule permits a covered entity to assign to, and retain with, the health information a code or other means of record identification if that code is not derived from or related to the information about the individual and could not be translated to identify the individual. The covered entity may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

Will you be receiving de-identified information from a covered entity for the purpose of this project?

☒ Yes ☐ No ☐ Clear

Responses must be provided for MUSC IRB review.

If the answer is "yes" to the question above, indicate how the data will be de-identified.

Click Continue.

Health Sciences south carolina MUSC

Edit: Study - Pro00005345

VIEW4457064C07C00

**Accessing Protected Health Information (PHI) Through De-identification**

1.0 Select one below:  
☐ The research dataset will contain none of the 18 elements defined by HIPAA as identifiers.  
☐ The research dataset has been reviewed by a statistician, or other qualified expert, de-identified PHI through generally accepted statistical and scientific methods and determined that the risk of re-identifying the information is very small.  
 Clear

2.0 If applicable, attach the recommendation from the statistician along with documentation of the methods and analysis used for justification.  
Click on the Add button to upload the document(s):  
Add

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display.				

A response must be provided for MUSC IRB review.

For VA studies, indicate medical record flagging waiver requests.

Click Continue.

VA Medical Record Flagging  
Per VA regulations, medical records must be flagged if the subjects' participation in the study involves

- Any invasive research procedure (e.g. muscle biopsy or bronchoscopy);
- Interventions that will be used in the medical care of the subjects, or that could interfere with other care the subject is receiving or may receive (e.g., administration of a medication, treatment, or use of an investigational device);
- Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as a part of the study), or that could interfere with other care the subject is receiving or may receive; or
- The use of a survey or questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interests of the subject (e.g., an interview study of victims of sexual assault).

Under Certain circumstances, flagging may be waived. Examples include

- Retrospective chart audit studies
- Studies involving only one encounter
- Participation in the study involves the use of a questionnaire or previously collected biological specimens; and/or
- Studies where identification of the patient as a subject in the study would place the subject at greater than minimal risk.

\*1.0 Waiver of Medical Record Flagging Requested:  
☐ Yes ☐ No ☐ Clear

If yes, please provide the rationale for waiver request:

## Drugs

If you indicated that drugs are used for the study, complete the drug information section. Click Continue.

*\*\*Note: Depending on your responses, you will be required to answer questions specific to investigational drugs, marketed drugs or other types of drugs.*

Click Continue.

Health Sciences  
south carolina STG

Edit: Study - Pro00005028

Drugs

1.0 \*Indicate which of the following will be involved in this research study  
 Select all that apply:  
☐ Investigational drugs will be used in this study  
☐ Marketed drugs will be used in this research study  
☐ Chemicals, metabolites, nutritional substances, biological agents or other substances will be used in this study

2.0 Applicable forms (ie, 1571, 1572, and/or 310)  
 Click on the Add button to upload applicable document(s):

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

## Devices

If you indicated you would be using a device, begin the series of questions related to the device activities on your study, including IDE application, IDE exemption, 510K letters, risk determinations, HUDs and storage & dispensing.

Click Continue.

Medical Devices - IDE Information - Medical Device #1

1.0 Name of Sponsor of IDE #1:

2.0 \* IDE#:

3.0 \* Attach FDA correspondence stating the IDE#:

Name	Version	Orig. Author	Orig. Created
There are no items to display			

14 - Medical Devices

- Medical Devices - Humanitarian Use Device
- Medical Devices - Sponsor IDE1 - v2
- Medical Devices - IDE Information1 - v2
- Medical Devices - Storage and Dispensing1
- Medical Devices - Device2

- Privacy - Protected Health Information (PHI) for Research

- Privacy - Use of De-Ident to Access PHI

- Privacy - Accessing PHI Through De-Ident - Part 1

## General Comments

Include any General Comments and upload any additional documents that may assist with the review of the study.

*\*\*Note: Upload a CV here if the study is privately funded, requires an IND or IDE application to FDA, or as requested by IRB.\*\**

Click Continue.

The screenshot displays the 'General Comments' page in the Health Sciences South Carolina eIRB system. The header includes the logo and name of the institution, the text 'a collaborative to advance health sciences', and the study identifier 'Edit: Study - Pro00024043'. A navigation bar at the top contains links for '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: >> General Comments <', and 'Continue >>'. The main content area is titled 'General Comments' and includes a reference ID 'VIEW44APP21C4EC00'. It features two numbered sections: 1.0 'Add any additional comments to assist in the review of this research study.' with a large text input box, and 2.0 'Add any miscellaneous documents that do not fit in other sections of the study application.' which includes a note for Palmetto Health IRB applications and a link to upload documents. Below this is an 'Add' button and a table with columns for Name, Description, Orig. Author, Orig. Created, and Last Modified, currently showing 'There are no items to display'. A footer navigation bar at the bottom repeats the navigation links.

Health Sciences  
south carolina  
a collaborative to advance health sciences

Edit: Study - Pro00024043

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: >> General Comments < Continue >>

General Comments VIEW44APP21C4EC00

1.0 Add any additional comments to assist in the review of this research study.

2.0 Add any miscellaneous documents that do not fit in other sections of the study application.  
Palmetto Health IRB applications ONLY: please upload the completed PHARR Documentation.  
Click Add to upload document(s)

Add

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: >> General Comments < Continue >>

## S.C. Research Studies Directory Online Posting

The study will be included on [SCResearch.org](http://SCResearch.org), a state-wide online directory of studies actively recruiting subjects.

***\*\*Note: if you DO NOT want your study included in this directory, you must remove the checkbox\*\****

Continue to the next screen to enter in the recruitment coordinator's name, phone & e-mail and select from a list of keywords to associate with the study.

The screenshot shows a web browser window with the title "SCResearch.org Directory". The address bar shows "Save | Exit | Hide/Show Errors | Print... | Jump To: SCResearch.org Directory". The main content area has the heading "SCResearch.org Directory" and a sub-heading "VIEU44FF75C91F800". The text reads: "SCResearch.org is a web based research studies directory designed to promote research opportunities available within the HSSC Consortium. Use of this directory is appropriate for any research study currently recruiting human subjects. Specific information from this eIRB application will be used to populate the directory." Below this, it says "This study will automatically be included in the directory unless you un-check the box below." There is a checkbox labeled "INCLUDE this study on the SCResearch.org website" which is checked. At the bottom, there are navigation buttons: "<< Back", "Save | Exit | Hide/Show Errors | Print... | Jump To: SCResearch.org Directory", and "Continue >>".

The screenshot shows a web browser window with the title "SCResearch.org Directory". The address bar shows "Save | Exit | Hide/Show Errors | Print... | Jump To: SCResearch.org Directory". The main content area has the heading "SCResearch.org Directory" and a sub-heading "Recruitment Contact and Keywords: The following information is required to populate SCResearch.org and can be edited at any time without requiring IRB review:". Below this, there are four numbered sections: 1.0 Recruitment Coordinator: Click the Select button and choose the person who should be contacted by potential volunteers. There is a text input field and a "Select..." button. Below this, it says "If name is not found, enter it here:" followed by a text input field. 2.0 \* Recruitment Coordinator Phone: There is a text input field. 3.0 \* Recruitment Coordinator Email: There is a text input field. 4.0 \* Keyword(s): Click the Add button and select as many keywords that apply to this study: There is a text input field and an "Add" button. At the bottom, there are navigation buttons: "<< Back", "Save | Exit | Hide/Show Errors | Print... | Jump To: SCResearch.org Directory", and "Continue >>".



Review a preview of how the study will appear on [SCResearch.org](http://SCResearch.org).

Follow the instructions on this screen to make changes and finalize the study application.

Posting the study on the registry & the information in this section can be revised at any point by accessing the 'Edit SC Research Studies Directory Posting' option on the protocol's main page.



**SCResearch.org Directory**

Below is a preview of how your study will appear on SCResearch.org.

In addition to other study details (Study Title, PI Name, etc.), your Brief Study Summary will be displayed for public view. To change this language, Jump To the Study Identification Smartform page and edit the textbox *Brief Study Summary*. **Once IRB approved, an amendment will be required to change this language as well as other study details (with the exception of the recruitment contact information and Keywords).**

Click "Continue" if no edits are required.

The Use of Acamprosate in Alcohol Dependent Individuals with Comorbid Anxiety and Depressive Disorders		
<b>Date Added</b>	<b>Keywords</b> Psychiatry, Mental Health	<b>Institution</b> Medical University of South Carolina
<b>PRO Number</b> Pro00011713	<b>Summary</b> This study is being conducted to see if the drug Campral® (also called acamprosate) is safe and effective in treating adults who are alcohol dependent and who are also experiencing anxiety disorder or depression. This study will be conducted at three sites across the country and will involve approximately 90 volunteers between the ages of 18-60.	<b>Recruitment Contact</b> Stephanie Gentilin 843-792-6300 success@musc.edu
<b>Researcher</b> musc-surgery-pi musc		

**Health Sciences south carolina**  
a collaborative to advance care

**eIRB Studies**

Studies > Acamprosate in Alcohol

**Current State**

Approved

View Study  
Printer Version  
View Differences

**My Activities**

- Edit Guest Access
- PI Suspend
- Copy Study
- Edit Communication Leads
- Edit SC Research Studies Directory Posting**

**Edit SC Research Studies Directory Posting**

**Post Study online in S.C. Research Studies Directory:**

☒ INCLUDE study in S.C. Research Studies Directory.

**Recruitment Coordinator:**  
Clare Tyson [Select] [Clear]

**if name is not found, enter it here:**

**\* Recruitment Coordinator Phone:**  
843-792-1534

**\* Recruitment Coordinator Email:**  
tysonc@musc.edu

**\* Edit/Add Keyword(s):**

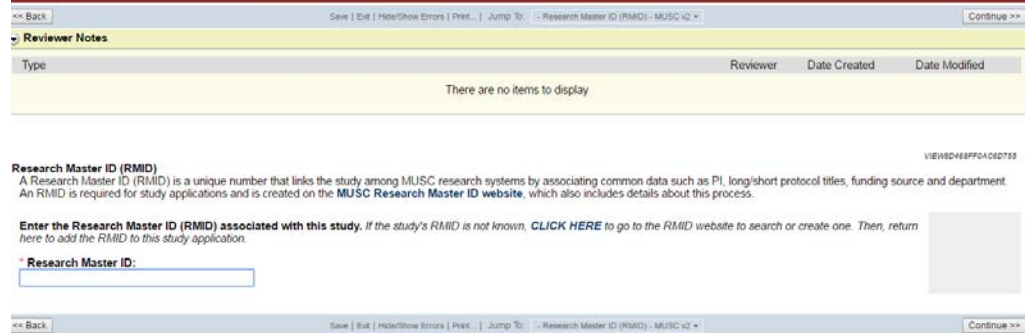
Alcohol [Remove]  
Anxiety [Remove]  
Depression [Remove]  
Mental Health [Remove]  
Psychiatry [Remove]

## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#). [Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Enter the study's Research Master ID.

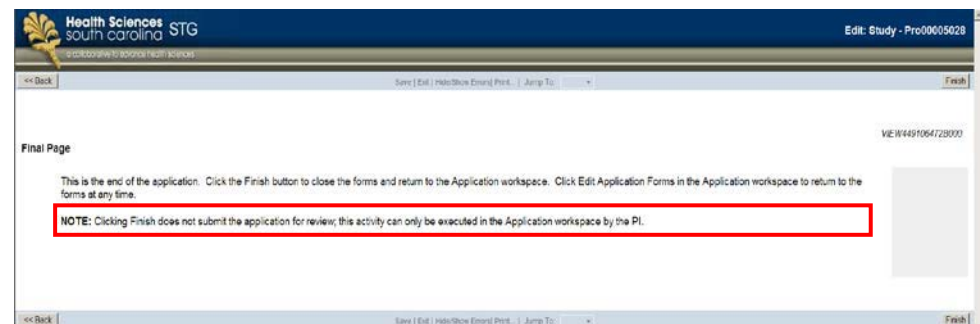
Click Continue.



## End of Application

Click "Finish" to close the forms and return to the Application workspace.

***\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB. \*\****



The system will return to the protocol workspace.

*\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.*

*To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document. \*\**

**eIRB Studies**  
Studies > TEST HCC STUDY

**Current State**

**Pre Submission**

- Edit Study
- Printer Version
- View Differences
- View Smartform Progress

**My Activities**

- Submit Study
- Edit Guest Access
- Withdraw
- Log Public Comment
- Copy Study

**Study Short Title:** TEST HCC STUDY ( Pro00035002 )

**Full Title:** TEST HCC STUDY

**Principal Investigator:** Kathleen Brady

**Study Coordinator:** Brigitte White

**IRB Campus:** Medical University of South Carolina

**Review Type:** Expedited

**PI Department:** CLINICAL NEUROSCIENCE - MUSC

**PI Institution:** Medical University of South Carolina

**Pre-Conversion Study ID:**

**Sponsors:** NIH/NCI

**Study Team Approval to Post on SCresearch.org:** yes

**IRB Approval to Post on SCresearch.org:** no

**History** | Personnel | Attachments | Pre Review Status | Reviewer Notes | Change Log

This area shows instructions and questions and important notifications regarding this Study.

## Request for Expedited Review (Category 5 Retrospective Studies)

These steps are expedited review for category 5 retrospective only studies. Complete steps in the ['Expedited Review'](#) section if this is not a study that includes **only** data that existed before this study's IRB application.

### Retrospective Review Study

You will be asked to verify if your research activities will be done retrospectively. A 'yes' response will confirm that you are conducting a retrospective only study.

Click continue.

The screenshot shows the 'Health Sciences south carolina' header with the tagline 'a collaborative to advance health sciences'. The top right corner says 'Edit: Study - Pro00024043'. Below the header is a navigation bar with 'Save | Exit | Hide/Show Errors | Print... | Jump To: - Review Type - Retrospective Review Study -'. The main content area is titled 'Review Type - Retrospective Review Study' and contains a question: '1.0 \* Do research activities involve **only** the collection or study of currently existing data, documents, records or specimens (i.e., is this a retrospective study)?'. There are radio buttons for 'Yes' (selected) and 'No', and a 'Clear' button. At the bottom right, there is a 'Continue >>' button.

### Protocol Information

Select the type of study category that applies to your protocol and upload an electronic copy of your protocol within the system.

***\*\*Note: a scientific protocol template is available at the IRB's website here\*\****

Click Continue.

The screenshot shows the 'Health Sciences south carolina' header with the tagline 'a collaborative to advance health sciences'. The top right corner says 'Edit: Study - Pro00024043'. Below the header is a navigation bar with 'Save | Exit | Hide/Show Errors | Print... | Jump To: - Study Protocol -'. The main content area is titled 'Study Protocol' and contains two sections: '1.0 \* Select the category that applies to your research study protocol:' and '2.0 \* Protocol document, grant application, or research proposal'. Section 1.0 has a list of categories: 'Corporate/industry generated protocol for industry sponsored study' (selected), 'Protocol generated by Cooperative Group (national cancer groups, etc.)', 'Protocol from Federal grant application', 'Investigator generated protocol/research plan', and 'Dissertation or thesis proposal'. Section 2.0 has a text box for uploading documents, with an 'Add' button circled in red. An orange callout box points to the 'Add' button with the text: 'Click "Add" to upload an electronic copy of your protocol. You may add multiple documents. Click "OK" when finished uploading.' Below section 2.0 is a section titled '3.0 Protocol Summary Information (as applicable):' with two sub-sections: '3.1 Study Protocol Version: [ ] Dated: [ ]' and '3.2 Sponsor Assigned Amendment Number: [ ] Dated: [ ]'. An orange callout box points to the 'Dated' field in section 3.1 with the text: 'If available, this information must be provided for MUSC IRB review. \*\*Note: This information is often required for sponsored research. If left blank, it will not appear on the IRB review letter. \*\*'.

<p><b>Record Review</b></p> <p>Enter the estimated number of records, date ranges and inclusion and exclusion criteria for the study.</p> <p>Click Continue.</p>	<div> <div>Record Review</div> <div>Describe the records/data that will be reviewed, including estimated number of records, date range and study population.</div> <div> <div>1.0 * Estimate number of records:</div> <div></div> </div> <div> <div>2.0 Date range of records to be included in the review:</div> <div> <div>* From:</div> <div></div> </div> <div> <div>* To:</div> <div></div> </div> </div> <div> <div>3.0 * Inclusion/Exclusion Criteria:</div> <div></div> </div> </div>
<p><b>Study Funding</b></p> <p>Indicate study funding sources.</p> <p><i>**Note: If the 'Federal Government' is the funding source, a <a href="#">Favorable Funding Score</a> Letter must be included.</i></p> <p><i>PIs (not including students) with internally or non-funded studies may be prompted to include details from the Intra-Institutional Transfer (IIT) form for an IRB review fee.</i></p> <p>Click Continue.</p>	<div> <div>Study Funding Information</div> <div> <div>1.0 * Primary Funding Source (Active or Pending)</div> <div>Select primary (active or pending) funding sources for this study:</div> <div> <input type="checkbox"/> Federal Government <input type="checkbox"/> Private Industry <input type="checkbox"/> Private Not-for-Profit Organization <input type="checkbox"/> State or Local Government <input type="checkbox"/> Internal Funding <input type="checkbox"/> Non-US Funding <input type="checkbox"/> Other <input type="checkbox"/> No Funding </div> </div> </div>
<p>Indicate details of study sponsorship.</p> <p><i>**Note: if any of this information is omitted, it will not appear on the IRB review letter**</i></p> <p>Click Continue.</p>	<div> <div>Study Sponsorship</div> <div> <div>1.0 Sponsor(s)</div> <div>Click the Add button and select the sponsor(s)</div> <div> <div></div> <div>Add</div> </div> <div> <div>Name</div> <div>Forest Labs, Inc.</div> <div>Remove</div> </div> </div> <div> <div>2.0 Other Sponsor(s)</div> <div>If sponsor(s) is/are not in the above list above, enter name(s) here:</div> <div></div> </div> <div> <div>3.0 External Identifier (if applicable):</div> <div>(e.g. agency/sponsor assigned numbers)</div> <div></div> </div> <div> <div>4.0 Internal Identifier (if applicable):</div> <div>(e.g. proposal or award Number)</div> <div></div> </div> </div> <div> <div>At minimum, sponsor name must be provided for MUSC IRB review.</div> </div>

The Intra-Institutional Transfer (IIT) Smartform is required for faculty researchers of unfunded or internally funded IRB studies.

*Please continue to consult with your business administrators to obtain the information required for IRB submission.*

Click Continue.

Internally Sponsored or Un-sponsored Research

1.0 **PAYING UDAK**  
Please enter the paying UDAK for the \$100 IRB fee.

Entity: MUC	Account: 50228	Unit: *	Project: *	Reporting: *	If Entity is MUCR, Enter Project Year (a sequential number representing the current grant year [i.e., 01, 02, etc.]):
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UDAK:

2.0 **IIT Number**  
An IIT is not necessary; however, you may enter an IIT number along with the UDAK.

## Application Checklist

Check all applicable items for this project.

*\*\*Note: Waiver of Informed Consent/Alteration is a required form for these studies and is automatically checked on the application\*\**

Click Continue.


Application Checklist

1.0 **Will the following be involved in the research study?**  
Select all that apply

<input checked="" type="checkbox"/>	Waiver of Informed Consent of Subjects or Alteration of Consent Elements
<input type="checkbox"/>	Medical Record/Chart Review
<input type="checkbox"/>	Cancer Patients
<input type="checkbox"/>	Specimens (blood, urine, tissue and other human products)
<input type="checkbox"/>	Recombinant DNA, gene transfer, infectious agents, select agents or microorganism exposure to human subjects
<input type="checkbox"/>	This research study is being conducted by other investigators in other countries
<input type="checkbox"/>	Data required from HSSC Clinical Data Warehouse

All study activities must be indicated for MUSC IRB review.



<h3>Clinical Trials</h3> <p>Indicate the type of clinical trial applicable for the project.</p> <p>Click Continue.</p>	<div> <div> Clinical Trials 1.0 * What is the phase of the clinical trial? <input type="checkbox"/> Phase I clinical trial <input type="checkbox"/> Phase II clinical trial <input type="checkbox"/> Phase III clinical trial <input type="checkbox"/> Phase IV clinical trial <input type="checkbox"/> Symptom Management <input type="checkbox"/> Prevention Trial <input type="checkbox"/> Observational <input type="checkbox"/> Interventional <input type="checkbox"/> Other <input type="checkbox"/> This study does not involve a clinical trial <input type="checkbox"/> Open-Label Extension Study 2.0 If OTHER, describe: </div> <div> Visit <a href="http://ClinicalTrials.gov">ClinicalTrials.gov</a> for descriptions of trial <a href="#">Phases</a>. Additional descriptions are below: <p><b>Symptom Management trials</b> improve comfort and the quality of life for individuals with a serious or life-threatening illness.</p> <p><b>Prevention trials</b> look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals or lifestyle changes.</p> <p><b>Observational trials</b> assess outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine clinical care, but participants are not assigned to specific intervention by the investigator.</p> <p><b>Interventional trials</b> involve participants receiving specific interventions according to a research plan or protocol. These trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.</p> <p><b>Open-Label Extension Studies</b> are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.</p> </div> </div>
<h3>Risks</h3> <p>Describe all potential risks and discomforts and precautions to minimize risks.</p> <p>Click Continue.</p>	<div> <div> Study Risks and Precautions 1.0 * Risks, Discomforts and Potential Harms Briefly describe the risks associated with all aspects of the study. Include consideration of physical, psychological, social, financial, and other factors, as applicable. 2.0 * Describe the safety precautions that will be taken to minimize risks/harms. This should include your data protection management plan: </div> </div>
<h3>Potential Benefit</h3> <p>Select the potential benefit category and explain potential benefits to the subject and/or society.</p> <p>Click Continue.</p>	<div> <div> <div>  Edit: Study - Pro0024043 </div> <div> Back Save Exit Hide/show errors Print Jump To: Other Study Specifics - Potential Benefits Continue </div> </div> <div> <div> Potential Benefits Benefit - A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation is generally not considered to be a research benefit. 1.0 * Benefit Category Select a benefit Category <input type="radio"/> This research study is not expected to directly benefit individual subjects, but is likely to yield generalizable knowledge which contributes to the field. <input type="radio"/> This research study involves the prospect of direct benefit to the individual subject. Clear 2.0 * What are the potential benefits of the research study to the subject and/or to society? Explain: </div> </div> </div>

## Conflict of Interest

Indicate potential Conflict of Interest.

Click Continue.

*\*\*Note: A 'Yes' or privately funded studies response will require responses on the next screen in the system to disclose the interest. In addition, conflicts of interest must be verified at the time of continuing review. \*\**

The screenshot shows the 'Conflict of Interest' form in the Health Sciences South Carolina system. The header includes the logo and 'Edit: Study - Pro0024043'. The form title is 'Conflict of Interest'. A definition of conflict of interest is provided. Below, question 1.0 asks if any participating study investigators or other research personnel (or their immediate family) have a financial and/or intellectual property interest in the sponsor or products used with this research study. The form includes 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue' buttons.

## Waiver of Informed Consent or Alteration of Consent Elements

Describe why a Waiver of Informed Consent is being requested.

Click Continue.

The screenshot shows the 'Waiver of Informed Consent of Subjects or Alteration of Consent Elements' form. It includes instructions and four numbered questions (1.0 to 4.0) requiring explanations for the waiver. Below these is a 'Debrief form' section with an 'Add' button and a table with columns: Name, Description, Orig. Author, Orig. Created, and Last Modified. The table currently shows 'There are no items to display'. Question 5.0 asks if an informed consent document will also be used. The form includes 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue' buttons.

## Privacy and Confidentiality

Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

Select where study records and data collected will be stored.

Indicate whether this project will use a federal Certificate of Confidentiality.

Click Continue.

***\*\*Note: A NIH Certificate of Confidentiality protects investigators and institutions from being forced to disclose research participants' identifying information in research projects with 'sensitive' topics (studies in which disclosure can have adverse consequences for the participant). \*\****

**Health Sciences south carolina**

1.0 Describe the procedures and safeguards that will be implemented to protect the privacy and confidentiality of the participants' data. Include details, as applicable to the study, such as: privacy of interview site, procedures for coding/identifying data, provisions to avoid public identification/embarassment of participants; persons with access to private identifiable data, etc.

2.0 Where will study records and data collected at this site be stored?  
Select all that apply:  
☐ In a locked office  
☐ In a locked cabinet  
☐ Password protected network storage  
☐ Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)  
☐ Other

OTHER, describe:

If information will be stored on an end-user/portable device, describe the security on the end-user/portable device that will be used to prevent unauthorized access to the data in the event the device is lost or stolen:

3.0 Will the study use a National Institutes of Health (NIH) Certificate of Confidentiality?  
☐ Yes ☐ No Clear

If YES, what is the NIH Certificate of Confidentiality status?  
☐ The NIH Certificate of Confidentiality has been approved  
☐ Will apply for a NIH Certificate of Confidentiality for this study  
 Clear

**Callout boxes:**

- If "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)" is selected then explain how this device will be protected.
- As applicable, responses must be provided for MUSC IRB review.

Indicate if the study will access (view, obtain or use) participant protected health data.

Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI).

Click Continue.

**Protected Health Information (PHI) for Research**

Protected Health Information (PHI) is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future physical or mental health or conditions of an individual.

Covered Entity - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form.

1.0 To determine if this research study is using/disclosing PHI, select any of the following 18 elements that your study will require access to, as defined by the Health Insurance Portability and Accountability Act (HIPAA), as identifiers. If none of these 18 identifiers will be used/disclosed, then select the final option.

- ☐ Names
- ☐ All geographic subdivision smaller than a state including street address, city, county, precinct, zip code, and/or equivalent geocodes.
- ☐ All elements of date (except year) for dates directly related to an individual (DOB, admission date, discharge date, date of death)
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ Social security numbers
- ☐ Medical record number
- ☐ Health plan Beneficiary number
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Any other unique identifying number, characteristic or code
- ☐ None of the above 18 identifiers will be used/disclosed for this research study

**Callout boxes:**

- Checking the last option means **no access to protected health information** is needed for the study. However, if the study **has to access any of these identifiers** in order to obtain or associate health information, you must check all applicable identifiers on this page. *See notes on this Smartform page.*
- If the study requires access to any of the 18 identifiers but will not be linked to PHI, please select those that are applicable to the left. On the next screen, you will be able to select "Study where health information is not linked to identifiers."

If indicating that PHI is accessed, check all the sources of health information and how the project is requesting access to it.

***\*\*Note: HIPAA Waiver of Authorization is a required form for these studies and is automatically checked on the application\*\****

Click Continue.

Access to Protected Health Information (PHI) for Research

1.0 Indicate the sources of health information to be used  
Select all that apply:

- ☐ Medical Records/Physician Notes/Hospital Discharge Records
- ☐ Psychotherapy Notes
- ☐ Medical Test Results
- ☐ Payment/Billing/Insurance records
- ☐ Biological samples obtained from subjects for non research purposes
- ☐ Databases/Registries
- ☐ Tissue Repositories
- ☐ Other

If OTHER, indicate any other source(s) of health information to be collected/used:

2.0 How will PHI be accessed for the research study? (Check all those that apply)

- ☐ HIPAA Research Authorization
- ☒ HIPAA Waiver of Authorization for Research
- ☐ Accessing Information for Preparatory Work for Research
- ☐ Accessing Information Through Limited Data Sets
- ☐ Accessing Deceased Persons' Information
- ☐ Access information through De-identification
- ☐ Study where health information is not linked to identifiers

Responses to all questions must be provided for MUSC IRB review.

## HIPAA Waiver of Authorization for Research

Explain why HIPAA Waiver of Authorization is appropriate for this study.

Click Continue.

HIPAA Waiver of Authorization for Research

For some types of research, it may be impracticable for researchers to obtain written authorization from research participants. To address these situations, the Privacy Rule contains criteria for waiving or altering the authorization requirement by an IRB. Under the Privacy Rule, the IRB may waive or alter, in whole or in part, the Privacy Rule's Authorization requirements for the use and disclosure of PHI in connection with a particular research project. If the IRB approves such a waiver, which is permissible and not mandatory, the approval permits a covered entity to use or disclose PHI in connection with a particular research project without authorization.

1.0 Explain why the use or disclosure of PHI involves no more than minimal risk to the privacy of the individuals and why the risks are reasonable in relation to the expected benefits of the research as well as the importance of the knowledge that may be reasonably expected to result from the research:

2.0 Describe the plan to protect the identifiers from improper use and disclosure, and indicate where the PHI will be stored and who will have access:

3.0 Describe the plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, then so indicate:

4.0 Please provide written assurance that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permissible:

5.0 Explain why the research study could not practicably be conducted without the waiver or alteration:

6.0 Explain why the research study could not practicably be conducted without access to and use of the PHI:

7.0 Provide a detailed list of the PHI for which use or access is necessary to the research study:

8.0 Explain why the PHI to be used or disclosed is the minimum necessary to accomplish the research study objectives:

9.0 Describe measures that will be taken to ensure the waiver or alteration will not adversely affect the rights and welfare of the subjects:

Indicate whether de-identified information will be accessed (viewed, obtained or used) for this study.

***\*\*Note: The intent of this question is to document whether the study data is received through a de-identification method (i.e., via a de-identified database warehouse). \*\****

Click Continue.

Health Sciences  
south carolina  
a consortium to advance health science

Edit: Study - Pro00024043

Save | Exit | Hide/Show Errors | Print... | Jump To: | Privacy - Use of De-Ident to Access PHI | Continue >>

Use of De-identification to Access Protected Health Information (PHI)

1.0 The Privacy Rule permits covered entities, depending on IRB approval, to use and disclose data that have been de-identified without obtaining an authorization. The Principal Investigator must receive the data from the covered entity in a de-identified format. A covered entity may de-identify PHI in one of two ways. The first method requires the removal of every one of 18 identifiers enumerated at section 164.514(b)(2) of the Privacy Rule. Data that are stripped of these 18 identifiers are regarded as de-identified. The second way to de-identify PHI is to have a qualified statistician determine, using generally accepted statistical and scientific principles and methods, that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the anticipated recipient to identify the subject of the information.

The Privacy Rule permits a covered entity to assign to, and retain with, the health information a code or other means of record identification if that code is not derived from or related to the information about the individual and could not be translated to identify the individual. The covered entity may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

Will you be receiving de-identified information from a covered entity for the purpose of this project?

☒ Yes ☐ No Clear

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: | Privacy - Use of De-Ident to Access PHI | Continue >>

## General Comments

Include any General Comments and upload any additional documents that may assist with the review of the study.

Click Continue.

## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#). [Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Enter the study's Research Master ID.

Click Continue..

## End of Application

Click "Finish" to close the forms and return to the Application workspace.

***\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB.\*\****



The system will return to the protocol workspace.

*\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.*

*To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document. \*\**

The screenshot shows the eIRB Studies interface for a study titled 'TEST HCC STUDY ( Pro00035002 )'. The interface is divided into several sections:

- Current State:** Includes links for 'Pre Submission' (Edit Study, Printer Version, View Differences, View Smartform Progress) and 'My Activities' (Submit Study, Edit Guest Access, Withdraw, Log Public Comment, Copy Study).
- Study Information:** Displays the study short title, full title, principal investigator (Kathleen Brady), study coordinator (Brigette White), IRB campus (Medical University of South Carolina), PI department (CLINICAL NEUROSCIENCE - MUSC), PI institution (Medical University of South Carolina), pre-conversion study ID, and sponsors (NIH/NCI).
- Approvals:** Shows 'Study Team Approval to Post on SCresearch.org' as 'yes' and 'IRB Approval to Post on SCresearch.org' as 'no'.
- History:** Includes tabs for Personnel, Attachments, Pre Review Status, Reviewer Notes, and Change Log.

At the bottom, a note states: 'This area shows instructions and questions and important notifications regarding this Study.'

*\*\*Note: The continuing review process for these expedited review category 5 retrospective only studies follows a different path, as described in the [Continuing Review](#) section of this document.\*\**



## Requests for Central IRB Review

Centralized IRB (CIRB) review is the review model where the internal (local) IRB has agreed to serve as the single IRB of Record for the local site and other, external sites involved in a multi-site study. An IRB authorization agreement among study sites is required; therefore researchers should contact the local IRB to determine the status of appropriate authorization agreements prior to submitting the study to IRB.

Central IRB Review is indicated early in the application, as described in the '[IRB Review Request](#)' section of this document. These types of studies are completed as other review types (Full Board Review, Expedited Review, Exempt Review) and include additional application pages to complete for the CIRB process. If not already completed, follow the steps in the '[Beginning the Application](#)' to complete an application for the appropriate review type.

The remainder of this section describes **only** the additional pages/processes to complete a request for CIRB review. Additional resource documents are available in the [Education & Training](#) section of eIRB.

On the Study Identification – IRB Review Request page, the request began by responding ‘Yes’ to the Central Review question.

IRB OF RECORD IS YOUR INTERNAL IRB

Central Review

1.0

The review model where your internal IRB has agreed to serve as the single, central IRB of Record for other sites involved in a multi-site study. Be sure to contact your local IRB to assure that appropriate authorization agreements have been or will be executed.

The institution that allows this in eIRB is MUSC.

Is this a Central Review?

Yes

No

Clear

On a new Study Sites page, record the local sites, if there are foreign locations and whether the PI is the lead study investigator.

Study Sites - CIRB

1.0

\* Indicate all local sites that will be involved in the research study.

Check all that apply:

MUSC

VAMC

SCTR Research Nexus (formerly CTSC)

Hollings Cancer Center

Investigational Drug Service (Investigator MUST contact Pharmacy Services 843-792-9643 to get information on requirements and budget)

MUSC Simulation Center

2.0

\* Will you or your research personnel conduct this research study at other institutions/sites outside of the US?

Yes

No

Clear

3.0

Are you the lead investigator of this multi-site study?

Yes

No

Clear

Within the Remote Site Required Documents section, establish which attached study documents are required, optional or not applicable for the remote site locations to later upload for IRB approval.

Type of Document

Document Title

Document

Required

Optional

Not Applicable

Consent Form

Opiate\_Consent

Opiate\_Consent(0.09)

HIPAA Form

Opiate\_HIPAA

Opiate\_HIPAA(0.04)

Survey

Phone Screen

Phone Screen(0.02)

Advertisements

General Ad Format

General Ad Format(0.01)

General Comments

CV

CV(0.02)

The Lead PI submits the study to IRB for review via the existing review processes (see the [Human Subjects Research Requirements](#) section of this document to complete an application for the applicable study review type).

After approval, a Central IRB tab is included on the study to request review & house remote site documentation.

**Current State**  
**Approved**  
Edit Study  
Printer Version  
View Differences



History Personnel Amendments Continuing Reviews Status Changes Reportable Events Attachments Stamped ICF Coop. Review Status Reviewer Notes **Central IRB**

Add Remote Sites

**Central IRB - Summary Page**

Remote Site	Remote Site Status	RSD State
There are no items to display		

At that point, the Lead Site (researcher or study staff with edit rights) can add external (remote) sites by choosing the site from a pre-populated list of sites.

*Sites not found in the pick list must be added – contact the IRB for assistance.*

History Personnel Amendments Continuing Reviews Status Changes Reportable Events Attachments Stamped ICF Coop. Review Status Reviewer Notes **Central IRB**

Add Remote Sites

**Central IRB - Summary Page**

Remote Site	Remote Site Status	RSD State
There are no items to display		

**Add Remote Sites**

Select all remote sites: Add

Name	Remove
Boston University	Remove
Columbia University	Remove
Dartmouth College	Remove

OK Cancel

Select the 'Generate RSD' button to begin the request to add the site.

**RSD = Remote Site Documentation.** This is the mechanism for adding and updating sites, its personnel and site specific documentation for submission to IRB. RSDs be created and submitted independent of study amendments.

The Lead Site must initiate the first RSD to add the Remote Site personnel. At that point, the Remote Site personnel can edit the RSD.

Only one RSD can be open per site.

History Personnel Amendments Continuing Reviews Status Changes Reportable Events Attachments Stamped ICF Coop. Review Status Reviewer Notes **Central IRB**

Add Remote Sites

**Central IRB - Summary Page**

Approved Study Doc.	Generate RSD	Remote Site	Remote Site Status	RSD State
Approved Study Doc.	Generate RSD	Louisiana State University A & M	Approved for Accrual	Approved
Approved Study Doc.	Generate RSD	North Shore LIJ Health Systems	Inactive	Approved
Approved Study Doc.	Generate RSD	Ohio University		
Approved Study Doc.	Generate RSD	The Scripps Research Institute	Approved for Accrual	Approved

Remove Site

**Generate Remote Site Documentation**

Click OK to begin a request to add or update the below site's personnel and/or documentation.

Remote Site: Ohio University

OK Cancel

'Remove Site' deletes a site added before IRB Review. After IRB approves the site, removal can occur during an annual review

The RSD Workspace opens, which is similar to the Amendment Workspace.

Select 'Edit Remote Site Doc' to begin including the remote site details

On the first page of the RSD application, edit the RSD name, indicate the type of change requested and site enrollment status and may enter in a brief summary.

*Question #3 differentiates sites that require documents given to research subjects from sites that do not (e.g., site only serves as a data coordinating center) later in the application.*

Add the Remote site personnel.

*This then provides the Remote Site personnel access to update the RSD to add/edit additional site personnel and documentation.*

*Remote site personnel must have registered eIRB user IDs.* Additional information about this process is also available under the "Study Conduct" tab in the [Research Toolkit](#), as needed.

Upload required remote site documents and local context information on the final pages of the RSD application.

Submit the completed RSD to IRB.

*The Lead PI or other study personnel with edit rights can submit directly to IRB.*

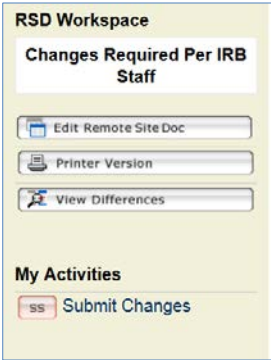


*This is usually the next step when the Lead Site personnel has completed the RSD application on behalf of the Remote Site.*

**Alternatively**, the system also supports a process where:

- 1) the Remote Site personnel completes the RSD application and submits it to the Lead site for review before IRB submission.
- 2) The Lead site personnel reviews the application for completeness and either
  - a. Submits it to IRB or
  - b. Request the Remote Site personnel make changes, after which the Lead site personnel can submit to IRB

Access RSD applications within the study's Amendments tab from the time of its creation.

Amendments						
Continuing Reviews   Status Changes   Reportable Events   Attachments   Stamped ICF   Coop. Review Status   Reviewer Notes   Central IRB						
Filter by	ID	Go	Clear	Advanced		
ID	Name	Remote Site	State	Last State Change	Review Type	
RSD10_Pro00053206	RSD 10 for IRB Study #Pro00053206	University of Pennsylvania	Changes Required Per Lead Site	3/17/2016 11:55 AM	Expedited	
RSD9_Pro00053206	RSD 9 for IRB Study #Pro00053206	Tulane University	IRB Staff Review	3/15/2016 11:13 AM		
rsd1_Baylor_Research_Institute	Add Baylor Research Institute	Baylor Research Institute	In Review	3/14/2016 4:41 PM	Expedited	
RSD6_Pro00053206	RSD 6 for IRB Study #Pro00053206	The Rockefeller University	Withdrawn	3/14/2016 4:28 PM		
RSD7_Pro00053206	RSD 7 for IRB Study #Pro00053206	Marshall University	Withdrawn	3/14/2016 4:20 PM		
rsd6_Pro00053206	Add Med Col of Wisconsin	Medical College of Wisconsin	Approved	3/8/2016 12:01 PM	Expedited	
rsd5_Northwestern_University_Pro00053206	Add North Western	Northwestern University	Approved	3/3/2016 3:14 PM	Expedited	
rsd4_University_of_Alabama_Birmingham	Add UAB	University of Alabama Birmingham	Approved	3/1/2016 4:25 PM	Expedited	
rsd2_Columbia_University	Add Columbia U as a new site	Columbia University	Approved	3/1/2016 4:14 PM	Expedited	
rsd3_University_of_Southern_California	Add U South Cal	University of Southern California	Withdrawn	3/1/2016 4:06 PM		
10 Items		page 1 of 1		10 / page		

<p>Respond to IRB change requests in the same manner for study amendments.</p> <p><i>Both the Lead site personnel and Remote site personnel have the ability to respond to comments.</i></p>	
<p>Upon RSD review, approved personnel and documents (along with the draft document versions) appear in the <i>Central IRB</i> tab, <i>Approved Site Docs</i> button</p>	
<p>Summaries of each remote site details are accessible on the study's Central IRB tab. This includes the approved personnel, documents, remote site status and state of the most recent RSD.</p> <p><i>The Central IRB tab is also the location where:</i></p> <ol style="list-style-type: none"> <li><i>the Lead Site personnel can add more sites and create new RSDs to update site details and create new remote site Reportable Events</i></li> <li><i>current Remote Site personnel can create new RSDs and Reportable Events</i></li> </ol>	

[Amendments](#), [Continuing Reviews](#) and [Reportable Events](#) for the **Lead Study Site** continue to be reported through the routine mechanisms for these, as described in the respective sections of this document. *The process for reporting Reportable Events for the Remote Site is available in the [CIRB resources](#). The process for reporting Continuing Reviews for the Remote Site is in progress.*



## Request for Facilitated Review

A facilitated review is one in which another IRB (non-HSSC IRB) is providing the primary review. MUSC provides a facilitated review of the study in these instances.

Facilitated Review is indicated early in the application. If not already completed, follow the steps in the ['Beginning the Application'](#) and then ['IRB Review Request'](#) section of this document to initiate this review request.

### Facilitated Review Documents

Provide documentation supporting the approval of the study.

*\*\*Note: The Protocol and HIPAA authorization form (if applicable) will be uploaded here instead of separate sections within the application. \*\**

The screenshot displays the 'Facilitated Review Documents' section of the MUSC eIRB application. The interface includes a top navigation bar with 'Back' and 'Continue' buttons. The main content area is divided into several sections for uploading documents:

- 1.0 Provide the initial CIRB application:** Includes an 'Add' button and a table with columns: Name, Description, Orig. Author, Orig. Created, and Last Modified. A message states 'There are no items to display'.
- 2.0 Upload scientific review comments/forms:** Similar to section 1.0, with an 'Add' button and a table.
- 3.0 Provide the current CIRB Approval Protocol:** Includes an 'Add' button and a table. One entry is visible: 'A Protocol.doc' by 'musc-radiology-pi musc' created on '7/26/2011 10:28 AM'.
- 3.1 CIRB Approval Date:** Two date pickers for 'CIRB Approval Date' and 'CIRB Expiration Date'.
- 4.0 Protocol Summary Information (as applicable):** Includes text input fields for 'Study Protocol Version' and 'Dated:'. A date picker is also present.
- 5.0 Provide a copy of all the current CIRB approved consent forms:** Includes an 'Add' button and a table.
- 6.0 Approved Full Board Minutes from CIRB or external IRB:** Includes a 'Date of Minutes' date picker and an 'Add' button for uploading minutes.
- 7.0 Upload HIPAA Research Authorization Form:** Includes an 'Add' button and a table.
- 8.0 Approval Letters:** Includes an 'Add' button and a table.

On the right side of the interface, there is a sidebar with the text 'Examples: CIRB Primary Reviewer Comments, Pharmacy Reviewer Comments, Other Reviewer Comments' and a 'From CIRB' label at the bottom.



## Study Identification

The system will route the application to complete information regarding the IRB Board, Personnel and Study Locations

See the [Adding Study Personnel](#) section of this document for additional instructions to complete these sections, if desired.

The screenshot shows the 'MUSC Institutional Review Board Selection' screen. At the top, there is a navigation bar with buttons: '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', and a dropdown menu 'Study Identification - MUSC IRB Selection'. The main heading is 'MUSC Institutional Review Board Selection'. Below it, section 1.0 is titled '\* Select the appropriate committee:'. There are three radio button options: 'IRB-I - Medical' (selected), 'IRB-II - Medical', and 'IRB-III - Medical'. Each option has a list of departments associated with it. For IRB-I, the departments are: Cell Biology and Anatomy, Cell and Molecular Pharmacology & Experimental Therapeutics, Clinical Services, College of Health Professions, College of Nursing, College of Pharmacy, Dermatology, Harper Student Life Center, Medical Lab Sciences, Otolaryngology, Pathology and Laboratory Medicine, Pediatrics, Pharmaceutical Sciences, Pharmacy Practice, Physical Therapy, Psychiatry and Behavioral Sciences, Radiology, Urology. For IRB-II, the departments are: Anesthesiology, Biochemistry and Molecular Biology, Center For Health Care Research, Experimental Oncology, Family Medicine, General Dentistry, Graduate Studies, Medicine, Microbiology and Immunology, Molecular and Structural Biology, Neurosciences, Obstetrics and Gynecology, Ophthalmology, Oral & Maxillofacial Surgery, Orthopedic Surgery, Pediatric Dentistry/Orthodontics, Physical Medicine & Rehabilitation, Prosthodontics, Public Health Sciences, Radiation Oncology, Stomatology, Surgery. For IRB-III, the department is 'Industry Sponsored Trials'. At the bottom left is a 'Clear' button.

The screenshot shows the 'Study Personnel Affiliation' screen. At the top right, there is a 'Help' button and a 'VIEW WORKSHEET' link. The main heading is 'Study Personnel Affiliation'. Below it, section 1.0 is titled '\* Are all personnel on this research study affiliated with the institution of the designated IRB? If no, the next screen will contain a list of HSSC eIRB users for all institutions.' There are two radio button options: 'Yes' (selected) and 'No'. There is also a 'Clear' button. At the bottom left is a '<< Back' button. At the bottom right is a 'Continue >>' button. The navigation bar at the bottom includes: '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', and a dropdown menu 'Study Identification - Study Personnel Affiliation'.

The screenshot shows the 'Study Sites' screen. At the top right, there is a 'Help' button and a 'VIEW WORKSHEET' link. The main heading is 'Study Sites'. Below it, section 1.0 is titled '\* Indicate all affiliated sites that will be involved in the research study. Check all that apply:'. There is a list of checkboxes for various sites: MUSC, VAMC, SCTR Research Nexus (formerly CTIC), Charleston Memorial, Georgetown Hospital, Hollings Cancer Center, Investigational Drug Service (Investigator MUST contact Pharmacy Services 843-712-9643 to get information on requirements and budget), Off-Campus, Carolina Regional Cancer Center (CROC), and MUSC Simulation Center. Below this list is a text box labeled 'List any other affiliated facilities where research activities will take place:'. At the bottom left is a '<< Back' button. At the bottom right is a 'Continue >>' button. The navigation bar at the bottom includes: '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', and a dropdown menu 'Study Identification - Study Sites'.

## CITI Training Records

This form assists the research team in verifying research staff training required for initial and continued study approval.

For additional guidance for this feature is located in the [Education & Training](#) section of eIRB.

**CITI Training Records**

Review this information when considering if human subjects research education/training is complete for all investigators and study staff. Personnel training displayed are the current and historical records required by the institution associated with the team member's eIRB user account.

**NOTE: All study team members must be in compliance with training requirements prior to beginning any role in the study.**

If training is missing or expired:

1. Instructions for completing research education requirements can be found at [www.musc.edu/citi](http://www.musc.edu/citi).
2. Verify this institution's affiliation has been added to the CITI user profile and complete the required training.
3. Verify the first name, last name and preferred email of the CITI user profile matches the eIRB user profile.

The content on this page is provided as a tool to display research training records in real time. These data are routinely updated and are, therefore, current at the present viewing of this content.

1.0 Principal Investigator CITI Completion Records						
Name	Organization	Completed CITI Training				
		Curriculum	Group	Stage	Date Earned	Date Expires

2.0 Study Coordinator CITI Completion Records						
Name	Organization	Completed CITI Training				
		Curriculum	Group	Stage	Date Earned	Date Expires

## Study Subject

Enter information regarding the subjects you will include in the study

Check all subject populations that are involved in this study.

***\*\*Note: The system will prompt you to answer questions regarding vulnerable populations if they are a part of your study or if there is no intent to include set groups. \*\****

Describe the population, inclusion/exclusion & recruitment procedures.

Click Continue.

### Study Subjects

#### 1.0 \* Estimated Local Enrollment Goal

Enter the anticipated number of subjects to be enrolled at local site:

#### 2.0 Estimated Study-Wide Enrollment Goal

Enter the anticipated number of subjects to be enrolled at all sites:

#### 3.0 \* Briefly describe the setting in which the research will be conducted.

#### 4.0 \* Participant Remuneration (Payment/Academic Credit)

Will subject(s) receive remuneration?

☒ Yes ☐ No [Clear](#)

#### 5.0 \* Will prospective participants be vulnerable to coercion or undue influence?

☐ Yes ☒ No [Clear](#)

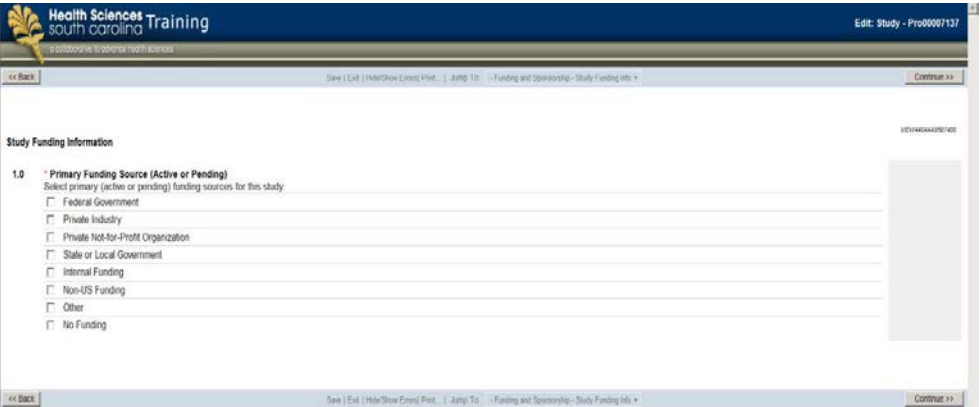
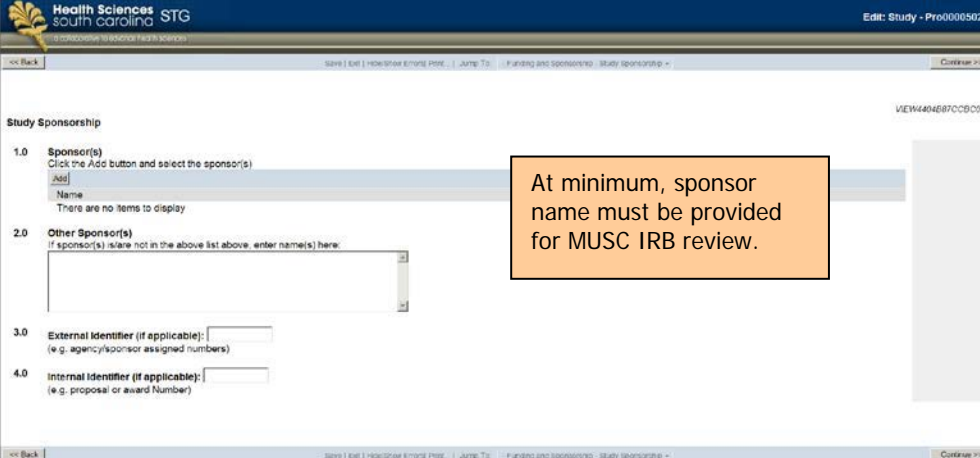
If yes, briefly describe additional safeguards included in the protocol to protect the rights and welfare of participants likely to be vulnerable.

A 'Yes' response indicates your population may be considered to be a vulnerable one (i.e., pregnant women, children, prisoners, cognitively impaired or another category for specialized research). Information must also be included in the text box.

6.0 \* Identify targeted subject population(s) involved in this research study (Note: The purpose of this question is to determine equitable selection of subjects and to identify vulnerable populations.)

Select all that apply:

- ☐ Adults (18+)
- ☐ Males
- ☐ Females
- ☐ Pregnant Women
- ☐ Human Fetuses or Neonates
- ☐ Minorities
- ☐ Children (<18 years of age)
- ☐ Prisoners
- ☐ Comatose persons
- ☐ Cognitively Impaired persons
- ☐ Terminally Ill persons
- ☐ Employees of the principal investigator's institution
- ☐ Students enrolled at the principal investigator's institution
- ☐ Non-English speaking persons
- ☐ Socially/Economically disadvantaged persons
- ☐ Caregivers
- ☐ Elderly/Aged persons
- ☐ Institutionalized individuals

	<p>7.0 * <b>Study Population</b> Briefly describe the study population? (e.g. healthy volunteers, adults with Type II Diabetes, children with Asthma):</p> <p>8.0 * <b>Describe the selection criteria (inclusion/exclusion criteria):</b></p> <p>9.0 * <b>Describe recruitment procedures, including how subjects will be contacted, by whom, and how eligibility will be determined.</b></p>
<p><b>Study Funding</b></p> <p>Indicate study funding sources.</p> <p><i>**Note: If the 'Federal Government' is the funding source, a <a href="#">Favorable Funding Score Letter</a> must be included.</i></p> <p><i>PIs (not including students) with internally or non-funded studies may be prompted to include details from the Intra-Institutional Transfer (IIT) form for an IRB review fee.</i></p> <p>Click Continue.</p>	
<p>Indicate details of study sponsorship.</p> <p><i>**Note: If any of this information is omitted, it will not appear on the IRB review letter. **</i></p> <p>Click Continue.</p>	
<p>The Intra-Institutional Transfer (IIT) Smartform is required for faculty researchers of unfunded or internally funded IRB studies.</p>	

Please continue to consult with your business administrators to obtain the information required for IRB submission.

Click Continue.

Internally Sponsored or Un-sponsored Research

1.0 PAYING UDAK

Please enter the paying UDAK for the \$100 IRB fee.

Entity: MUC Account: 50228 Unit: \* Project: \* Reporting: \* If Entity is MUCR, Enter Project Year (a sequential number representing the current grant year [i.e., 01, 02, etc.]):

UDAK:

2.0 IIT Number

An IIT is not necessary; however, you may enter an IIT number along with the UDAK.

## Application Checklist

Check all applicable items for this project.

**\*\*Note:** The program will prompt you for additional information depending on your responses (i.e. if you are using drugs/devices, surveys, advertisements, radioactive substances, HSSC Clinical Data Warehouse (CDW), etc.). You will also be prompted to upload a copy of all forms you'll use (i.e., advertisements, surveys/questionnaires, consents, etc.). \*\*\*

Click Continue.

## Application Checklist

### 1.0 Will the following be involved in the research study?

Select all that apply

- ☒ Informed consent document(s)
- ☐ Waiver of the Requirement to Obtain Written Informed Consent
- ☐ Waiver of Informed Consent of Subjects
- ☐ Clinical trials
- ☐ Data Safety Monitoring Plan is used in the research study
- ☐ Medical Record/Chart Review
- ☐ Vaccine Trials
- ☐ Human Genetic Research
- ☐ Human In Vitro Fertilization
- ☐ Transplantation
- ☐ Alcohol and Drug Abuse Research
- ☐ Use of survey, questionnaire, focus group/interview questions
- ☐ Healthy, normal volunteers as research subjects
- ☐ Individuals with HIV/AIDS as research subjects
- ☐ Cancer-related research
- ☐ Drugs will be used in this research study
- ☐ Chemicals, metabolites, nutritional substances, biological agents or other substances whether regulated or not that will be administered to subjects
- ☐ Use of Placebos
- ☒ Investigation of medical device, instrument, machine, computer program or other device, FDA approved
- ☐ Specimens (blood, urine, tissue and other human products)
- ☐ The storage of biological specimens (e.g. biological material, tissue, blood, etc.) or Data (e.g. subject data) for potential future, yet undesignated, research
- ☐ Recombinant or synthetic nucleic acid molecules, gene transfer, infectious agents, select agents or Botulinum toxins) exposure to human subjects
- ☐ The use of diagnostic or therapeutic ionizing radiation, or radioactive isotopes that are not part of the research as part of this research study
- ☐ Advertisements or recruiting materials
- ☐ Data from the statewide Health Sciences South Carolina (HSSC) Clinical Data Warehouse

A clinical trial is a prospective biomedical or behavioral human subject research study that is designed to answer specific questions about biomedical or behavioral interventions or lab test evaluations and determine whether these are safe, efficacious and effective. These trials often require Data and Safety Monitoring Plans (DSMPs).

All study activities must be indicated for MUSC IRB review.

## Clinical Trials

Indicate the type of clinical trial applicable for the project.

Click Continue.

### Clinical Trials

1.0 \* What is the phase of the clinical trial?

- ☐ Phase I clinical trial
- ☐ Phase II clinical trial
- ☐ Phase III clinical trial
- ☐ Phase IV clinical trial
- ☐ Symptom Management
- ☐ Prevention Trial
- ☐ Observational
- ☐ Interventional
- ☐ Other
- ☐ This study does not involve a clinical trial
- ☐ Open-Label Extension Study

2.0 If OTHER, describe:

Visit [ClinicalTrials.gov](http://ClinicalTrials.gov) for descriptions of trial [Phases](#). Additional descriptions are below:

**Symptom Management trials** improve comfort and the quality of life for individuals with a serious or life-threatening illness.

**Prevention trials** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals or lifestyle changes.

**Observational trials** assess outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine clinical care, but participants are not assigned to specific intervention by the investigator.

**Interventional trials** involve participants receiving specific interventions according to a research plan or protocol. These trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.

**Open-Label Extension Studies** are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.

[ClinicalTrials.gov](http://ClinicalTrials.gov)

## Conflict of Interest

Indicate potential Conflict of Interest.

Click Continue.

*\*\*Note: A 'Yes' or privately funded studies response will require responses on the next screen in the system to disclose the interest. In addition, conflicts of interest must be verified at the time of continuing review. \*\**



## Consent Process

Describe Consent Process and upload consent form(s).

*\*\*Note: A watermark approval stamp template must be included in consenting documents. Access to the consent template & watermark stamp is available at the IRB's website [here](#).*

Click Continue.

The screenshot shows the 'Consent Process' form in the eIRB system. It includes sections for describing the consent process (1.0-5.0) and uploading consent forms (6.0). Annotations highlight key requirements: a watermark approval stamp template must be included, and a response must be provided for MUSC IRB review. A red circle highlights the 'Add' button for uploading documents, and a note instructs users to click 'Add' to upload an electronic copy of their consent form(s) and click 'OK' when finished.

**Consent Process**

1.0 Will the consent be obtained from the subject?  
☐ Yes ☐ No Clear

2.0 Will the consent be obtained from the subject's legally authorized representative?  
☐ Yes ☐ No Clear

3.0 Describe any waiting period between informing the prospective participant and obtaining consent:

4.0 Who will obtain consent?  
Please list Research Personnel Authorized and Qualified to obtain Informed Consent

5.0 Describe the process (where, when and how) for obtaining consent.

6.0 **Consent Forms**  
To allow for documentation of IRB approval and electronic watermarking, please use the following link to access your institution's Informed Consent Form Template:  
link\_url  
No template or form available  
(If no template is available, please leave at least a one inch margin at the bottom of each page of the final "clean" version of the consent document(s).)

**NOTE:** When reviewing when uploading a

\* Click the Add button to upload a new document.

Click "Add" to upload an electronic copy of your consent form(s). You may add multiple documents. Click "OK" when finished

Name	Version	Orig. Author	Orig. Created	Last Modified
Consent	0.01	musc-radiology-pi musc	12/19/2011 9:34 AM	12/19/2011 9:34 AM

Buttons: Upload New Version, Add, Delete



## Privacy and Confidentiality

Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

Select where study records and data collected will be stored.

Indicate whether or not this project will use a federal Certificate of Confidentiality.

***\*\*Note: A NIH Certificate of Confidentiality protects investigators and institutions from being forced to disclose research participants' identifying information in research projects with 'sensitive' topics (studies in which disclosure can have adverse consequences for the participant). \*\****

Click Continue.

The screenshot shows the 'Privacy and Confidentiality' section of the MUSC eIRB Smartform. The header includes the 'Health Sciences south carolina' logo and navigation links. The main content area is titled 'Privacy and Confidentiality' and contains several questions. Question 1.0 asks for procedures to protect privacy and confidentiality. Question 2.0 asks where study records and data will be stored, with options for locked office, locked cabinet, password-protected network storage, password-protected end-user/portable device, or other. Question 3.0 asks if the study will use a National Institutes of Health (NIH) Certificate of Confidentiality. There are two callout boxes: one for question 2.0 stating that if a password-protected end-user/portable device is selected, the user must explain how it will be protected; and another for question 3.0 stating that as applicable, responses must be provided for MUSC IRB review. Arrows point from the callout boxes to the relevant questions.

Indicate if the study will access (view, obtain or use) participant protected health data.

Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI).

Click Continue.

The screenshot shows the 'Protected Health Information (PHI) for Research' section of the MUSC eIRB Smartform. The header includes the 'Health Sciences south carolina' logo and navigation links. The main content area is titled 'Protected Health Information (PHI) for Research' and contains several questions. Question 1.0 asks to determine if the research study is using/disclosing PHI, and to select any of the following 18 elements that the study will require access to, as defined by the Health Insurance Portability and Accountability Act (HIPAA), as identifiers. The list of identifiers includes: Names, All geographic subdivision smaller than a state including street address, city, county, precinct, zip code, or rural delivery point; All elements of date (except year) for dates directly related to an individual (DOB, admission date, discharge date, etc.); Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record number; Health plan beneficiary number; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; Full face photographic images and any comparable images; Any other unique identifying number, characteristic or code; and None of the above 18 identifiers will be used/disclosed for this research study. There are two callout boxes: one for question 1.0 stating that checking the last option means no access to protected health information is needed for the study; and another for question 1.0 stating that however, if the study has to access any of these identifiers in order to obtain or associate health information, the user must check all applicable identifiers on this page. See notes on this Smartform page. Arrows point from the callout boxes to the relevant questions.

If indicating that PHI is accessed, check all the sources of health information and how the project is requesting access to it.

Click Continue.

Responses to all questions must be provided for MUSC IRB review.

For VA studies, indicate medical record flagging waiver requests.

Click Continue.

## Drugs

If you indicated that drugs are used for the study, complete the drug information section.

Click Continue.

*\*\*Note: Depending on your responses, you will be required to answer questions specific to investigational drugs, marketed drugs or other types of drugs.*

## Devices

If you indicated you would be using a device, begin the series of questions related to the device activities on your study, including IDE application, IDE exemption, 510K letters, risk determinations, HUDs and storage & dispensing. Click Continue.

## General Comments

Include any General Comments and upload any additional documents that may assist with the review of the study.

***\*\*Note: upload a CV here if the study is privately funded, involves drug intervention or as requested by IRB\*\****

Click Continue.

The screenshot shows the 'General Comments' section of the eIRB application. At the top, there is a header for 'Health Sciences South Carolina' and a sub-header 'eIRB Application for Human Subjects Research'. The page number 'Edit: Study - Pro00024043' is in the top right. Below the header, there are navigation links: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: >> General Comments <', and 'Continue >>'. The main content area is titled 'General Comments' and contains two numbered sections: 1.0 'Add any additional comments to assist in the review of this research study.' with a large text input box, and 2.0 'Add any miscellaneous documents that do not fit in other sections of the study application.' with a note about Palmetto Health IRB applications and a 'Click Add to upload document(s)' button. Below this is a table with columns: 'Add', 'Name', 'Description', 'Orig. Author', 'Orig. Created', and 'Last Modified'. The table currently shows 'There are no items to display'. A vertical sidebar on the right contains the ID 'VEH444F021C48C00'.

## S.C. Research Studies Directory Online Posting

The study will be included on [SCResearch.org](http://SCResearch.org), a state-wide online directory of studies actively recruiting subjects.

***\*\*Note: if you DO NOT want your study included in this directory, you must remove the checkbox\*\****

Continue to the next screen to enter in the recruitment coordinator's name, phone & e-mail and select from a list of keywords to associate with the study.

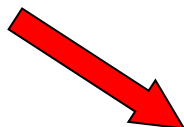
The screenshot shows the 'SCResearch.org Directory' posting form. At the top, there is a header for 'SCResearch.org Directory' and a sub-header 'Recruitment Contact and Keywords: The following information is required to populate SCResearch.org and can be edited at any time without requiring IRB review:'. The page number 'Edit: Study - Pro00024043' is in the top right. Below the header, there are navigation links: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: >> SCResearch.org Directory <', and 'Continue >>'. The main content area is titled 'SCResearch.org Directory' and contains a paragraph explaining the directory's purpose. Below this is a checkbox labeled 'INCLUDE this study on the SCResearch.org website', which is currently checked. A vertical sidebar on the right contains the ID 'VEH444F021C48C00'.

The screenshot shows the 'Recruitment Contact and Keywords' section of the SCResearch.org Directory posting form. It contains four numbered sections: 1.0 'Recruitment Coordinator:' with a 'Select' button and a note 'Click the Select button and choose the person who should be contacted by potential volunteers.'; 2.0 '\* Recruitment Coordinator Phone:' with a text input field; 3.0 '\* Recruitment Coordinator Email:' with a text input field; and 4.0 '\* Keyword(s):' with a note 'Click the Add button and select as many keywords that apply to this study:' and an 'Add' button. A vertical sidebar on the right contains the ID 'VEH444F021C48C00'.

Review a preview of how the study will appear on SCResearch.org.

Follow the instructions on this screen to make changes and finalize the study application.

Posting the study on the registry & the information in this section can be revised at any point by accessing the 'Edit SC Research Studies Directory Posting' option on the protocol's main page.



**SCResearch.org Directory**

Below is a preview of how your study will appear on SCResearch.org.

In addition to other study details (Study Title, PI Name, etc.), your Brief Study Summary will be displayed for public view. To change this language, Jump To the Study Identification Smartform page and edit the textbox *Brief Study Summary*. **Once IRB approved, an amendment will be required to change this language as well as other study details (with the exception of the recruitment contact information and Keywords).**

Click "Continue" if no edits are required.

The Use of Acamprosate in Alcohol Dependent Individuals with Comorbid Anxiety and Depressive Disorders		
<b>Date Added</b>	<b>Keywords</b> Psychiatry, Mental Health	<b>Institution</b> Medical University of South Carolina
<b>PRO Number</b> Pro00011713	<b>Summary</b> This study is being conducted to see if the drug Campral® (also called acamprosate) is safe and effective in treating adults who are alcohol dependent and who are also experiencing anxiety disorder or depression. This study will be conducted at three sites across the country and will involve approximately 90 volunteers between the ages of 18-60.	<b>Recruitment Contact</b> Stephanie Gentlin 843-792-8300 success@musc.edu
<b>Researcher</b> musc-surgery-pi musc		

**Health Sciences south carolina**  
a collaborative to advance health

**eIRB Studies**

Studies > Acamprosate in Alcohol

**Current State**

Approved

View Study  
Printer Version  
View Differences

**My Activities**

- Edit Guest Access
- PI Suspend
- Copy Study
- Edit Communication Leads
- Edit SC Research Studies Directory Posting**

**Edit SC Research Studies Directory Posting**

Post Study online in S.C. Research Studies Directory:

☒ **INCLUDE** study in S.C. Research Studies Directory.

**Recruitment Coordinator:**  
Clare Tyson | Select... | Clear

**if name is not found, enter it here:**

**\* Recruitment Coordinator Phone:**  
843-792-1534

**\* Recruitment Coordinator Email:**  
tysonc@musc.edu

**\* Edit/Add Keyword(s):**

Alcohol Remove  
Anxiety Remove  
Depression Remove  
Mental Health Remove  
Psychiatry Remove

## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#). [Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Save | Edit | Hide/Show Errors | Print... | Jump To: Research Master ID (RMID) - MUSC v2 | Continue >>

**Reviewer Notes**

Type	Reviewer	Date Created	Date Modified
There are no items to display			

**Research Master ID (RMID)**

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for study applications and is created on the [MUSC Research Master ID website](#), which also includes details about this process.

Enter the Research Master ID (RMID) associated with this study. If the study's RMID is not known, [CLICK HERE](#) to go to the RMID website to search or create one. Then, return here to add the RMID to this study application.

**\* Research Master ID:**

Save | Edit | Hide/Show Errors | Print... | Jump To: Research Master ID (RMID) - MUSC v2 | Continue >>

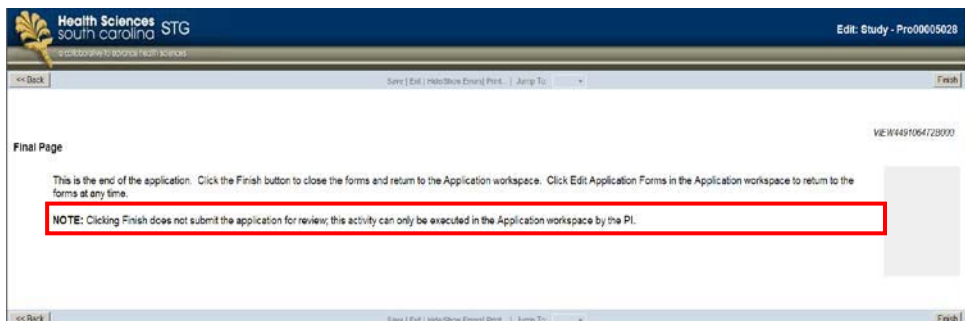
Enter the study's Research Master ID.

Click Continue.

## End of Application

Click "Finish" to close the forms and return to the Application workspace.

*\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB.*

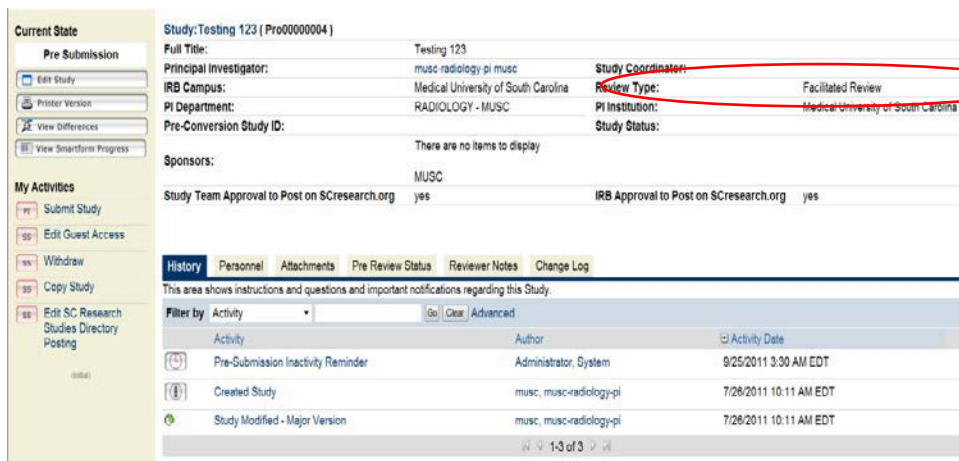


The system will return to the protocol workspace.

A facilitated review type is indicated.

*\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.*

*To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document. \*\**



Activity	Author	Activity Date
Pre-Submission Inactivity Reminder	Administrator, System	9/25/2011 3:30 AM EDT
Created Study	musc, musc-radiology-pi	7/26/2011 10:11 AM EDT
Study Modified - Major Version	musc, musc-radiology-pi	7/26/2011 10:11 AM EDT



## Request for NCI Independent Review

A NCI Independent review is one in which the NCI Central IRB is providing the primary review. MUSC provides limited review of specified, local study activities in these instances.

If not already completed, follow the steps in the ['Beginning the Application'](#).

<p><b>IRB Review Request</b></p> <p>Indicate Study Review Type as "Independent Review (NCI CIRB)".</p> <p>Click Continue.</p>	<div data-bbox="493 422 1482 596"><p><b>Independent Review Model</b></p><p>3.0 The review model where the NCI CIRB is the sole IRB of Record responsible for both study review as well as review of local context considerations for enrolled institutions.</p><p><u>The institutions that allow this review in eIRB are MUSC, OHS, PPI, AnMod and Self Regional.</u></p><p>* Is this an Independent Review (NCI CIRB)?</p><p><input checked="" type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p></div>																								
<p>NCI CIRB documents</p> <p>Upload the NCI CIRB approval documents where indicated.</p> <p>Click Continue.</p>	<div data-bbox="493 827 1424 1331"><p><b>Independent Review Documents</b></p><p>1.0 <b>Provide the current CIRB Approval Protocol:</b></p><p>* Click the Add button to upload document(s):</p><div data-bbox="545 932 1424 1003"><p><a href="#">Add</a></p><table border="1"><thead><tr><th>Name</th><th>Description</th><th>Orig. Author</th><th>Orig. Created</th></tr></thead><tbody><tr><td><a href="#">test2</a></td><td></td><td>Brigette White</td><td>1/25/2015 10:53 AM</td></tr></tbody></table><p><a href="#">Upload Revision</a></p></div><p>2.0 <b>Provide a copy of all the current CIRB approved consent and/or HIPAA authorization forms:</b></p><p>* Click the Add button to upload documents(s):</p><div data-bbox="545 1100 1424 1171"><p><a href="#">Add</a></p><table border="1"><thead><tr><th>Name</th><th>Description</th><th>Orig. Author</th><th>Orig. Created</th></tr></thead><tbody><tr><td><a href="#">Conpar3.doc</a></td><td></td><td>Erin Klintworth</td><td>4/8/2015 2:03 PM</td></tr></tbody></table><p><a href="#">Upload Revision</a></p></div><p>3.0 <b>Approval Letters</b></p><p>* Click the Add button to upload the current CIRB Approval Letter:</p><div data-bbox="545 1268 1424 1331"><p><a href="#">Add</a></p><table border="1"><thead><tr><th>Name</th><th>Description</th><th>Orig. Author</th><th>Orig. Created</th></tr></thead><tbody><tr><td><a href="#">Conpar3.doc</a></td><td></td><td>Erin Klintworth</td><td>4/8/2015 2:03 PM</td></tr></tbody></table><p><a href="#">Upload Revision</a></p></div></div>	Name	Description	Orig. Author	Orig. Created	<a href="#">test2</a>		Brigette White	1/25/2015 10:53 AM	Name	Description	Orig. Author	Orig. Created	<a href="#">Conpar3.doc</a>		Erin Klintworth	4/8/2015 2:03 PM	Name	Description	Orig. Author	Orig. Created	<a href="#">Conpar3.doc</a>		Erin Klintworth	4/8/2015 2:03 PM
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Name	Description	Orig. Author	Orig. Created																						
<a href="#">Conpar3.doc</a>		Erin Klintworth	4/8/2015 2:03 PM																						



The system will route the application to complete information regarding the IRB Board, Personnel and Study Locations

<< Back      Save | Exit | Hide/Show Errors | Print... | Jump To:    - Study Identification - MUSC IRB Selection -

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MUSC Institutional Review Board Selection

1.0 \* Select the appropriate committee:

IRB-I - Medical ⑧ University of South Carolina	Cell Biology and Anatomy, Cell and Molecular Pharmacology & Experimental Therapeutics, Clinical Services, College of Health Professions, College of Nursing, College of Pharmacy, Dermatology, Harper Student Life Center, Medical Lab Sciences, Otolaryngology, Pathology and Laboratory Medicine, Pediatrics, Pharmaceutical Sciences, Pharmacy Practice, Physical Therapy, Psychiatry and Behavioral Sciences, Radiology, Urology
IRB-II - Medical ⑧ University of South Carolina	Anesthesiology, Biochemistry and Molecular Biology, Center For Health Care Research, Experimental Oncology, Family Medicine, General Dentistry, Graduate Studies, Medicine, Microbiology and Immunology, Molecular and Structural Biology, Neurosciences, Obstetrics and Gynecology, Ophthalmology, Oral & Maxillofacial Surgery, Orthopedic Surgery, Pediatric Dentistry/Orthodontics, Physical Medicine & Rehabilitation, Prosthodontics, Public Health Sciences, Radiation Oncology, Stomatology, Surgery
IRB-III - Medical ⑧ University of South Carolina	Industry Sponsored Trials

Clear

Help

VIEW WORKBOOK SCHEMATA

Study Personnel Affiliation

1.0

\* Are all personnel on this research study affiliated with the institution of the designated IRB? If no, the next screen will contain a list of HSSC eIRB users for all institutions.

☐ Yes ☒ No Clear

<< Back

Save | Exit | Hide/Show Errors | Print | Jump To

Study Identification - Study Personnel Affiliation >

Continue >>

**Study Sites**

1.8 \* Indicate all affiliated sites that will be involved in the research study.  
Check all that apply:

☐ MUSC

☐ VAMC

☐ SCTR Research Nexus (formerly CTRC)

☐ Charleston Memorial

☐ Georgetown Hospital

☐ Hollings Cancer Center

☐ Investigational Drug Service (Investigator MUST contact Pharmacy Services 643-752-9643 to get information on requirements and budget)

☐ Off Campus

☐ Carolina Regional Cancer Center (CRCC)

☐ MUSC Simulation Center

List any other affiliated facilities where research activities will take place:

2.8 \* Does this study involve other non-affiliated institutions, organizations or sites?  
☒ Yes ☐ No Clear

## CITI Training Records

This form assists the research team in verifying research staff training required for initial and continued study approval.

For additional guidance for this feature is located in the [Education & Training](#) section of eIRB.

**CITI Training Records** V0100201502050404

Review this information when considering if human subjects research education/training is complete for all investigators and study staff. Personnel training displayed are the current and historical records required by the institution associated with the team members' eIRB user account.

**NOTE:** All study team members must be in compliance with training requirements prior to beginning any role in the study.

If training is missing or expired:

1. Instructions for completing research education requirements can be found at [www.musc.edu/citi](http://www.musc.edu/citi).
2. Verify this institution's affiliation has been added to the CITI user profile and complete the required training.
3. Verify the first name, last name and preferred email of the CITI user profile matches the eIRB user profile.

The content on this page is provided as a tool to display research training records in real time. These data are routinely updated and are, therefore, current at the present viewing of this content.

**1.0 Principal Investigator CITI Completion Records**

Name	Organization	Completed CITI Training	Curriculum	Group	Stage	Date Earned	Date Expires
------	--------------	-------------------------	------------	-------	-------	-------------	--------------

**2.0 Study Coordinator CITI Completion Records**

Name	Organization	Completed CITI Training	Curriculum	Group	Stage	Date Earned	Date Expires
------	--------------	-------------------------	------------	-------	-------	-------------	--------------

## Study Subjects

Check all subject populations that are involved in this study.

Click Continue.

**Study Subjects**

**1.0 \* Participant Remuneration (Payment/Academic Credit)**  
Will subject(s) receive remuneration?  
☐ Yes ☐ No

**2.0 \* Identify targeted subject population(s) involved in this research study (Note: The purpose of this question is to determine equitable selection of subjects and to identify vulnerable populations.)**  
Select all that apply:  
☐ Adults (18+)  
☐ Males  
☐ Females  
☐ Pregnant Women  
☐ Human Fetuses or Neonates  
☐ Minorities  
☐ Children (<18 years of age)  
☐ Prisoners  
☐ Comatose persons  
☐ Cognitively impaired persons  
☐ Terminally ill persons  
☐ Employees of the principal investigator's institution  
☐ Students enrolled at the principal investigator's institution  
☐ Non-English speaking persons  
☐ Socially/Economically disadvantaged persons  
☐ Caregivers  
☐ Elderly/Aged persons  
☐ Institutionalized individuals

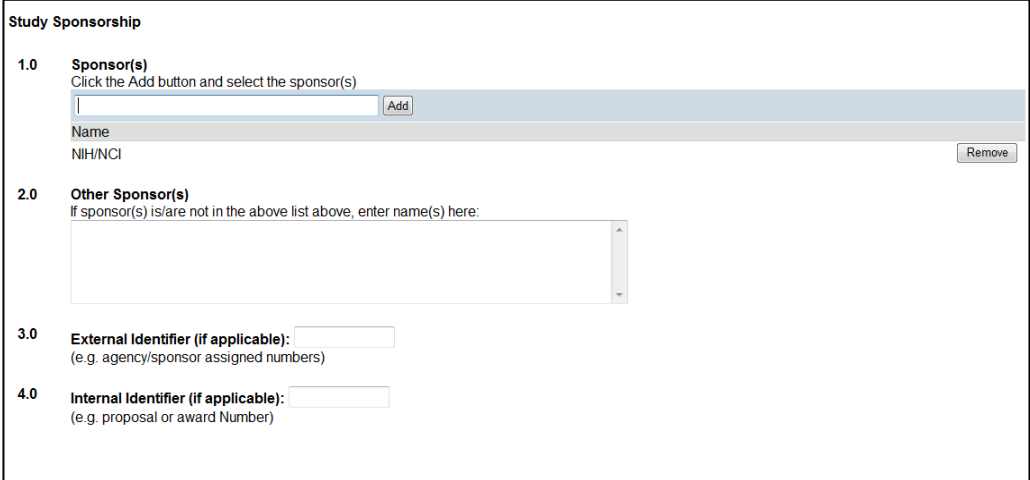
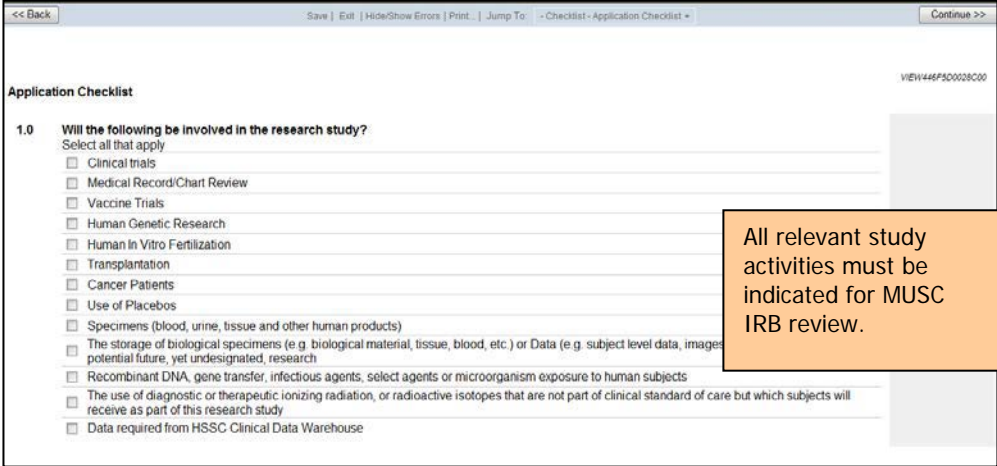
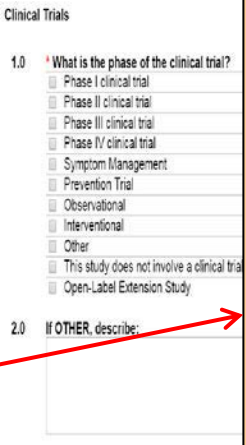
## Study Funding

Indicate study funding sources.

Click Continue.

**Study Funding Information**

**1.0 \* Primary Funding Source (Active or Pending)**  
Select primary (active or pending) funding sources for this study:  
☐ Federal Government  
☐ Private Industry  
☐ Private Not-for-Profit Organization  
☐ State or Local Government  
☐ Internal Funding  
☐ Non-US Funding  
☐ Other  
☐ No Funding

<p><b>Study Sponsorship</b></p> <p>Indicate details of study sponsorship.</p> <p><i>**Note: If any of this information is omitted, it will not appear on the IRB review letter. **</i></p> <p>Click Continue.</p>	
<p><b>Application Checklist</b></p> <p>Check all applicable items for this project.</p> <p>Click Continue.</p>	
<p><b>Clinical Trials</b></p> <p>Indicate the type of clinical trial applicable for this project.</p> <p>Click continue.</p> <p>Visit <a href="http://ClinicalTrials.gov">ClinicalTrials.gov</a> for descriptions of trial Phases.</p> <p>Descriptions of the other listed trial types are included here</p>	 <div data-bbox="743 1415 1507 1894"> <p><b>Symptom Management trials</b> improve comfort and the quality of life for individuals with a serious or life-threatening illness.</p> <p><b>Prevention trials</b> look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals or lifestyle changes.</p> <p><b>Observational trials</b> assess outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine clinical care, but participants are not assigned to specific intervention by the investigator.</p> <p><b>Interventional trials</b> involve participants receiving specific interventions according to a research plan or protocol. These trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.</p> <p><b>Open-Label Extension Studies</b> are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.</p> </div>

## Conflict of Interest

Indicate potential Conflict of Interest.

Click Continue.

*\*\*Note: A 'Yes' or privately funded studies response will require responses on the next screen in the system to disclose the interest. In addition, conflicts of interest must be verified at the time of continuing review. \*\**

The screenshot shows the 'Conflict of Interest' form. At the top, there are navigation buttons: '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', and 'Continue >>'. The title 'Conflict of Interest' is centered. Below it, a definition states: 'Definition - Conflict of Interest: conflict of interest means that because of activities or relationships with other persons or organizations, an individual is unable, or potentially unable, to remain impartial, that the individual's objectivity is, or might be otherwise impaired, or that the individual has, or might acquire, an unfair competitive advantage. Information that is relevant to a conflict of interest determination includes stock holdings and investments of the individual, the individual's spouse or dependent children; current positions held or under negotiation; any other sources of income; involvement in the design, conduct, or reporting of the research and any other relevant information that may have a bearing on the individual's proposed participation.' Another definition follows: 'Definition- Financial Interest Related to the Research: means financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.' A question is listed: '1.0 \* Do any of the participating study investigators or other research personnel (or their immediate family) have a financial and/or intellectual property interest in the sponsor or products used with this research study?'. Below the question are radio buttons for 'Yes' and 'No', and a 'Clear' button.

## Privacy and Confidentiality

Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

Select where study records and data will be collected and stored.

Indicate whether this project will use a federal Certificate of Confidentiality.

*\*\*Note: A NIH Certificate of Confidentiality protects investigators and institutions from being forced to disclose research participants' identifying information in research projects with 'sensitive' topics (studies in which disclosure can have adverse consequences for the participant). \*\**

Click Continue.

The screenshot shows the 'Privacy and Confidentiality' form. At the top, there is a header for 'Health Sciences south carolina' and a 'Edit: \$' button. Navigation buttons include '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', and 'Continue >>'. The title 'Privacy and Confidentiality' is centered. Below it, a question is listed: '1.0 \* Describe the procedures and safeguards that will be implemented to protect the privacy and confidentiality of the participants' data. Include details, as applicable to the study, such as: privacy of interview site, procedures for coding/de-identifying data, provisions to avoid public identification/embarassment of participants, persons with access to private identifiable data, etc.'. Below the question is a text area. A callout box points to this area with the text: 'If "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)" is selected then explain how this device will be protected.' Another callout box points to the 'If OTHER, describe:' section with the text: 'As applicable, responses must be provided for MUSC IRB review.' Below the 'If OTHER, describe:' section is another text area. Below that is a question: '2.0 \* Where will study records and data collected at this site be stored?'. Below this question are radio buttons for 'In a locked office', 'In a locked cabinet', 'Password protected network storage', 'Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)', and 'Other'. Below the 'Other' option is a text area. Below that is a question: '3.0 \* Will the study use a National Institutes of Health (NIH) Certificate of Confidentiality?'. Below this question are radio buttons for 'Yes' and 'No', and a 'Clear' button. Below the 'Yes' option is a question: 'If YES, what is the NIH Certificate of Confidentiality status?'. Below this question are radio buttons for 'The NIH Certificate of Confidentiality has been approved', 'Will apply for a NIH Certificate of Confidentiality for this study', and 'Clear'.

Indicate if the study will access (view, obtain or use) participant protected health data.

Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI).

Click Continue.

#### Protected Health Information (PHI) for Research

Protected Health Information (PHI) is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future physical or mental health or conditions of an individual.

Covered Entity - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form.

1.0 \* To determine if this research study is using/disclosing PHI, select any of the following 18 elements that your study will require access to, as defined by the Health Insurance Portability and Accountability Act (HIPAA), as identifiers. If none of these 18 identifiers will be used/disclosed, then select the final option.

- ☐ Names
- ☐ All geographic subdivision smaller than a state including street address, city, county, or zip code
- ☐ All elements of date (except year) for dates directly related to an individual (DOB, admission/discharge dates, etc.)
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ Social security numbers
- ☐ Medical record number
- ☐ Health plan Beneficiary number
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Any other unique identifying number, characteristic or code
- ☐ None of the above 18 identifiers will be used/disclosed for this research study

Checking the last option means **no access to protected health information** is needed for the study.

However, if the study **has to access any of these identifiers** in order to obtain or associate health information, you must check all applicable identifiers on this page. *See notes on this Smartform page.*

If the study requires access to any of the 18 identifiers but will not be linked to PHI, please select those that are applicable to the left. On the next screen, you will be able to select "Study where health information is not linked to identifiers".

If indicating that PHI is accessed, check all the sources of health information and how the project is requesting this access.

Click Continue.

If the study application indicates that no identifiers are used/accessed then this page will not populate.

Responses to all questions must be provided for MUSC IRB review.

## General Comments

Include any General Comments and upload any additional documents that may assist with the review of the study.

*\*\*Note: upload a CV here if the study is privately funded, involves drug intervention or as requested by IRB\*\**

Click Continue.

The screenshot shows the 'General Comments' section of the eIRB system. It contains two numbered items: 1.0 'Add any additional comments to assist in the review of this research study.' with a large text area, and 2.0 'Add any miscellaneous documents that do not fit in other sections of the study application.' with a sub-instruction for Palmetto Health IRB applications to upload PHARR documentation. Below this is a table with columns: Name, Description, Orig. Author, Orig. Created, and Last Modified. The table is currently empty with the message 'There are no items to display'. At the bottom, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: > General Comments <', and 'Continue >>'.

## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#). [Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Enter the study's Research Master ID.

Click Continue.

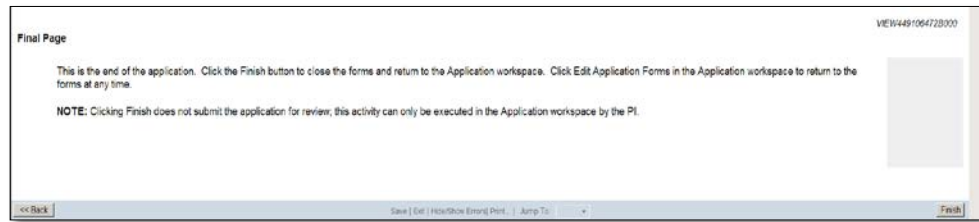
The screenshot shows the 'Research Master ID (RMID)' section. It includes a 'Reviewer Notes' table with columns: Type, Reviewer, Date Created, and Date Modified. The table is empty with the message 'There are no items to display'. Below this is a text box for 'Research Master ID (RMID)' with a sub-instruction: 'Enter the Research Master ID (RMID) associated with this study. If the study's RMID is not known, CLICK HERE to go to the RMID website to search or create one. Then, return here to add the RMID to this study application.' There is a link 'CLICK HERE' and a text input field for the RMID. At the bottom, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: > Research Master ID (RMID) < MUSC v2 <', and 'Continue >>'.



## End of Application

Click "Finish" to close the forms and return to the Application workspace.

*\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB.*



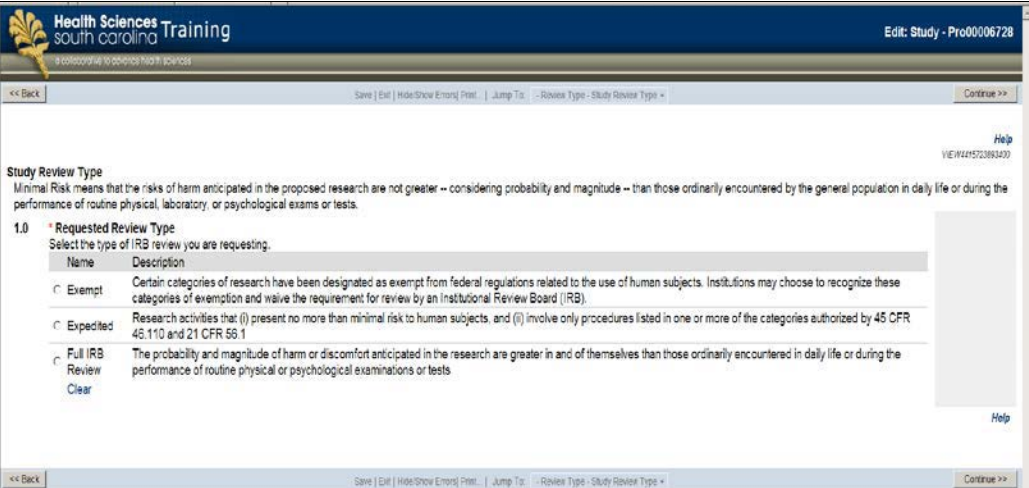
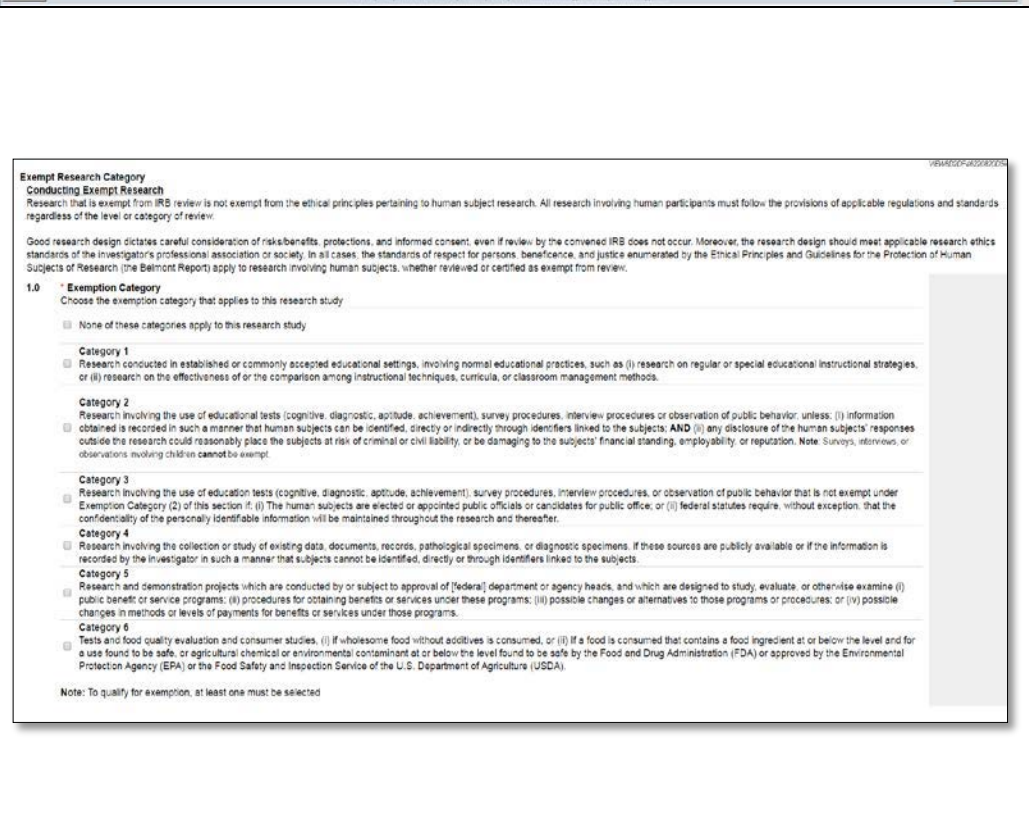
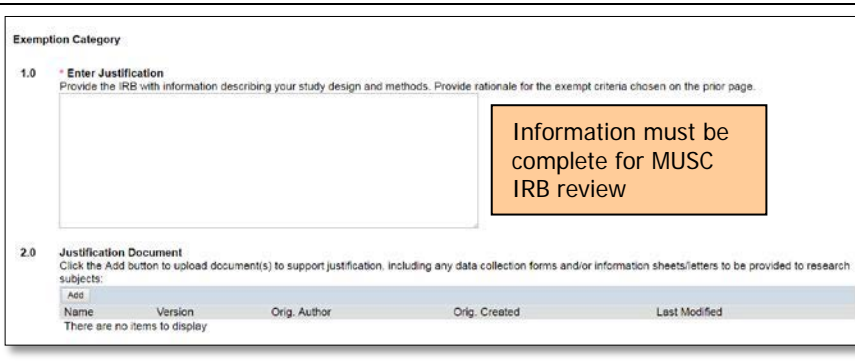
The system will return to the protocol workspace.

*To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document.*

*\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission. \*\**

# Request for Exempt Review

If not already completed, follow the steps in the ['Beginning the Application'](#) section.

<p>Indicate Study Review Type as "Exempt".</p> <p>Click Continue.</p>	
<p><b>Category</b></p> <p>Select the exempt research category(ies) most applicable to the study.</p> <p>If none of these categories apply, you will be routed to select another type of review.</p> <p>Click Continue.</p>	
<p>Describe the study design and methods and upload supporting documentation.</p> <p>Click Continue.</p>	

## Study Funding

Indicate study funding sources.

*\*\*Note: If the 'Federal Government' is the funding source, a [Favorable Funding Score Letter](#) (or other similar supporting documentation) must be included.*

Click Continue.

The screenshot shows the 'Study Funding Information' form in the Health Sciences Training system. The form is titled 'Study Funding Information' and includes a section for '1.0 Primary Funding Source (Active or Pending)'. Below this, there is a list of funding sources with checkboxes: Federal Government, Private Industry, Private Not-for-Profit Organization, State or Local Government, Internal Funding, Non-US Funding, Other, and No Funding. The 'Continue' button is visible at the bottom right of the form.

Indicate details of study sponsorship.

*\*\*Note: If any of this information is omitted, it will not appear on the IRB review letter. \*\**

Click Continue.

The screenshot shows the 'Study Sponsorship' form in the Health Sciences Training system. The form is titled 'Study Sponsorship' and includes sections for '1.0 Sponsor(s)', '2.0 Other Sponsor(s)', '3.0 External Identifier (if applicable)', and '4.0 Internal Identifier (if applicable)'. The '1.0 Sponsor(s)' section has a text input field for the sponsor name and a list of existing sponsors. The '2.0 Other Sponsor(s)' section has a text input field for additional sponsors. The '3.0 External Identifier' and '4.0 Internal Identifier' sections have text input fields. The 'Continue' button is visible at the bottom right of the form.

At minimum, a sponsor name must be provided for MUSC IRB review.

Indicate the costs associated with the study.

Click Continue.

The screenshot shows the 'Study Costs' form in the Health Sciences Training system. The form is titled 'Study Costs' and includes sections for '1.0 Drug(s)', '2.0 Device(s)', and '3.0 Supplies'. Each section has a list of cost types with checkboxes: N/A, Sponsor, Participant, and Other. Below each list is a text input field for 'If OTHER, specify:'. The 'Continue' button is visible at the bottom right of the form.

Responses to each question on this page must be provided for MUSC IRB review.

<h3>Application Checklist</h3> <p>Check all applicable items for this project.</p> <p>Click Continue.</p>	<div> <div> <h4>Application Checklist</h4> <p><b>1.0 Will the following be involved in the research study?</b> Select all that apply</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Medical Record/Chart Review</li> <li><input type="checkbox"/> Use of survey, questionnaire, focus group/interview questions</li> <li><input type="checkbox"/> Specimens (blood, urine, tissue and other human products)</li> <li><input type="checkbox"/> Data required from HSSC Clinical Data Warehouse</li> </ul> </div> <div> <p>All relevant study activities must be indicated for MUSC IRB review.</p> </div> </div>
<h3>Clinical Trial</h3> <p>Indicate the type of clinical trial applicable for the project.</p> <p><i><b>**Note: A clinical trial is a prospective biomedical or behavioral human subjects research study that is designed to answer specific questions about biomedical or behavioral interventions or lab test evaluations and determine whether these are safe, efficacious and effective. **</b></i></p> <p>Click Continue.</p>	<div> <div> <h4>Clinical Trials</h4> <p><b>1.0 *What is the phase of the clinical trial?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Phase I clinical trial</li> <li><input type="checkbox"/> Phase II clinical trial</li> <li><input type="checkbox"/> Phase III clinical trial</li> <li><input type="checkbox"/> Phase IV clinical trial</li> <li><input type="checkbox"/> Symptom Management</li> <li><input type="checkbox"/> Prevention Trial</li> <li><input type="checkbox"/> Observational</li> <li><input type="checkbox"/> Interventional</li> <li><input type="checkbox"/> Other</li> <li><input type="checkbox"/> This study does not involve a clinical trial</li> <li><input type="checkbox"/> Open-Label Extension Study</li> </ul> <p><b>2.0 If OTHER, describe:</b></p> <div></div> </div> <div> <p><b>Visit ClinicalTrials.gov for descriptions of trial <a href="#">Phases</a>. Additional descriptions are below:</b></p> <p><b>Symptom Management trials</b> improve comfort and the quality of life for individuals with a serious or life-threatening illness.</p> <p><b>Prevention trials</b> look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals or lifestyle changes.</p> <p><b>Observational trials</b> assess outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine clinical care, but participants are not assigned to specific intervention by the investigator.</p> <p><b>Interventional trials</b> involve participants receiving specific interventions according to a research plan or protocol. These trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.</p> <p><b>Open-Label Extension Studies</b> are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.</p> <p><a href="#">ClinicalTrials.gov</a></p> </div> </div>

## Study Procedures

Describe all procedures, those used solely for research and those performed as standard of care.

Click Continue.

### Study Procedures

(Blood draw, Imaging, Lab Tests, Physical Exam, Medical History)

1.0 \* Briefly describe the procedures to be performed solely as part of this research study.

2.0 \* Briefly describe the procedures being performed already for diagnostic or treatment purposes (standard of care).

## Privacy and Confidentiality

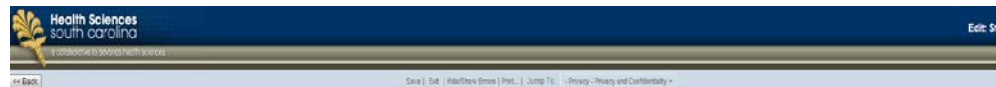
Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

Select where study records and data collected will be stored.

Indicate whether this project will use a federal Certificate of Confidentiality.

Click Continue.

***\*\*Note: A NIH Certificate of Confidentiality protects investigators and institutions from being forced to disclose research participants' identifying information in research projects with 'sensitive' topics (studies in which disclosure can have adverse consequences for the participant). \*\****



### Privacy and Confidentiality

1.0 \* Describe the procedures and safeguards that will be implemented to protect the privacy and confidentiality of identifying data, provisions to avoid public identification/embarassment of participants, persons with a

If "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)" is selected then explain how this device will be protected.

2.0 \* Where will study records and data collected at this site be stored

Select all that apply:

- ☐ In a locked office
- ☐ In a locked cabinet
- ☐ Password protected network storage
- ☐ Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)
- ☐ Other

If OTHER, describe:

If information will be stored on an end-user/portable device, describe the security on the end-user/portable device

3.0 \* Will the study use a National Institutes of Health (NIH) Certificate of Confidentiality?

☐ Yes ☐ No Clear

If YES, what is the NIH Certificate of Confidentiality status?

- ☐ The NIH Certificate of Confidentiality has been approved
- ☐ Will apply for a NIH Certificate of Confidentiality for this study

Clear

Responses must be provided (if applicable) for MUSC IRB review.

## Protected Health Information (PHI)

Indicate if the study will access (view, obtain or use) participant protected health data.

Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI).

Click Continue.

Protected Health Information (PHI) for Research

Protected Health Information (PHI) is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future physical or mental health or conditions of an individual.

Covered Entity - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form.

1.0 \* To determine if this research study is using/disclosing PHI, select any of the following 18 elements that your study will require access to, as defined by the Health Insurance Portability and Accountability Act (HIPAA), as identifiers. If none of these 18 identifiers are applicable to your study, select "None of the above 18 identifiers will be used/disclosed for this research study."

- ☐ Names
- ☐ All geographic subdivision smaller than a state including street address, city, county, precinct
- ☐ All elements of date (except year) for dates directly related to an individual (DOB, admission)
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ Social security numbers
- ☐ Medical record number
- ☐ Health plan Beneficiary number
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Any other unique identifying number, characteristic or code
- ☐ None of the above 18 identifiers will be used/disclosed for this research study

Checking the last option means **no access to protected health information** is needed for the study.

However, if the study **has to access any of these identifiers** in order to obtain or associate health information, you must check all applicable identifiers on this page. *See notes on this Smartform page.*

If the study requires access to any of the 18 identifiers but will not be linked to PHI, please select those that are applicable to the left. On the next screen, you will be able to select "Study where health information is not linked to identifiers."

If indicating that PHI is accessed, check all the sources of health information and how the project is requesting access to this.

Click Continue.

Health Sciences south carolina

1.0 Indicate the sources of health information to be used

Select all that apply:

- ☐ Medical Records/Physician Notes/Hospital Discharge Records
- ☐ Psychotherapy Notes
- ☐ Medical Test Results
- ☐ Payment/Billing/Insurance records
- ☐ Biological samples obtained from subjects for non research purposes
- ☐ Databases/Registries
- ☐ Tissue Repositories
- ☐ Other

IF OTHER, indicate any other source(s) of health information to be collected/used:

2.0 How will PHI be accessed for the research study? (Check all those that apply)

- ☐ HIPAA Research Authorization
- ☐ HIPAA Waiver of Authorization for Research
- ☐ Accessing Information for Preparatory Work for Research
- ☐ Accessing Information Through Limited Data Sets
- ☐ Accessing Deceased Persons' Information
- ☐ Access Information through De-Identification
- ☐ Study where health information is not linked to identifiers

Responses to all questions must be provided for MUSC IRB review.



Indicate whether de-identified information will be accessed (viewed, obtained or used) for this study.

***\*\*Note: The intent of this question is to document whether the study data is received through a de-identification method (i.e., via a de-identified database warehouse). \*\****

Click Continue.

The screenshot shows the 'Use of De-identification to Access Protected Health Information (PHI)' section of the eIRB application. The header includes the Health Sciences South Carolina logo and the text 'eIRB application to advance health sciences'. The top right corner displays 'Edit: Study - Pro00024043'. The main content area contains a paragraph explaining the Privacy Rule and de-identification methods. Below this, a question asks: 'Will you be receiving de-identified information from a covered entity for the purpose of this project?'. There are two radio buttons: 'Yes' and 'No', followed by a 'Clear' link. The bottom of the screen shows navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: - Privacy - Use of De-Ident to Access PHI -', and 'Continue >>'.

If the answer is “yes” to the question above, indicate how the data will be de-identified.

Click Continue.

The screenshot shows the 'Accessing Protected Health Information (PHI) Through De-identification' section. It includes a 'Select one below:' section with two radio buttons: 'The research dataset will contain none of the 18 elements defined by HIPAA as identifiers.' and 'The research dataset has been reviewed by a statistician, or other qualified expert, de-identified PHI through generally accepted statistical and scientific methods and determined that the risk of re-identifying the information is very small.' Below this is a section for 'If applicable, attach the recommendation from the statistician along with documentation of the methods and analysis used for justification.' with an 'Add' button and a table with columns: Name, Description, Orig. Author, Orig. Created, and Last Modified. The table currently shows 'There are no items to display'. An orange callout box with the text 'A response must be provided for MUSC IRB review.' is overlaid on the right side of the form. The bottom navigation bar is identical to the previous screenshot.

## General Comments

Include any General Comments and upload any additional documents that may assist with the review of the study.

Click Continue.

The screenshot shows the 'General Comments' section of the eIRB application. It includes a text area for 'Add any additional comments to assist in the review of this research study.' and a section for 'Add any miscellaneous documents that do not fit in other sections of the study application.' with a note: 'Palmetto Health IRB applications ONLY: please upload the completed PHARR Documentation.' and a 'Click Add to upload document(s)' instruction. Below this is an 'Add' button and a table with columns: Name, Description, Orig. Author, Orig. Created, and Last Modified. The table currently shows 'There are no items to display'. The bottom navigation bar is identical to the previous screenshots.

## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#). [Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Enter the study's Research Master ID.

Click Continue.

The screenshot shows a web application interface for entering a Research Master ID (RMID). At the top, there is a navigation bar with links: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: < Research Master ID (RMID) - MUSC v2 <', and 'Continue >>'. Below this is a section titled 'Reviewer Notes' with a table header: 'Type', 'Reviewer', 'Date Created', and 'Date Modified'. The table body contains the text 'There are no items to display'. Below the table, there is a section titled 'Research Master ID (RMID)' with a description: 'A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for study applications and is created on the [MUSC Research Master ID website](#), which also includes details about this process.' Below this description, there is a text input field labeled 'Research Master ID:' and a 'Continue >>' button. The bottom of the form has a navigation bar with links: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: < Research Master ID (RMID) - MUSC v2 <', and 'Continue >>'.

## End of Application

Click "Finish" to close the forms and return to the Application workspace.

***\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB. \*\****

Final Page

VIEW4491064728000

This is the end of the application. Click the Finish button to close the forms and return to the Application workspace. Click Edit Application Forms in the Application workspace to return to the forms at any time.

**NOTE:** Clicking Finish does not submit the application for review; this activity can only be executed in the Application workspace by the PI.

< Back Save | Edit | Hide/Show Errors Print... | Jump To: Finish

The system will return to the protocol workspace.

***\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.***

***To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document. \*\****

Current State

Study: Randy Test ( Pro00005489 )

**Pre Submission**

Full Title: De-identified Tissue repository

Principal Investigator: musc-radiology-pi musc

Study Coordinator: musc-ss2 musc

IRB Campus: Medical University of South Carolina

Review Type: Exempt

PI Department: RADIOLOGY - MUSC

PI Institution: Medical University of South Carolina

Pre-Conversion Study ID:

Study Status:

Sponsors: There are no items to display

**My Activities**

Edit Guest Access

Withdraw

Copy Study

(initial)

History Personnel Attachments Pre Review Status Reviewer Notes Change Log

This area shows instructions and questions and important notifications regarding this Study.

The query produced no results.

## Request for Not Human Research Review

If not already completed, follow the steps in the [‘Beginning the Application’](#) section through [Study Locations](#).

<p>Indicate if this study is considered research involving human subjects.</p> <p><i>As noted on the screen, a project involving a Humanitarian Use Device (HUD) should respond ‘Yes’ to both questions. This requires Full IRB Review – click <a href="#">here</a> for steps to submit a full review application</i></p> <p>Click Continue if proceeding with a Not Human Subjects Research request.</p>	<div data-bbox="812 241 1453 493"> <p><b>Question 1.0</b> is the federal definition of ‘research’ and captures whether the proposal fits this definition. If the proposal is not research (i.e., response to Q1.0 is ‘No’), then submission to IRB is <b>not required</b> and you should exit and withdraw the application.</p> <p><i>An exception to this response is if the project involves a HUD, as instructed on the screen.</i></p> </div> <div data-bbox="516 493 1453 777"> <p><b>Human Subjects Research</b> The following questions will assist you in determining whether this research study meets the federal requirements for Human Subjects Research.</p> <p>1.0 * Is this research study a systematic investigation, including research development, testing, and evaluation, designed to develop or to contribute to generalizable knowledge? Note: Please check ‘Yes’ if the study involves a Humanitarian Use Device (HUD).</p> <p><input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p>Note: <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cf46.html#46.102">http://www.hhs.gov/ohrp/humansubjects/guidance/45cf46.html#46.102</a></p> <p>2.0 * Does this research study involve the investigator obtaining data about living individuals through 1) Intervention or interaction with the individual; or 2) identifiable private information? Note: Please check ‘Yes’ if the study involves a Humanitarian Use Device (HUD).</p> <p><input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p>Note: <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cf46.html#46.102">http://www.hhs.gov/ohrp/humansubjects/guidance/45cf46.html#46.102</a></p> </div> <div data-bbox="730 777 1477 1134"> <p><b>Question 2.0</b> is the federal definition of ‘human subject’ and captures whether the research involves human subjects. If the proposal IS research and DOES NOT involve human subjects (i.e., response to Q2.0 is ‘No’), <i>then you can proceed with this section of the document to submit an application for Not Human Subject Research.</i> Otherwise, you must continue through the application to select the correct review type, as described in the <a href="#">Human Subjects Research Requirements section</a>.</p> <p><i>As with Q1.0, the exception to this is if the project involves a HUD, as instructed on the screen.</i></p> </div>										
<p>Indicate a justification for submission as not human research.</p> <p>Click Continue.</p>	<div data-bbox="516 1171 1453 1386"> <p><b>Not Human Subjects Research</b> Based on the responses you provided on the previous screen, this study does not qualify as research on human subjects. If you think this is not accurate, you may click the Back button to go to the previous page and read the questions and check your responses.</p> <p>1.0 Select applicable justification:</p> <p><input type="checkbox"/> a. the specimens and/or private information/data were not collected specifically for the currently proposed research project through an interaction/intervention with living individuals AND</p> <p><input type="checkbox"/> b. the investigator(s) including collaborators on the proposed research cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researchers access to subject identities is prohibited by written repository policies and/or through an agreement signed between the recipient researcher and the repository).</p> <p><input type="checkbox"/> c. the research uses only cadaver specimens. Caveat: South Carolina law requires a documented informed consent separate from the autopsy consent to use autopsy tissue for research. The IRB does not review or approve these consents.</p> <p><a href="#">Clear</a></p> </div>										
<p>The system will confirm your response based on what you selected on the previous page and ask that you upload a protocol.</p> <p><i>**Note: This is NOT an IRB review via a not human research application method. The system is only recognizing that your responses apply to not human research categories. **</i></p>	<div data-bbox="516 1570 1469 1732"> <p><b>Not Human Subjects Research</b> Based on the information provided, this research study is not considered Human Subject Research. Click the Finish button and submit application to the IRB.</p> <p>1.0 * Upload protocol document(s) so that the IRB may validate that this is Not Human Subject Research.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Description</th> <th>Orig. Author</th> <th>Orig. Created</th> <th>Last Modified</th> </tr> </thead> <tbody> <tr> <td colspan="5">There are no items to display</td> </tr> </tbody> </table> </div>	Name	Description	Orig. Author	Orig. Created	Last Modified	There are no items to display				
Name	Description	Orig. Author	Orig. Created	Last Modified							
There are no items to display											

## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#).

[Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Enter the study's Research Master ID.

Click Continue.

## Final Page

Click Finish

***\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to the IRB\*\****

The system will return to the protocol workspace.

***\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.***

***To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document. \*\****

## Request for External Review

External Institutional Review Board review occurs when an internal IRB (i.e., an institution's IRB) defers IRB review to an external contracted IRB (e.g., Western IRB [WIRB]). The external IRB then becomes the study's IRB of record upon approving the study. In these types of reviews, institutional agreements and requirements typically describe eligibility, submission processes and the responsibilities of the researcher, internal IRB and external IRB. For more information on the process and studies eligible for WIRB submissions at MUSC, please see the [IRB's website](#).

If not already completed, follow the steps in the ['Beginning the Application'](#) section through ['IRB Review Request'](#).

### Creating and Submitting the Request

<p>Select the PI of the study.</p> <p><i>**Note: All other study team members should be listed on the <a href="#">Request for Submission WIRB Form</a>.</i></p>	<div data-bbox="688 520 1308 703"> <p><b>Principal Investigator</b></p> <p>1.0 * <b>Principal Investigator</b> Please select the PI associated with this study:</p> <div> <input type="text"/> <input type="button" value="Select..."/> </div> </div>
<p>Upload external IRB review documents and all associated approvals and attachments, as required by your institution.</p> <p><i>**Note: any required committee approvals (i.e., Hollings Cancer Center or Radiation Safety) must be completed outside of the eIRB application process, and required documentation included as an uploaded document in the application. All documents required by MUSC's IRB can be found on the <a href="#">IRB's website</a>.</i></p> <p><i>The research team may grant study guest access to any committee or service members that wish to review attached study information prior to local IRB submission. **</i></p>	<div data-bbox="526 1024 1471 1278"> <p><b>External IRB Review Documents</b></p> <p>Upload the IRB application and attachments, including any committee or impacted services approvals required by your institution.</p> <p>1.0 * <b>Upload the IRB application and attachments</b> Click the Add button to upload document(s):</p> <div> <input type="button" value="Add"/> </div> </div>



## Research Master ID (RMID)

A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the [MUSC Research Master ID website](#).

[Resources and trainings on the RMID process](#) are available online. The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.

Enter the study's Research Master ID.

Click Continue.

Research Master ID (RMID)

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Enter the Research Master ID (RMID) associated with this study. If the study's RMID is not known, [CLICK HERE](#) to go to the RMID website to search or create one. Then, return here to add the RMID to this study application.

\* Research Master ID:

The application is complete for system required Smartforms.

**\*\*Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB. \*\***

Returning to the study's main page, its state is Pre Submission and it is ready for IRB submission.

**\*\*Note: e-IRB does not send automatic notification of these items. If someone other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.**

To send application, complete steps in the [Submission to Mentor/Departmental Review](#) section of this guidance document. \*\*

### Final Page

This is the end of the application. Click the Finish button to close the forms and return to the Application workspace. Click Edit Application Forms in the Application workspace to return to the forms at any time.

**NOTE:** Clicking Finish does not submit the application for review; this activity can only be executed in the Application workspace by the PI.

Current State

Pre Submission

Study Short Title:

Full Title:

Principal Investigator:

IRB Campus:

PI Department:

Pre-Conversion

Study ID:

Sponsors:

Study Team Approval to Post on

IRB Approval to Post on

Study Coordinator:

Review Type:

PI Institution:

Study Status:

SCResearch.org

SCResearch.org

History Personnel Attachments Pre Review Status Reviewer Notes Change Log

When the study is received in the IRB office, it will move into the External IRB Review state, initiating IRB review of the request.

Current State

External IRB Review

View Study

Printer Version

My Activities

Edit Study Access

Edit Guest Access

Withdraw

Log Public Comment

Copy Study

Edit Communication Leads

(Approved)

Study Short Title:

Full Title:

Principal Investigator:

Expiration Date:

Approval Date:

Review Type:

PI Department:

Pre-Conversion Study ID:

Study Status:

Sponsor(s):

Study Team Approval to Post on SCresearch.org

Study Coordinator:

IRB Coordinator:

Initial Approval Date:

IRB Campus:

PI Institution:

Letter of Approval:

Committee:

Snapshot:

IRB Approval to Post on SCresearch.org

History

Filter by 

Activity

Go

Clear

Advanced

Activity

Author

(i) Activity Date

## Responding to IRB Change Requests

Upon consideration, if changes to the External Review study are requested by the local IRB, the study will return to the PI and the personnel who initiated the application. Any IRB comments will appear as comments within the application's history log.

To make changes, select 'Edit Study' and go to the necessary study page to make changes.

When done, return to the study's main page and select 'Submit Changes for External IRB Review'.

**Current State**

**Changes Required for External IRB Review**

[Edit Study](#)

[Printer Version](#)

[View Differences](#)

**My Activities**

[Edit Guest Access](#)

[Log Public Comment](#)

[Copy Study](#)

[Edit Communication Leads](#)

[Submit Changes for External IRB Review](#)

(Approved)

**Study Short Title:** TESTING #5 WIRB REVIEW 3/12/13 ( Pro00023217 )

**Full Title:** TESTING WIRB REVIEW 3/12/13

**Principal Investigator:**

**Expiration Date:**

**Approval Date:**

**Review Type:**

**PI Department:**

**Pre-Conversion Study ID:**

**Study Status:**

**Sponsor(s):** There are no items to display

**Study Team Approval to Post on SCresearch.org**

**Study Coordinator:**

**IRB Coordinator:**

**Initial Approval Date:**

**IRB Campus:**

**PI Institution:**

**Letter of Approval:**

**Committee:**

**Snapshot:**

**IRB Approval to Post on SCresearch.org**

**History**

Filter by

Activity Author Activity Date

Enter in any comments in response to IRB, if necessary and select 'OK'. This will return the application to IRB for review.

*\*\*Note: changes cannot be made to the study application to request a different review type (i.e., an exempt, expedited, full board or facilitated review). In these cases, the External IRB Review request must be withdrawn. The application can be submitted as a new request type.\*\**

**Current State**

**Changes Required for External IRB Review**

[Edit Study](#)

[Printer Version](#)

**My Activities**

[Edit Guest Access](#)

[Withdraw](#)

[Log Public Comment](#)

[Copy Study](#)

[Edit Communication Leads](#)

[Submit Changes for External IRB Review](#)

(Approved)

**Submit Changes for External IRB Review**

In addition to any changes made to the application, please provide any other summary information, if necessary:

**Comments:**

## IRB Acceptance of the External IRB Review Application

If the study is eligible, the IRB can indicate an acceptance of the application for external IRB review. The study's State will read 'External IRB Review Archive'.

*\*\*Note: the contract with the industry sponsor must be fully executed before the IRB will issue an acceptance of the external IRB review. \*\**

While there is not a study maintenance function, comments can be logged and additional documents uploaded into the system.

*\*\*Note: all documents that have been included in the application are accessible by viewing the study or selecting the 'External IRB Document Upload' activity. \*\**

For read-only, historical viewing and document uploads, the study is accessible from All Studies and Archived tabs at login.

## IRB Rejection of the External IRB Review Application

If the study is not eligible for external IRB review, the IRB will issue a non-acceptance review and the study will enter into the 'Withdrawn' state.

**Researchers planning to proceed with the study must create a new application and submit it for IRB review.**

The screenshot shows a web form for an IRB application. On the left, a sidebar indicates the 'Current State' is 'Withdrawn' with buttons for 'View Study' and 'Print Version'. The main form area is divided into two columns. The left column contains fields for: Study Short Title, Full Title, Principal Investigator, Expiration Date, Approval Date, Review Type, PI Department, Pre-Conversion, Study ID, Study Status (with a note 'There are no items to display'), Sponsor(s), and Study Team Approval to Post on 6Cresearch.org. The right column contains fields for: Study Coordinator, IRB Coordinator, Initial Approval Date, IRB Campus, PI Institution, Letter of Approval, Committee, Snapshot, and IRB Approval to Post on 6Cresearch.org. At the bottom, there is a 'History' section with a filter dropdown set to 'Activity', and buttons for 'Go', 'Clear', and 'Advanced'. A table header shows 'Activity' and 'Author'.

The withdrawn study will be accessible from the All Studies and Archived tabs available at login.

The screenshot shows the 'Studies' page of the Click Commerce IRB system. It includes a welcome message: 'Welcome to Click Commerce IRB. View all studies by In Progress, Approved, and Archived groupings. Use the 'My Home' link to see the list of submissions related to you.' Below this is a navigation bar with tabs: 'All' (selected), 'In Progress', 'Approved', 'Archived', 'Terminated', and 'Expirations'. Under the 'All' tab, there is a filter section with a 'Filter by' dropdown set to 'ID', and buttons for 'Go', 'Clear', and 'Advanced'.

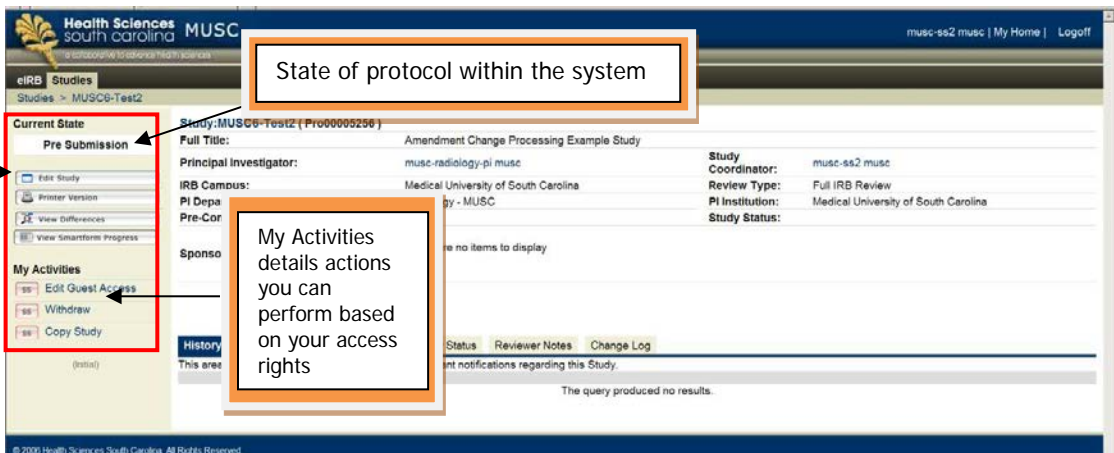
# How to Navigate the Protocol Workspace

For additional assistance, view the recorded demonstrations 'Navigating the Study Workspace' and 'Locating, Editing and Copying Studies' in the eIRB [Education & Training](#) section.

After you select the "Finish" button, you are sent to the workspace for the specific study you just created. Below is a description of the Workspace and activities you can perform.

Protocol State, Tools and Activities

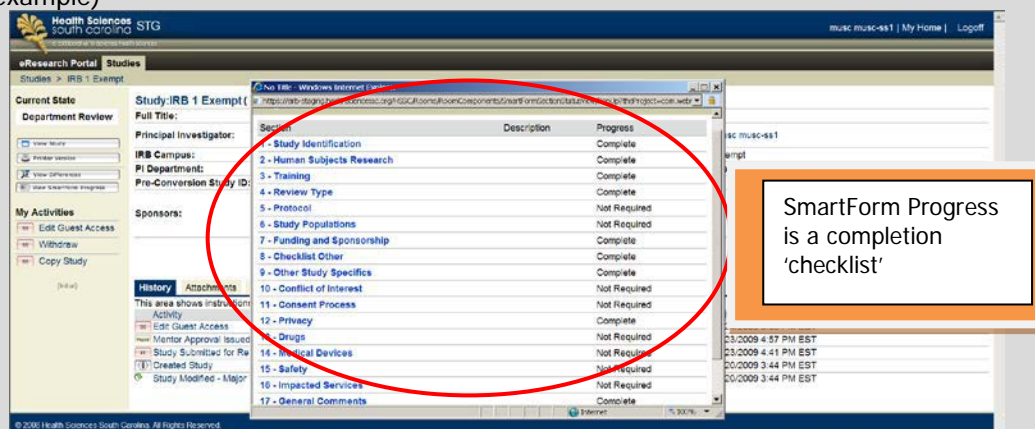
Tools, allow you to perform study functions or view study details



**Current State:** This will tell you the stage of study development within the system, where the protocol is in the review process, and the review outcome of your protocol. For example, a *Pre-Submission* state indicates entry of information that has not yet been sent to IRB. *\*\*Note the difference between the State and the [Study Status](#). For example, closing a study to accrual changes the status from "open to accrual" but does not change the Study State of "Approved" \*\**

**Tools:** Buttons that, when clicked, activate certain functions of the program. When you have finished the application, the buttons that will appear include:

- **Edit Study:** Goes back to application so that you may make changes to data entered into the study's application
- **Printer Version:** Compiles all sections for that study into an easily printable format.
- **View Differences:** When changes are made to an IRB approved version of the study; this tool shows you where changes have been made in the study
- **View SmartForm Progress:** Shows the progress of each section of the application (see below as an example)



**Activities:** A list of actions that can be taken within the submission process. The types of actions permissible are specific to the state of the protocol. The types of actions permissible are managed by roles, for example:

- **SS=Study Staff** is allowed to only initiate activities with the SS icon.
- **PI=Principal Investigator** is allowed to initiate all of the activities (even those with SS icon because PI is part of the SS role)

*Note: Only the PI can submit the study, and it will be routed to the appropriate department officials for IRB submission.*



In this example, the activities as study staff include:

- Edit guest access (users you'd like to be able to have a 'read only' review of the application)
- Withdraw the study
- [Copy](#) the study as a template

## Protocol Information

The top middle section of the workspace shows a synopsis of the study, such as title, PI, department, coordinator, study status, etc.

## Protocol details

The lower portion of the workspace shows Workspace Tab.

**History** tab details all activities associated with the review of the submission.

**Personnel** tab lists the study team members you have indicated as participating in the study.

**Attachments** tab includes all application sections that include documents and all documents uploaded as part of submission.

**Pre-review status\*** tab provides approval status of any other committee approvals needed (i.e., department approval, etc.)

**Reviewer Notes** tab lists all notes, comments, recommendations from IRB reviewers who have assessed the submission using Reviewer Notes application

**Change Log\*** tab lists all changes to an application performed by the study team after the activity is returned from the IRB. This tab is for IRB use only and disappears after the activity is completed by the IRB.

*\*These tabs will no longer be available after the study has been approved by IRB. After IRB approval, amendments, continuing review, status changes, reportable events and stamped ICF the tabs will also become available. See section [Post IRB Approval Navigation](#) for descriptions of these tabs.*

## Accessing Protocols at Log In

### Retrieve Pre-Submission Study

Click on 'My Home', which will bring you back to your home page. The Pre-Submission study will appear in your **'Inbox'**

Click on the name of the study.

Health Sciences South Carolina STG

musc-musc-ss2 | My Home | Logout

eResearch Portal Studies

Folder for musc-musc-ss2

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox** - Items appearing here require immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor** - the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

Filter by ID Name Date Modified Owner State Last State Change Type Review Type PI Campus

Pro00005048	Test	1/25/2010 4:51 PM	musc-irbc3, musc	Changes Required By IRB Staff	1/25/2010 4:51 PM	Study	Full IRB Review	musc-musc-radiology-pi	Medical University of South Carolina
Amst1_Pro00005021	Amendment 1 for IRB Study #Pro00005021	1/25/2010 10:22 AM	musc-irbc2, musc	Pre Submission	1/21/2010 10:11 AM	Amendment		musc-musc-radiology-pi	Medical University of South Carolina
Pro00005028	Test	1/29/2010 2:01 PM		Pre Submission	12/22/2009 10:24 AM	Study	Expedited	musc-musc-radiology-pi	Medical University of South Carolina

### Search for a study

Click on 'My Home', which will bring you back to your home page. Select the **'Studies'** tab. You can filter choices by selecting a field from the drop down, entering information for the study and selecting 'Go'.

There's also an option to search from several drop down fields by performing an 'Advanced' search

Health Sciences South Carolina STG

musc-musc-ss2 | My Home | Logout

eResearch Portal Studies

Folder for musc-musc-ss2

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox** - Items appearing here require immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor** - the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

Filter by ID Name Date Modified Owner State Last State Change Type Review Type PI Campus

Pro00005022	IRB II Not Human Research	12/3/2009 10:38 AM	IRB Staff Review					musc-radiology-pi	Medical University of South Carolina
Pro00005021	IRB II Exempt Study	12/2/2009 2:11 PM	IRB Staff Review	Exempt				musc-radiology-pi	Medical University of South Carolina
Pro00005019	IRB II Expedited	12/1/2009 9:31 PM	IRB Staff Review	Expedited				musc-radiology-pi	Medical University of South Carolina
Pro00005017	IRB II Full Board	12/1/2009 9:16 AM	IRB Staff Review	Full IRB Review				musc-radiology-pi	Medical University of South Carolina

### View Studies by Protocol States

From your homepage, select the 'Studies' link.

Health Sciences South Carolina STG

musc-musc-ss2 | My Home | Logout

eResearch Portal Studies

Folder for musc-musc-ss2

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox** - Items appearing here require immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor** - the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

Filter by ID Name Date Modified Owner State Last State Change Type Review Type PI Campus

Pro00005022	IRB II Not Human Research	12/3/2009 10:38 AM	IRB Staff Review					musc-radiology-pi	Medical University of South Carolina
Pro00005021	IRB II Exempt Study	12/2/2009 2:11 PM	IRB Staff Review	Exempt				musc-radiology-pi	Medical University of South Carolina
Pro00005019	IRB II Expedited	12/1/2009 9:31 PM	IRB Staff Review	Expedited				musc-radiology-pi	Medical University of South Carolina
Pro00005017	IRB II Full Board	12/1/2009 9:16 AM	IRB Staff Review	Full IRB Review				musc-radiology-pi	Medical University of South Carolina

The tabs on the Studies link include:

**All** = all of your studies that are within the system

**In Progress** = new studies that have been completed by the study teams/PI and sent to Department for review or that require action after submission and prior to IRB approval

**Approved** = those studies that are currently IRB approved for performing research activities

**Archived** = those studies that are in a closed state (i.e., completed, withdrawn, expired, terminated, suspended, disapproved)

**Expired** = those studies that have expired with IRB

**Expirations** = those studies that will expired in 60 days

### View Study Completion Progress

Select the study by following steps in the [Retrieving Pre-Submission Study](#) section.

Select 'View SmartForm Progress'

Health Sciences south carolina STG  
eResearch Portal Studies  
Studies > Erlotinib in breast cancer

Current State: Study: Erlotinib in breast cancer (Pro00005017)

Pre Submission

Full Title: Phase II study of erlotinib in breast cancer

Principal Investigator: musc-musc-surgery-pi

IRB Campus: Medical University of South Carolina

PI Department: Surgery - MUSC

Study Coordinator: musc-musc-ss2

Review Type: Full IRB Review

PI Institution: Medical University of South Carolina

Study Status:

My Activities

Edit Guest Access

Withdraw

Copy Study

Request Co-Investigator Assurance

History Attachments Pre Review Status Reviewer Notes Change Log

This area shows instructions and questions and important notifications regarding this Study.

View the details of the SmartForm Progress completion 'checklist'.

If any sections are incomplete, edit the study as described in the '[Edit Study](#)' section of this manual and finalize the application questions.

Health Sciences south carolina MUSC  
eIRB Studies  
Studies > Behavioral Problems in Adolescents

Current State: Study: Behavioral Problem

Pre Submission

Full Title: Behavioral Problem in Adolescents

Principal Investigator: musc-musc-surgery-pi

PI Department: Surgery - MUSC

Pre-Conversion Study ID:

Sponsors:

History Personnel Alta

This area shows instructions and questions and important notifications regarding this Study.

Progress

Section	Description	Progress
1 - Study Identification		Complete
2 - Human Subjects Research		Complete
3 - Training		Complete
4 - Review Type		Complete
5 - Protocol		Not Required
6 - Study Populations		Not Required
7 - Funding and Sponsorship		Complete
8 - Checklist Other		Complete
9 - Other Study Specifics		Complete
10 - Conflict of Interest		Not Required
11 - Conflict Process		Incomplete
12 - Privacy		Complete
13 - Drugs		Not Required
14 - Medical Devices		Not Required
15 - Safety		Not Required
16 - Impacted Services		Not Required
17 - General Comments		Complete

Completion progress can also be reviewed by editing the study and selecting 'Hide/Show Errors' link.

Click on one of the hyperlinks in the 'Jump To' section to correct the information and finalize the application questions.

Select 'Refresh' to update the Hide/Show Errors list. To exit this view, click on the 'Hide/Show Errors' link again.

Message	Field Name	Jump To
This is a required field; therefore, you must provide a value.	involves_no_more_than_minimal_risk_tx	Consent Process - Waiver of Informed Consent of Sub or Alter of Cons Elem
This is a required field; therefore, you must provide a value.	not_adversely_affect_rights_and_welfare_tx	Consent Process - Waiver of Informed Consent of Sub or Alter of Cons Elem
This is a required field; therefore, you must provide a value.	cannot_be_done_no_waiver_or_alteration_tx	Consent Process - Waiver of Informed Consent of Sub or Alter of Cons Elem
This is a required field; therefore, you must provide a value.	additional_info_after_participation_tx	Consent Process - Waiver of Informed Consent of Sub or Alter of Cons Elem
This is a required field; therefore, you must provide a value.	consent_form_yr	Consent Process - Waiver of Informed Consent of Sub or Alter of Cons Elem
This is a required field; therefore, you must provide a value.	minor_risk_category	Minors as Participant
This is a required field; therefore, you must provide a value.	justification_for_risk_tx	Minors as Participant

## Edit Study

Select the study by following steps in the [Retrieving Pre-Submission Study](#) section.

Click 'Edit Study'

Use the 'Jump To' feature to select the section to edit.

Select the Back and Continue button to make changes to the application.

Save and Exit the application when done.



## Copy a Study

The system allows you to copy a study with the option to save it as a template from which to create other similar studies. Using a copied study is beneficial when the study is similar to the original application. A copied study will include the same document attachments as the original study.

Select the study to copy.

Click 'Copy Study'

In the pop-up box, enter in the New Study Name and whether or not you would like to make this copy a template.

*Note: if you want to create a study to later edit, leave the response to question 'Copy this study to My Templates' as **No**. Otherwise, if you do want to create a non-editable, template study from which to copy to create new studies, respond **Yes**.*

Click 'Ok'

If you chose to save the study as a template, the copied study will now appear under the 'Template' tab on your homepage.

*Note: If you created the study as a template, you will not be able to edit and submit the template study. To use the template for a new submission, you must create a new study by selecting the template study and copying it.*

You have now completed the study application. The next section will describe how to submit the application for review.

# SUBMITTING APPLICATIONS

This section will explain how to submit studies for review and respond to comments.

## Submission to Mentor/Department for Review

The system will allow the study to be routed for approval by mentors and departments. Studies will be routed this way before it will go to IRB.

*\*Note: study staff **can not** send the application to any department on behalf of the PI. The PI must log in and send the study to a mentor (if the PI is a student) and the Department.*

After logging in with your MUSC account username/password, studies that require submission will be located under the "My Inbox" or "Inbox" tab.

Click on the hyperlinked name of the study.

*\*\*Note: If you don't see the study in your inbox, you may have multiple roles in the system. Make sure the role of 'Study Staff' has been selected. \*\**

The screenshot shows the Health Sciences South Carolina portal. The user is logged in as 'sr sr-pi'. The 'My Roles' section on the left has 'Study Staff' selected. A red arrow points to the 'Inbox' tab in the 'Folder for shyam sr-pi' section. Below the tabs is a table of studies with columns: ID, Name, Date Modified, Type, Owner, State, Last State Change, Review Type, PI, and Campus. The table lists several studies, including '2008 Review for Pro00000070', 'Compliance Test Study', 'CTMS test', 'last', 'Adverse Event - Tue Sep 11 13:20:46 EDT 2007', and 'swag 0957'.

From the protocol workspace page, click 'Submit Study'

*\*\*Note: If the study required editing submitting to IRB, see the section called 'Edit Pre-Submission Study' in this guidance document. \*\**

The screenshot shows the Health Sciences South Carolina portal. The user is logged in as 'musc musc-ss1'. The 'My Activities' section on the left has 'Submit Study' selected. The main content area shows the 'Current State' of the study 'Study:zserfzer (Pro00003766)'. It includes fields for Full Title, Principal Investigator, IRB Campus, PI Department, Pre-Conversion Study ID, Study Coordinator, Review Type, PI Institution, and Study Status. Below this is a table of study activities with columns: Activity, Author, and Activity Date. The table lists 'Created Study' and 'Study Modified - Major Version'.



An investigator statement of assurance window will be displayed.

Check the box to indicate an agreement to comply with all applicable policies and procedures for the protection of human subjects.

Click 'OK' to continue.

The screenshot shows the MUSC eIRB system interface. The main window is titled "Submit Study" and contains the "Investigator Assurances" section. The "Current State" is "Pre Submission". The "Study" is "MUSC5-Test3a (Pro)". The "Principal Investigator" is "PI Department". The "IRB Campus" is "PI Department". The "Pre-Conversion Study ID" is "History". The "Investigator Assurances" section includes a statement of assurance and a list of six numbered items. The "I agree with the above statement" checkbox is checked. The "Done" button is at the bottom.

Health Sciences south carolina MUSC

musc-radiology-pi musc | My Home | Logout

Submit Study

Investigator Assurances:

Subject to approval of this project by the Institutional Review Board (IRB), I agree not to involve human subjects in this project until I have received the IRB's formal written approval, nor to involve human subjects in this project until I have obtained the legally effective informed consent of the subjects' legally authorized representative. No changes in the protocol affecting human subjects or the text of the informed consent documentation will be made without the prior written approval of the IRB.

I understand that approval of this research study involving human participants is contingent upon my agreement to:

1. Notify the Institutional Review Board (IRB) immediately upon changes to this research study prior to implementation
2. Completion of continuing education as required by the IRB.
3. Adhere to the principles of the Belmont Report
4. Conduct this research study according to the Code of Federal Regulations (21 CFR Parts 50, 56, 312 and 812 and/or 45 CFR Parts 46 and 164), as applicable
5. Conduct this research study according to ICH (International Conference on Harmonisation) guidance relating to GCP (Good Clinical Practice), as applicable and the Policies and Procedures of the IRB
6. Follow all established institutional compliance policies

By checking the box, the Principal investigator assures that any and all regulations will be complied with, including suspension and disbarment, conflict of interest and misconduct in research.

I agree with the above statement: ☒

If you have finished filling out your application, then click OK. After you click OK you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

If you are not ready to submit your application, click Cancel.

Done

The study is now accessible under the "Studies" tab on the home page and the study state has changed to **"Department Review"** (or "Mentor Review" if the PI is a student).

In this state the version of the study submission is locked and only viewing options are available (instead of previously being able to edit the study).

After the department has approved the study, it will be automatically routed to IRB administrators for review.

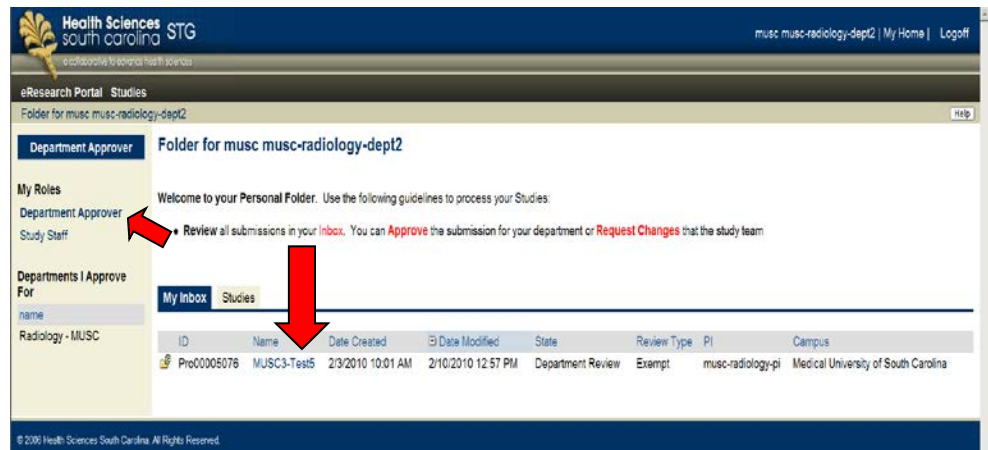
## Mentor/Departmental Review

As the Mentor or Department Chair/Designee, you will be required to review and approve the study before it is routed to IRB. An e-mail notification that a new study is ready for your review will be sent to your e-mail inbox. After the final departmental level approval has been granted, the study will be automatically routed to IRB for review.

After logging into eIRB using your MUSC accounts username/password, the studies for which you must provide an approval are located under the "My Inbox" or "Inbox" tab.

To access a study, click on its hyperlinked name.

*\*\*Note: If you don't see 'My Inbox' make sure 'Mentor' or 'Department Approver' has been selected as your role. \*\**



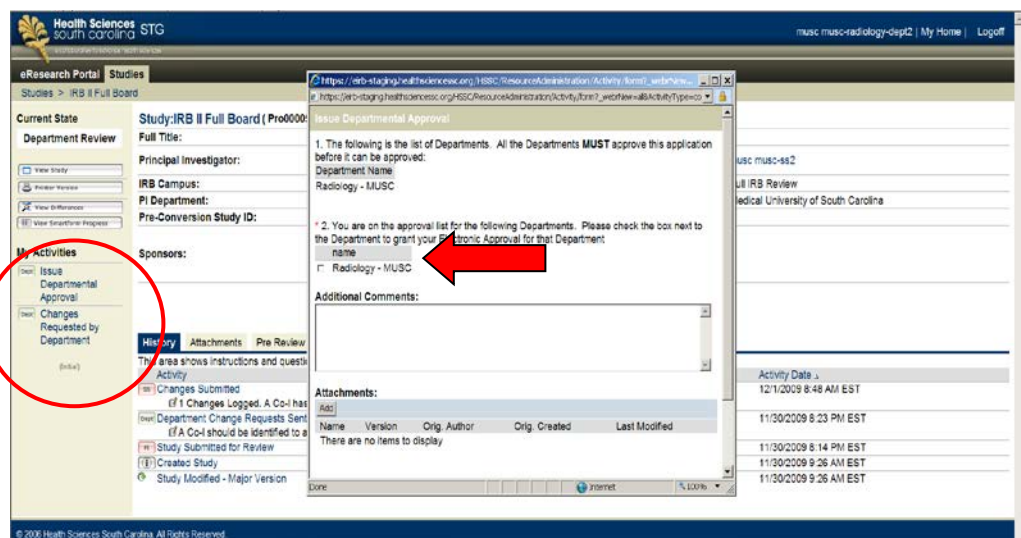
Select the review options from the left toolbar.

In this is an example 'Issue Departmental Approval' on the left side of the screen was selected

In the pop up window, check the box next to the correct department for this approval. Add any comments or attach documents if needed.

Click the 'Ok' button.

This will send the application to the IRB.



As the Mentor or Chair, if you would like the PI to include additional information or make changes, select the option 'Changes requested by department' on the left toolbar. A similar pop up window will appear that allows you to enter in your comments. These will be sent to the PI after you select the 'ok' button. You will repeat this review process until you approve the project, at which time it will be routed to IRB for review.

## Responding to Departmental Review Comments

If the mentor/department reviews the study and requests changes, the PI or study staff must respond to these changes before the study will go to IRB.

Log into the system and locate the study.

The mentor/department's review comments appear under the study's 'History' tab.

Make the requested changes within the study application by clicking 'Edit Study'. For details on this process go to the section '[Edit Pre-Submission Study](#)' in this guidance document.

The screenshot shows the MUSC eIRB interface. On the left, a sidebar contains buttons for 'Edit Study', 'Print Version', 'View Differences', 'View Summary Progress', 'Edit Guest Access', 'Submit Changes', 'Withdraw', and 'Copy Study'. The 'Submit Changes' button is highlighted with a red circle. The main area displays the 'History' tab for the study 'MUSC-Test3a (Pro0000149)'. A red circle highlights a history entry: 'Department Change Requests Sent' by 'musc-radiology-dept2 musc' on '3/22/2010 3:51 PM EDT'. The entry includes a note: '(If This has been submitted as a Phase III study, but the protocol says Phase I)'. Other tabs visible include 'Personnel', 'Attachments', 'Pre Review Status', 'Reviewer Notes', and 'Change Log'.

When the appropriate changes have been made and are ready to be submitted the study back to the department, select 'Submit Changes' on the left toolbar.

In the pop up screen, enter any text in response to the comments and any additional uploads that weren't appropriate to upload elsewhere in the application.

When done, select 'Ok'. This will send the response to the mentor or department for review.

The screenshot shows the 'Submit Changes' pop-up window in the MUSC eIRB system. The window has a title bar 'Health Sciences south carolina STG' and a user bar 'musc musc-radiology-pi | My Home | Logout'. The main area of the pop-up contains a text box for 'In addition to your response to the Reviewer Notes, please provide any other summary information for the reviewer:'. Below this is a 'Documents' section with a table header: 'Name', 'Description', 'Orig. Author', 'Orig. Created', and 'Last Modified'. The table is currently empty. At the bottom of the pop-up are 'OK' and 'Cancel' buttons. In the background, the 'Submit Changes' button in the left sidebar is also circled in red.

The mentor or department will then have the option to approve the changes or request additional changes as indicated in the [‘Mentor/Department Review’](#) section.

After the department approves the study, it is automatically routed to IRB administrators for review.

The state of the study changes to IRB Staff Review.

The screenshot displays the MUSC eIRB system interface. The top navigation bar includes the 'Health Sciences South Carolina' logo and the user's name 'music-music-radiology-pl' with a 'Logout' link. The main content area is titled 'eResearch Portal' and 'Studies'. A sidebar on the left contains a 'Current State' section with a red circle around the 'IRB Staff Review' option, and a 'My Activities' section with links for 'Edit Guest Access', 'Withdraw', and 'Copy Study'. The main content area shows details for 'Study: IRB II Exempt Study (Pro00005021)'. The study title is 'Research on educational strategies'. The Principal Investigator is 'music-music-radiology-pl'. The IRB Campus is 'Medical University of South Carolina'. The PI Department is 'Radiology - MUSC'. The Pre-Conversion Study ID is 'Study ID: 123456789'. The Study Coordinator is 'music-music-ss2'. The Review Type is 'Exempt'. The PI Institution is 'Medical University of South Carolina'. The Study Status is 'IRB Staff Review'. The Sponsors section states 'There are no items to display'. The History section shows a table of activities:

Activity	Author	Activity Date
Departmental Approval Issued	music-music-radiology-dept2	12/2/2009 2:11 PM EST
Study Submitted for Review	music-music-radiology-pl	12/2/2009 2:09 PM EST
Created Study	music-music-ss2	12/2/2009 1:53 PM EST
Study Modified - Major Version	music-music-ss2	12/2/2009 1:53 PM EST

The footer of the page states '© 2006 Health Sciences South Carolina. All Rights Reserved'.

## Responding to IRB Comments

For additional assistance, view the recorded demonstration 'Responding to IRB Reviewer Comments' in the eIRB Education & Training section.

The study's IRB contact personnel (as indicated within eIRB) will receive e-mails sent to his/her MUSC e-mail inboxes indicating that changes are requested by IRB.

***\*\*Note: study staff with study edit privileges can make and submit these changes to IRB\*\****

Responding to comments is a 2-step process.

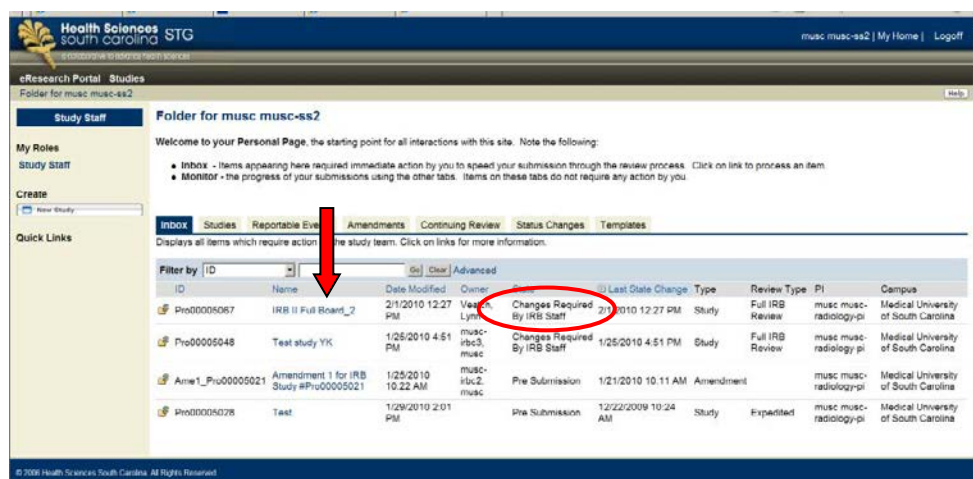
1. The changes must first be made within the study application; and
2. The changes must be documented as completed, not completed or for information only and include a summary of the responses.

Log into the system.

From the Home page, the study will appear in the eIRB 'Inbox'.

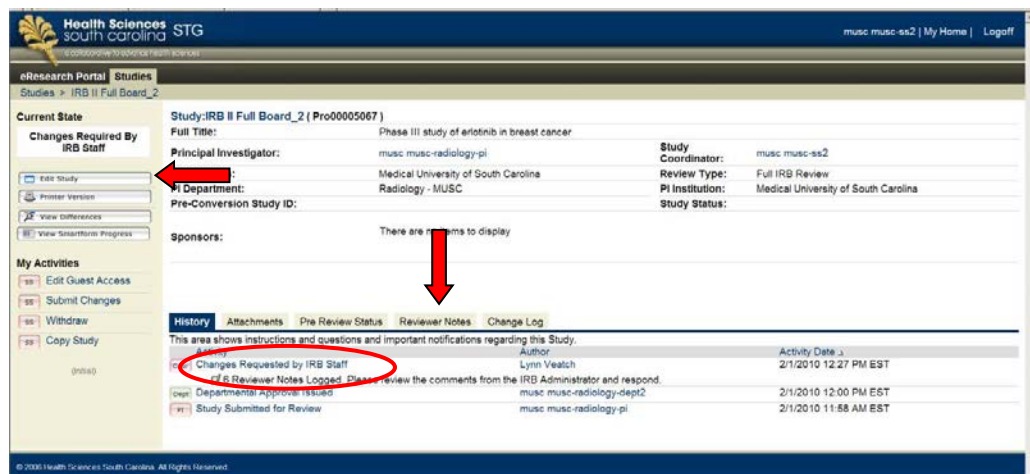
Click on the study 'Name'

***\*\*Note: notice that the state of the study has changed to 'Changes Required by IRB Staff'\*\****



The 'History' tab logs the change request. It will also include additional notes or clarification requested by IRB. However, your changes will not be made from this location.

Instead, click on either 'Edit Study' or the 'Reviewer Notes' tab to view the comments and to begin responding to them.





On the Review Notes tab, all comments will appear and the change request references the sections to change within the application.

To make these changes, click on the hyperlinked name of the referenced section.

***\*\*Note: do not select 'Click here to respond' at this point as that will be the second step in responding to the question\*\****

Health Sciences south carolina MUSC

musc-ss2 musc | My Home | Logoff

eIRB Studies

Studies > Blood study\_2

**Current State**

Changes Required By IRB Staff

Study: Blood study\_2 ( Pro00005403 )

Full Title: Pilot Study to Determine Relationship Between Protein Levels and Diabetes

Principal Investigator: musc-radiology-pi musc

IRB Campus: Medical University of South Carolina

PI Department: RADIOLOGY - MUSC

Pre-Conversion Study ID:

Study Coordinator: musc-ss2 musc

Review Type: Expedited

PI Institution: Medical University of South Carolina

Study Status:

Sponsors: There are no items to display

**My Activities**

Edit Guest Access

Submit Changes

Withdraw

Copy Study

Edit Communication Leads

History Personnel Attachments Pre Review Status **Reviewer Notes** Change Log

Filter by Type [Go] [Clear] Advanced

IRB Change Request

Jump To: Study Populations - Study Subjects

**Response Required!** Click here to respond...

Expand on the "clinic" where research will be conducted (Item 3.0). Please clarify the Study Population (Item 7.0) - the study title does not provide adequate information.

IRB Change Request

Jump To: Study Protocol

**Response Required!** Click here to respond...

Please include in the protocol the justification for the investigator.

The system will navigate to the question and form.

Make the requested changes to question within the application.

***\*\*Note: If previously submitted documents are required to be revised & uploaded, select 'Upload Revision' next to the document's name & locate the file from your computer. DO NOT use 'Add' or 'Delete' button unless this is the first time that document is included.***

***Comments may request uploading of documents when there is no upload feature on a particular smartform page. In that case, documents can be uploaded in the 'General Comments' section of the application.***

Health Sciences south carolina STG

Edit: Study - Pro00005067

Reviewer Notes

Filter by Type [Go] [Clear] Advanced

IRB Change Request

Jump To: Study Protocol

**Response Required!** Click here to respond...

Short Title should be revised

**Study Identification Information**

This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 Full Title: Enter the full study title

Phase III study of erlotinib in breast cancer

2.0 Short Title: Enter a short descriptive title for this study (65 characters maximum).

IRB II Full Board\_2

Click 'Save' or 'Continue' to save the changes you made within the application.

Name	Description	Orig. Author	Orig. Created	Last Modified	
Dummy Protocol.doc		Lynn M. Veatch Ph.D.	3/9/2011 1:48 PM	3/9/2011 1:48 PM	Upload Revision Delete



Step 2: Click within the Reviewer Notes section where indicated. This is the second step and will finalize a response to that comment only.

*\*\*Note: There may be multiple comments within one IRB Change Request section. The system allows you to save a response even if all comments haven't been addressed. For study management purposes, this second step should be completed only if all comments are addressed OR you have written in notes to go back and respond to remaining comments.*

In the pop-up window, select the 'Type' of change made, enter in a response (i.e., revision made, done, etc.) and click 'Ok'.

Health Sciences STG

Respond to Reviewer Notes - Windows Internet Explorer

Respond to Reviewer Notes

Author: Lynn Veatch  
Short Title should be revised

\* User: music music-sa2

\* Type: Change Request Completed

\* Response:

OK Cancel

Reviewer Notes

Filter by Type

Type

IRB Change Request

Response Required! Click here to respond

Short Title should be revised

Study Identification Information

This is the first step in your Human Research Application

1.0 \* Full Title:  
Enter the full study title  
Phase III study of erlotinib in breast cancer

2.0 \* Short Title:  
Enter a short descriptive title for this study (65 characters maximum)  
[IRB I] Full Board\_for reviewer comments

3.0 \* Briefly describe the scientific or scholarly

VIEW000072

Click 'Next' (or 'Previous') in the Reviewer Notes section to answer the next comment (will appear if there are multiple IRB comments).

Click 'Save' when you have finished addressing the comments or to save what you have done so far.

Click 'Exit' when done answering all comments.

Health Sciences STG

Reviewer Notes

Filter by Type

Type

IRB Change Request

Short Title should be revised

music music-sa2 - Change Request Completed - 2/2/2010 3:53 PM

Changed title as requested

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 \* Full Title:  
Enter the full study title  
Phase III study of erlotinib in breast cancer

2.0 \* Short Title:  
Enter a short descriptive title for this study (65 characters maximum)  
[IRB I] Full Board\_2

VIEW000072

Click on the 'Reviewer Notes' tab to ensure that all comments have been addressed in step #2 (i.e., a green bar appears indicating you have completed the final step in responding to that question).

Click on 'Submit Changes'. A pop-up window will allow you to enter in any other summaries or upload additional documents.

Click 'Ok' when done. This will send the response to the IRB.

The screenshot shows the 'eResearch Portal' for 'Health Sciences South Carolina STG'. The user is logged in as 'musc musc-ss2'. The main content area displays details for 'Study: IRB II Full Board\_2 (Pro00005067)'. The 'Full Title' is 'Phase III study of erlotinib in breast cancer'. The 'Principal Investigator' is 'musc musc-radiology-pi'. The 'IRB Campus' is 'Medical University of South Carolina'. The 'PI Department' is 'Radiology - MUSC'. The 'Pre-Conversion Study ID' is 'MUSC Internal Funding'. The 'Study Coordinator' is 'musc musc-ss2'. The 'Review Type' is 'Full IRB Review'. The 'PI Institution' is 'Medical University of South Carolina'. The 'Study Status' is 'Medical University of South Carolina'. The 'Sponsors' are 'MUSC Internal Funding'. The 'History' tab is selected, showing a list of activities. A red arrow points to the 'Submit Changes' button in the 'My Activities' section.

The 'History' tab on the study's main page will record that you have submitted the changes to IRB.

The Current State of the study is back to 'IRB Staff Review'.

The screenshot shows the 'eResearch Portal' for 'Health Sciences South Carolina STG'. The user is logged in as 'musc musc-ss2'. The main content area displays details for 'Study: IRB II Full Board\_2 (Pro00005067)'. The 'Full Title' is 'Phase III study of erlotinib in breast cancer'. The 'Principal Investigator' is 'musc musc-radiology-pi'. The 'IRB Campus' is 'Medical University of South Carolina'. The 'PI Department' is 'Radiology - MUSC'. The 'Pre-Conversion Study ID' is 'MUSC Internal Funding'. The 'Study Coordinator' is 'musc musc-ss2'. The 'Review Type' is 'Full IRB Review'. The 'PI Institution' is 'Medical University of South Carolina'. The 'Study Status' is 'Medical University of South Carolina'. The 'Sponsors' are 'MUSC Internal Funding'. The 'History' tab is selected, showing a list of activities. The 'Current State' is 'IRB Staff Review'.

# Post IRB Approval Navigation Options

For additional assistance, view the recorded demonstration 'Accessing IRB Reviewed Documents' in the [eIRB Education & Training](#) section.

After the study has been approved by IRB, several tabs become available within the study's home page, in addition to those described in the [Protocol Details](#) section of this document:

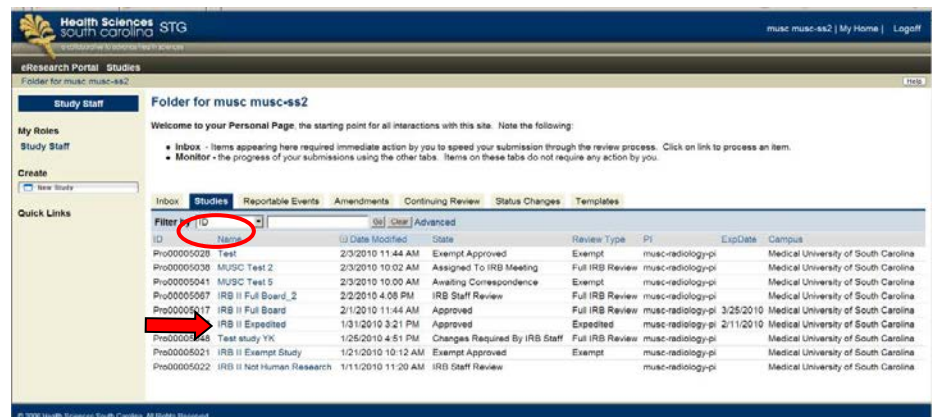
- **Amendments** include any study revision requests entered into the system
- **Continuing Review** includes all renewals entered into the system
- **Status Changes** include all requests to change the study subject accrual status (requests not included as a part of the continuing review) entered into the system
- **Reportable Events** include all reportable events, deviation and safety/monitoring correspondences entered into the system
- **Attachments** tab includes all application sections that include documents and all documents uploaded as part of submission. Stamped approved ancillary documents (e.g., stand-alone HIPAAs or ads) are also included at the bottom of this section).
- **Stamped ICF** includes the IRB approved water-marked consent forms
- **Coop. Review Status** includes review details for studies that are a part of the HSSC Cooperative Review process
- **Central IRB** includes external site details and workspaces for multi-site studies approved with MUSC as the Centralized IRB of Record



## Accessing IRB Approval Document

To access the IRB review letter, log into eIRB.

From your Homepage, select the 'Studies' tab and click on the name of the study.

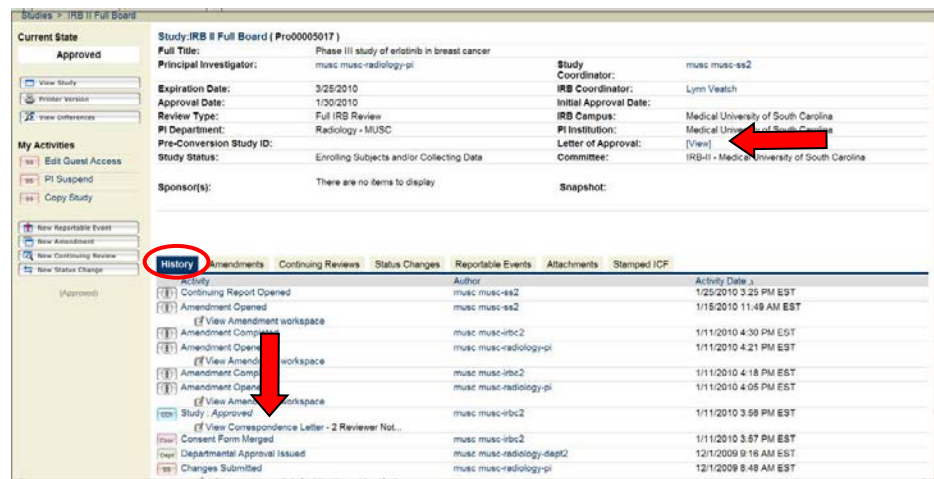


The 'History' tab on the study's home page will include a line indicating that the study is approved and an option to view the IRB review letter.

Click on 'View Correspondence Letter'.

You can also click on 'View' in the Letter of Approval section.

You will have the option to open or save the letter as a Microsoft Word document.

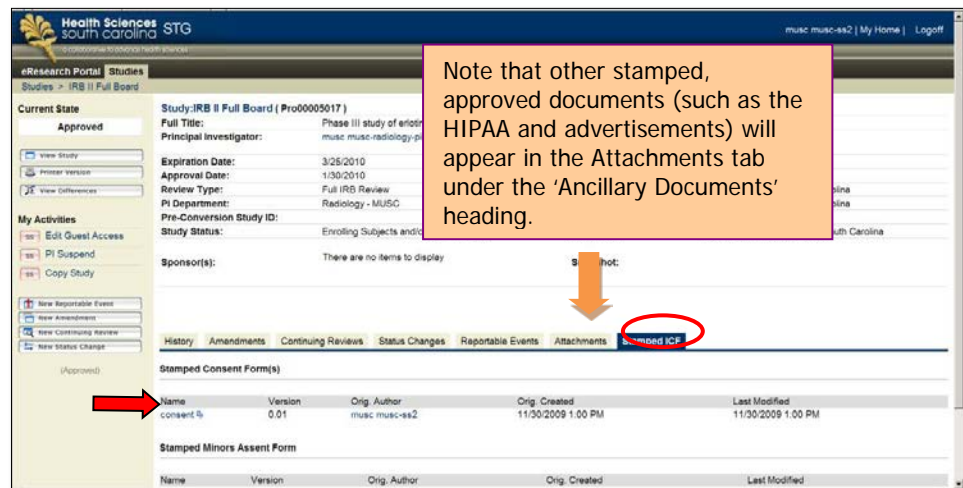


To view the approved consent document(s), select the 'Stamped ICF' tab.

Click on the Name of the document.

You will have the option to open or save the letter as a Microsoft Word document.

***\*\*Note: The consent document will include a protected IRB watermarked approval stamp. These versions of the documents must be used when enrolling participants to the study. The most currently approved consent will be included in this section. \*\****



# AMENDMENTS

## General amendment completion guidelines

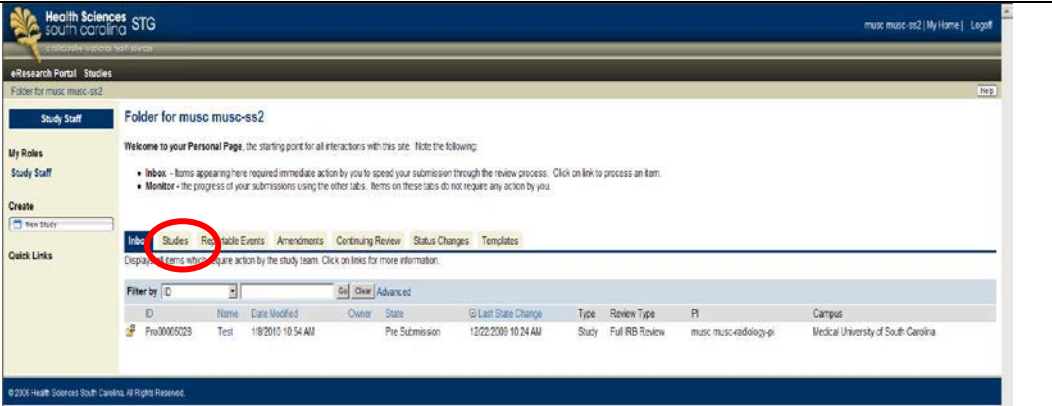
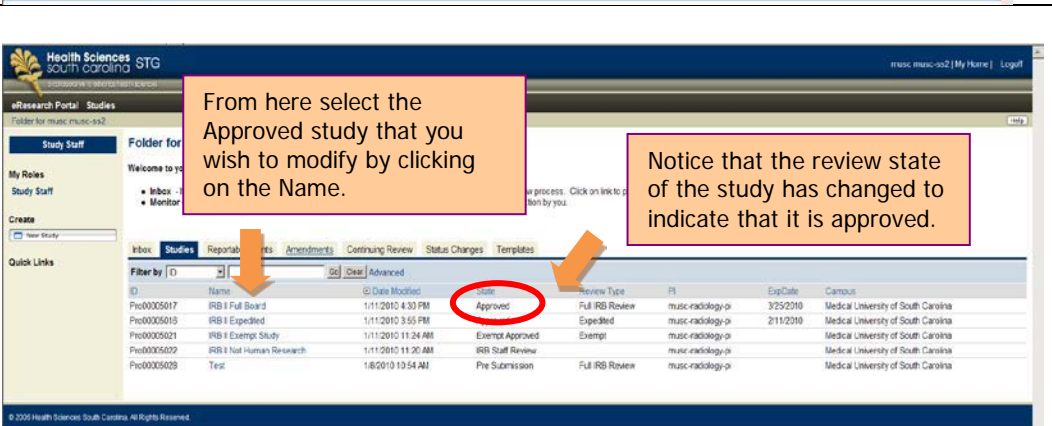
For additional assistance, view the recorded demonstrations 'Amendment Design' and 'Creating and Submitting Amendments' in the eIRB [Education & Training](#) section.

There are 2 important steps to complete all amendments.

1. Completion of the amendment type and summary of changes. All tracked changed documents and amendment summaries will be included in this section.
2. Incorporating the amendment changes within the original or currently approved study application. In this section, all finalized/untracked documents will be included and specific changes will be incorporated.

**\*\*Note:** prior to initiating an amendment request, it may be helpful to review a copy of the currently approved eIRB application and identify all sections & content that require revision as a result of the amendment\*\*

**\*\*Note:** only the PI can submit an amendment to IRB\*\*

<p>Log into eIRB and select the 'Studies' tab.</p>	
<p>Select the study for which you would like to submit an amendment.</p> <p><b>**Note:</b> The study must be IRB approved before an amendment can be completed.**</p>	



Under My Activities,  
select 'New  
Amendment'

**\*\*Note:** Only one  
amendment request at a  
time can be sent to IRB.  
However, several  
amendments can be  
combined within one  
request.

If you don't see the  
New Amendment button  
for an approved study,  
there is most likely an  
amendment already  
open (see the  
Amendments tab). It  
should be edited or  
withdrawn. \*\*

**Health Sciences South Carolina STG**  
eResearch Portal Studies

**Current State**  
Approved

**Study IRB # Full Board (Pro0005017)**  
Full Title: Phase II study of erlotinib in breast cancer  
Principal Investigator: music music-radiology-pi  
Expiration Date: 3/25/2010  
Approval Date:  
Review Type: Full IRB Review  
PI Department: Radiology - MUSC  
Pre-Conversion Study ID:  
Study Status: Approved for Accrual  
Sponsor(s): There are no items to display  
Study Coordinator: music music-abc2  
IRB Coordinator: music music-abc2  
Initial Approval Date:  
IRB Campus: Medical University of South Carolina  
PI Institution: Medical University of South Carolina  
Letter of Approval: [View]  
Committee: IRB-6 - Medical University of South Carolina

**My Activities**  
Edit Guest Access  
PI Suspend  
Copy Study  
New Amendment Request  
View Amendment  
New Continuing Review  
New Status Change  
(Approved)

**Amendments**  
Activity Date  
(1) Amendment Completed  
(1) Amendment Opened  
(1) View Amendment workspace  
(1) Amendment Completed  
(1) Amendment Opened  
(1) View Amendment workspace  
(1) Study Approved  
(1) View Correspondence Letter - 2 Reviewer Not  
(1) Consent Form Merged  
(1) Departmental Approval Issued  
(1) Changes Submitted  
(1) Changes Logged - A CoI has been identified  
(1) Change Log: Study Identification - Study Personnel  
(1) Department Change Requests Sent  
(1) A CoI should be identified to assist with this project

**Events**  
Author: music music-abc2  
music music-radiology-pi  
music music-abc2  
music music-radiology-pi  
music music-abc2  
music music-abc2  
music music-radiology-dept2  
music music-radiology-pi  
music music-radiology-dept2

**Attachments**  
Activity Date  
11/1/2010 4:30 PM EST  
11/1/2010 4:25 PM EST  
11/1/2010 4:18 PM EST  
11/1/2010 4:05 PM EST  
11/1/2010 3:58 PM EST  
11/1/2010 3:57 PM EST  
12/1/2009 9:18 AM EST  
12/1/2009 8:48 AM EST  
11/30/2009 8:26 PM EST  
11/30/2009 8:23 PM EST

1 of 2

Select whether it's a  
minor or major  
amendment and the  
changes in risks and  
benefits.

Click Continue

**Amendment - Category**  
VIEW448CDB1C5000

Amendment - Change(s) in previously approved research. An amendment request includes two parts in the eIRB portal: the **Amendment Smartforms** and the modifications to the Amendment copy of the **Study Smartforms**. Only one amendment request is allowed at any given time, i.e.: Amendment 1 must be approved, denied or withdrawn before Amendment 2 can be created.

**1.0 \* Category of amendment:**  
☐ Minor change(s), Minimal risk change(s)  
☐ Significant Change(s), Greater than minimal risk change(s)  
 Clear

**2.0 \* Are the risks to subjects affected by the amendment?**  
☐ Increased Risk  
☐ Decreased Risk  
☐ No effect to Risk  
 Clear

**If affected, explain:**

**3.0 \* Are the benefits to subjects affected by the amendment?**  
☐ Increased Benefit  
☐ Decreased Benefit  
☐ No effect to Benefit  
 Clear

**If affected, explain:**

Back | Edit | Print | Show Error | Print | Jump To: Category > | Continue >>

Edit the amendment's  
name, as desired.

Click Continue.

**\*\*Note:** The name given  
to the amendment is  
what will identify it in  
eIRB and what will  
appear on the IRB  
approval document.

**Health Sciences South Carolina STG**  
Edit: Amendment - Ame3\_Pro0005017

Back | Save | Edit | Print | Show Error | Print | Jump To: Name > | Continue >>

**Amendment - Name**  
Amendment name field is used to track the amendment within the eIRB system along with the system generated ID number.

**1.0 \* Amendment Name:**  
Amendment 3 for IRB Study #Pro0005017

Back | Save | Edit | Print | Show Error | Print | Jump To: Name > | Continue >>

If you need to finish the amendment later, you save can what you've done so far and exit the application.



<p>Select the type of amendment and enter in a description of the change.</p> <p>Indicate if subjects are currently enrolled and if the amendment is at the request of the study sponsor.</p> <p><i>**Note: If you indicate the amendment has been requested by the sponsor, you will later upload the summary/rationale of changes and specify the name/date of the change. **</i></p> <p>Click Continue.</p>	<div style="border: 1px solid #ccc; padding: 5px;"> <div style="background-color: #f0f0f0; padding: 2px; margin-bottom: 5px;"> <a href="#">&lt;&lt; Back</a> <span style="float: right;">Save   Exit   Hide/Show Errors   Print   Jump To: Request ▾</span> </div> <p><b>Amendment - Request</b></p> <p><b>1.0 * Type of change(s) this amendment is requesting:</b>  Check all that apply. <i>Note: Checking any of these options requires revisions to the applicable Smartform page(s) in the Amendment copy of the Study Smartforms (located on the 'Instructions for Completing Amendments' page).</i></p> <div style="list-style-type: none; padding-left: 0;"> <input type="checkbox"/> Study Personnel  <input type="checkbox"/> Advertisements/Study Recruitment Materials  <input type="checkbox"/> Informed Consent Document/Procedures  <input type="checkbox"/> Protocol Document(s)  <input type="checkbox"/> Investigator's brochure  <input type="checkbox"/> Editorial/Administrative Changes  <input type="checkbox"/> Additional Sites for Treatment/Follow-up  <input type="checkbox"/> Modification In Subject Enrollment Goals  <input type="checkbox"/> Location of Program Activities  <input type="checkbox"/> Questionnaires &amp; Assessment Tools  <input type="checkbox"/> Risk Change(s)  <input type="checkbox"/> Study Procedure(s)  <input type="checkbox"/> Subject Confidentiality/Anonymity  <input type="checkbox"/> Subject Population  <input type="checkbox"/> Other Changes  <input type="checkbox"/> HIPAA Authorization  <input type="checkbox"/> Study Funding Source/Sponsorship  <input type="checkbox"/> Conflict of Interest (COI) </div> <p><b>2.0 * Change Description</b>  Briefly summarize changes:</p> <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div> <p><b>3.0 * Current Subjects</b>  Are there subjects currently enrolled in the study?  <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p><b>4.0 * Has this amendment been requested by the study sponsor?</b>  <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p><b>if Yes,</b>  <b>Study Sponsor Amendment Number:</b>  <div style="border: 1px solid #ccc; height: 20px; width: 150px; margin-top: 5px;"></div> </p> </div> <div style="background-color: #f0f0f0; padding: 5px; margin-top: 5px; text-align: center;"> <p><i><b>If desired, select an amendment type below for specific submission details. Otherwise, continue through the manual for General Completion guidance.</b></i></p> </div>
<p><a href="#">Change personnel</a>  <a href="#">Protocol Changes</a>  <a href="#">Informed Consent</a></p>	<div style="display: flex; justify-content: space-around;"> <div> <p><a href="#">Investigator's Brochure</a>  <a href="#">Editorial/Administrative Changes</a></p> </div> <div> <p><a href="#">Sites/locations of Activities</a>  <a href="#">Subject Information</a></p> </div> </div>

## Finalizing the amendment

Add additional comments and upload any new or revised documents that aren't uploaded in another section of the amendment request and click Continue.

***\*\*Note: The finalized (unmarked) documents will be uploaded in another step.\*\****

Health Sciences south carolina STG  
Edit: Amendment - Ame3\_Pro00005017

<< Back | Save | Edit | Hide/Show Errors | Print... | Jump To: General Comments | Continue >>

General Comments

1.0 Add any additional comments to assist in the review of this research amendment:

2.0 Add any miscellaneous documents that do not fit in other sections of the amendment or study application

Click Add to upload document(s)

Name	Description	Orig. Author	Orig. Created	Last Modified
file: brochure		music music-ss2	1/15/2010 1:06 PM	1/15/2010 1:06 PM

<< Back | Save | Edit | Hide/Show Errors | Print... | Jump To: General Comments | Continue >>

A Summary of the amendment changes will be presented.

Verify the information and click Continue.

<< Back | Save | Edit | Hide/Show Errors | Print... | Jump To: Summary of Changes | Continue >>

Summary of Changes

This Amendment is changing/updating the following items:

Category: Minor change(s). Minimal risk change(s)

Types of changes: Advertisements/Study Recruitment Materials

<< Back | Save | Edit | Hide/Show Errors | Print... | Jump To: Summary of Changes | Continue >>

You must manually enter into the current IRB application the information that changed with this amendment.

Review the steps on this page and click on the red 'CLICK HERE' text to open up the currently approved application and incorporate the changes.


***\*\*Note: Any final/unmarked documents for the amendment should be uploaded in the current IRB application and not in the amendment summary section that was just completed. \*\****

VIEW449AFE1F91800

### Instructions for Completing Amendments

An amendment requires two parts: the Amendment summary form and edits to the IRB study application pages.

Step 1: So far, you have filled out the Amendment summary form.  
 Step 2: You will now begin to make changes to the IRB study application pages (see [CLICK HERE](#) link below).  
 Step 3: Documents uploaded in the Amendment summary form must also be uploaded in the IRB study application.  
 Step 4: Once all changes have been made to the IRB study application, click Finish.  
 Step 5: After returning to this Amendment instructions page, click Continue for next steps to submit the Amendment for IRB review.

 **CLICK HERE** to edit the IRB study application, as described in Steps 2-4 above.

<< Back      Save | Exit | Hide/Show Errors | Print... | Jump To: Instructions for Completing Amendments      Continue >>

Make changes to the appropriate section so that it reflects what has changed in the amendment.

Click on the 'Jump To' drop down list to see which sections of the application require changes.

Upload any final documents that are a part of the amendment.

***\*\*Note: Upload revised documents (i.e., protocol, consent, ads, etc.) in the applicable section by clicking on the 'Upload Revision' button (NOT the 'Add' or 'Delete'). \*\****

When you have finished making the changes, save the information. You can then exit the application.

Edit: Study - MS3\_Pro00005017

<< Back      Show | Exit | Hide/Show Errors | Print... | Jump To: 1 - Study Identification      Continue >>

**Study Identification Information**  
 This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submission.

1.0 \* Full Title:  
 Enter the full study title  
 Phase III study of erlotinib in breast cancer

2.0 \* Short Title:  
 Enter a short descriptive title for this study (85 characters maximum):  
 IRB II Full Board

3.0 \* Briefly describe the scientific or scholarly rationale:  
 (i.e. purpose of research)  
 See if drug will delay cancer growth

4.0 \* Brief Study Summary  
 Non-scientific description of the research study, using 3 to 10 sentences.  
 Statements such as "see protocol" are not acceptable.  
 Subjects will get 20 mg of erlotinib once a week in 21 day cycles.

When you finished making changes, click **Save** then **Exit** to go back to Modification.

Or selected the 'Jump To' drop down, select General Comments section and click finish from there

Click the Add button to upload these document(s). (Note: Do NOT upload consent or any other documents here.)

Name	Description	Orig. Author	Orig. Created	Last Modified	
IRB 3 FB protocol.final.docx		musc-radiology-pi musc	5/5/2011 12:33 PM	5/5/2011 12:33 PM	Delete

The 'Instructions for Completing Amendments' screen will re-appear.

Click Continue.

Select 'Finish' to complete the amendment in the system.

***\*\*Reminder: only the Principal Investigator can send the amendment to the IRB\*\****

The system will return to the protocol amendment workspace.

***\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the amendment, the PI must be notified through routine communication that the amendment is pending submission. \*\****

***\*\*Note: The amendment is in the Pre Submission state until it has been submitted to IRB. \*\****

The amendment will now show up in the 'Amendment' tab on your Home page and on the 'Amendment' tab in the study's details.

Follow the steps in the ['Sending Amendment to IRB'](#) section.

The screenshot shows the 'eResearch Portal' for Health Sciences South Carolina. The user is logged in as 'musc-musc-ss2'. The 'Amendments' tab is selected, showing a table of amendments for the study 'musc-musc-ss2'. A red circle highlights the 'Amendments' tab and the table.

ID	Name	Date Modified	Owner	State
Amc3_Pro00005017	Amendment 3 for IRB Study #Pro00005017	1/15/2010 1:18 PM	musc-irbc2, musc	Pie Submission
Amc2_Pro00005017	Amendment 2 for IRB Study #Pro00005017	1/11/2010 4:30 PM	musc-irbc2, musc	Approved
Amc1_Pro00005017	Amendment 1 for IRB Study #Pro00005017	1/11/2010 4:18 PM	musc-irbc2, musc	Approved

## Specific amendment details

### Change in personnel

If not already completed, follow steps in the [General Completion Guidelines](#) section, selecting 'Study Personnel' as the amendment type.

You will be asked to indicate the type of personnel change.

***\*\*Note: All personnel should be manually added/deleted in the current IRB application Smart Form towards the end of the amendment request\*\****

***\*\*Note: To be located in eIRB, personnel must have an MUSC netID assigned. If the name is not found, contact an [eIRB systems administrator](#) for assistance. \*\****

Click Continue.

See steps in the '[Finalizing the amendment](#)' section for instructions on completing the amendment request.

The screenshot shows a web-based form titled "Amendment - Study Personnel Changes" with a version number "v15.0/0000179" in the top right corner. The form contains four numbered sections, each with a radio button for "Yes", "No", or "Clear":

- 1.0 \*Principal Investigator**  
Is there a change in the principal investigator for this study?  
☐ Yes ☐ No ☐ Clear
- 2.0 \*Co-Investigator(s)**  
Is there a change in the co-investigator(s) for this study?  
☐ Yes ☐ No ☐ Clear
- 3.0 \*Study Coordinator**  
Is there a change in the study coordinator for this study?  
☐ Yes ☐ No ☐ Clear
- 4.0 \*Other Study Team Members**  
Is there a change in the study team members for this study?  
☐ Yes ☐ No ☐ Clear

Below these sections is a note: "Note: Changes to personnel require a review of the Conflict of Interest section of the Amendment copy of the Study Smartform." At the bottom of the form, there is a navigation bar with buttons for "<< Back", "Save | Exit | Hide/Show Errors | Print...", "Jump To: Study Personnel Changes", and "Continue >>".



## Protocol changes

If not already completed, follow steps in the [General Completion Guidelines](#) section, selecting 'Protocol Document' as the amendment type.

<< Back Save | Exit | Hide/Show Errors | Print | Jump To: Request >

**Amendment - Request**

**1.0 \* Type of change(s) this amendment is requesting:**  
Check all that apply. *Note: Checking any of these options requires revisions to the applicable Smartform page(s) in the Amendment copy of the Study Smartforms (located on the 'Instructions for Completing Amendments' page).*

- ☐ Study Personnel
- ☐ Advertisements/Study Recruitment Materials
- ☐ Informed Consent Document/Procedures
- ☐ Protocol Document(s)
- ☐ Investigator's brochure
- ☐ Editorial/Administrative Changes
- ☐ Additional Sites for Treatment/Follow-up
- ☐ Modification In Subject Enrollment Goals
- ☐ Location of Program Activities
- ☐ Questionnaires & Assessment Tools
- ☐ Risk Change(s)
- ☐ Study Procedure(s)
- ☐ Subject Confidentiality/Anonymity
- ☐ Subject Population
- ☐ Other Changes
- ☐ HIPAA Authorization
- ☐ Study Funding Source/Sponsorship
- ☐ Conflict of Interest (COI)

**2.0 \* Change Description**  
Briefly summarize changes:

**3.0 \* Current Subjects**  
Are there subjects currently enrolled in the study?  
☐ Yes ☐ No Clear

**4.0 \* Has this amendment been requested by the study sponsor?**  
☐ Yes ☐ No Clear

If Yes,  
**Study Sponsor Amendment Number:**

Summarize the changes and click 'Add' to upload the tracked changes version of the protocol.

**\*\*Note: you will upload the clean copy document directly into the current IRB application part of the amendment request\*\***

Protocol Document Changes - Redlined Copy (changes marked) VIEW4494FA56CSC00

**1.0 \* Description**  
Summarize the changes to the research protocol:

**2.0 Latest red-lined/tracked changes version of the protocol**  
Click the Add button to upload document(s):

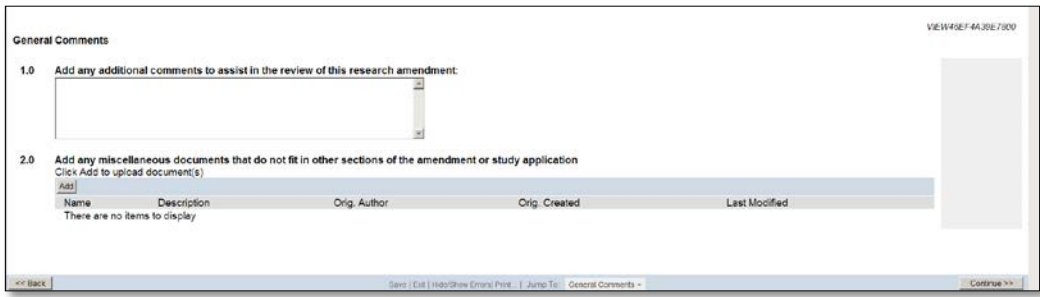

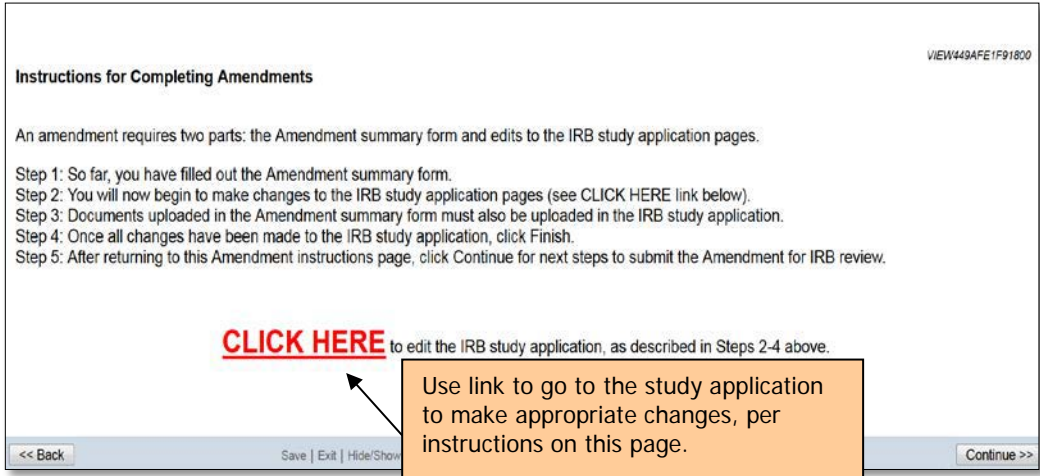
Add

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

**NOTE:** Upload the clean copy of the protocol directly to the study.

<< Back Save | Exit | Info/Show Errors | Print | Jump To: Protocol Document Changes - Redlined Copy changes marked > Continue >>

A revised protocol must be provided for MUSC IRB review.

<p>Add any additional comments and upload relevant documents that aren't uploaded in another section of the amendment request.</p>	
<p>The next screen will show a summary of changes you selected.</p> <p>Verify the information and click Continue.</p>	
<p>You must manually enter into the current IRB application the information that changed with this amendment.</p> <p>Review the steps on the page and click the <b>CLICK HERE</b> text to open up the currently approved application and incorporate the changes.</p> <p><i><b>**Note: Any final/unmarked protocol for the amendment should be uploaded in the current IRB application and not in the amendment summary section that was just completed. **</b></i></p>	

Make changes to the protocol section so that it reflects what has changed in the amendment.

Click on the 'Jump To' drop down list to go to the Protocol section of the application.

**When you finished making changes, click **Save** then **Exit** to go back to Modification.**

**Or selected the 'Jump To' drop down, select General Comments section and click finish from there**

**Study Identification Information**  
This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 **\* Full Title:**  
Enter the full study title  
Phase III study of erlotinib in breast cancer

2.0 **\* Short Title:**  
Enter a short descriptive title for this study (65 characters maximum):  
IRB II Full Board

3.0 **\* Briefly describe the scientific or scholarly rationale:**  
(i.e. purpose of research)  
See if drug will delay cancer growth

4.0 **\* Brief Study Summary**  
Non-scientific description of the research study, using 3 to 10 sentences:  
*Statements such as "see protocol" are not acceptable.*  
Subjects will get 20 mg of erlotinib once a week in 21 day cycles.

Upload final/unmarked version of the protocol click on the 'Upload Revision' button (NOT the 'Add' or 'Delete'). \*\*

***\*\*Note: Choose the 'Upload Revision' button when revising the currently approved protocol document. \*\****

***DO NOT select the 'Add' button unless this is an additional protocol document that was not previously approved.***

***DO NOT click 'Delete' button unless an incorrect document that has not yet been IRB approved was uploaded in error\*\****

A pop-up box will appear. Locate the file and click 'OK' to attach it.

When changes are finished, save and exit the application.

**Revise the version dates as applicable.**  
***\*\*Note: This information is often required for sponsored research. If left blank, it will not appear on the IRB review letter. \*\****

**\* Protocol document, grant application, or research proposal**  
Click the Add button to upload these document(s). (Note: Do NOT upload consent or any other documents here.)

Add

Name	Description	Orig. Author	Orig. Created	Last Modified
IRB 3 FB protocol.final.docx		musc-radiology-pi musc	5/5/2011 12:33 PM	5/5/2011 12:33 PM

Upload Revision Delete

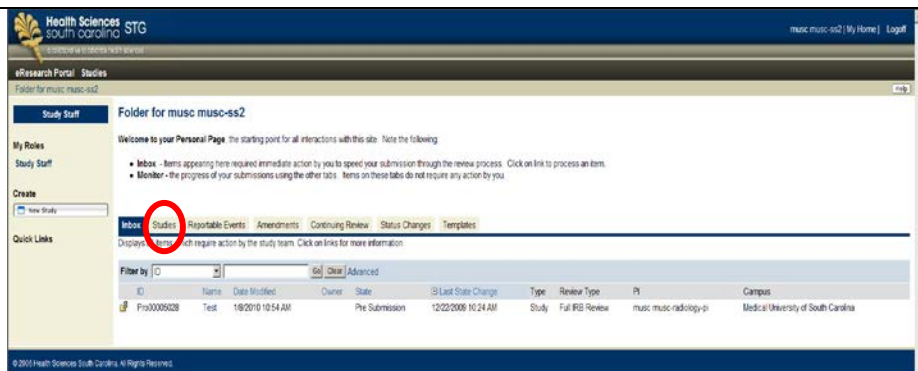
<p>The system will take you back to the Amendment Summary to complete the submission.</p> <p>Click Continue.</p>	<div><div>VIEW449AFE1F91800</div><div><h3>Instructions for Completing Amendments</h3><p>An amendment requires two parts: the Amendment summary form and edits to the IRB study application pages.</p><p>Step 1: So far, you have filled out the Amendment summary form.</p><p>Step 2: You will now begin to make changes to the IRB study application pages (see <a href="#">CLICK HERE</a> link below).</p><p>Step 3: Documents uploaded in the Amendment summary form must also be uploaded in the IRB study application.</p><p>Step 4: Once all changes have been made to the IRB study application, click Finish.</p><p>Step 5: After returning to this Amendment instructions page, click Continue for next steps to submit the Amendment for IRB review.</p><p><b><u>CLICK HERE</u></b> to edit the IRB study application, as described in Steps 2-4 above.</p></div><div><div>&lt;&lt; Back</div><div>Save   Exit   Hide/Show Errors   Print...   Jump To: Instructions for Completing Amendments</div><div>Continue &gt;&gt;</div></div></div>
<p>Click 'Finish'</p> <p><i>**NOTE: only the Principal Investigator can send the amendment to the IRB**</i></p>	<div><div><div><div>Health Sciences south carolina STG</div><div>STG</div><div>© 2008 Health Sciences South Carolina. All Rights Reserved</div></div><div>VIEW47C649FFB401</div><div>Edit: Amendment - Ame4_Pro00005017</div><div>&lt;&lt; Back</div><div>Save   Exit   Hide/Show Errors   Print...   Jump To: Amendment - Next Steps</div><div>Finish</div><div>Next Steps</div><div>Select the 'Finish' button to exit this page. If you are the Principal Investigator, you may select on the 'Submit' activity in the amendment workspace to send to the IRB Office.</div><div>&lt;&lt; Back</div><div>Save   Exit   Hide/Show Errors   Print...   Jump To: Amendment - Next Steps</div><div>Finish</div></div></div>
<p>The system will return to the protocol amendment workspace.</p>	<div><div><div><div>Current State</div><div>Pre Submission</div><div>Amendment: Amendment 4 for IRB Study #Pro00005021</div><div>PI: musc-irbc2, musc</div><div>Amendment #: Ame4_Pro00005017</div><div>Date Created: 6/24/2010 10:01 AM EDT</div><div>Description of change: add people</div><div>Study Personnel</div><div>VIEW000187</div><div>History</div><div>Change Log</div><div>Activity</div><div>Amendment Created</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 10:01 AM EDT</div><div>6/24/2010 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## Informed consent

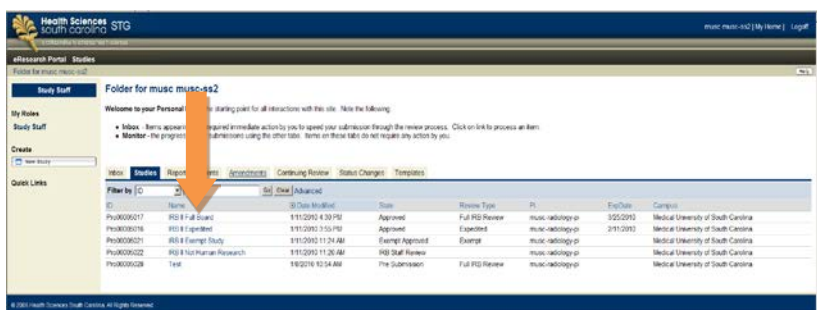
### Locating Current Consent Form

Before submitting an informed consent amendment, be sure that you are using the most recently approved consent form. Although you have saved your consent documents to a location outside of eIRB (i.e., folder on a network server), eIRB does store all consent versions in the system.

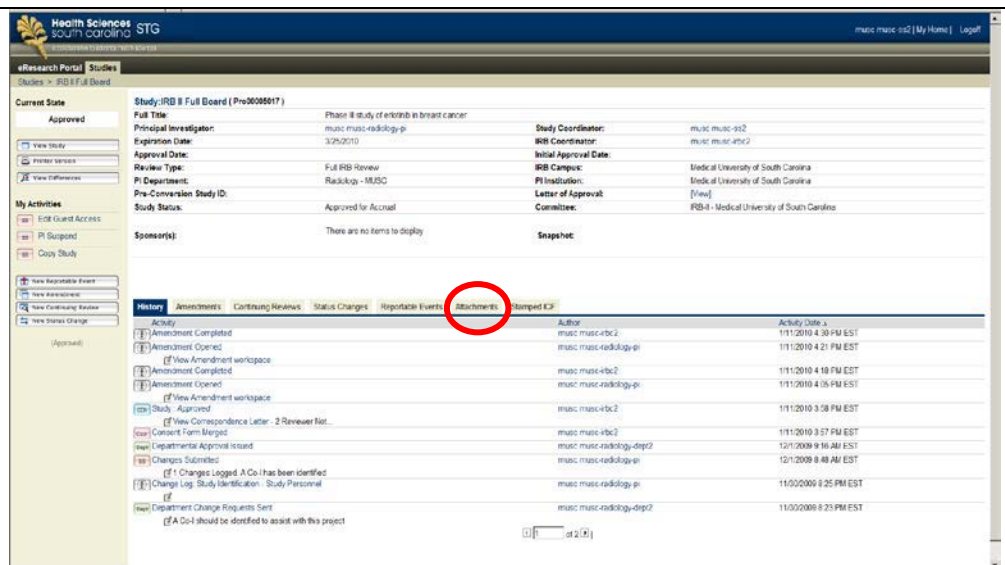
To locate the most recent consent form in eIRB, log into eIRB and select the 'Studies' tab.



Click on the study the name of the study.



Select the 'Attachments' tab.





Scroll to the Consent Process section and locate the 'Draft Consent Form for Researcher' (or the appropriate title for whichever type of consent/assent you are revising).

The draft version of the currently approved consent in eIRB will be listed.

Click on the name of the document to open it. The document should have the shell of the date-stamped watermark.

*\*\*Note: to review previous versions of the consent form(s), select the 'History' link next to the document's name\*\**

**Smartform Section 11 - Consent Process**

Debriefing form(s):

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

Waiver of Written or Signed Consent:

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

Draft Consent Forms from Researcher:

Name	Version	Orig. Author	Orig. Created	Last Modified
Consent	History	0.01	Brigitte White	5/26/2011 3:52 PM

Minges - Draft Assent Form from Researcher:

Name	Version	Orig. Author	Orig. Created	Last Modified
There are no items to display				

**Smartform Section 12 - Privacy**

HIPAA Research Authorization:

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

## Completing Consent Amendment

If not already completed, follow steps in the [General Completion Guidelines](#) section, selecting 'Informed Consent Document/Procedures' as the amendment type.

**Amendment - Request**

1.0 **\* Type of change(s) this amendment is requesting:**  
Check all that apply. Note: Checking any of these options requires revisions to the applicable Smartform page(s) in the Amendment copy of the Study Smartforms (located on the 'Instructions for Completing Amendments' page).

- ☐ Study Personnel
- ☐ Advertisements/Study Recruitment Materials
- ☐ Informed Consent Document/Procedures
- ☐ Protocol Document(s)
- ☐ Investigator's brochure
- ☐ Editorial/Administrative Changes
- ☐ Additional Sites for Treatment/Follow-up
- ☐ Modification in Subject Enrollment Goals
- ☐ Location of Program Activities
- ☐ Questionnaires & Assessment Tools
- ☐ Risk Change(s)
- ☐ Study Procedure(s)
- ☐ Subject Confidentiality/Anonymity
- ☐ Subject Population
- ☐ Other Changes
- ☐ HIPAA Authorization
- ☐ Study Funding Source/Sponsorship
- ☐ Conflict of Interest (COI)

2.0 **\* Change Description**  
Briefly summarize changes:

3.0 **\* Current Subjects**  
Are there subjects currently enrolled in the study?  
☐ Yes ☐ No Clear

4.0 **\* Has this amendment been requested by the study sponsor?**  
☐ Yes ☐ No Clear

If Yes,  
Study Sponsor Amendment Number:



Complete information about changes made to the currently approved consent document, whether it involves a new consent, whether it involves a modification of consenting processes, and if subjects will be notified of the change.

If you will be giving subjects written notification other than the consent form, upload it here.

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Edit: Amendment - Ame1\_Pro00006814

Amendment - Informed Consent Document/Procedures

1.0 Are these changes being made to a currently approved consent document?  
Yes No Clear

2.0 Does the change include a new consent form not previously approved?  
Yes No Clear

3.0 Does the change include a modification of the informed consent process/procedures?  
Yes No Clear

4.0 Subject Notification of Change  
How will subjects be notified of changes (if necessary?)  
(ie Full Revised Informed Consent, Consent Addendum, Letter/Other Notification)

Click the Add button to upload a copy of the notification

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

If notifying subjects of the change (i.e., if re-consenting is required) this information must be included for MUSC IRB review.

If the change is for a currently IRB approved consent form, summarize the changes.

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Edit: Amendment - Ame1\_Pro00005021

Amendment - Currently Approved Consent Document Changes/Deletions

1.0 Description  
Summarize all the changes to the currently approved consent document(s)

2.0 Latest red-lined/track changes version of the currently approved consent document  
Click the Add button to upload document(s)

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

Note: Upload the clean copy of the revised consent document directly to the Amendment copy of the Study Smartforms.

Add any comments and upload relevant documents that aren't uploaded in another section of the amendment request.

***\*\*Note: the final version of the documents will be NOT be uploaded here\*\****

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south carolina

Edit: Amendment - Ame1\_Pro00005021

General Comments

1.0 Add any additional comments to assist in the review of this research amendment

2.0 Add any miscellaneous documents that do not fit in other sections of the amendment or study application  
Click Add to upload document(s)

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

The next screen will show a summary of changes you selected.

Verify the information and click Continue.

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Edit: Amendment - Ame1\_Pro00005021

Summary of Changes

This Amendment is changing/updating the following items:

Category: Minor change(s), Minimal risk change(s)

Types of changes: Informed Consent Document/Procedures

You must manually enter into the original/current IRB application the information that changed with this amendment.

Review the steps and click on the **CLICK HERE** text to incorporate the changes in the study application.

*\*\*Note: the final/unmarked consenting documents will be uploaded in the current IRB application, which will appear after clicking on the 'Smartform' link\*\**

Instructions for Completing Amendments

VIEW44SAFE1F91000

An amendment requires two parts: the Amendment summary form and edits to the IRB study application pages.

Step 1: So far, you have filled out the Amendment summary form.  
Step 2: You will now begin to make changes to the IRB study application pages (see **CLICK HERE** link below).  
Step 3: Documents uploaded in the Amendment summary form must also be uploaded in the IRB study application.  
Step 4: Once all changes have been made to the IRB study application, click Finish.  
Step 5: After returning to this Amendment instructions page, click Continue for next steps to submit the Amendment for IRB review.

**CLICK HERE** to edit the IRB study application, as described in Steps 2-4 above.

<< Back      Save | Exit | Hide/Show Errors | Print...      Continue >>

Use link to go to the study application to make appropriate changes, per instructions on this page.

To make changes to the consent process section click on the 'Jump To' drop down list and go to the Consent Process section of the application.

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a subsidiary of the South Carolina Health Sciences

Edit: Study - MS3\_Pro0005017

<< Back      Save | Exit | Hide/Show Errors | Print...      Jump To: 1 - Study Identification <      Continue >>

Reviewer Notes (0 Notes Total)

**Study Identification Information**  
This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 \* Full Title:  
Enter the full study title  
Phase III study of erlotinib in breast cancer

2.0 \* Short Title:  
Enter a short descriptive title for this study (65 characters maximum):  
IRB II Full Board

3.0 \* Briefly describe the scientific or scholarly rationale:  
(i.e. purpose of research)  
See if drug will delay cancer growth

4.0 \* Brief Study Summary  
Non-scientific description of the research study, using 3 to 10 sentences:  
Statements such as "see protocol" are not acceptable.  
Subjects will get 20 mg of erlotinib once a week in 21 day cycles.

Select the 'Jump To' drop down to go to the Consent Process section of the application.

Edit all information in this section that has changed as a result of the amendment.

To upload the untracked (final) version of the consent form, click 'Upload Revision' (NOT the 'Add' or 'Delete').

***\*\*Note: 'Upload Revision' is the button of choice when revising the currently approved consenting document.***

***DO NOT select the 'Add' button unless this is a different consent document that was not previously IRB approved.***

***DO NOT select the 'Delete' button unless an incorrect document that has not been IRB approved was uploaded in error. \*\****

When changes are finished, save and exit the application.

6.0 Consent Forms  
To allow for documentation of IRB approval and electronic watermarking, please use the following link to access your institution's Informed Consent Form Template:

link\_url  
No template or form available

If no template is available, please leave at least a **one inch margin at the bottom of each page** of the final "clean" version of the consent document(s).

**NOTE:** When revising a consent document associated with an amendment or continuing review, Click "Upload Revision" to upload the revised version of the consent document. Use ADD only when uploading a new consent document.

\* Click the Add button to upload a copy of the consent form(s), including translated versions for this research study.

Add

Name	Version	Orig. Author	Orig. Created	Last Modified	
Consent	0.01	musc-radiology-pi musc	5/25/2011 4:29 PM	5/25/2011 4:29 PM	Delete

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Consent Process >> Continue >>

The system will return to the Amendment Summary to finalize the amendment

Click Continue.

Instructions for Completing Amendments VIEW/49APE/19/1800

An amendment requires two parts: the Amendment summary form and edits to the IRB study application pages.

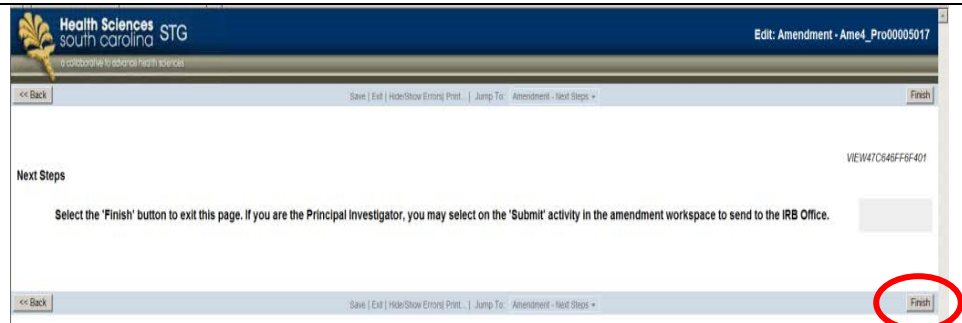
Step 1: So far, you have filled out the Amendment summary form.  
Step 2: You will now begin to make changes to the IRB study application pages (see [CLICK HERE](#) link below).  
Step 3: Documents uploaded in the Amendment summary form must also be uploaded in the IRB study application.  
Step 4: Once all changes have been made to the IRB study application, click Finish.  
Step 5: After returning to this Amendment instructions page, click Continue for next steps to submit the Amendment for IRB review.

**[CLICK HERE](#)** to edit the IRB study application, as described in Steps 2-4 above.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Instructions for Completing Amendments >> Continue >>

Click 'Finish'

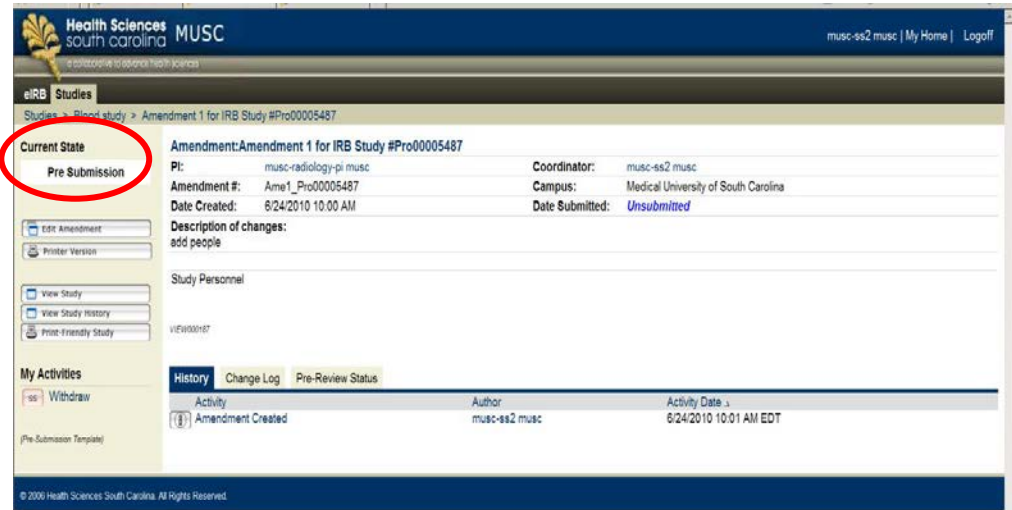
**\*\*NOTE:** This action does not submit the amendment. Only the Principal Investigator is able to send the amendment to the IRB. \*\*



The system will return to the protocol amendment workspace.

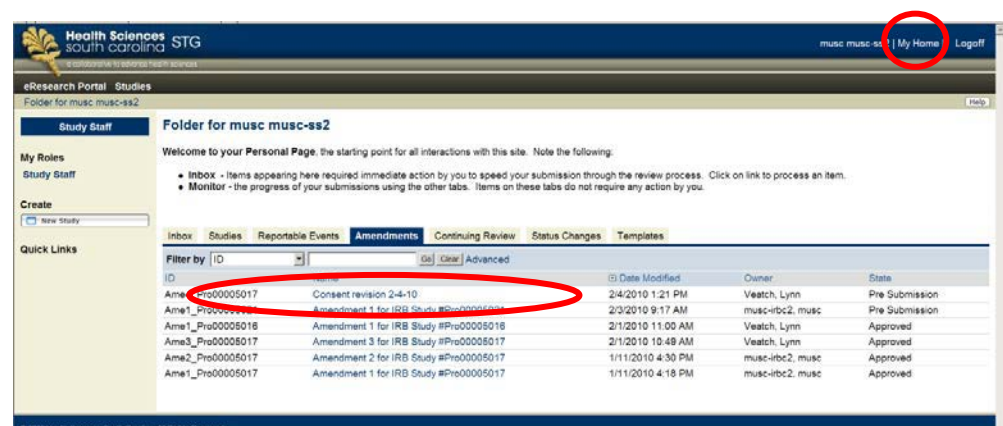
**\*\*Note:** e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the amendment, the PI must be notified through routine communication that the amendment is pending submission. \*\*

**\*\*Note:** The amendment is in the Pre Submission state until it has been submitted to IRB. \*\*



The amendment shows up in the 'Amendment' tab on your Home page and on the 'Amendment' tab in the study's details.

Follow the steps in the ['Sending Amendment to IRB'](#) section.



## Investigator's Brochure

If not already completed, follow steps in the [General Completion Guidelines](#) section, selecting 'Investigator's Brochure' as the amendment type

Amendment - Request

1.0 \* Type of change(s) this amendment is requesting:  
Check all that apply. Note: Checking any of these options requires revisions to the applicable Smartform page(s) in the Amendment copy of the Study Smartforms (located on the 'Instructions for Completing Amendments' page).

- ☐ Study Personnel
- ☐ Advertisements/Study Recruitment Materials
- ☐ Informed Consent Document/Procedures
- ☐ Protocol Document(s)
- ☐ Investigator's brochure
- ☐ Editorial/Administrative Changes
- ☐ Additional Sites for Treatment/Follow-up
- ☐ Modification in Subject Enrollment Goals
- ☐ Location of Program Activities
- ☐ Questionnaires & Assessment Tools
- ☐ Risk Change(s)
- ☐ Study Procedure(s)
- ☐ Subject Confidentiality/Anonymity
- ☐ Subject Population
- ☐ Other Changes
- ☐ HIPAA Authorization
- ☐ Study Funding Source/Sponsorship
- ☐ Conflict of Interest (COI)

2.0 \* Change Description  
Briefly summarize changes:

3.0 \* Current Subjects  
Are there subjects currently enrolled in the study?  
☐ Yes ☐ No Clear

4.0 \* Has this amendment been requested by the study sponsor?  
☐ Yes ☐ No Clear

If Yes,  
Study Sponsor Amendment Number:

Provide a summary of the changes and tracked changes of the brochure (if available).

**\*\*Note: You will upload the un-tracked (clean) copy document directly into the current IRB application part of the amendment request. \*\***

Click Continue.

See steps in the [Finalizing the amendment](#) section for instructions on completing the amendment request.

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Edit: Amendment - Amr1\_Pro00005021

Investigator's Brochure

1.0 \* Description  
Summarize all the changes to the currently approved Investigator's brochure:

2.0 Investigator's Brochure  
Click the Add button to upload the latest red-lined/tracked changes version (if available):

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

Note: Upload the clean copy of the revised investigator's brochure directly to the Amendment copy of the Study Smartforms.

Upload the summary of changes to the brochure as available.



## Editorial/Administrative Changes

If not already completed, follow steps in the [General Completion Guidelines](#) section, selecting 'Editorial/Administrative Changes' as the amendment type.

**\*\* Note: if the protocol has changed as a result of this amendment, you must also select 'Protocol Document(s)' so that options to upload marked and unmarked versions of the protocol become available in the system (this will be the next set of screens if it applies) \*\***

**\*\*Note: after selecting a Smartform link, you will upload the un-tracked (clean) copy document directly into the current IRB application part of the amendment request\*\***

Click Continue

See steps in the [Finalizing the amendment](#) section or the [Protocol changes details](#) section for instructions on completing the amendment request

[<< Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print...](#) [Jump To: Request](#)

### Amendment - Request

**1.0 \* Type of change(s) this amendment is requesting:**  
Check all that apply. *Note: Checking any of these options requires revisions to the applicable Smartform page(s) in the Amendment copy of the Study Smartforms (located on the 'Instructions for Completing Amendments' page).*

<input type="checkbox"/>	Study Personnel
<input type="checkbox"/>	Advertisements/Study Recruitment Materials
<input type="checkbox"/>	Informed Consent Document/Procedures
<input type="checkbox"/>	Protocol Document(s)
<input type="checkbox"/>	Investigator's brochure
<input type="checkbox"/>	Editorial/Administrative Changes
<input type="checkbox"/>	Additional Sites for Treatment/Follow-up
<input type="checkbox"/>	Modification in Subject Enrollment Goals
<input type="checkbox"/>	Location of Program Activities
<input type="checkbox"/>	Questionnaires & Assessment Tools
<input type="checkbox"/>	Risk Change(s)
<input type="checkbox"/>	Study Procedure(s)
<input type="checkbox"/>	Subject Confidentiality/Anonymity
<input type="checkbox"/>	Subject Population
<input type="checkbox"/>	Other Changes
<input type="checkbox"/>	HIPAA Authorization
<input type="checkbox"/>	Study Funding Source/Sponsorship
<input type="checkbox"/>	Conflict of Interest (COI)

**2.0 \* Change Description**  
Briefly summarize changes:

**3.0 \* Current Subjects**  
Are there subjects currently enrolled in the study?  
☐ Yes ☐ No [Clear](#)

**4.0 \* Has this amendment been requested by the study sponsor?**  
☐ Yes ☐ No [Clear](#)

If Yes,  
Study Sponsor Amendment Number:



## Changing sites/location of activities

If not already completed, follow steps in the [General Completion Guidelines](#) section, selecting 'Sites' or 'Location' as the amendment type

**\*\* Note: if the protocol has changed as a result of this amendment, you must also select 'Protocol Document(s)' so that options to upload marked and unmarked versions of the protocol become available in the system (this will be the next screen if it applies) \*\***

**\*\*Note: after selecting a Smartform link, you will upload un-tracked (clean) copy documents directly into the current IRB application part of the amendment request, as applicable \*\***

See steps in the [Finalizing the amendment](#) section for instructions on completing the amendment request

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: | Request \*

Amendment - Request

1.0

**\* Type of change(s) this amendment is requesting:**  
Check all that apply. *Note: Checking any of these options requires revisions to the applicable Smartform page(s) in the Amendment copy of the Study Smartforms (located on the 'Instructions for Completing Amendments' page).*

☐ Study Personnel  
☐ Advertisements/Study Recruitment Materials  
☐ Informed Consent Document/Procedures  
☐ Protocol Document(s)  
☐ Investigator's brochure  
☐ Editorial/Administrative Changes  
☐ Additional Sites for Treatment/Follow-up  
☐ Modification in Subject Enrollment Goals  
☐ Location of Program Activities  
☐ Questionnaires & Assessment Tools  
☐ Risk Change(s)  
☐ Study Procedure(s)  
☐ Subject Confidentiality/Anonymity  
☐ Subject Population  
☐ Other Changes  
☐ HIPAA Authorization  
☐ Study Funding Source/Sponsorship  
☐ Conflict of Interest (COI)

2.0

**\* Change Description**  
Briefly summarize changes:

3.0

**\* Current Subjects**  
Are there subjects currently enrolled in the study?  
☐ Yes ☐ No

4.0

**\* Has this amendment been requested by the study sponsor?**  
☐ Yes ☐ No

If Yes,  
Study Sponsor Amendment Number:

## Changing subject information

Follow steps in the [General Completion Guidelines](#) section, selecting 'Sites' or 'Location' as the amendment type

**\*\* Note: if the protocol has changed as a result of this amendment, you must also select 'Protocol Document(s)' so that options to upload marked and unmarked versions of the protocol become available in the system (this will be the next set of screens if it applies)\*\***

**\*\*Note: after selecting a Smartform link, you will upload un-tracked (clean) copy documents directly into the current IRB application part of the amendment request, as applicable\*\***

See steps in the [Finalizing the amendment](#) section for instructions on completing the amendment request

[<< Back](#) [Save](#) | [Exit](#) | [Hide/Show Errors](#) | [Print...](#) | [Jump To:](#) [Request](#) ▼

**Amendment - Request**

**1.0 \* Type of change(s) this amendment is requesting:**  
Check all that apply. *Note: Checking any of these options requires revisions to the applicable Smartform page(s) in the Amendment copy of the Study Smartforms (located on the 'Instructions for Completing Amendments' page).*

☐ Study Personnel  
☐ Advertisements/Study Recruitment Materials  
☐ Informed Consent Document/Procedures  
☐ Protocol Document(s)  
☐ Investigator's brochure  
☐ Editorial/Administrative Changes  
☐ Additional Sites for Treatment/Follow-up  
☐ Modification in Subject Enrollment Goals  
☐ Location of Program Activities  
☐ Questionnaires & Assessment Tools  
☐ Risk Change(s)  
☐ Study Procedure(s)  
☐ Subject Confidentiality/Anonymity  
☐ Subject Population  
☐ Other Changes  
☐ HIPAA Authorization  
☐ Study Funding Source/Sponsorship  
☐ Conflict of Interest (COI)

**2.0 \* Change Description**  
Briefly summarize changes:

**3.0 \* Current Subjects**  
Are there subjects currently enrolled in the study?  
☐ Yes ☐ No [Clear](#)

**4.0 \* Has this amendment been requested by the study sponsor?**  
☐ Yes ☐ No [Clear](#)  
  
If Yes,  
**Study Sponsor Amendment Number:**

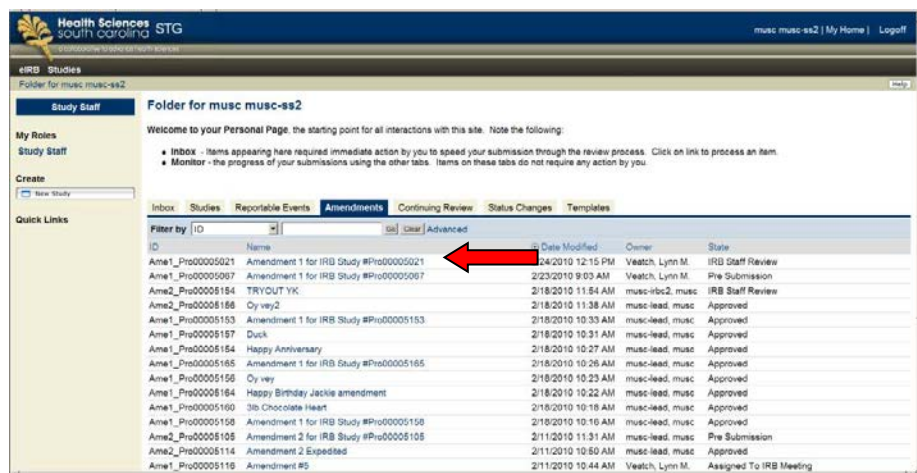
## Withdrawing an Amendment

When amendments are entered into the system, they can be withdrawn if they have not yet been IRB reviewed.

Log into the system and select the 'Amendments' tab.

Locate the study's amendment that needs to be withdrawn.

Click on the name of the amendment.



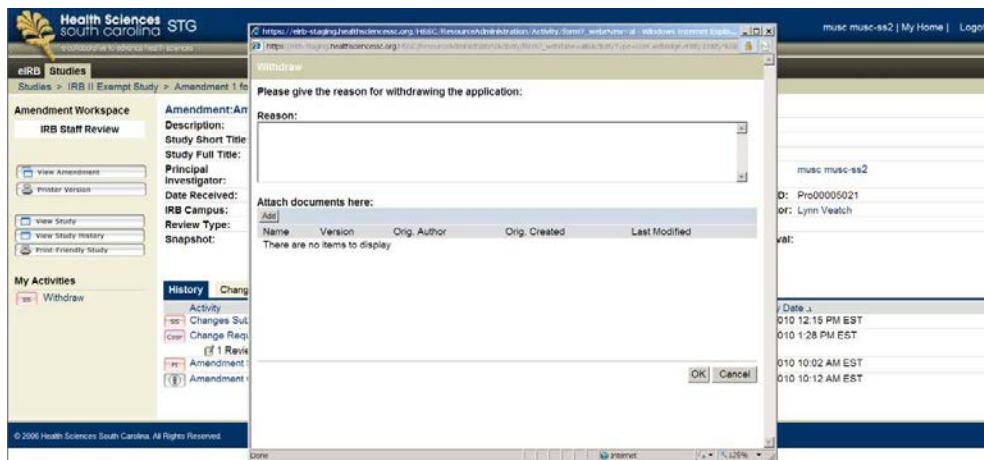
Click on 'Withdraw' under 'My Activities' on the left toolbar

*\*\*Note: you will not be able to reinstate or copy a withdrawn amendment\*\**



In the pop-up window, enter in a reason and attach any relevant documents (entering & attaching information is optional).

Click 'Ok'



The system has stored the study. To see a copy of the withdrawn amendment, select 'View Amendment'.

**Health Sciences**  
south carolina  
a collaborative to advance health sciences

musc-sa2 musc | My Home | Logout

---

**eIRB Studies**

Studies > IRB II Exempt Study > Amendment 1 for IRB Study #Pro00005021

**Amendment Workspace**

**Withdrawn**

- View Amendment
- Printer Version
- View Study
- View Study History
- Print-Friendly Study

**Amendment:Amendment 1 for IRB Study #Pro00005021 (Ame1\_Pro00005021)**

**Study Short Title:** IRB II Exempt Study

**Study Full Title:** Research on educational strategies

**Principal Investigator:** musc-radiology-pi musc

**Date Received:** 2/18/2010

**IRB Campus:** Medical University of South Carolina

**Review Type:** Snapshot

**Study Coordinator:** musc-sa2 musc

**Original Study ID:** Pro00005021

**IRB Administrator:** Lynn Veatch

**Study Status:**

**Letter of Approval:**

---

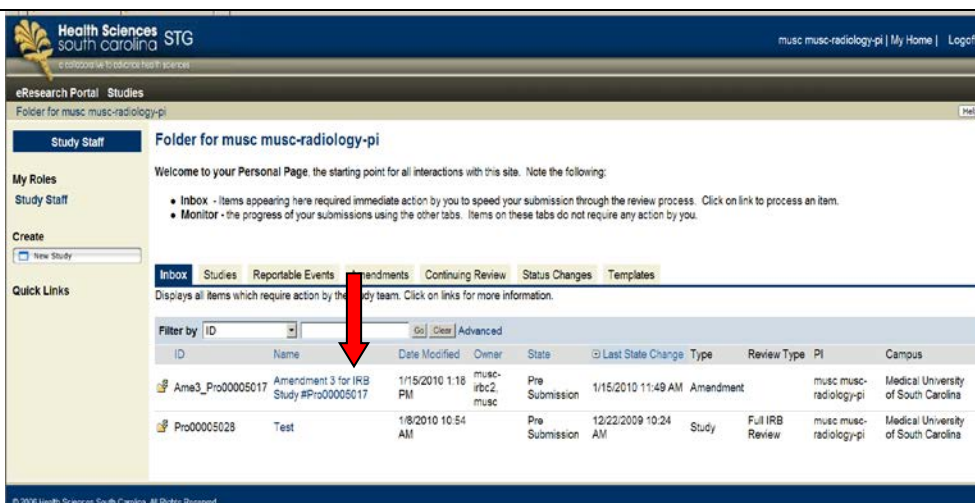
**My Activities**

History	Change Log	Reviewer Notes	Study Attachments	Pre-Review Status
Activity				Author
[W] Withdrawal				musc-sa2 musc
[I] Issue				
[S] Changes Submitted				musc-sa2 musc
[C] Change Requests By IRB Staff Sent				Lynn Veatch
[L] 1 Reviewer Notes Logged.				
[P] Amendment Submitted				musc-radiology-pi musc
[T] Amendment Created				musc-sa2 musc

## Submission to IRB

*Reminder: only the PI can send the amendment to the IRB.*

Log into the system and select the name of the Amendment that is in your Inbox.



Health Sciences south carolina STG

musc musc-radiology-pi | My Home | Logoff

eResearch Portal Studies

Folder for musc musc-radiology-pi

Study Staff

Folder for musc musc-radiology-pi

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox** - Items appearing here require immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor** - the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

Inbox Studies Reportable Events Amendments Continuing Review Status Changes Templates

Displays all items which require action by the study team. Click on links for more information.

Filter by ID Go Clear Advanced

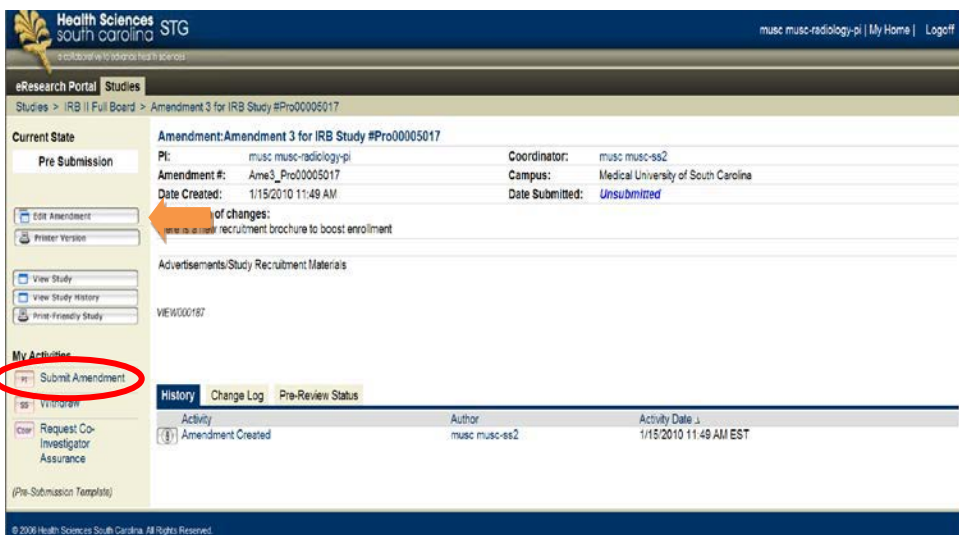
ID	Name	Date Modified	Owner	State	Last State Change	Type	Review Type	PI	Campus
Ame3_Pro00005017	Amendment 3 for IRB Study #Pro00005017	1/15/2010 1:18 PM	musc-irbc2, musc	Pre Submission	1/15/2010 11:49 AM	Amendment		musc musc-radiology-pi	Medical University of South Carolina
Pro00005028	Test	1/8/2010 10:54 AM		Pre Submission	12/22/2009 10:24 AM	Study	Full IRB Review	musc musc-radiology-pi	Medical University of South Carolina

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If you would like to review the amendment details before IRB submission, see steps in the ['View Specific Changes'](#) section of these instructions.

To edit the amendment, select 'Edit Amendment' button on the left side of the screen. Navigate to the specific pages of the amendment that require changes. See [General Amendment Complete Guidelines](#) in this guidance manual for more information on completed/editing an amendment.

When you are ready to send to IRB, select the 'Submit Amendment' button on the left side of the screen under the My Activities section.



Health Sciences south carolina STG

musc musc-radiology-pi | My Home | Logoff

eResearch Portal Studies

Studies > IRB II Full Board > Amendment 3 for IRB Study #Pro00005017

Current State

Amendment: Amendment 3 for IRB Study #Pro00005017

PI: musc musc-radiology-pi Coordinator: musc musc-es2

Amendment #: Ame3\_Pro00005017 Campus: Medical University of South Carolina

Date Created: 1/15/2010 11:49 AM Date Submitted: Unsubmitted

of changes:

Advertisements/Study Recruitment Materials

VIEW000197

My Activities

Submit Amendment

History Change Log Pre-Review Status

Activity	Author	Activity Date
Amendment Created	musc musc-es2	1/15/2010 11:49 AM EST

(Pre-Submission Template)

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A pop up screen will appear where you can enter in any additional questions, upload any final documents and confirm that you are ready to send the amendment to IRB.

If so, click 'Ok'.

Otherwise, click 'Cancel' and make the appropriate changes needed.

***\*\*NOTE: you will not be able to make any changes after the amendment has been sent to IRB\*\****

The amendment will now show up as submitted in the 'Amendment' tab on your Home Page and on the 'Amendment' tab in the study's details.

**eIRB Education and Training**  
Studies > "DKI Stroke" > A

**Current State**  
**Pre Submission**

Edit Amendment  
Printer Version

View Study  
View Study History  
Print-Friendly Study

**My Activities**  
PI Submit Amendment  
SS Withdraw  
(Pre-Submission Template)

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**Submit Amendment**

I certify that all information provided in this submission is accurate.

Use this form to submit your **completed application amendment**. If you click **ok**, you are no longer able to modify the application. You will be notified about the review result by email.

If you are not ready for submission, click **cancel**.

**Comments:**

**Documents:**

Name	Version	Orig. Author	Orig. Created	Last Modified
There are no items to display				

**OK Cancel**

When the amendment is reviewed by IRB, an e-mail regarding the review status will be sent to designated personnel's MUSC e-mail account inbox.



## Viewing Details of Changes Submitted

### Viewing a Summary of the Amendment

Select the Amendment tab on the study's Home page and select the amendment name.

Health Sciences south carolina STG

musc-musc-ss2 | My Home | Logout

eResearch Portal Studies

Studies > IRB II Expedited

Current State

Approved

View Study  
Printer Version  
View Differences

My Activities

Edit Guest Access  
PI Suspend  
Copy Study

New Reportable Event  
New Continuing Review  
New Status Change

(Amendment Outstanding)

Study: IRB II Expedited (Pro00005016)

Full Title: Saline repository access

Principal Investigator: musc-musc-radiology-pi

Study Coordinator: musc-musc-ss2

Expiration Date: 2/11/2010

IRB Coordinator: musc-musc-irc2

Approval Date: 1/12/2010

Initial Approval Date: 1/12/2010

Review Type: Expedited

IRB Campus: Medical University of South Carolina

PI Department: Radiology - MUSC

PI Institution: Medical University of South Carolina

Pre-Conversion Study ID: [View]

Letter of Approval: [View]

Study Status: Approved for Accrual

Committee: IRB-II - Medical University of South Carolina

Sponsor(s): There are no items to display

Snapshot: MUSC

History Amendments Continuing Reviews Status Changes Reportable Events Attachments Stamped ICF

Filter by ID Name State Last State Change

ID	Name	State	Last State Change
Ame1_Pro00005016	Amendment 1 for IRB Study #Pro00005016	IRB Staff Review	1/15/2010 3:44 PM

Select the 'View Amendment' or 'Printer version' button on the study's amendment Home page.

This view will provide only a summary of the amendment changes.

Health Sciences south carolina STG

musc-musc-ss2 | My Home | Logout

eResearch Portal Studies

Studies > IRB II Expedited > Amendment 1 for IRB Study #Pro00005016

Amendment Workspace

IRB Staff Review

View Amendment  
Printer Version

View Study  
View Study History  
Print Friendly Study

My Activities

Withdraw

Amendment: Amendment 1 for IRB Study #Pro00005016 (Ame1\_Pro00005016)

Description: need to add a regulatory coordinator

Study Short Title: IRB II Expedited

Study Full Title: Saline repository access

Principal Investigator: musc-musc-radiology-pi

Study Coordinator: musc-musc-ss2

Date Received: 1/15/2010

Original Study ID: Pro00005016

IRB Campus: Medical University of South Carolina

IRB Administrator: musc-musc-irc2

Review Type: Expedited

Study Status: Approved for Accrual

Letter of Approval: [View]

Snapshot:

History Change Log Reviewer Notes Study Attachments Pre-Review Status

Activity	Author	Activity Date
Amendment Submitted	musc-musc-radiology-pi	1/15/2010 3:44 PM EST
Amendment Created	musc-musc-radiology-pi	1/15/2010 1:48 PM EST

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The 'View Amendment' selection requires navigation through the amendment pages.

Select the 'Continue' button to navigate through pages or select the 'Jump To' drop down list to go to a specific section of the amendment summary

Health Sciences south carolina STG

View: Amendment - Ame1\_Pro00005016

Back | Home | Show Error | Print | Jump To: Category | Continue >>

Reviewer Note

Type	Reviewer	Modified
There are no items to display		

VIEW#48CC8B1C5600

Amendment - Category

Amendment - Change(s) is previously approved research. An amendment request includes two parts in the eIRB portal: the Amendment Smartforms and the modifications to the Amendment copy of the Study Smartforms. Only one amendment request is allowed at any given time, i.e. Amendment 1 must be approved, denied or withdrawn before Amendment 2 can be created.

1.0 \* Category of amendment:  
Minor change(s), Minimal risk change(s)

Back | Home | Show Error | Print | Jump To: Category | Continue >>

## Viewing Amendment Changes

The amendment change log documents where changes were made, who made changes and when. Here, you will also have the option to view the portion of the application that changed.

Select the Amendment tab on the study's Home page and select the amendment name.

Health Sciences south carolina STG

musc musc-es2 | My Home | Logoff

eResearch Portal Studies

Studies > IRB II Expedited

Current State: Approved

Study: IRB II Expedited (Pro00005016)

Full Title: Saliva repository access

Principal Investigator: musc musc-radiology-pi

Study Coordinator: musc musc-es2

Expiration Date: 2/11/2010

IRB Coordinator: musc musc-irbc2

Approval Date: 1/12/2010

Initial Approval Date: 1/12/2010

Review Type: Expedited

IRB Campus: Medical University of South Carolina

PI Department: Radiology - MUSC

PI Institution: Medical University of South Carolina

Pre-Conversion Study ID:

Letter of Approval: [View]

Study Status: Approved for Accrual

Committee: IRB-II - Medical University of South Carolina

Sponsor(s): There are no items to display

Snapshot:

MUSC

History Amendments Continuing Reviews Statuses Reportable Events Attachments Stamped ICF

Filter by ID Name State Last State Change

ID	Name	State	Last State Change
Ame1_Pro00005016	Amendment 1 for IRB Study #Pro00005016	IRB Staff Review	1/15/2010 3:44 PM

Click 'View Study History'

Health Sciences south carolina STG

musc musc-es2 | My Home | Logoff

eResearch Portal Studies

Studies > IRB II Expedited > Amendment 1 for IRB Study #Pro00005016

Amendment Workspace

IRB Staff Review

View Amendment

Print Version

View Study History

My Activities

Withdraw

Amendment: Amendment 1 for IRB Study #Pro00005016 (Ame1\_Pro00005016)

Description: need to add a regulatory coordinator

Study Short Title: IRB II Expedited

Study Full Title: Saliva repository access

Principal Investigator: musc musc-radiology-pi

Study Coordinator: musc musc-es2

Date Received: 1/15/2010

Original Study ID: Pro00005016

IRB Campus: Medical University of South Carolina

IRB Administrator: musc musc-irbc2

Review Type:

Study Status: Approved for Accrual

Snapshot:

Letter of Approval:

History Change Log Reviewer Notes Study Attachments Pre-Review Status

Activity	Author	Activity Date
Amendment Submitted	musc musc-radiology-pi	1/15/2010 3:44 PM EST
Amendment Created	musc musc-radiology-pi	1/15/2010 1:45 PM EST

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Select 'View Differences'. This will show you the differences between the previous study details and what you submitted in this amendment.

The screenshot shows the 'eResearch Portal Studies' interface. On the left sidebar, under 'Current State', the 'View Differences' link is circled in red. The main content area displays details for 'Modified Study: IRB II Expedited (MS1\_Pro00005016)'. It includes fields for Full Title, Principal Investigator, Expiration Date, Letter of Approval, IRB Campus, Study Status, Sponsor(s), Study Coordinator, Amendment, Review Type, Pre-Conversion Study ID, and Snapshot. A 'Change Log' table is also visible at the bottom.

Activity	Author	Activity Date
(1) Change Tracking for Amendment	musc musc-radiology-pi	1/15/2010 3:44 PM EST
(1) Change Log: Study Identification - Study Personnel (Institution Specific)	musc musc-radiology-pi	1/15/2010 3:43 PM EST
(1) [Jump To: Study Identification - Study Personnel (Institution Specific)]		
(1) Change Tracking for Amendment	musc musc-radiology-pi	1/15/2010 1:46 PM EST
(1) Amendment Started	musc musc-radiology-pi	1/15/2010 1:46 PM EST

This view shows what was changed in each section of the current application as a result of this amendment.

Select the drop down arrow in the 'Changed Steps' section to see other portions of the application that changed.

***\*\*Note: to see changes that applied only to the SmartForms that are relevant to that change, select 'Limit Steps to Current SmartForm Path'\*\****

Click 'Close' when done.

The screenshot shows the 'View Changes to Study: Pro00009191' page. In the 'Changed Steps' section, the checkbox 'Limit Steps to Current SmartForm Path' is circled in red. A red arrow points from a text box on the right to this checkbox. The page also shows a list of changes with filters for 'Type' and 'Reviewer Notes'.

*Choosing this option is helpful to filter out forms not associated with the current change. For example, if the amendment changed the study from an expedited, prospective chart review to retrospective chart review, selecting this option would show only the forms associated with the new retrospective review application change.*

## Viewing the Amended Study After IRB Submission

After IRB submission of the amendment, you can view the final study application with all changes incorporated during the amendment submission process. To do so, you can select one of the following from the study's amendment home page:

- View Study: Allows you to view the original or current application for the study that has been modified
- View Study History: Goes back to the Study Workspace where you can view the changes that have been made to the Protocol Application for the modification.
- Printer-Friendly Study: Compiles all study information in an easily printable format

The screenshot shows the 'Amendment Workspace' for 'Amendment 1 for IRB Study #Pro0005016 (Ame1\_Pro0005016)'. On the left sidebar, under 'My Activities', the 'View Study' button is circled in red. The main content area displays study details: Description (need to add a regulatory coordinator), Study Short Title (IRB II Expedited), Study Full Title (Saliva repository access), Principal Investigator (musc musc-radiology-pi), Date Received (1/15/2010), IRB Campus (Medical University of South Carolina), Review Type (Snapshot), Study Coordinator (musc musc-ss2), Original Study ID (Pro0005016), IRB Administrator (musc musc-ibc2), Study Status (Approved for Accrual), and Letter of Approval.

Selecting 'View Study' will allow you to navigate through the complete study application to view the incorporated changes.

Select 'Exit' to go back to the Amendment workspace main page.

The screenshot shows the 'Reviewer Notes' page for 'Study Identification Information'. It includes fields for Full Title, Short Title, Scientific Rationale, and Brief Study Summary. An orange arrow points to the 'Continue >>' button at the top right of the page.

Click the drop down arrow to go to the specific section or Click the continue button to go through each page.

Selecting 'View Study History' and 'View Differences' the tracked changed differences between the previous study details and what you submitted in the amendment.

See section '[Viewing Amendment Changes](#)' section for additional information.

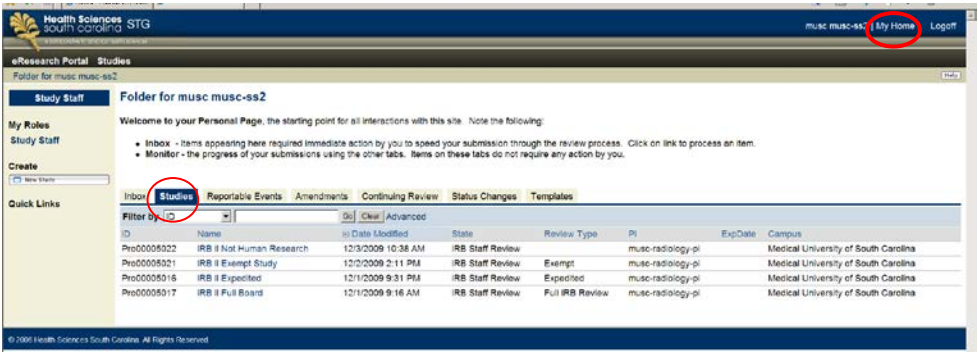

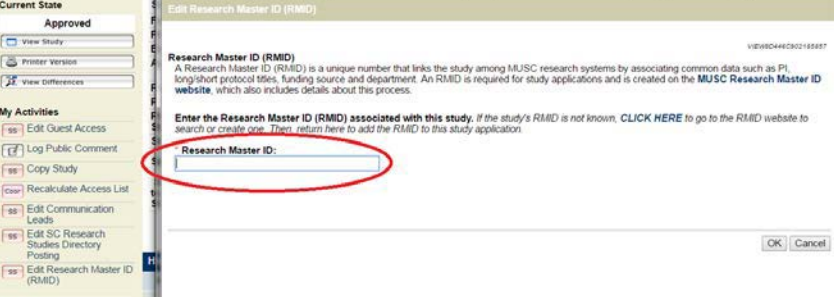
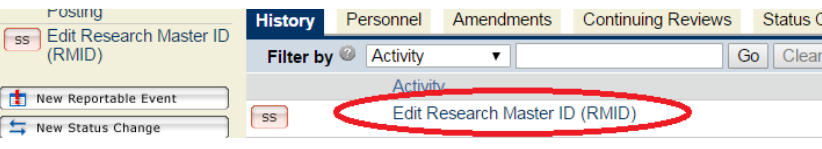
The screenshot displays the 'eResearch Portal' interface for the Health Sciences South Carolina STG. The breadcrumb trail indicates the user is viewing 'Amendment 1 for IRB Study#Pro00005016'. The 'Current State' section shows 'Amendment Open'. In the 'My Activities' sidebar, the 'View Differences' link is circled in red. The main content area displays study details for 'MS1\_Pro00005016', including the full title 'Saliva repository access', principal investigator 'musc-musc-radiology-pi', expiration date '2/11/2010', and study status 'Approved for Accrual'. A 'Change Log' table at the bottom tracks activities such as 'Change Tracking for Amendment' and 'Amendment Started'.

Activity	Author	Activity Date
(8) Change Tracking for Amendment	musc-musc-radiology-pi	1/15/2010 3:44 PM EST
(8) Change Log: Study Identification - Study Personnel (Institution Specific)	musc-musc-radiology-pi	1/15/2010 3:43 PM EST
(8) Change Tracking for Amendment	musc-musc-radiology-pi	1/15/2010 1:46 PM EST
(8) Amendment Started	musc-musc-radiology-pi	1/15/2010 1:46 PM EST



## Edit the Research Master ID (RMID)

A Research Master ID (RMID) is a unique numeric identifier that links a research study across multiple MUSC electronic research systems. An RMID is required for all study applications. Revisions to the RMID can be reported after a study has IRB approval and can be done without requiring a study amendment. The instructions below outline how to make changes to an RMID.

<p>Log into eIRB.</p> <p>Choose the study by selecting the 'Studies' tab from 'My Home' or the 'Studies' link toward the top of the page.</p> <p>Click on the Name of the study.</p>	
<p>Select 'Edit Research Master ID (RMID)' under 'My Activities'.</p>	
<p>A window will populate entitled 'Edit Research Master ID RMID'. Enter the correct RMID in the 'Research Master ID' field.</p> <p>Select 'OK'.</p>	
<p>Check under the History tab to ensure there is a new activity of 'Edit Research Master ID (RMID)' documenting that the RMID has been updated.</p>	

Additional information about the RMID process can be located on the [RMID website](#). The [Office of Clinical Research \(OCR\)](#) can also provide guidance about this process.



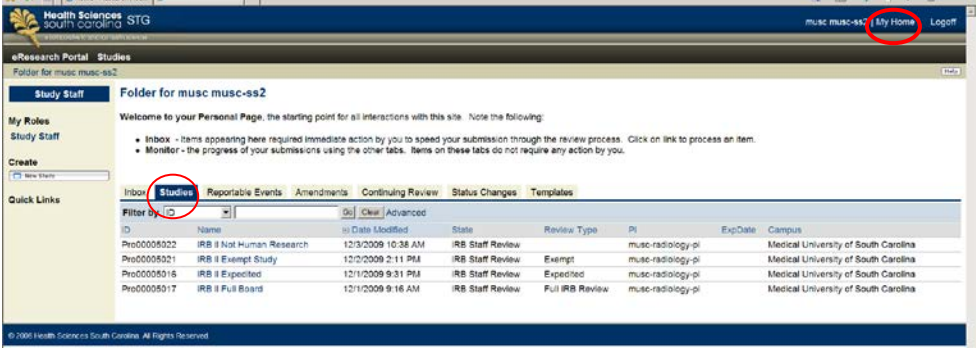
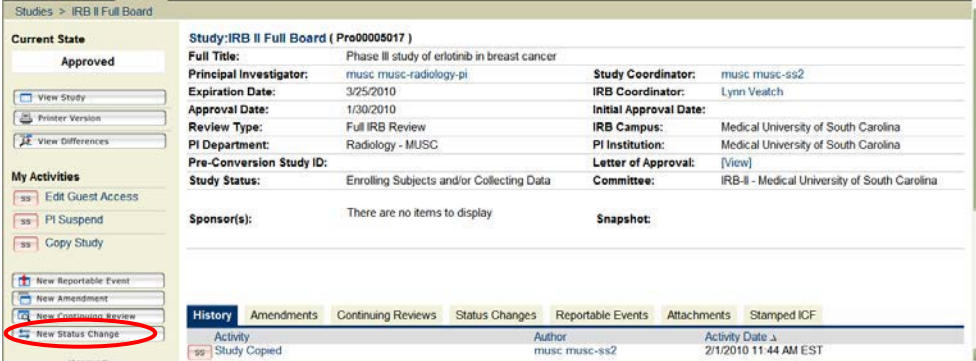
## Study Status Changes

For additional assistance, view the recorded demonstration 'Creating and Submitting Study Status Changes' in the eIRB [Education & Training](#) section.

Changes in study statuses due to subject enrollment changes can be reported before continuing review time. The system will edit the current continuing review to include the status change updates indicated through this process.

### Notes:

1. If you are changing the study status due to a reportable event, you must submit a [reportable event](#) to IRB in addition to completing a study status change
2. You cannot complete a study status change to terminate a study. You must complete a [continuing review application](#) to terminate the study.

<p>Log into eIRB.</p> <p>Choose the study by selecting the 'Studies' tab from 'My Home' or the 'Studies' link toward the top of the page.</p> <p>Click on the Name of the study.</p>	
<p>Select 'New Status Change'</p> <p><b>**Note: Exempt, Not Human Subjects and External IRB Review studies <u>cannot</u> create new status change applications. **</b></p>	

Select the updated, current status and include why the status changed (if necessary).

Click Continue.

**Status Change**

1.0 \* **Current Study Status:**

- ☐ Enrolling Subjects and/or Collecting Data
- ☐ Enrolling Subjects - No accrual/enrollment to date
- ☐ Enrollment Closed - Subjects continue to receive study treatment/intervention
- ☐ Enrollment Closed - Follow-up and collecting data only
- ☐ Data Analysis Only - Identifiable
- ☐ Data Analysis Only - De-identified
- ☐ Transfer to External IRB
- ☐ Enrollment Temporarily Suspended
- ☐ Clear

2.0 **If enrollment status changed, explain why:**

If enrollment status has changed, a rationale must be provided for MUSC IRB review.

Include information regarding the number of subjects.

Click Continue.

*\*\*Note: If number of proposed & enrolled subjects have NOT changed, ensure the information entered here is the same as the information previously reported. \*\**

**Health Sciences south carolina STG** Edit: Continuing Review - CR00001096

Number of Subjects

1.0 Number of subjects study-wide - proposed: Study Value: 800

2.0 Number of subjects at local site - proposed: Study Value: 10

3.0 Number of subjects enrolled study wide - actual: Study Value: 10

4.0 Number of subjects enrolled at local site - actual: Study Value: 10

5.0 Number of subjects enrolled at local site since last review: Study Value: 10

Indicate the statuses of subjects enrolled and estimated study completion date.

Click Continue.

**Health Sciences south carolina STG** Edit: Continuing Review - CR00001096

Number of Subjects (Continued)

1.0 Subjects receiving treatment/intervention - local: Study Value: 10

2.0 Subjects in follow-up only - local: Study Value: 10

3.0 Total subjects completed - local: Study Value: 10

4.0 Estimated date of study completion: Study Value: 10

Responses must be provided for MUSC IRB review.

Add any additional comments or documents.

The system will present a summary of changes you selected.

Verify the information and click Finish.

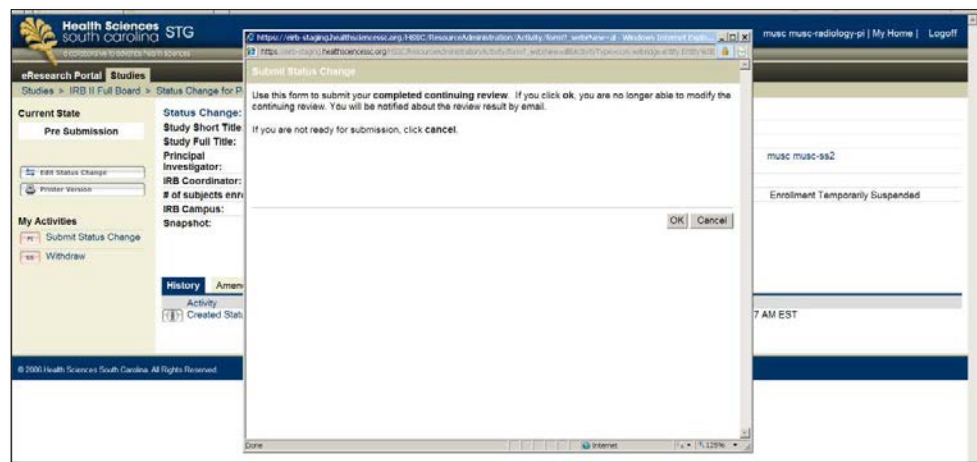
***\*\*Note: This does not send the status change to IRB. Only the PI can send the status change to IRB\*\****

The system will return to the status change workspace. The status change can be edited, viewed or submitted to IRB.

***\*\*Note: The status change is in the Pre Submission state until it has been submitted to IRB. Only the PI can submit to IRB; there is no automatic notification of these items. If study staff other than the PI has completed this, the PI must be notified through routine communication that the amendment is pending submission. \*\****

As the PI, to send the status change to IRB, click 'Submit Status Change'.

A pop-up window will appear. Click 'OK' to send to IRB.



The state of the status change is now 'IRB Staff Review'.

You can now only view the information.



When the status change is reviewed by IRB, an e-mail regarding the review status will be sent to designated personnel's MUSC e-mail account inbox.

## Responding to IRB Comments

For additional assistance, view the recorded demonstration 'Responding to IRB Reviewer Comments' in the eIRB Education & Training section.

Designated study personnel (e.g., eIRB communication coordinator) will receive an e-mail indicating that changes are requested by IRB.

**\*\*Note: study staff with study edit privileges can make and submit these changes to IRB\*\***

Responding to comments is a 2-step process.

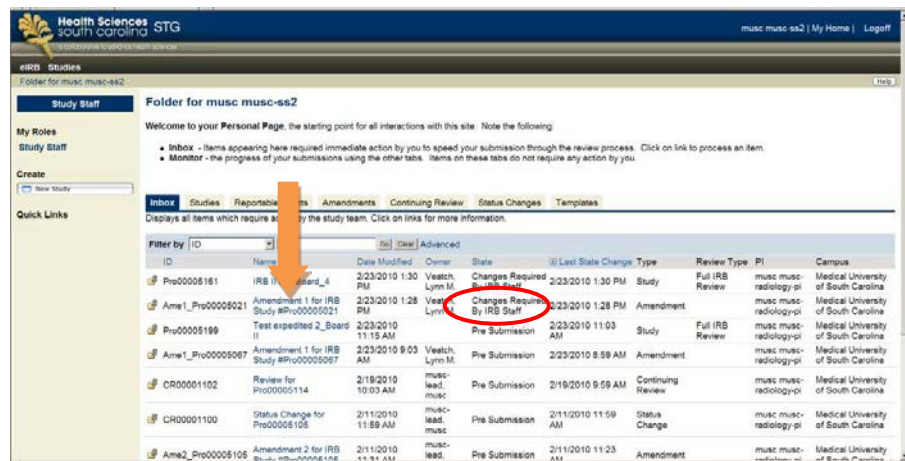
1. The changes must first be made within the study application; and
2. The changes must be documented as completed, not completed or for information only and include a summary of the responses.

Log into the system.

From your Home page, the study will appear in your eIRB 'Inbox'.

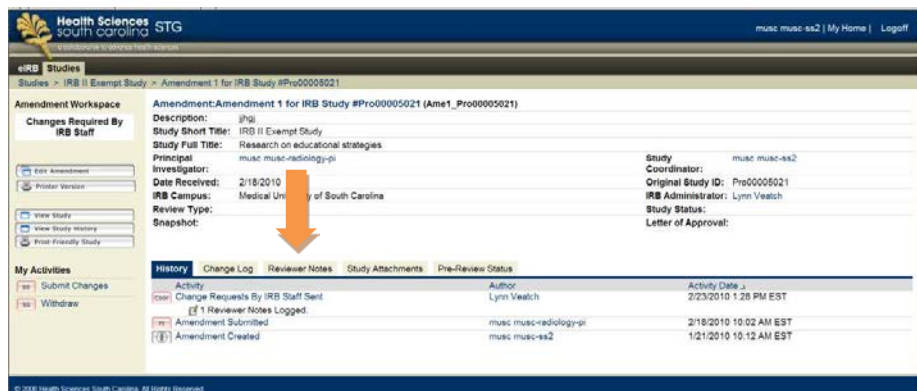
Click on the study 'Name'

**\*\*Note: Notice that the state of the study has changed to 'Changes Required by IRB Staff'.\*\***



The 'History' tab logs the change request. IT will also include additional notes or clarification requested by IRB. However, your changes will not be made from this location.

Instead, click on either 'Edit Amendment' or the Reviewer Notes tab to access the comments & begin responding.



On the Reviewer Notes tab, all comments will appear and the change request references the sections to change within the application.

To make the changes within the application, click on the hyperlinked name of the referenced Smartform section.

Health Sciences South Carolina STG

music-musc-es2 | My Home | Logout

Studies > IRB II Exempt Study > Amendment 1 for IRB Study #Pro00005021

Amendment Workspace

Changes Required By IRB staff

IRB Assignment

IRB Study

View Study History

Print Study

My Activities

Submit Changes

Withdraw

Amendment: Amendment 1 for IRB Study #Pro00005021 (Ame1\_Pro00005021)

Description: IRB II Exempt Study

Study Short Title: Research on educational strategies

Study Full Title: musc-musc-radiology-rpt

Principal Investigator: musc-musc-radiology-rpt

Date Received: 2/18/2010

IRB Campus: Medical University of South Carolina

Review Type: Snapshot

Study Coordinator: musc-musc-es2

Original Study ID: Pro00005021

IRB Administrator: Lynn Veatch

Study Status: Letter of Approval

History | Change Log | Reviewer Notes | Study Attachments | Pre-Review Status

Type: IRB Change Request

Jump To: Protocol Document Changes - Redlined Copy (changes marked)

Response Required! Click here to respond...

Please clarify the description of the changes made to the protocol. Thank you!

Reviewer: Lynn Veatch

Modified: 2/23/2010 1:27 PM

The system will take you to the question and appropriate form to review.

Step 1: View the comments and make the requested changes directly into the application.

***\*\*Note: If previously submitted documents are required to be revised & uploaded, select 'Upload Revision' next to the document's name & locate the file from your computer. DO NOT use 'Add' or 'Delete' button unless this is the first time that document is included.***

***\*\*Note: Comments may request uploading of documents when there is no upload feature on a particular smartform page. In that case, documents can be uploaded in the 'General Comments' section of the application.***

***Be sure to click 'Save' or 'Continue' to save the changes you made within the application. \*\****

Health Sciences South Carolina STG

Edit: Amendment - Ame1\_Pro00005021

Save | Edit | Hide/Show Errors | Print | Jump To: Protocol Document Changes - Redlined Copy (changes marked) | Continue >>

Filter by Type

Type: IRB Change Request

Response Required! Click here to respond...

Please clarify the description of the changes made to the protocol. Thank you!

Reviewer: Lynn Veatch

Modified: 2/23/2010 1:27 PM

Protocol Document Changes - Redlined Copy (changes marked)

1.0 Description

Summarize the changes to the research protocol:

2.0 Latest red-lined back changes version of the protocol

Add

Name	Description	Orig. Author	Orig. Created	Last Modified
Dummy Protocol.doc		Lynn M. Veatch Ph.D.	3/9/2011 1:48 PM	3/9/2011 1:48 PM

Upload Revision

Delete



Step 2: Click within the Reviewer Notes section where indicated. This is the second step and will finalize the response to that comment only.

From the pop-up box, select the 'Type' of change made and enter in your response (i.e., revision made, done, see attachment, etc.) and click 'Ok'.

*\*\*Note: There may be multiple comments within one IRB Change Request section. The system allows you to save a response even if all comments haven't been addressed. For study management purposes, this second step should be completed only if all comments are addressed OR you have written in notes to go back and respond to remaining comments.*

Click 'Save' when you have finished addressing the comments or to save what you have done so far.

*\*\*Note: if there are additional comments to address, select the 'Previous' or 'Next' button next to the Reviewer Note text at the top of the screen\*\**

Click 'Exit' when done responding to all comments.

If desired, click on the 'Reviewer Notes' tab to ensure that all comments have been addressed (i.e., a green bar appears indicating you have completed the step #2 in responding to that question).

When ready to send changes to IRB, click on 'Submit Changes'.

In the pop-up window, enter in any other summaries or upload additional documents.

Click 'Ok' when done.

This will send the response to the IRB.

The amendment is now in the 'IRB Staff Review' state.

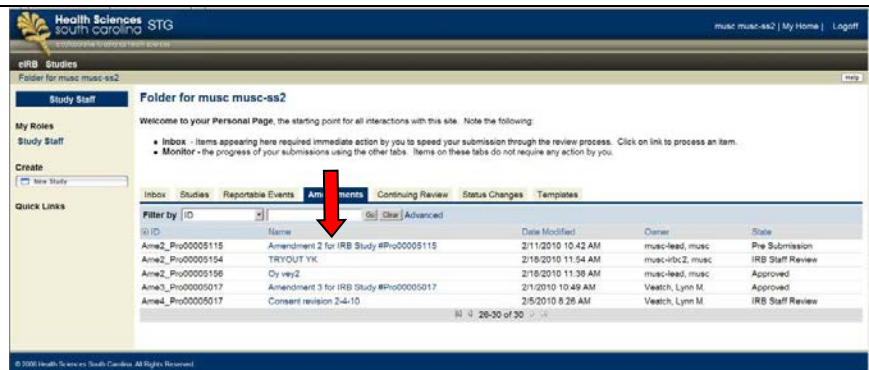
When the amendment is reviewed by IRB, an e-mail regarding the review status will be sent to designated personnel's MUSC e-mail account inbox.

## Accessing IRB Review Letter

For additional assistance, view the recorded demonstration 'Accessing IRB Reviewed Documents' in the [eIRB Education & Training](#) section.

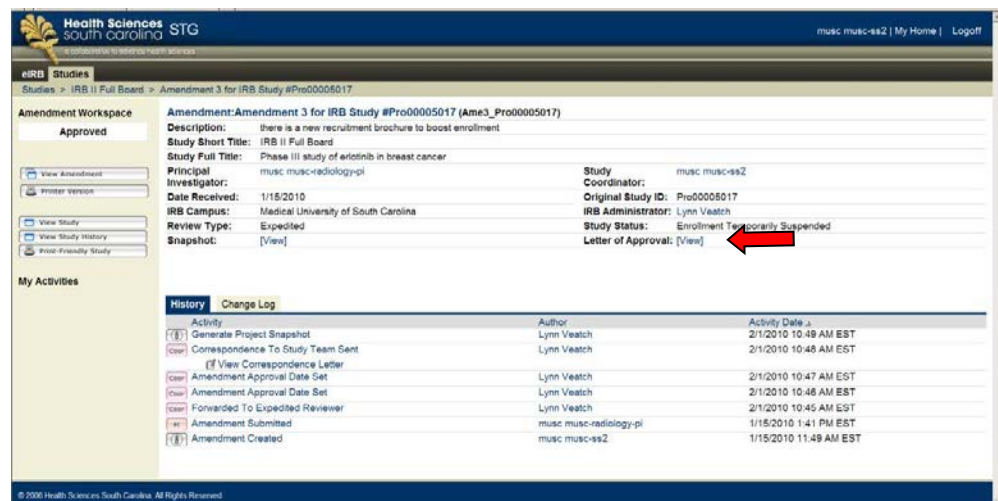
To access the IRB review letter, log into eIRB.

From your Homepage, select the 'Amendments' tab and click on the name of the study.



Click on 'View' next the Letter of Approval text.

You will have the option to open or save the letter as a Microsoft Word document.



# REPORTABLE EVENTS

For additional assistance, view the recorded demonstration 'Creating and Submitting Reportable Events' in the eIRB [Education & Training](#) section.

This section will explain how to submit adverse events, unanticipated problems, deviations and other reportable events.

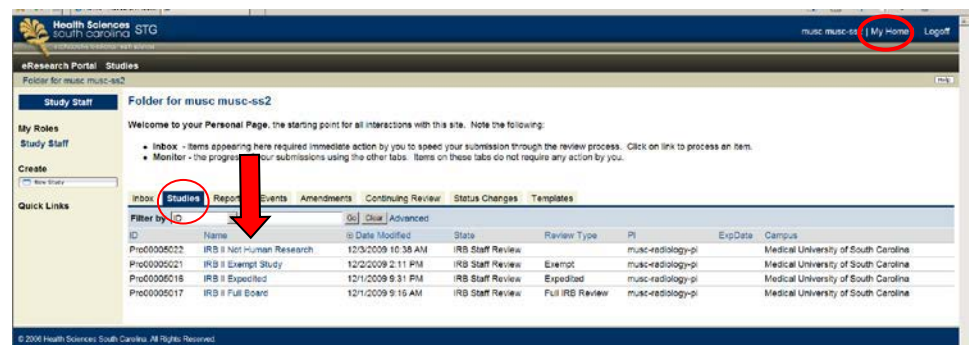
## Creating Reportable Events

### Adverse Events

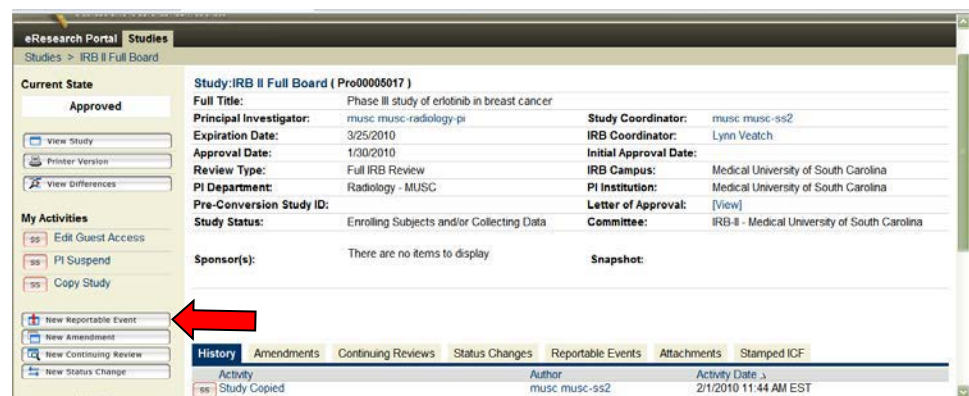
Log into eIRB.

Choose the study by selecting the 'Studies' tab from 'My Home' or the 'Studies' link toward the top of the page.

Click on the Name of the study.



Select 'New Reportable Event'



Select 'adverse event' as the reportable event and enter in an event name.

Click Continue.

The system will provide a reporting guidance to help determine if the event is reportable.

Click Continue.

Indicate the event location (internal or external source)

*\*\*Note: see on-screen definitions\*\**

Click Continue.

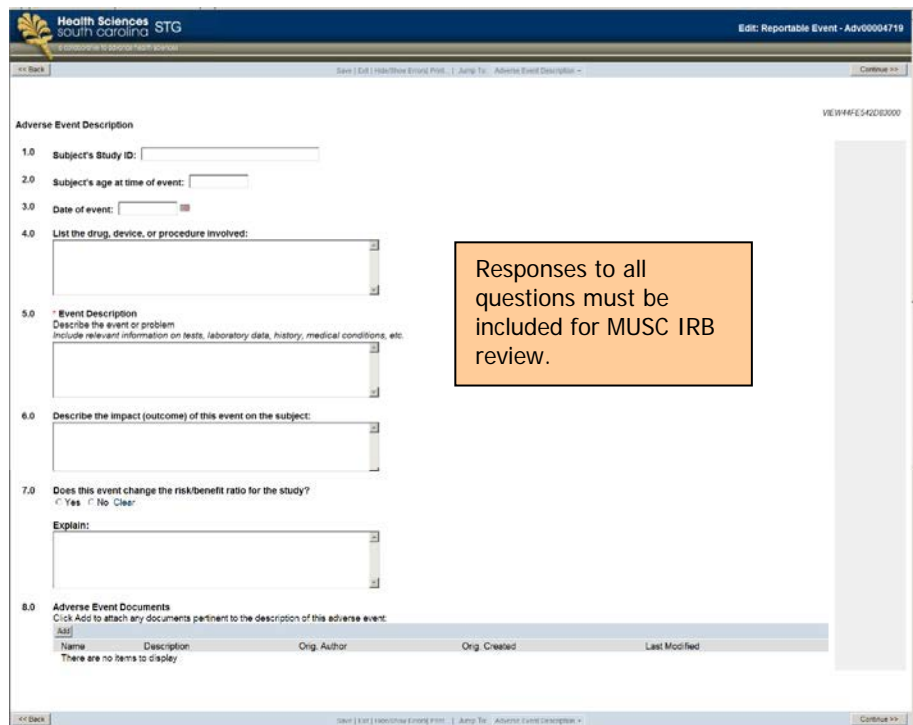


## Internal Adverse Event

If not already done, complete steps in the [Adverse Events](#) section, selecting Internal (Local Site) as the event location.

Complete information to describe the adverse event and upload any relevant documents.

Click Continue.



Health Sciences south carolina STG

Edit: Reportable Event - Adv00004719

Adverse Event Description

1.0 Subject's Study ID: [Text Box]

2.0 Subject's age at time of event: [Text Box]

3.0 Date of event: [Text Box]

4.0 List the drug, device, or procedure involved: [Text Box]

5.0 Event Description  
Describe the event or problem  
Include relevant information on tests, laboratory data, history, medical conditions, etc.  
[Text Box]

6.0 Describe the impact (outcome) of this event on the subject: [Text Box]

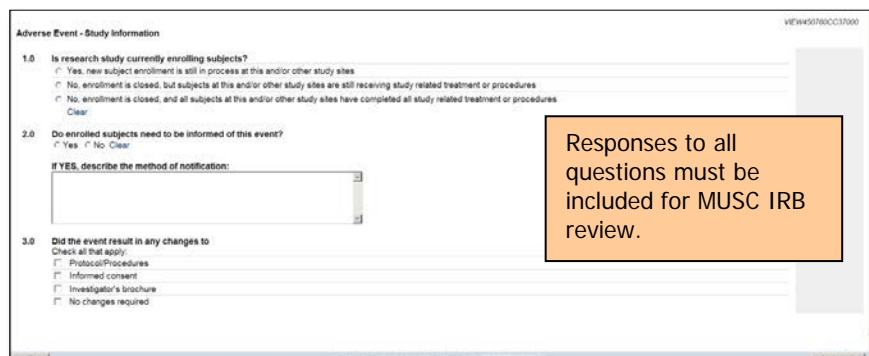
7.0 Does this event change the risk/benefit ratio for the study?  
☐ Yes ☐ No ☐ Clear  
Explain: [Text Box]

8.0 Adverse Event Documents  
Click Add to attach any documents pertinent to the description of this adverse event.  
Add  
Name Description Orig. Author Orig. Created Last Modified  
There are no items to display

Responses to all questions must be included for MUSC IRB review.

Indicate whether or not the study is currently enrolling subjects, if subjects need to be informed of the event and if the event results in changes to protocol documents.

Click Continue.



Adverse Event - Study Information

1.0 Is research study currently enrolling subjects?  
☐ Yes, new subject enrollment is still in process at this and/or other study sites.  
☐ No, enrollment is closed, but subjects at this and/or other study sites are still receiving study related treatment or procedures.  
☐ No, enrollment is closed, and all subjects at this and/or other study sites have completed all study related treatment or procedures.  
Clear

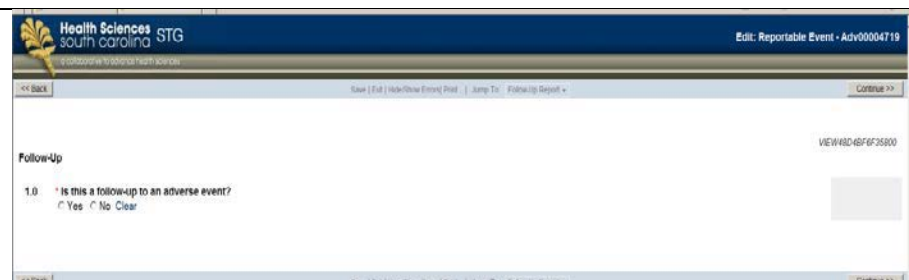
2.0 Do enrolled subjects need to be informed of this event?  
☐ Yes ☐ No ☐ Clear  
If YES, describe the method of notification: [Text Box]

3.0 Did the event result in any changes to  
Check all that apply:  
☐ Protocol/Procedures  
☐ Informed consent  
☐ Investigator's brochure  
☐ No changes required

Responses to all questions must be included for MUSC IRB review.

Indicate if this is a follow up event.

Click Continue.



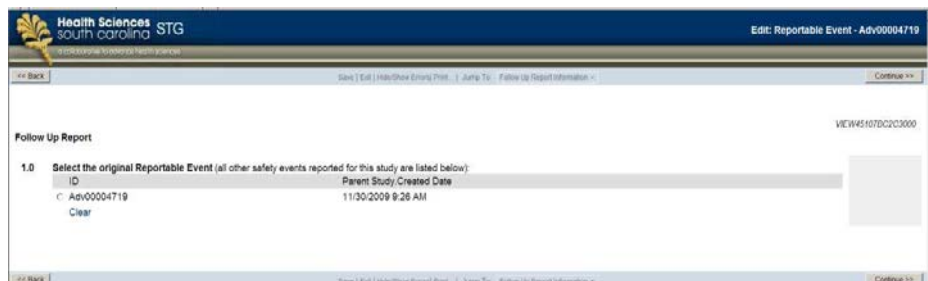
Health Sciences south carolina STG

Edit: Reportable Event - Adv00004719

Follow-Up

1.0 Is this a follow-up to an adverse event?  
☐ Yes ☐ No ☐ Clear

**\*\*Note: if the event is a Follow-up Report, select the original event if previously reported to IRB\*\***



Health Sciences south carolina STG

Edit: Reportable Event - Adv00004719

Follow Up Report

1.0 Select the original Reportable Event (all other safety events reported for this study are listed below):

ID	Parent Study Created Date
Adv00004719	11/30/2009 9:26 AM

Clear



The next three screens require an assessment of the event's expectation, relationship to the study and seriousness.

Click Continue after each screen.

Responses to all questions must be included for MUSC IRB review.

The system will provide a summary.

***\*\*Note: if the event changes the protocol, consent, drug brochure, etc. you must submit a separate amendment for IRB review\*\****

Click Finish.

***\*\*Note: This action does not send the report to IRB. Only the PI can send the event to IRB\*\****

The event is now logged in the system in the Pre-Submission state and can be accessed from the study's Home page or the main protocol page under the 'Reportable Events' tab.

*\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the amendment, the PI must be notified through routine communication that the amendment is pending submission.\*\**

As the PI, to send the event to IRB, follow the steps in [Submission to IRB](#) section of these instructions.

## External Adverse Event

If not already done, complete steps in the [Adverse Events](#) section, selecting External as the event location.

Complete information to describe the adverse event and upload the report/correspondence documents.

Click Continue.

Indicate if this is a follow up event.

Click Continue.

***\*\*Note: if the event is a Follow-up Report, select the original event if previously reported to IRB\*\****

The next three screens require an assessment of the event's expectation, relationship to the study and seriousness.

Click Continue after each screen.

Responses to all questions must be included for MUSC IRB review.

The system will provide a summary.

*\*\*Note: If the event changes the protocol, consent, drug brochure, etc. you must submit a separate amendment for IRB review\*\**

Click Finish.

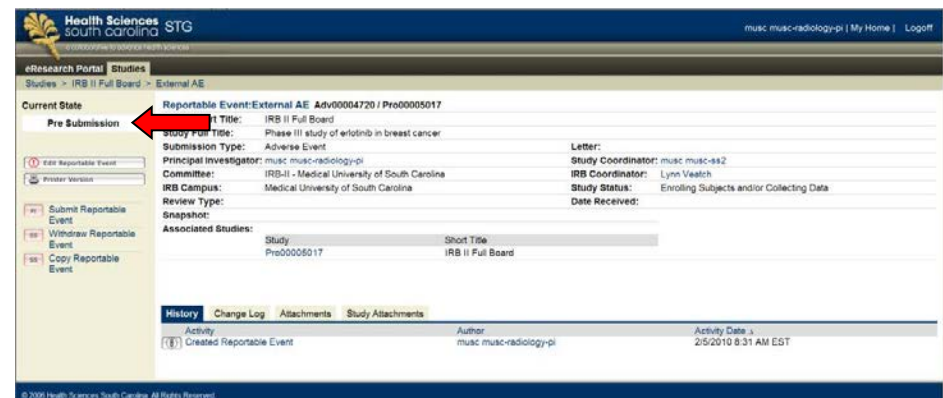
*\*\*Note: This action does not send the report to IRB. Only the PI can send the event to IRB.\*\**



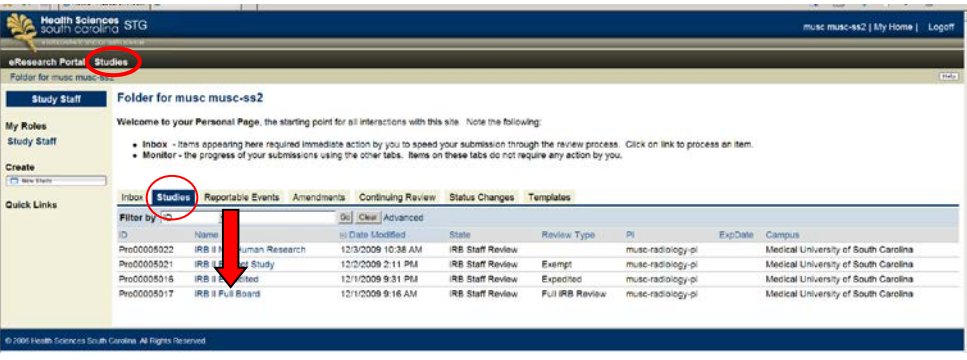
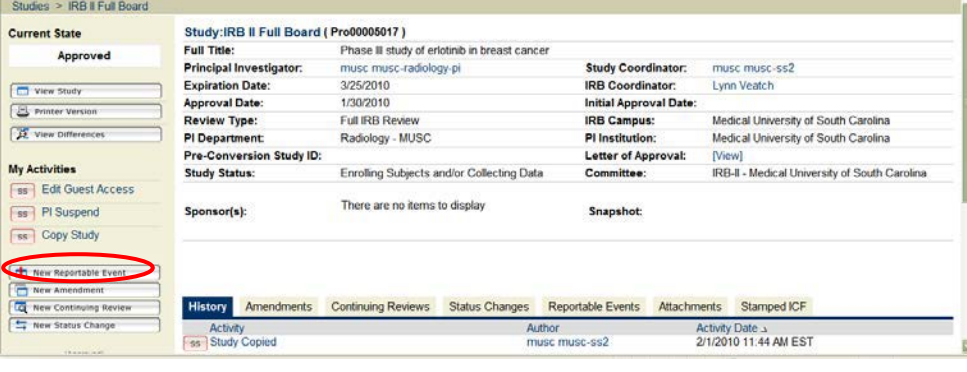
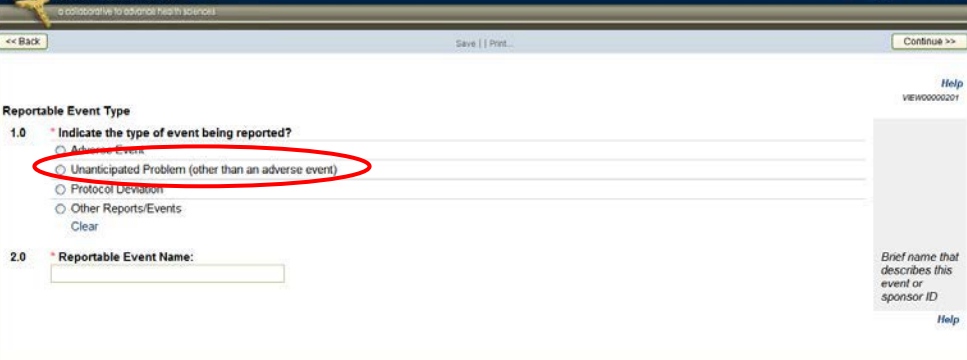
The event is now logged in the system in the Pre-Submission state and can be accessed from the study's Home page or main protocol page under the 'Reportable Events' tab.

*\*\*Note: e-IRB does not send automatic notification of these items. Study staff must be notify PI through routine communication that the amendment is pending submission.\*\**

As the PI, to send the event to IRB, follow the steps in [Submission to IRB](#) section of these instructions.



## Unanticipated Problem (non adverse event)

<p>Log into eIRB.</p> <p>Choose the study by selecting the 'Studies' tab from 'My Home' or the 'Studies' link toward the top of the page.</p> <p>Click on the Name of the study.</p>	
<p>Select 'New Reportable Event'</p>	
<p>Select 'unanticipated problem' as the reportable event and enter in an event name.</p> <p>Click Continue.</p>	

The system will provide a reporting guidance to help you determine if the event is reportable.

Click Continue.

The screenshot shows the 'Reporting Guidance' screen. At the top, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Reporting Guidance', and 'Continue >>'. The main content area is titled 'Reporting Guidance' and contains the following text: 'What events must be reported to the IRB? According to 45 CFR Part 46, to be considered "reportable" (required to be submitted to the IRB) an event must be considered to be an Unanticipated Problem, which means that the event must be: 1. Unexpected (in nature, severity or frequency) 2. Related or possibly related to participation in research and 3. Suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized. OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective action in order to protect the safety, welfare, or rights of subjects or others. Adverse events are a sub-group of Unanticipated Problems and should be reported to the IRB, if they meet the criteria outlined above. Events not considered to be an Unanticipated Problem may be reported under Other Reportable Events. See OHRP guidance for additional information: <http://www.hhs.gov/ohrp/policy/adventguid.html>'. At the bottom, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Reporting Guidance', and 'Continue >>'. A view ID 'VIEW489E08D7E9C00' is visible in the top right corner.

Indicate the event location (internal or external source)

**\*\*Note: see on-screen definitions\*\***

Click Continue.

The screenshot shows the 'Event Location' screen. At the top, there is a header for 'Health Sciences STG south carolina' and a title 'Edit: Reportable Event - Adv00004721'. Below the header, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Adverse Event Location', and 'Continue >>'. The main content area is titled 'Event Location' and contains the following text: '1.0 Where did the event occur? ☐ Internal (Local Site) ☐ External  Clear. In the context of multicenter clinical trials, adverse events can be characterized as either internal adverse events or external adverse events. From the perspective of one particular institution engaged in a multicenter clinical trial, internal adverse events are those adverse events experienced by subjects enrolled by the investigator(s) at that institution, whereas external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial. In the context of a single-center clinical trial, all adverse events would be considered internal adverse events.' At the bottom, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Adverse Event Location', and 'Continue >>'. A view ID 'VIEW44E71F7712000' is visible in the top right corner.

Complete information to describe the unanticipated problem and upload reports or correspondence documents.

Click Continue.

The screenshot shows the 'Unanticipated Problem - Other' screen. At the top, there is a header for 'Health Sciences STG south carolina' and a title 'Edit: Reportable Event - Adv00004721'. Below the header, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Unanticipated Problem - Other', and 'Continue >>'. The main content area is titled 'Unanticipated Problem - Other' and contains the following text: '1.0 Provide a detailed description with an explanation of why the event or series of events has/have been determined to be an Unanticipated Problem. Describe any increase in risk to subject(s) or changes in the risk/benefit ratio for the study. 2.0 Provide a description of actions taken or proposed for the study at this site in response to the Unanticipated Problem. 3.0 Has enrollment of new subjects been suspended? ☐ Yes ☐ No  Clear. 4.0 Did the event result in any recommended changes to Check all that apply: ☐ Protocol/Procedures ☐ Informed consent ☐ Investigator's brochure ☐ No changes required. If changes are recommended, the required changes must be submitted to the IRB for review through an amendment. 5.0 Reports and/or correspondence from the sponsor related to the event. Click the Add button to upload document(s). A table with columns: Name, Description, Orig. Author, Orig. Created, Last Modified. There are no items to display.' At the bottom, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Unanticipated Problem - Other', and 'Continue >>'. A view ID 'VIEW4856A165DC0000' is visible in the top right corner.

Responses to all questions must be included for MUSC IRB review.



The system will provide a summary.

***\*\*Note: if the event changes the protocol, consent, drug brochure, etc. you must submit a separate amendment for IRB review\*\****

Click Finish.

***\*\*Note: This action does not send the report to IRB. Only the PI can send the event to IRB.\*\****

Health Sciences South Carolina STG

Edit: Reportable Event - Adv00004721

Summary of Event and Next Steps

1.0 Submission Type: Unanticipated Problem (other than an adverse event)

2.0 You will need to submit an Amendment if this report requires a change in the protocol/procedures, informed consent, investigator's brochure or if there is a change in the overall risk.

3.0 Select the 'Finish' button to exit this page. If you are the Principal Investigator, you may select on the 'Submit' activity in the Reportable Event workspace to send to the IRB Office.

Finish

The event is now logged in the system in the Pre-Submission state and can be accessed from the study's Home page under the 'Reportable Events' tab.

***\*\*Note: e-IRB does not send automatic notification of these items. Study staff must notify PI through routine communication that the amendment is pending submission.\*\****

As the PI, follow the steps in [Submission to IRB](#) section of these instructions.

Health Sciences South Carolina STG

musc musc radiology: pi | My Home | Logout

eResearch Portal Studies

Studies -> IRB II Full Board -> Unanticipated problem

Current State: Reportable Event: Unanticipated problem Adv00004721 / Pro00005017

Pre-submission

Study Full Title: IRB II Full Board

Submission Type: Phase III study of erlotinib in breast cancer

Submission Type: Unanticipated Problem (other than an adverse event)

Principal Investigator: musc musc-radiology-pi

Committee: IRB-II - Medical University of South Carolina

IRB Campus: Medical University of South Carolina

Review Type: Letter:

Snapshot: Study Coordinator: musc musc-rs2

Associated Studies: IRB Coordinator: Lynn Vaach

Study: Pro00005017

Short Title: IRB II Full Board

History Change Log Attachments Study Attachments

Activity: Created Reportable Event

Author: musc musc-radiology-pi

Activity Date: 2/5/2010 9:09 AM EST

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## Protocol Deviation

Log into eIRB.

Choose the study by selecting the 'Studies' tab from 'My Home' or the 'Studies' link toward the top of the page.

Click on the Name of the study.

Health Sciences South Carolina STG

music-musc-as2 | My Home | Logout

eResearch Portal **Studies**

Folder for music-musc-as2

Study Staff

My Roles

Study Staff

Create

Quick Links

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox - links appearing here require immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor - the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

Inbox **Studies** Reportable Events Amendments Continuing Review Status Changes Templates

Filter by

ID	Name	Date Modified	State	Review Type	PI	ExpDate	Campus
Pro000005022	IRB II Human Research	12/3/2009 10:38 AM	IRB Staff Review		music-radiology-pi		Medical University of South Carolina
Pro000005021	IRB II Human Research Study	12/2/2009 2:11 PM	IRB Staff Review	Exempt	music-radiology-pi		Medical University of South Carolina
Pro000005016	IRB II Expedited	12/1/2009 9:31 PM	IRB Staff Review	Expedited	music-radiology-pi		Medical University of South Carolina
Pro000005017	IRB II Full Board	12/1/2009 9:16 AM	IRB Staff Review	Full IRB Review	music-radiology-pi		Medical University of South Carolina

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Select 'New Reportable Event'

**eResearch Portal** | Studies

Studies > IRB II Full Board

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**Current State**

<p><b>Approved</b></p> <ul style="list-style-type: none"> <li><a href="#">View Study</a></li> <li><a href="#">Printer Version</a></li> <li><a href="#">View Differences</a></li> </ul>	<p><b>Study:IRB II Full Board ( Pro00005017 )</b></p> <p><b>Full Title:</b> Phase III study of erlotinib in breast cancer</p> <p><b>Principal Investigator:</b> musc musc-radiology-pi</p> <p><b>Expiration Date:</b> 3/25/2010</p> <p><b>Approval Date:</b> 1/30/2010</p> <p><b>Review Type:</b> Full IRB Review</p> <p><b>PI Department:</b> Radiology - MUSC</p> <p><b>Pre-Conversion Study ID:</b></p> <p><b>Study Status:</b> Enrolling Subjects and/or Collecting Data</p> <p><b>Sponsor(s):</b> There are no items to display</p>	<p><b>Study Coordinator:</b> musc musc-ss2</p> <p><b>IRB Coordinator:</b> Lynn Veatch</p> <p><b>Initial Approval Date:</b></p> <p><b>IRB Campus:</b> Medical University of South Carolina</p> <p><b>PI Institution:</b> Medical University of South Carolina</p> <p><b>Letter of Approval:</b> [View]</p> <p><b>Committee:</b> IRB-II - Medical University of South Carolina</p> <p><b>Snapshot:</b></p>
--	---	---

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**My Activities**

- [Edit Guest Access](#)
- [PI Suspend](#)
- [Copy Study](#)
- [New Reportable Event](#)**
- [New Amendment](#)
- [New Continuing Review](#)
- [New Status Change](#)


---

**History**   Amendments   Continuing Reviews   Status Changes   Reportable Events   Attachments   Stamped ICF

Activity	Author	Activity Date
<a href="#">Study Copied</a>	musc musc-ss2	2/1/2010 11:44 AM EST

Select 'protocol deviation' as the reportable event and enter in an event name.

Click Continue.



Health Sciences

south carolina STG

a collaborative to advance health sciences

New: Reportable Event

<< Back

Save | Print

Continue >>

Reportable Event Type

1.0 \* Indicate the type of event being reported?

☐ Adverse Event
 ☐ Unanticipated Problem (other than an adverse event)
 ☒ Protocol Deviation
 ☐ Other Reports/Events
 

Clear

2.0 \* Reportable Event Name:

Help

VIEW00000201

Brief name that describes this event or sponsor ID

Help

Indicate the event location (internal or external source)

*\*\*Note: see on-screen definitions\*\**

Click Continue.

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south carolina STG

Edit: Reportable Event - Adv00004721

Back | Edit | Hide/Show Event | Print | Jump To: Adverse Event Location | Continue

VIEW#44E71F7712000

**Event Location**

1.0 \* Where did the event occur?

☒ Internal (Local Site)

☐ External

[Clear](#)

In the context of multicenter clinical trials, adverse events can be characterized as either internal adverse events or external adverse events. From the perspective of one particular institution engaged in a multicenter clinical trial, internal adverse events are those adverse events experienced by subjects enrolled by the investigator(s) at that institution, whereas external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial. In the context of a single-center clinical trial, all adverse events would be considered internal adverse events.

Back | Edit | Hide/Show Event | Print | Jump To: Adverse Event Location | Continue

Complete information to describe the deviation and upload supporting documents (as applicable).

Click Continue.

#### Protocol Deviation

1.0

\* The deviation by the research team involved:

- ☐ Inclusion/exclusion criteria
  - ☐ Dose, dosage schedule, or use of device
  - ☐ Use of medications not allowed by protocol
  - ☐ Non-adherence to scheduled lab work, tests, procedures, study visits
  - ☐ Other
- [Clear](#)

If OTHER, specify:

2.0

\* Provide a description of the protocol deviation:

3.0

Date of deviation:

Date of discovery:

Subject's Study ID:

4.0

\* Did the protocol deviation result in increased risk or consequences to the subject(s)?

☐ Yes ☐ No [Clear](#)

If YES, explain:

5.0

Was/were subject(s) informed of deviation?

☐ Yes ☐ No [Clear](#)

6.0

Will involved subject(s) remain in the study?

☐ Yes ☐ No [Clear](#)

7.0

\* Describe measures to be taken to prevent the possibility of a similar violation or deviation from occurring:

8.0

\* Does this deviation affect the integrity of the research study data?

☐ Yes ☐ No [Clear](#)

If YES, explain:

9.0

\* Has this deviation been reported to the sponsor?

- ☐ Yes
  - ☐ No
  - ☐ Not a sponsored study
- [Clear](#)

10.0

\* Did this protocol deviation result in any changes to the following:

Select all that apply

- ☐ Protocol/Procedures
- ☐ Informed consent
- ☐ Investigator's brochure
- ☐ No changes required
- ☐ Other

If OTHER, explain:

11.0

Support documentation (if available)

Example: Physicians Notes, Hospital Records

Add		
Name	Description	Orig. Author
There are no items to display		

Responses to all questions, as applicable, must be included for MUSC IRB review.

The system will provide a summary.

***\*\*Note: if the event changes the protocol, consent, drug brochure, etc. you must submit a separate amendment for IRB review\*\****

Click Finish.

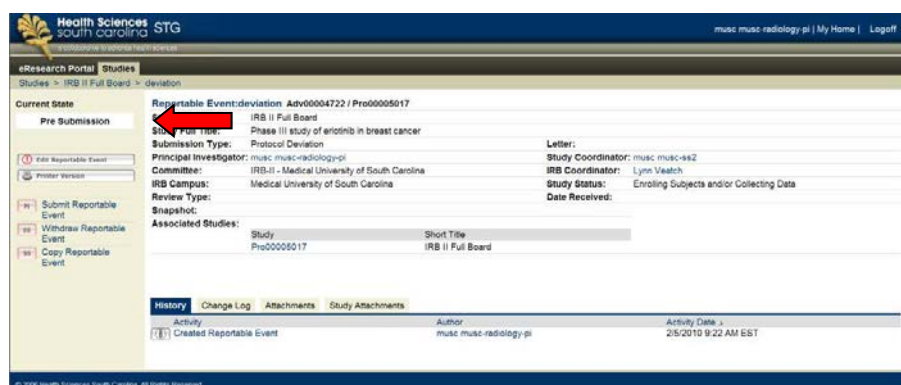
***\*\*Note: This action does not send the report to IRB. only the PI can send the event to IRB.\*\****



The event is now logged in the system in the Pre-Submission state and can be accessed from the study's Home page or the main protocol page under the 'Reportable Events' tab.

***\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the amendment, the PI must be notified through routine communication that the amendment is pending submission.\*\****

As the PI, to send the event to IRB, follow the steps in [Submission to IRB](#) section of these instructions.



## Other Reports/Events

Other reports types, such submitting Data Safety Monitoring Board minutes and monitoring reports, can also be completed in eIRB.

*\*\*Note: submit these types of reports as reportable events only if they are not being reported with the continuing review\*\**

Log into eIRB.

Choose the study by selecting the 'Studies' tab from 'My Home' or the 'Studies' link toward the top of the page.

Click on the Name of the study.

Health Sciences South Carolina STG

mus musc-ss2 | My Home | Logout

eResearch Portal Studies

Folder for musc musc-ss2

Study Staff

My Roles

Study Staff

Create

Quick Links

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- Inbox - Items appearing here required immediate action by you to speed your submission through the review process. Click on link to process an item.
- Monitor - the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

Filter by: [dropdown] [Go] [Clear] [Advanced]

ID	Name	Date Modified	State	Review Type	PI	ExpDate	Campus
Pro00005022	IRB II Human Research	12/3/2009 10:38 AM	IRB Staff Review		musc-radiology-pi		Medical University of South Carolina
Pro00005021	IRB II Human Study	12/2/2009 2:11 PM	IRB Staff Review	Exempt	musc-radiology-pi		Medical University of South Carolina
Pro00005016	IRB II Expedited	12/1/2009 9:31 PM	IRB Staff Review	Expedited	musc-radiology-pi		Medical University of South Carolina
Pro00005017	IRB II Full Board	12/1/2009 9:16 AM	IRB Staff Review	Full IRB Review	musc-radiology-pi		Medical University of South Carolina

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Select 'New Reportable Event'

eResearch Portal Studies

Studies > IRB II Full Board

Current State

Approved

View Study

Printer Version

View Differences

My Activities

SS Edit Guest Access

SS PI Suspend

SS Copy Study

**New Reportable Event**

New Amendment

New Continuing Review

New Status Change

Study: IRB II Full Board (Pro00005017)

Full Title: Phase II study of erlotinib in breast cancer

Principal Investigator: musc musc-radiology-pi

Study Coordinator: musc musc-ss2

Expiration Date: 3/25/2010

IRB Coordinator: Lynn Veatch

Approval Date: 1/30/2010

Initial Approval Date:

Review Type: Full IRB Review

IRB Campus: Medical University of South Carolina

PI Department: Radiology - MUSC

PI Institution: Medical University of South Carolina

Pre-Conversion Study ID:

Letter of Approval: [View]

Study Status: Enrolling Subjects and/or Collecting Data

Committee: IRB-II - Medical University of South Carolina

Sponsor(s): There are no items to display

Snapshot:

History

Amendments

Continuing Reviews

Status Changes

Reportable Events

Attachments

Stamped ICF

Activity

Author: musc musc-ss2

Activity Date: 2/1/2010 11:44 AM EST

Select 'other reports/events' as the reportable event and enter in an event name.

Click Continue.

Health Sciences South Carolina STG

New Reportable Event

Save | Print | Continue >>

Reportable Event Type

1.0 \* Indicate the type of event being reported?

☐ Adverse Event

☐ Unanticipated Problem (other than an adverse event)

☐ Protocol Deviation

**☒ Other Reports/Events**

Clear

2.0 \* Reportable Event Name:

Brief name that describes this event or sponsor ID

Help

VIEW00000201



Indicate the event location (internal or external source)

**\*\*Note: see on-screen definitions\*\***

Click Continue.

Indicate the type of event/information, upload documents and provide additional information as needed.

Click Continue.

The system will provide a summary.

**\*\*Note: if the event changes the protocol, consent, drug brochure, etc. you must submit a separate amendment for IRB review\*\***

Click Finish.

**\*\*Note: This action does not send the report to IRB. Only the PI can send the event to IRB. \*\***

The event is now logged in the system in the Pre-Submission state and can be accessed from the study's Home page or main protocol page under the 'Reportable Events' tab.

***\*\*Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the amendment, the PI must be notified through routine communication that the amendment is pending submission. \*\****

As the PI, to send the event to IRB, follow the steps in [Submission to IRB](#) section of these instructions.

The screenshot displays the 'eResearch Portal' interface for 'Health Sciences South Carolina STG'. The user is logged in as 'music.musc-radiology-pi'. The main content area shows the 'Current State' of a 'Reportable Event' for 'Adv00004723 / Pro00005017'. The event is in the 'Pre Submission' state. The left sidebar contains a 'Current State' section with a 'Pre Submission' button and a list of actions: 'Edit Reportable Event', 'Print Version', 'Submit Reportable Event', 'Withdraw Reportable Event', and 'Copy Reportable Event'. The main content area displays the following information:

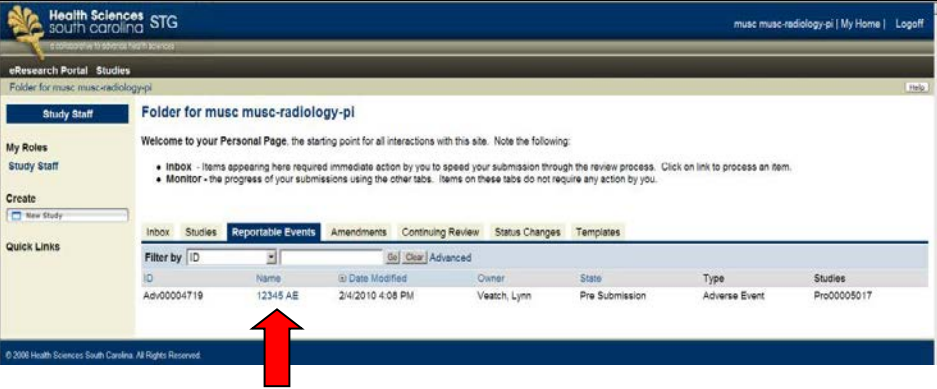
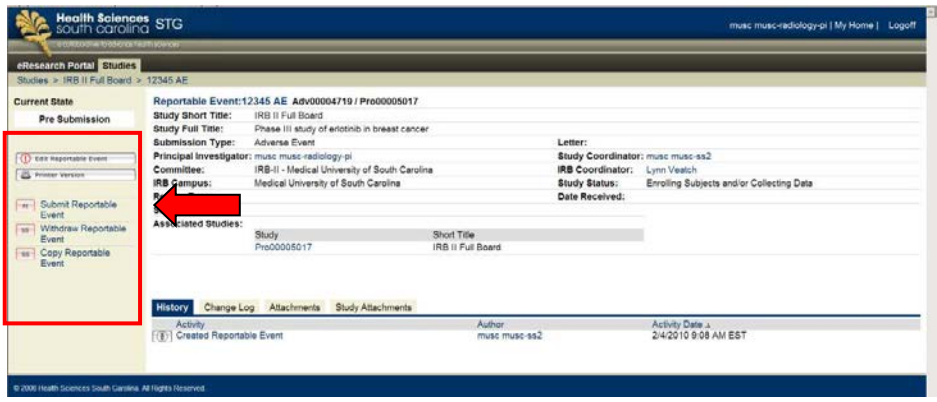
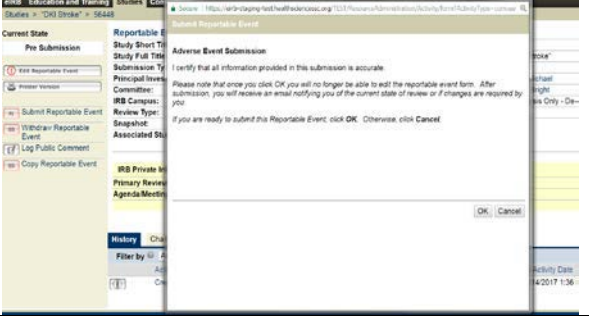

Reportable Event:	other events Adv00004723 / Pro00005017
Study Short Title:	IRB II Full Board
Study Full Title:	Phase III study of erlotinib in breast cancer
Submission Type:	Other Reports/Events
Principal Investigator:	music.musc-radiology-pi
Committee:	IRB-II - Medical University of South Carolina
IRB Campus:	Medical University of South Carolina
Review Type:	
Snapshot:	
Letter:	
Study Coordinator:	music.musc-ss2
IRB Coordinator:	Lynn Veatch
Study Status:	Enrolling Subjects and/or Collecting Data
Date Received:	

Below this information, there is a section for 'Associated Studies' with a table showing the study ID and short title. At the bottom, there is a 'History' tab with a table showing the activity log.

Activity	Author	Activity Date
Created Reportable Event	music.musc-radiology-pi	2/5/2010 9:39 AM EST

## Submission to IRB

**\*\*\*Only the PI can submit reportable events to IRB\*\*\***

<p>Log into eIRB.</p> <p>Select the 'Reportable Events' tab on your home page.</p> <p>Choose the Name of the event.</p>	
<p>Options to Edit, View, Submit, Withdraw or Copy the Event are available.</p> <p>To View the event, select 'Printer Version'.</p> <p>To Edit the event, select 'Edit Reportable Event' and change the information in the applicable sections.</p> <p>When ready to send the event to IRB, select 'Submit Reportable Event'.</p>	
<p>A pop-up box will appear that includes information certifying that the event description is accurate.</p> <p>Click 'OK'.</p>	
<p>The event has now been sent to IRB. The state has changed to 'IRB Staff Review' and is no longer able to be edited.</p> <p>If there was an amendment completed due to the event, see instructions regarding completing and sending the <a href="#">Amendment</a> to IRB.</p>	

## Responding to IRB Comments

For additional assistance, view the recorded demonstrations 'Responding to IRB Reviewer Comments' in the eIRB Education & Training section.

Designated personnel (e.g., eIRB communication coordinator) will receive an e-mail indicating that changes are requested by IRB.

**\*\*Note: study staff with study edit privileges can make and submit these changes to IRB\*\***

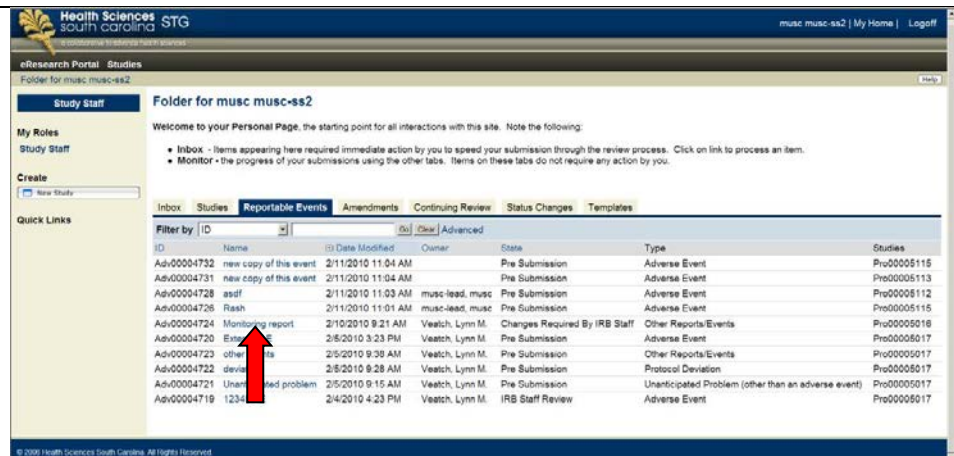
Responding to comments is a 2-step process.

1. The changes must first be made within the study application; and
2. The changes must be documented as completed, not completed or for information only and include a summary of the responses.

Log into eIRB.

Select the 'Reportable Events' tab on the home page.

Choose the Name of the event.



The 'History' tab logs the change request. It will also include additional notes or clarification requested by IRB. However, your changes will not be made from this location.

Instead, click on the 'Edit Reportable Event' or 'Reviewer Notes' tab to access the comments & begin responding.

**\*\*Note: the Current State is 'Changes Required by IRB Staff'\*\***



On the 'Reviewer Notes' tab all comments will appear and the change request references the sections to change within the application. Select the hyperlinked text next to 'Jump To' to taken to the area to begin addressing the comments.

***\*\*Note: do not select 'Click here to respond' at this time, as that is the second step in responding to comments\*\****

The screenshot shows the 'Reviewer Notes' tab for a monitoring report. The 'Reviewer Notes' tab is highlighted with a red circle. A red arrow points to the 'Jump To: Adverse Event Location' link in the first reviewer note. The note text is: 'IRB Change Request: Jump To: Adverse Event Location. Response Required! Click here to respond... IRB Reviewer requests, similar to the previous note, to please add additional detail to describe the circumstances behind this event.' The reviewer is Lynn Veatch, dated 2/10/2010 9:21 AM.

Step 1: Address the comment on the Smartform screen. Make changes directly to the information on the screen.

***\*\*Note: If previously submitted documents are required to be revised & uploaded, select 'Upload Revision' button next to the document's name & locate the file from your computer. DO NOT use the 'Add' or 'Delete' button unless this is the first time that document is included.***

***Comments may request uploading of documents when there is no upload feature on the smartform page. In that case, documents can be uploaded in the 'General Comments' section of the application.\*\****

The screenshot shows the 'Reportable Event Type' section of the smartform. The 'Reportable Event Type' section is highlighted with a red circle. The 'Reportable Event Name' field is filled with 'Monitoring report'. The 'Reportable Event Type' section includes a list of event types: Adverse Event, Unanticipated Problem (other than an adverse event), Protocol Deviation, and Other Reports/Events. The 'Other Reports/Events' option is selected. The 'Reportable Event Name' field is filled with 'Monitoring report'. The 'Reportable Event Type' section is highlighted with a red circle.

Step 2: After addressing the comments, select 'Click here to respond'. This is the second step and will finalize that comment only.

In the pop-up window, select the response 'Type' from the drop down and enter in a response.

Click 'OK' when done.

*\*\*Note: There may be multiple comments within one IRB Change request section. The system allows you to save a response even if all comments haven't been addressed. For study management purposes, this second step should be complete only if all comments are address OR you have written in notes to go back and respond to the remaining comments. \*\**

The system will recognize that you have entered in a response.

*\*\*Note: If there are multiple comments, select the 'Next' (or 'Previous') button to address the remaining comments. \*\**

When done, click 'Save' and then 'Exit' to return to the Reportable Event main page.



If desired, click on the 'Reviewer Notes' tab to ensure that all comments have been addressed (i.e., a green bar appears indicating you have completed step #2 in responding to that question).

Health Sciences south carolina STG

musc-musc-ss2 | My Home | Logout

eIRB Studies

Studies > IRB II Exempt Study > Amendment 1 for IRB Study #Pro00005021

Amendment Workspace

Changes Required By IRB Staff

Amendment: Amendment 1 for IRB Study #Pro00005021 (Amet1\_Pro00005021)

Description: [P]

Study Short Title: IRB II Exempt Study

Study Full Title: Research on educational strategies

Principal Investigator: musc-musc-radiology-pi

Date Received: 2/10/2010

IRB Campus: Medical University of South Carolina

Review Type: Snapshot

Study Coordinator: musc-musc-ss2

Original Study ID: Pro00005021

IRB Administrator: Lynn Veatch

Letter of Approval:

History Change Log Reviewer Notes Study Attachments Pre-Review Status

Type Reviewer Is Modified

IRB Change Request Lynn Veatch 2/24/2010 12:03 PM

Jump To: Protocol Document Changes - Redlined Copy (changes marked)

Please clarify the description of the changes made to the protocol. Thank you!

If musc-musc-ss2 - Change Request Completed - 2/24/2010 12:03 PM

Add info to the protocol

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Click 'Submit Changes' to send the response to IRB.

Summarize your changes and attach any documents if needed (*this is optional*).

Click 'OK' when done.

This will send the response back to IRB for review.

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musc-musc-ss2 | My Home | Logout

eResearch Portal Studies

Studies > IRB II Expedited > Monitoring report

Current State

Changes Required By IRB Staff

Reportable Event: Monitoring report Adv00004724 / Pro00005016

Study Short Title: IRB II Expedited

Study Full Title: Saliva repository access

Submission Type: Other Reports/Events

Principal Investigator: musc-musc-radiology-pi

Committee: IRB II - Medical University of South Carolina

IRB Campus: Medical University of South Carolina

Review Type: Letter

Study Coordinator: musc-musc-ss2

IRB Coordinator: Lynn Veatch

Study Status: Enrolling Subjects - No accrual/enrollment to date

Date Received: 2/9/2010

Associated Studies:

Study	Short Title
Pro00005016	IRB II Expedited

History Change Log Reviewer Notes Attachments Study Attachments

Activity Author Activity Date

Requested Changes By IRB Staff Lynn Veatch 2/10/2010 9:21 AM EST

Forwarded to Expedited Reviewer Lynn Veatch 2/10/2010 9:13 AM EST

Reportable Event Submitted musc-musc-radiology-pi 2/9/2010 12:55 PM EST

Created Reportable Event musc-musc-radiology-pi 2/9/2010 12:52 PM EST

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musc-musc-ss2 | My Home | Logout

eResearch Portal Studies

Studies > IRB II Expedited > Monitoring report

Current State

Changes Required By IRB Staff

Reportable Event: Monitoring report

Study Short Title: IRB II Expedited

Study Full Title: Saliva repository access

Submission Type: Other Reports/Events

Principal Investigator: musc-musc-radiology-pi

Committee: IRB II - Medical University of South Carolina

IRB Campus: Medical University of South Carolina

Review Type: Letter

Study Coordinator: musc-musc-ss2

IRB Coordinator: Lynn Veatch

Study Status: Enrolling Subjects - No accrual/enrollment to date

Date Received: 2/9/2010

Associated Studies:

History Change

Activity Author Activity Date

Requested Changes By IRB Staff Lynn Veatch 2/10/2010 9:21 AM EST

Forwarded to Expedited Reviewer Lynn Veatch 2/10/2010 9:13 AM EST

Reportable Event Submitted musc-musc-radiology-pi 2/9/2010 12:55 PM EST

Created Reportable Event musc-musc-radiology-pi 2/9/2010 12:52 PM EST

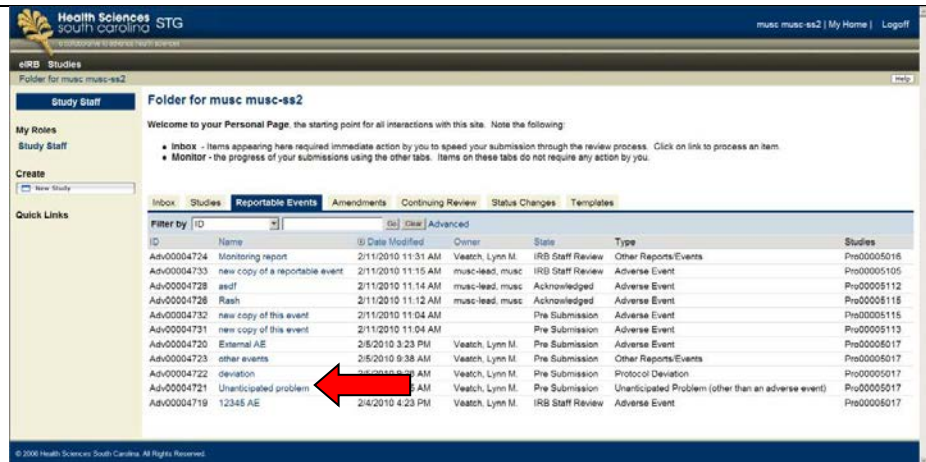
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## Withdrawing a Reportable Event

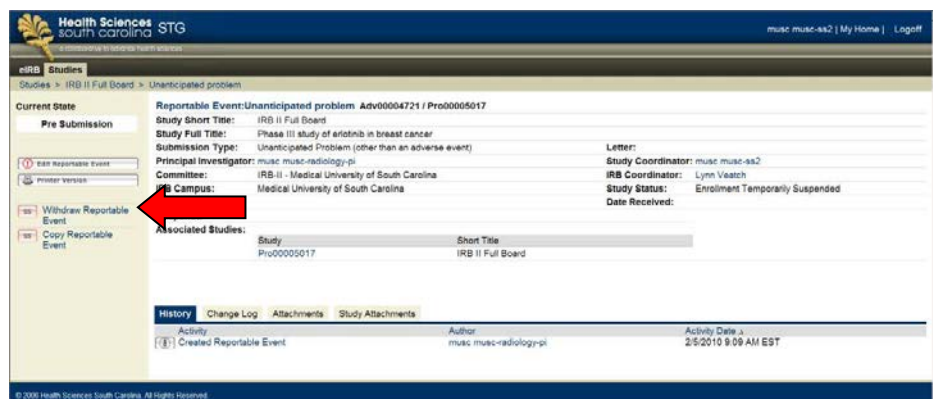
Reportable events can only be withdrawn before IRB submission has occurred.

***\*\*Note: events that are withdrawn CANNOT be restored to an editable state in the system\*\****

From your Homepage, locate the 'Reportable Event' tab and select the study name.

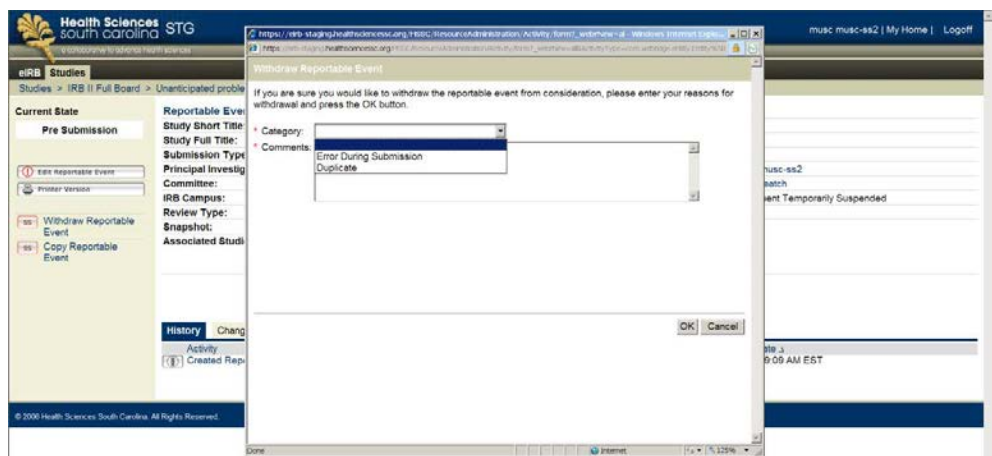


Select 'Withdraw Reportable Event' on the left toolbar



Select the rationale for withdrawing the reportable event and include comments.

Click 'OK'



The state of the event is now 'Withdrawn'

To see the event, select 'View Reportable Event' or 'Printer Version'

The event cannot be restored in the system. If the event was withdrawn in error, you must copy it and create a new event.

**Health Sciences South Carolina STG**  
musc musc-ss2 | My Home | Logoff

**eIRB Studies**  
Unanticipated problem

**Current State:** Withdrawn

**Reportable Event:** Unanticipated problem Adv00004721 / Pro00005017

**Study Short Title:** IRB II Full Board

**Study Full Title:** Phase III study of erlotinib in breast cancer

**Submission Type:** Unanticipated Problem (other than an adverse event)

**Letter:**

**Study Coordinator:** musc musc-ss2

**IRB Coordinator:** Lynn Veatch

**Study Status:** Enrollment Temporarily Suspended

**Date Received:**

**IRB Campus:** Medical University of South Carolina

**Review Type:**

**Snapshot:**

**Associated Studies:**

Study	Short Title
Pro00005017	IRB II Full Board

**History** | Change Log | Attachments | Study Attachments

Activity	Author	Activity Date
Reportable Event Withdrawn	musc musc-ss2	3/3/2010 12:50 PM EST
Created Reportable Event	musc musc-radiology-pl	2/5/2010 9:09 AM EST

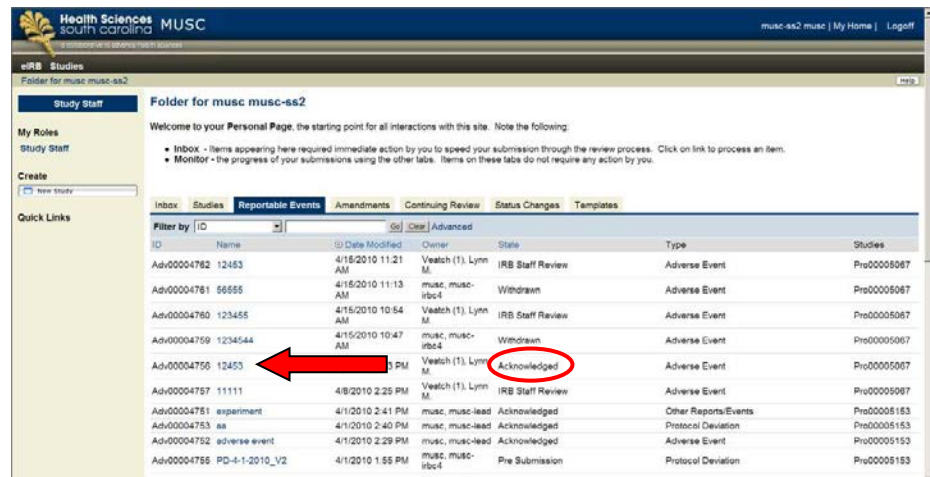
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## Accessing IRB Review Letter

For additional assistance, view the recorded demonstration 'Accessing IRB Reviewed Documents' in the eIRB Education & Training section.

From your Homepage, locate the 'Reportable Events' tab and select the study name.

*\*\*Note: the current State of the reportable event should be 'Acknowledged'\*\**



ID	Name	Date Modified	Owner	State	Type	Studies
Adv00004762	12453	4/15/2010 11:21 AM	Veatch (1), Lynn M.	IRB Staff Review	Adverse Event	Pro00005067
Adv00004761	56555	4/15/2010 11:13 AM	musc, musc-irbc4	Withdrawn	Adverse Event	Pro00005067
Adv00004760	123455	4/15/2010 10:54 AM	Veatch (1), Lynn M.	IRB Staff Review	Adverse Event	Pro00005067
Adv00004759	1234544	4/15/2010 10:47 AM	musc, musc-irbc4	Withdrawn	Adverse Event	Pro00005067
Adv00004756	12453	4/15/2010 1:15 PM	Veatch (1), Lynn M.	<b>Acknowledged</b>	Adverse Event	Pro00005067
Adv00004757	11111	4/8/2010 2:25 PM	Veatch (1), Lynn M.	IRB Staff Review	Adverse Event	Pro00005067
Adv00004751	experiment	4/1/2010 2:41 PM	musc, musc-lead	Acknowledged	Other Reports/Events	Pro00005153
Adv00004753	aa	4/1/2010 2:40 PM	musc, musc-lead	Acknowledged	Protocol Deviation	Pro00005153
Adv00004752	adverse event	4/1/2010 2:29 PM	musc, musc-lead	Acknowledged	Adverse Event	Pro00005153
Adv00004755	PD-4-1-2010_V2	4/1/2010 1:55 PM	musc, musc-irbc4	Prior Submission	Protocol Deviation	Pro00005153

Click on 'View'.

The option to open or save the letter as a Microsoft Word document will be available.



Reportable Event: 12453 Adv00004756 / Pro00005067

Study Short Title: IRB II Full Board\_2

Study Full Title: Phase III study of erlotinib in breast cancer

Submission Type: Adverse Event

Principal Investigator: musc-radiology-pi musc

Committee: IRB-II - Medical University of South Carolina

IRB Campus: Medical University of South Carolina

Review Type: Expedited

Snapshot:

Associated Studies:

Study	Short Title
Pro00005067	IRB II Full Board_2

Letter: [View](#)

Study Coordinator: musc-ss2 musc

IRB Coordinator: Lynn Veatch (1)

Study Status: Approved for Accrual

Date Received: 4/6/2010

History Change Log Reviewer Notes Attachments Study Attachments

Activity	Author	Activity Date
Reportable Event Submitted	musc-radiology-pi musc	4/6/2010 8:07 AM EDT
Created Reportable Event	musc-ss2 musc	4/6/2010 8:03 AM EDT

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## CONTINUING REVIEW

For additional assistance, view the recorded demonstrations 'Creating and Submitting Continuing Review Applications' in the eIRB [Education & Training](#) section.

### Completing the continuing review

**\*\*Note: only the PI can send the continuing review application to IRB\*\***

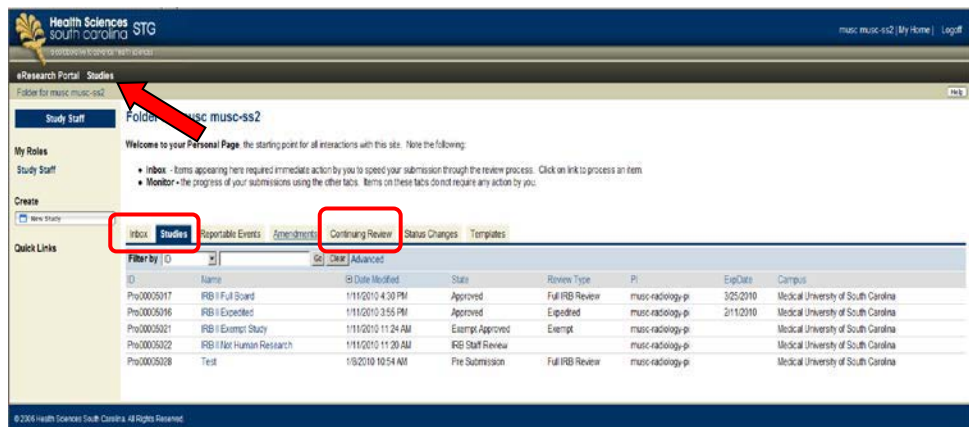
Log into eIRB. From your Home page, you can select the study by selecting either:

The 'Inbox' tab: includes studies where you've already begun and saved a continuing review application that has not yet been sent to IRB

The 'Studies' tab: includes all studies

The 'Continuing Review' tab: includes studies that have continuing reviews entered into the system

If the study will expire in 60 days, you can also access it by selecting the Studies link and locating the study under the 'Expirations' tab.

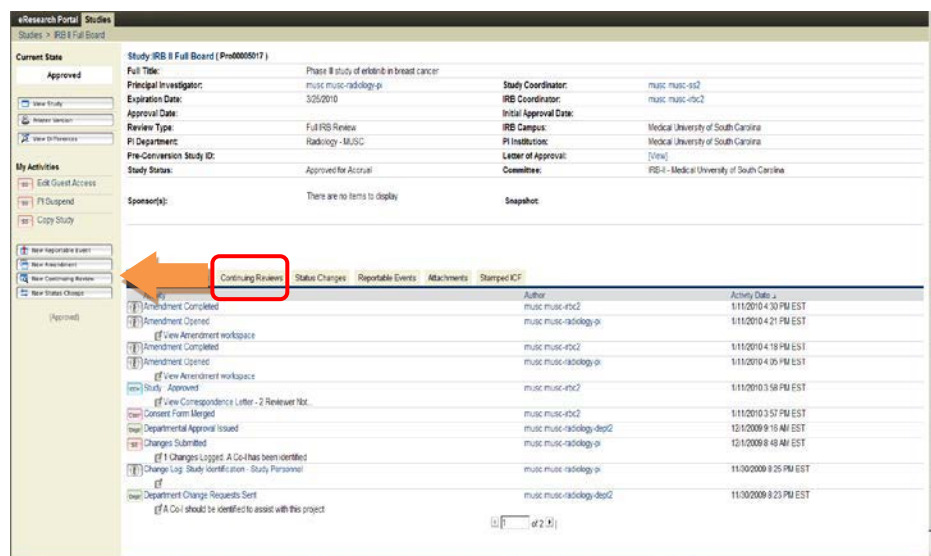


Under My Activities, select 'New Continuing Review'

**\*\*Note: only one continuing review application can be open at a time. If you do not see the New Continuing Review button, there is an application already open that must be edited or withdrawn.**

Access the Continuing Reviews tab to find the open application.

Exempt, Not Human Subjects and External IRB Review studies cannot create new continuing review applications.\*\*



Select the Current Study Status and reason for the change in enrollment status, if applicable.

Click Continue

*\*Note: you will not be able to proceed with a selection of 'Transfer to External IRB' – this option is not valid at MUSC.*

*If your study is an expedited review category 5 retrospective only study, follow the continuing review steps for Expedited Category 5 Retrospective studies.*

*If the study status is 'Enrolling Subjects – No accrual/enrollment to date', an abbreviated continuing review path will be completed. \*\**

1.0 \* Current Study Status:

- ☐ Enrolling Subjects and/or Collecting Data
- ☐ Enrolling Subjects - No accrual/enrollment to date
- ☐ Enrollment Closed - Subjects continue to receive study treatment/intervention
- ☐ Enrollment Closed - Follow-up and collecting data only
- ☐ Data Analysis Only - Identifiable
- ☐ Data Analysis Only - De-identified
- ☐ Transfer to External IRB
- ☐ Enrollment Temporarily Suspended
- ☐ Permanently Closed - All study activities are completed
- 

2.0 If enrollment status changed, explain why:

If enrollment status has changed, a rationale must also be included for MUSC IRB review.

Any study amendments, status changes and reportable events approved/acknowledged by the IRB since the last study review will be listed here.

Click Continue.

Changes Reviewed - IRB reviews since last application review

1.0 Amendments:

ID	Name	Description	Review Type
Ame2_Pro00002526	Amendment 2		
Ame1_Pro00002526	Amendment 1		I

2.0 Status Change:

No data to display

3.0 Reportable Events:

No data to display



Indicate if there have been any complaints, interim findings or multi-center trial reports.

Click Continue.

Include information about number of subjects enrollments

Click Continue.

*\*\*Note: hover over the question mark icons to view term definitions.*

*The # of subjects withdrawn must equal the same amount entered in on the Withdrawals - Reasons and Number page. \*\**

The **first year continuing review** presents two columns to record enrollments since the last (initial) review and the cumulative since initial review. *For the first renewal, these numbers will be the same.*

The **subsequent continuing reviews** present a three-column page that includes a middle column to correct previously reported numbers, if necessary as indicated in question #1.

### 1<sup>st</sup> year continuing review:

#### 1.0 Number of Subjects

Note: "last review" is the study's initial review or continuing review, whichever is most recent. For the first continuing review, the numbers will be the same in both columns.

1.0	Number of study wide subjects approved for enrollment	300	
2.0	Number of local subjects approved for enrollment	15	
		Number since LAST Review	Cumulative Number since INITIAL Review
3.0	Number of subjects enrolled study wide, or for a chart review number of records reviewed ?	<input type="text"/>	<input type="text"/>
4.0	Number of subjects enrolled locally, or for a chart review number of records reviewed ?	* <input type="text"/>	* <input type="text"/>
5.0	Number of subjects who screen failed ? ("0" if no screen failures or the study has no screening procedures)	* <input type="text"/>	* <input type="text"/>
6.0	Number of local subjects who have completed the study ? (including death(s) expected as an endpoint)	* <input type="text"/>	* <input type="text"/>
7.0	Number of local subjects who have withdrawn ?	* <input type="text"/>	* <input type="text"/>
8.0	Number of local subjects who died unexpectedly	* <input type="text"/>	* <input type="text"/>
9.0	Number of local subjects currently receiving treatment/intervention ? * <input type="text"/>		
10.0	Number of local subjects currently in follow-up only ? * <input type="text"/>		

### Subsequent continuing reviews:

#### 1.0 Adjustment to Number of Subjects Previously Reported

Check this box if adjustments are needed to the enrollment numbers reported in a previous continuing review. ☐

When making adjustments, complete column B in section 2.0 below so that column A + column B reports the total number of accumulated subjects in column C.

#### 2.0 Number of Subjects

Note: "last review" is the study's initial review or continuing review, whichever is most recent. For the first continuing review, the numbers will be the same in both columns.

1.0	Number of study wide subjects approved for enrollment	500		
2.0	Number of local subjects approved for enrollment	10		
		Column A Number since LAST Review	Column B Cumulative Number at LAST Review	Column C Cumulative Number since INITIAL Review (1)
3.0	Number of subjects enrolled study wide, or for a chart review number of records reviewed ?	<input type="text"/>	0	0
4.0	Number of subjects enrolled locally, or for a chart review number of records reviewed ?	* <input type="text"/>	5	5
5.0	Number of subjects who screen failed ? ("0" if no screen failures or the study has no screening procedures)	* <input type="text"/>	1	1
6.0	Number of local subjects who have completed the study ? (including death(s) expected as an endpoint)	* <input type="text"/>	0	0
7.0	Number of local subjects who have withdrawn ?	* <input type="text"/>	0	0
8.0	Number of local subjects who died unexpectedly	* <input type="text"/>	0	0
9.0	Number of local subjects currently receiving treatment/intervention ? * <input type="text"/>			
10.0	Number of local subjects currently in follow-up only ? * <input type="text"/>			

Include the demographics of subjects enrolled.

Click Continue

#### 1.0 Demographic Information - Race and Ethnicity

Include enrolled study participants (not screen failures).

CURRENT ENROLLMENT: Number of Subjects			
Ethnic Category	Females	Males	Total <sup>1</sup>
Hispanic/ Latino	<input type="text"/>	<input type="text"/>	<input type="text"/>
Not Hispanic or Latino	<input type="text"/>	<input type="text"/>	<input type="text"/>
Unknown/Other/Unreported	<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Ethnic Category: Total of All Subjects<sup>1</sup></b>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Racial Categories</b>			
American Indian/Alaska Native	<input type="text"/>	<input type="text"/>	<input type="text"/>
Asian	<input type="text"/>	<input type="text"/>	<input type="text"/>
Native Hawaiian or Other Pacific Islander	<input type="text"/>	<input type="text"/>	<input type="text"/>
Black or African American	<input type="text"/>	<input type="text"/>	<input type="text"/>
White	<input type="text"/>	<input type="text"/>	<input type="text"/>
Unknown/Other/Unreported	<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Racial Categories: Total of All Subjects<sup>1</sup></b>	<input type="text"/>	<input type="text"/>	<input type="text"/>

[1] Totals will be recalculated when the Save link or Continue button is selected

2.0 As applicable, include additional information that may explain absent or discrepant demographic data.

If subjects have been withdrawn, indicate the reason for withdrawal & number of subjects withdrawn for those reasons.

*\*\*Note: the numbers entered in on the Number of Subjects page, withdrawn section must equal the same amount entered in on this page\*\*.*

Click Continue.

<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Withdrawals - Reason and Number v2
Continue >>

VIEW8025F55A870098C

**Withdrawals - Reason and Number**  
Enter the number of subjects for each category since last review and explain.  
Note: "last review" is the study's initial review or continuing review; whichever is most recent.

1.0 \* Transferred to another study site:

Explain:

2.0 \* Investigator withdrew subject:

Explain:


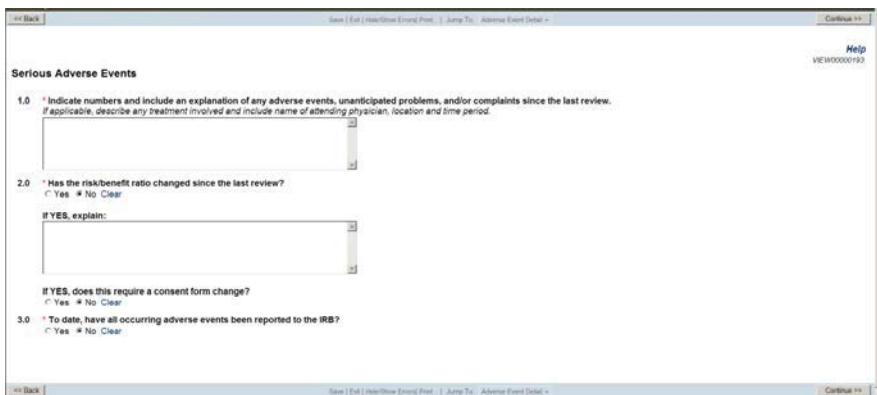
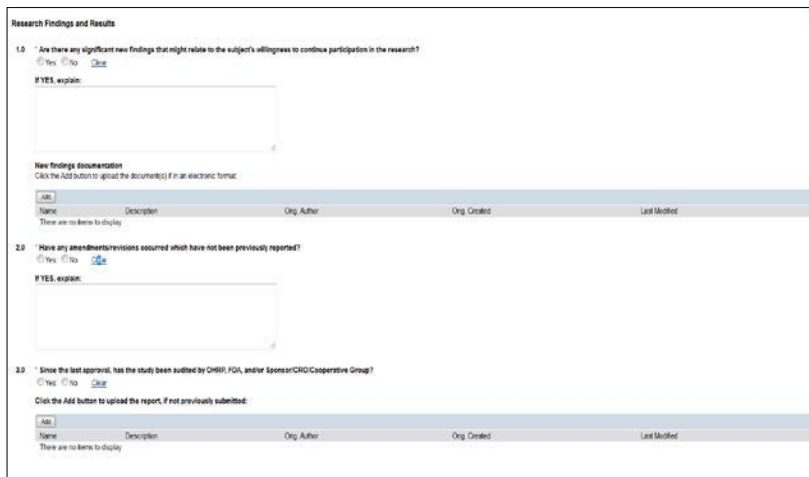
3.0 \* Treatment intolerance:


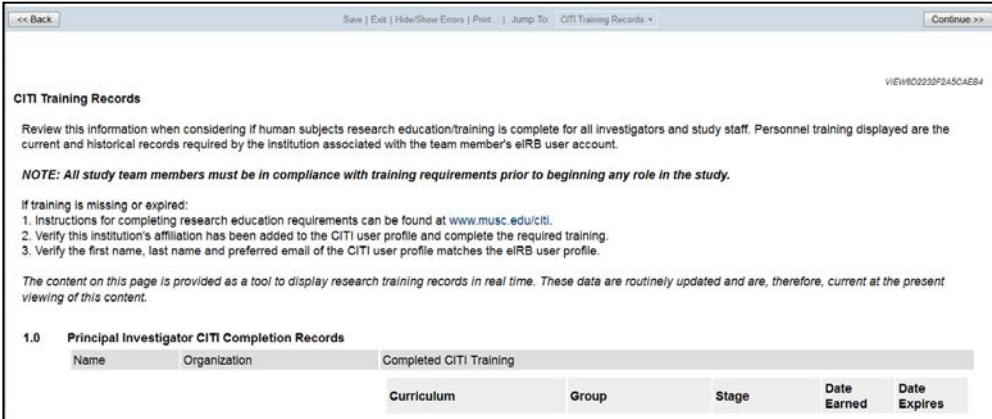
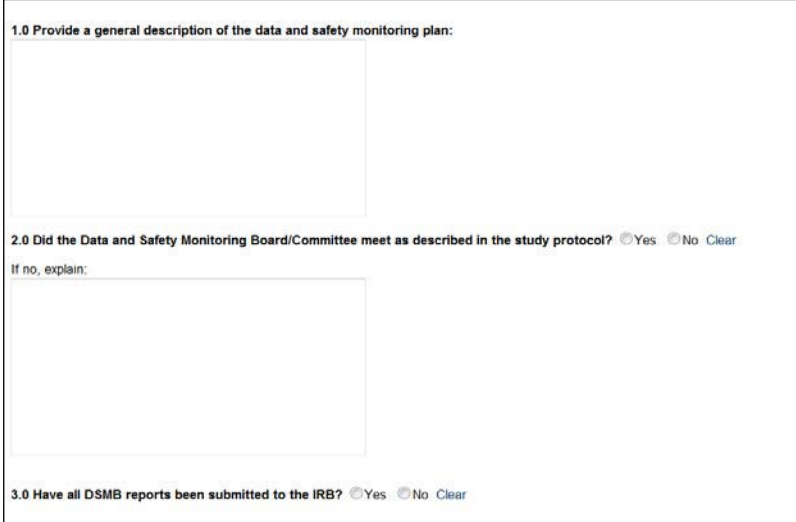
Explain:

Include transfer only when MUSC is no longer including the subject's information in MUSC's research reporting

Include investigator withdrew subject only if the subject was removed from the study by the Principal Investigator

If the treatment intolerance involved a reportable adverse event, ensure that it has been submitted to IRB

	<p>4.0 * Withdrew voluntarily: <input type="text"/> Explain:</p> <p>5.0 * Lost to follow-up: <input type="text"/> Explain:</p> <p>6.0 * Other Reasons for Subject Withdrawal: <input type="text"/> Explain:</p> <p>Include withdrew voluntarily only if the subject withdrew themselves from study participation.</p> <p>Include lost to follow-up only if the subject has also been withdrawn from the study with no additional attempts for re-contact for study data</p> <p>Indicate any other reasons that a subject withdrew from the study if the other categories do not apply.</p> <p>&lt;&lt; Back Save   Exit   Hide/Show Errors   Print...   Jump To: Withdrawals - Reason and Number v3 *</p>
<p>Indicate whether there have been any unanticipated problems or adverse events.</p> <p>Click Continue.</p>	
<p>If there have been any unanticipated problems or adverse events, include descriptions as requested.</p> <p>Click Continue.</p>	
<p>Indicate research findings results, pertinent literature, amendments, audits, and current training of research staff.</p> <p>Click Continue.</p>	

<p>Upload any new information or results published since the last review.</p> <p>Click Continue.</p>	
<p>CITI Training Records</p> <p>Review this information to verify that human subjects research education/training is current for all study staff.</p> <p>If training is missing or expired, review page instructions to troubleshoot missing data. Details are also available as a CITI resource in the <a href="#">Education &amp; Training</a> section of eIRB.</p>	
<p>If the study includes a Data Safety Monitoring Board (DSMB), respond to questions about DSMB meetings and reports.</p>	

If this is a study that received MUSC Facilitated IRB Review, provide the central IRB information and documents.

*\*\*Note: This form will only appear if the study was approved via a facilitated review. \*\**

If the study involves the VA Medical Center:

- upload the signed statement, attesting that all research subjects on a master enrollment log who signed consent did so prior to undergoing study activities **OR**
- if the research doesn't require this statement, include such justification.

Also, access the 'VA Addendum to MUSC IRB Continuing Review Application' form from MUSC's [forms](#) website.

Review the current Conflict of Interest information reported for the study and indicate whether the disclosure statement is correct.

*\*\*Note: The COI information is read-only. If it has changed, you must submit an amendment request to revise the disclosure. \*\**

Add additional comments and upload any other relevant documents not included elsewhere.

Click Continue.

A summary of the continuing review will display.

*\*\*Note: if the consent, protocol document or Conflict of Interest information has changed, it is necessary to submit an [Amendment](#) as a separate request\*\**

Click 'Finish'.

*\*\*Note: This action does not send the report to IRB. Only the PI is able to submit the continuing review to IRB.\*\**

The continuing review is now in the Pre Submission state, as it has not yet been sent to IRB.

It is able to be edited, withdrawn or viewed as a printable version. The PI will also have the option to submit the continuing review.

See instructions in the [Submitting a Continuing Review](#) section of this document.



The continuing review will also appear under the 'Continuing Review' tab on the protocol's main page.

The screenshot displays the 'eResearch Portal' for Health Sciences South Carolina. The main content area shows details for 'Study: IRB II Full Board (Pro00005017)'. The 'Continuing Reviews' tab is highlighted with a red circle. Below the tabs, a table lists the continuing reviews.

ID	Name	Status	Last State Change
CR00001058	Review for Pro00005017	Pre Submission	1/25/2010 3:25 PM

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## Completing the continuing review (Expedited Category 5 Retrospective Studies)

Indicate whether changes are required to consent or protocol.

***\*\*Note: If changes are required, these must be submitted to IRB via an amendment request. \*\****

If previous amendments have been IRB approved, include a summary of these changes.

Click Continue.

### Changes Required – Retrospective Review – Part 1

1.0 Are changes required to the currently approved waiver of consent?  
☒ Yes ☐ No [Clear](#)

2.0 Are changes required to the currently approved protocol document?  
☐ Yes ☐ No [Clear](#)

3.0 Describe and/or upload a summary of changes approved by the IRB since last review:

Responses to all questions (as applicable) must be included for MUSC IRB review.

[Add](#)

Name	Version	Orig. Author	Orig. Created	Last Modified
There are no items to display				

### Changes Required - Retrospective Review - Part 2

4.0 Have there been any complaints about the research?  
☒ Yes ☐ No [Clear](#)

If YES, describe:

5.0 Have there been any interim findings since the last annual review?  
☐ Yes ☐ No [Clear](#)

If YES, describe:

6.0 Have there been any relevant multi-center trial reports?  
☐ Yes ☐ No [Clear](#)

If YES, describe:

Enter in the number of records currently reviewed for the study.

***\*\*Note: The study value pulls over from what is reported on the study application. \*\****

### Records Reviewed

1.0 Enter the number of records reviewed:

Study Value:

150

Responses to all questions must be included for MUSC IRB review.

## Unanticipated Problems and-or Adverse Events

Indicate whether there have been any unanticipated problems or adverse events.

**\*\*Note: A *yes* answer will generate the smart form below where a description of the unanticipated event can be provided. \*\***

Click Continue.

### Unanticipated Problems and-or Adverse Events

1.0 \* Have there been any unanticipated problems and/or adverse events since the last review?  
☐ Yes ☐ No [Clear](#)

## Unanticipated Problems- Retrospective Review Studies

If there have been any unanticipated problems or adverse events, include descriptions as requested.

Click Continue.

### Unanticipated Problems – Retrospective Review Studies

1.0 \* Indicate numbers and include an explanation of any unanticipated problems, and/or complaints since the last review.

2.0 \* Has the risk/benefit ratio changed since the last review?  
☐ Yes ☐ No [Clear](#)

If YES, explain:

3.0 \* To date, have all occurring unanticipated problems been reported to the IRB?  
☐ Yes ☐ No [Clear](#)

## CITI Training Records

Review this information to verify that human subjects research education/training is current for all study staff.

If training is missing or expired, review page instructions to troubleshoot missing data. Details are also available as a CITI resource in the [Education & Training](#) section of eIRB.

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: CITI Training Records ▾

Continue >>

VIEW802232F245C4EB4

CITI Training Records

Review this information when considering if human subjects research education/training is complete for all investigators and study staff. Personnel training displayed are the current and historical records required by the institution associated with the team member's eIRB user account.

NOTE: All study team members must be in compliance with training requirements prior to beginning any role in the study.

If training is missing or expired:  
1. Instructions for completing research education requirements can be found at [www.musc.edu/citi](http://www.musc.edu/citi).  
2. Verify this institution's affiliation has been added to the CITI user profile and complete the required training.  
3. Verify the first name, last name and preferred email of the CITI user profile matches the eIRB user profile.

The content on this page is provided as a tool to display research training records in real time. These data are routinely updated and are, therefore, current at the present viewing of this content.

1.0 Principal Investigator CITI Completion Records

Name	Organization	Completed CITI Training					
		Curriculum	Group	Stage	Date Earned	Date Expires	

Add additional comments and upload any other relevant documents not included elsewhere.

Click Continue.

A summary of the continuing review will display.

***\*\*Note: if the consent waiver, protocol document or conflicts of interest has changed, it is necessary to submit an Amendment as a separate request\*\****

Click 'Finish'.

***\*\*Note: This action does not send the report to IRB. Only the PI is able to submit the continuing review to IRB. \*\****

The continuing review is now in the Pre Submission state, as it has not yet been sent to IRB.

It is able to be edited, withdrawn or viewed as a printable version. The PI will also have the option to submit the continuing review.

See instructions in the [Submitting a Continuing Review](#) section of this document.

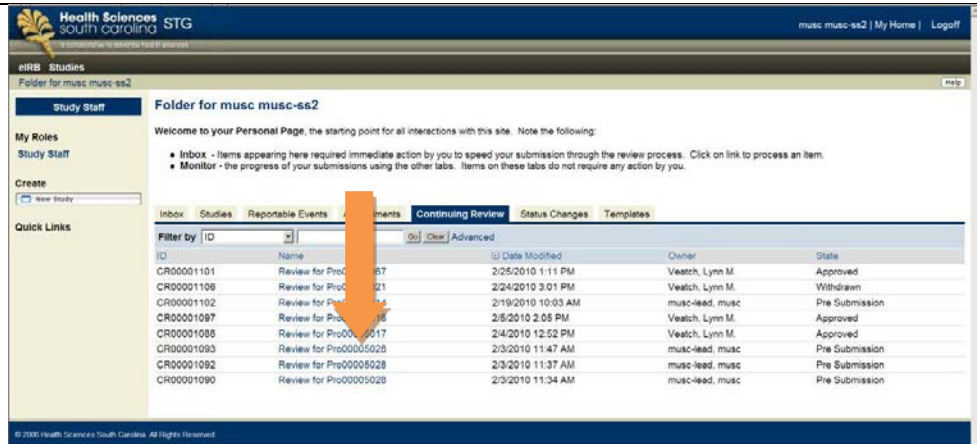
The continuing review will also appear under the 'Continuing Review' tab on the protocol's main page.

## Withdrawing a Continuing Review

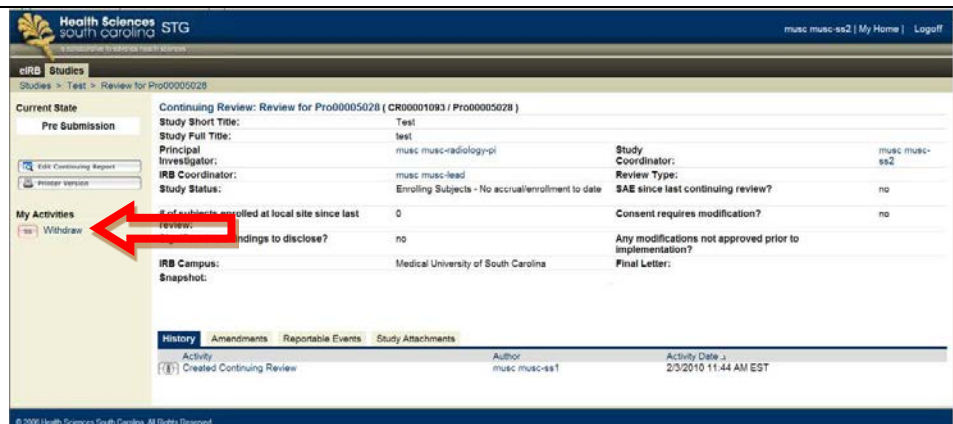
When continuing reviews are entered into the system, they can be withdrawn if have not yet been sent to IRB or IRB approved.

**\*\*Note: withdrawn continuing reviews CANNOT be restored to an editable state in the system\*\***

From your Home Page, select the 'Continuing Review' tab and locate the study name.

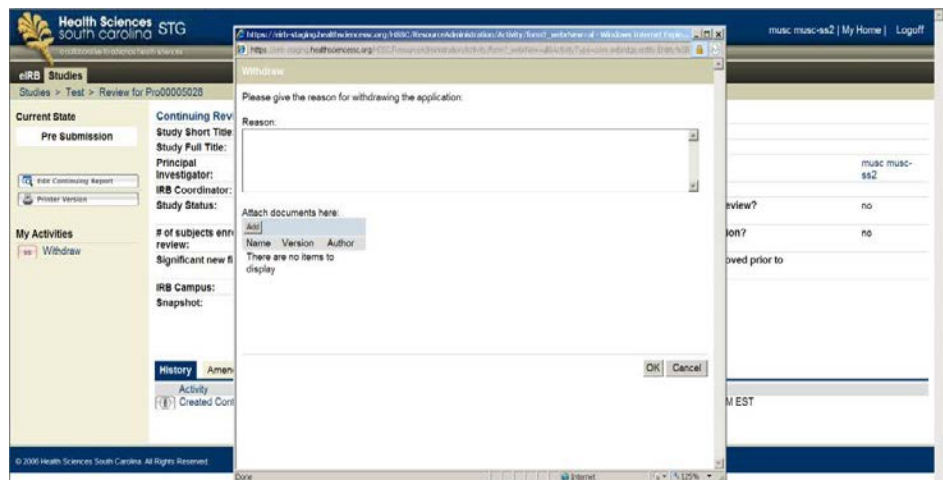


Select 'Withdraw' under 'My Activities'



In the pop-up window, enter in a reason and attach any relevant documents (*this is optional*).

Click 'Ok'



The state of the amendment is now 'Withdrawn'.

The system has stored the study. To see a copy of the amendment, select 'View Continuing Review'

You will not be able to restore the status of the continuing review from withdrawn.

The screenshot displays the eIRB interface for Health Sciences South Carolina. The top navigation bar includes the logo and user information: "music-musc-ss2 | My Home | Logout". The main content area is titled "eIRB Studies" and shows a breadcrumb trail: "Studies > Test > Review for Pro00005028". A red box highlights the "Current State" dropdown menu, which is set to "Withdrawn". Below this, there are buttons for "View Continuing Review" and "Print Version". The "My Activities" section is on the left. The main form displays details for the "Continuing Review: Review for Pro00005028 (CR00001093 / Pro00005028)". Fields include: Study Short Title (Test), Study Full Title (Test), Principal Investigator (music-musc-radiology-pi), IRB Coordinator (music-musc-lead), Study Status (Enrolling Subjects - No accrual/enrollment to date), # of subjects enrolled at local site since last review (0), Significant new findings to disclose? (no), IRB Campus (Medical University of South Carolina), and Snapshot. A table at the bottom shows the history of activities: "Withdraw" by music-musc-ss2 on 3/3/2010 12:29 PM EST, and "Created Continuing Review" by music-musc-ss1 on 2/3/2010 11:44 AM EST. The footer states "© 2006 Health Sciences South Carolina. All Rights Reserved".

Activity	Author	Activity Date
Withdraw	music-musc-ss2	3/3/2010 12:29 PM EST
Created Continuing Review	music-musc-ss1	2/3/2010 11:44 AM EST

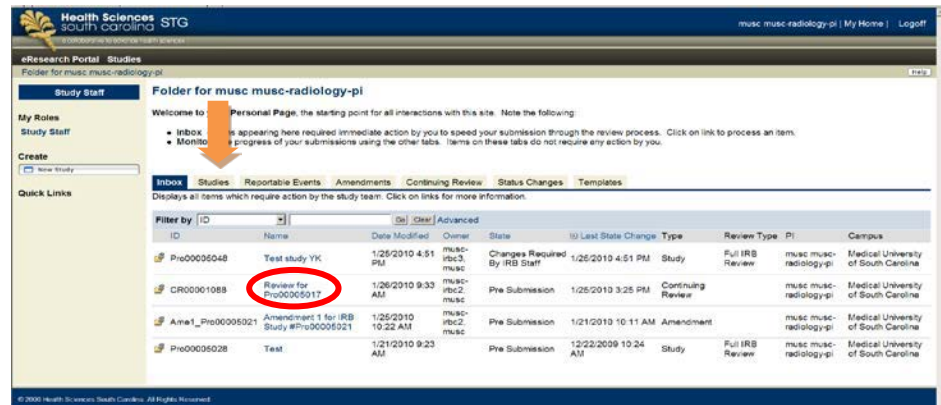


## Submission to IRB

***\*\*Only the PI can send the continuing review to IRB\*\****

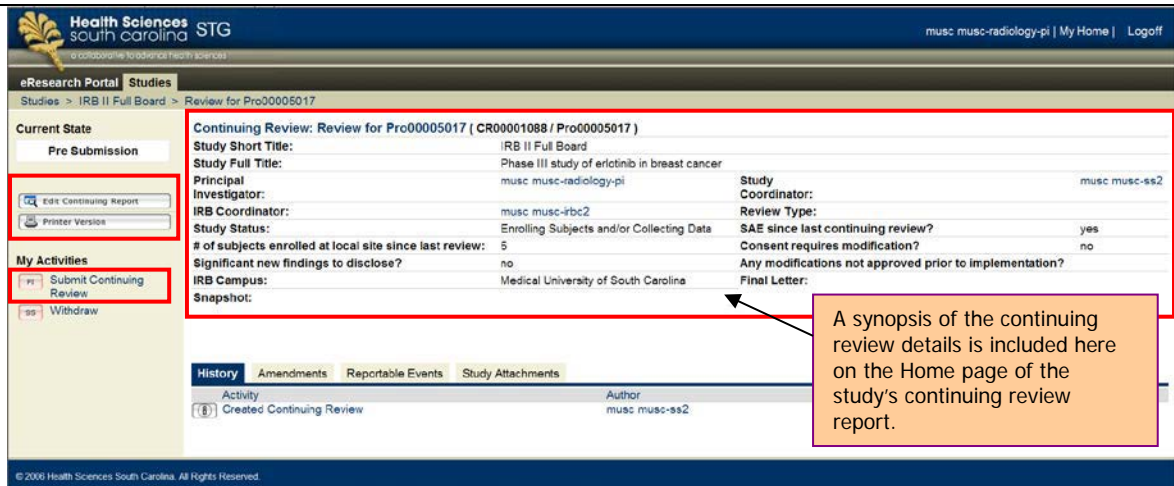
Log into eIRB (as applicable) and select the study from your eIRB Inbox on your Home page. If the continuing review has already been started, it will appear in your 'Inbox'.

You can also select the 'Continuing Review' tab and locate the study.



Options to edit, view or send the continuing review report are available.

- To *view* the continuing review, select the 'Printer Version' button in the left column.
- To *edit* the continuing review, select 'Edit Continuing Report' in the left column. Follow the applicable steps above to edit the report.
- To *send* the continuing review to IRB, select 'Submit Continuing Review' under 'My Activities' in the left column. ***\*\*Only the PI will see this activity and can send the continuing review to IRB\*\****



Click 'Ok' if you are ready to send in the continuing review.

After submitting the continuing review, the current state changes to 'IRB Staff Review' and the available options for the continuing review are viewing the report.

*\*\*Note: You are not able to edit the report after it's submitted to IRB, unless there are changes request by the IRB. \*\**

Activity	Author	Activity Date
Continuing Review Submitted	music music-radiology-pi	1/28/2010 9:51 AM EST
Created Continuing Review	music music-ss2	1/25/2010 3:25 PM EST

Designated personnel will receive an e-mail when the continuing review has been reviewed by IRB.

## Responding to IRB Comments

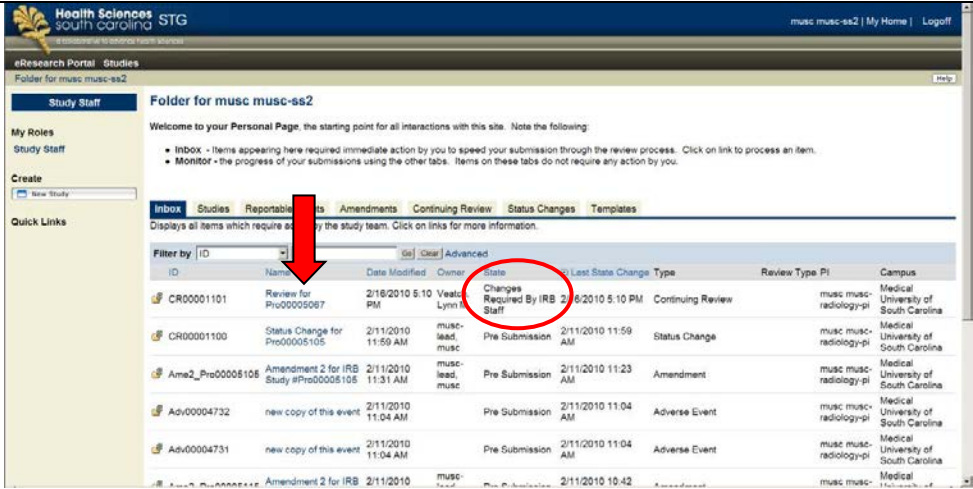
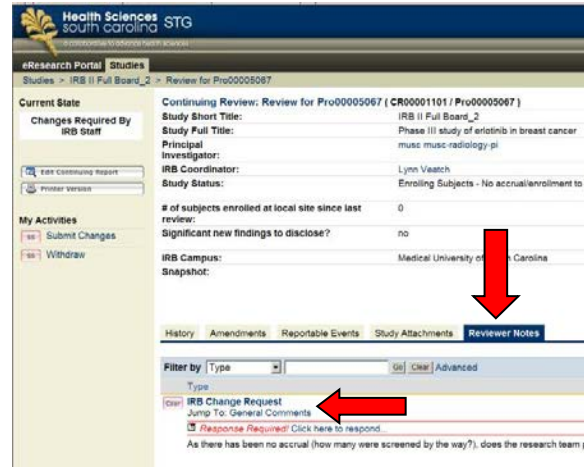
For additional assistance, view the recorded demonstration 'Responding to IRB Reviewer Comments' in the [eIRB Education & Training](#) section.

Designated personnel (e.g., eIRB communication coordinator) will receive an e-mail indicating that changes are request by IRB.

**\*\*Note: study staff can make and submit these changes to IRB\*\***

Responding to comments is a 2-step process.

1. The changes must first be made within the study application; and
2. The changes must be documented as completed, not completed or for information only and include a summary of the responses.

<p>Log into the system.</p> <p>From your Home page, the study will appear in your eIRB 'Inbox'.</p> <p>Click on the study 'Name'</p> <p><b>**Note: notice that the state of the study has changed to 'Changes Required by IRB Staff'**</b></p>	 <p>The screenshot shows the 'Inbox' tab selected. A table lists studies with columns: ID, Name, Date Modified, Owner, State, Last State Change, Type, Review Type PI, and Campus. The study CR00001101 is highlighted with a red circle around its 'State' column, which reads 'Changes Required by IRB Staff'.</p>
<p>The 'History' tab logs the change request. It will also include additional notes or clarification requested by IRB. However, your changes will not be made from this location.</p> <p>Instead, click on either 'Edit Continuing Report' or the 'Reviewer Notes' tab to access the comments &amp; begin responding.</p>	 <p>The screenshot shows the 'Reviewer Notes' tab for study CR00001101. A red arrow points to a link that says 'Response Required! Click here to respond.' Below this, there is a text area for the response.</p> <div data-bbox="1055 1287 1461 1669" style="border: 1px solid orange; padding: 5px;"> <p>On the Reviewer Notes tab, all comments will appear and the change request references the sections to change within the application. <b>To begin responding to the comments</b>, click on hyperlinked smartform name next to the 'Jump To:' text.</p> <p><b>**Note: DO NOT select the 'Click here to respond' link at this point, as this will be done later as the second step in the process**</b></p> </div>

Step 1: View the comment and make changes directly to the application.

*\*\*Note: If previously submitted documents are required to be revised & uploaded, select 'Upload Revision' next to the document's name & locate the file from your computer. DO NOT use the 'Add' or 'Delete' button unless this is the first time that document is included.*

*Comments may request uploading of documents when there is no upload feature on a particular smartform page. In that case, documents can be uploaded in the 'General Comments' section of the application.*

Save the information entered in on that page

Health Sciences south carolina STG Edit: Continuing Review - CR00001101

Back | Exit | Home/Show Errors/Print | Jump To: General Comments | Continue >>

Reviewer Note

Filter by Type [Type] [Go] [Clear] [Advanced]

Type

IRB Change Request

Response Required! Click here to respond...

Reviewer: Lynn Veatch 2/16/2010 5:10 PM

As there has been no accrual (how many were screened by the way?), does the research team plan any change in recruitment strategy?

General Comments

1.0 Add any additional comments to assist in the review

2.0 Add any miscellaneous documents that do not fit in other sections of the study application

Click Add to upload document(s)

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

Back | Exit | Home/Show Errors/Print | Jump To: General Comments | Continue >>

Add	Name	Modified	Version
Upload Revision	Sample Consent Form - Optional Study   History	10/27/2008 8:55 PM	0.01
Upload Revision	Sample Consent Form - Treatment   History	10/27/2008 8:54 PM	0.01
			Delete

Step 2: Select 'Click here to respond' as the second step & to finalize the response for that comment only.

Health Sciences south carolina STG Edit: Continuing Review - CR00001101

Back | Exit | Home/Show Errors/Print | Jump To: General Comments | Continue >>

Reviewer Note

Filter by Type [Type] [Go] [Clear] [Advanced]

Type

IRB Change Request

Response Required! Click here to respond...

Reviewer: Lynn Veatch 2/16/2010 5:10 PM

As there has been no accrual (how many were screened by the way?), does the research team plan any change in recruitment strategy?

General Comments

1.0 Add any additional comments to assist in the review

2.0 Add any miscellaneous documents that do not fit in other sections of the study application

Click Add to upload document(s)

Name	Description	Orig. Author	Orig. Created	Last Modified
There are no items to display				

Back | Exit | Home/Show Errors/Print | Jump To: General Comments | Continue >>

Choose the appropriate 'Type' from the drop down and enter in a response (such as 'done', attached, 'responded', etc.).

Click 'Ok'.

*\*\*Note: There may be multiple comments within one IRB Change Request section. The system allows you to save a response even if all comments haven't been addressed. For study management purposes, this second step should be completed only if all comments are addressed OR you have written in notes to go back and respond to the remaining comments. \*\**

The system indicates a response to that comment by highlighting the change request section.

*\*\*Note: If there are any additional comments, a 'Next' or 'Previous' button will appear in the Reviewer Notes section on this page to navigate to the next comment for a response. \*\**

Click 'Save' & 'Exit' when you are done responding to all questions.

Click 'Submit Changes'

Summarize the changes in the pop-up box (*this is optional*).

Click 'Ok' to send response to IRB.

The screenshot shows the Health Sciences South Carolina eIRB system interface. On the left, a sidebar contains a 'My Activities' section with a 'Submit Changes' button highlighted by a red arrow. The main content area displays a 'Submit Changes' pop-up box. This box has a title bar, a 'Please summarize your changes in the box below:' section with a text area, an 'Attach documents here:' section with a table (Name, Version, Author) and an 'Add' button, and 'OK' and 'Cancel' buttons at the bottom. A red arrow points to the 'OK' button. The background shows the main eIRB interface with various tabs and a 'History' section.



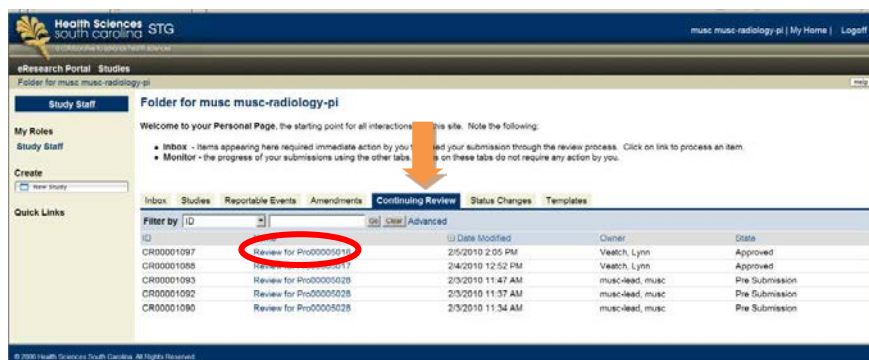
## Accessing IRB Review Letter

For additional assistance, view the recorded demonstration 'Accessing IRB Reviewed Documents' in the eIRB [Education & Training](#) section.

When the renewal is reviewed by IRB, an e-mail will be sent to the study's PI, coordinator & eIRB communication coordinator regarding the approval status.

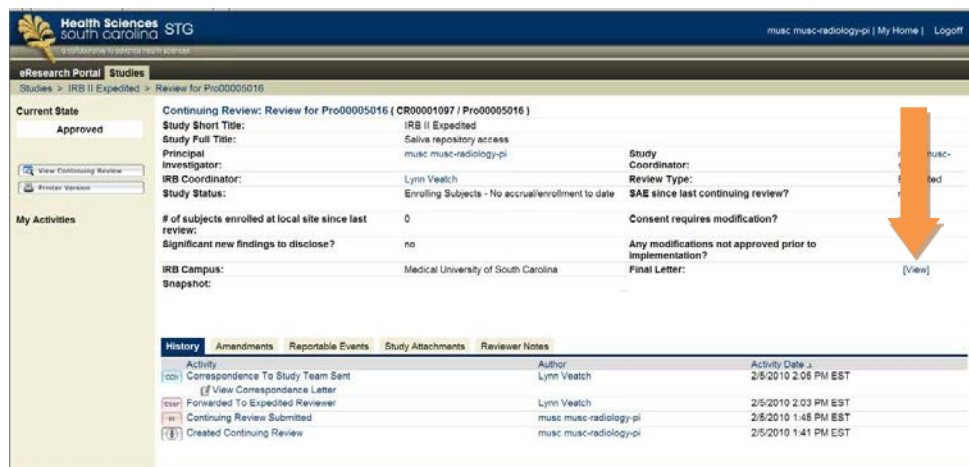
Log into eIRB (as applicable).

Select the 'Continuing Review' tab and click on the study name.



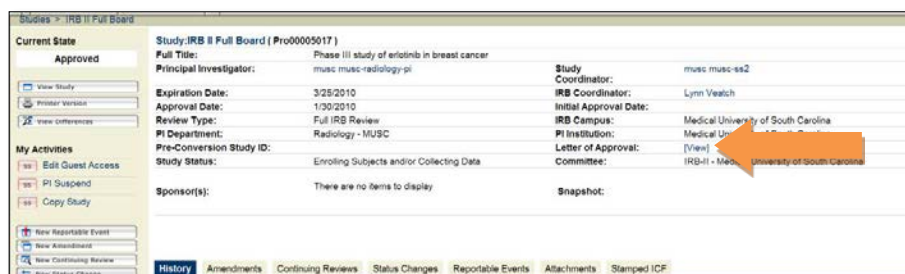
Select 'Final Letter' View.

Open or save the document as instructed.



If the continuing review is the most recent study approval, you can also view the letter on the study's main page in the Letter of Approval section.

**\*\*Note: the review letter on the study's main page updates with each continuing review, to reflect the most recent approval\*\*.**



## [S.C. Research Studies Directory](http://www.SCresearch.org)

The S.C. Research Studies Directory ([www.SCresearch.org](http://www.SCresearch.org)) is a state-wide initiative to assist potential research volunteers and researchers with locating studies actively recruiting subjects. This directory is an online listing of currently enrolling research studies at the [eIRB Health Sciences South Carolina \(HSSC\) consortium institutions](#). Study information (PI name, study location, study title, lay (brief) summary, recruitment coordinator's contact information & associated keywords) will be populated online as entered into eIRB.

The option for study inclusion in this directory is automatic for IRB approved full board, expedited and facilitated review studies with active enrollment, unless researchers opt-out within eIRB.

Studies that are no longer eligible for online posting (i.e., are no longer IRB approved or are closed for enrollment) are automatically removed from registry upon IRB approval of the change.

### Posting Before Initial IRB Submission

The lay summary information to be displayed in the directory is taken from the wording entered in the 'Brief Study Summary' box located under 'Study Identification Information' Smartform.

***\*\*Note: Any changes to this language after it has been IRB approved can be changed via an IRB amendment.\*\****

Continue entering in study information according to review requirements.

**Study Identification Information**  
This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 \* **Full Title:**  
Enter the full study title

2.0 \* **Short Title:**  
Enter a short descriptive title for this study (65 characters maximum):

3.0 \* **Briefly describe the scientific or scholarly rationale:**  
(i.e. purpose of research)

4.0 \* **Brief Study Summary**  
Non-scientific description of the research study, using 3 to 10 sentences. Statements such as "see protocol" are not acceptable.  
**Note:** Text entered in the Brief Study Summary field will be used to describe your study at [www.SCresearch.org](http://www.SCresearch.org) if indicated later in the application.

5.0 \* **Is this a pilot study?**  
☐ Yes ☐ No

On the S.C. Research Studies Directory smartform the option to include the study on the directory is pre-populated.

***\*\*Note: if you DO NOT want your study included in this directory, you must remove the checkbox\*\****

SCresearch.org Directory

SCresearch.org is a web based research studies directory designed to promote research opportunities available within the HSSC Consortium. Use of this directory is appropriate for any research study currently recruiting human subjects. Specific information from this eIRB application will be used to populate the directory.

This study will automatically be included in the directory unless you un-check the box below.

☒ **INCLUDE** this study on the S.C. Research Directory website

Enter in the recruitment coordinator's name, phone & e-mail.

Select the 'Add' button to choose from a list of keywords to associate with the study.

*\*\*Note: the listing of other study information, such as PI and title, will be populated in the directory as entered into the applicable sections within the study application\*\**

**SCResearch.org Directory**  
Recruitment Contact and Keywords: The following information is required to populate SCResearch.org and can be edited at any time without requiring IRB review:

**1.0 Recruitment Coordinator:**  
Click the Select button and choose the person who should be contacted by potential volunteers.  
Select  
If name is not found, enter it here:

**2.0 \* Recruitment Coordinator Phone:**

**3.0 \* Recruitment Coordinator Email:**

**4.0 \* Keyword(s):**  
Click the Add button and select as many keywords that apply to this study.  
Add

Only the information entered in on this page can be revised for online posting later *without* requiring an IRB approval.

Review a preview of how the study will appear on [SCResearch.org](http://SCResearch.org).

Follow the instructions on this screen to make changes and finalize the study application.

**SCResearch.org Directory**  
Below is a preview of how your study will appear on SCResearch.org.

In addition to other study details (Study Title, PI Name, etc.), your Brief Study Summary will be displayed for public view. To change this language, Jump To the Study Identification Smartform page and edit the textbox Brief Study Summary. Once IRB approved, an amendment will be required to change this language as well as other study details (with the exception of the recruitment contact information and Keywords).

Click "Continue" if no edits are required.

**The Use of Acamprosate in Alcohol Dependent Individuals with Comorbid Anxiety and Depressive Disorders**

Date Added	Keywords	Institution
PRO Number Pro00011713	Psychiatry, Mental Health	Medical University of South Carolina
Researcher muso-surgery-pi muso	Summary This study is being conducted to see if the drug Campral® (also called acamprosate) is safe and effective in treating adults who are alcohol dependent and who are also experiencing anxiety disorder or depression. This study will be conducted at three sites across the country and will involve approximately 90 volunteers between the ages of 18-60.	Recruitment Contact Stephanie Gentlin 843-792-8300 success@musc.edu

## Posting After Initial IRB Submission

After your study has been sent to IRB, registry posting can be edited by accessing the 'Edit SC Research Studies Directory Posting' option on the protocol's main page.

*\*\*Note: Remove the check from the box to remove the study from online. Only the information in this section can be revised without IRB approval.\*\**

**Health Sciences south carolina**  
a collaborative to advance research

**eIRB Studies**  
Studies > Acamprosate in Alcohol

**Current State**  
Approved  
View Study  
Printer Version  
View Differences

**My Activities**  
Edit Guest Access  
PI Suspend  
Copy Study  
Edit Communication Leads  
Edit SC Research Studies Directory Posting

**Edit SC Research Studies Directory Posting**  
Post Study online in S.C. Research Studies Directory:  
☒ INCLUDE study in S.C. Research Studies Directory.

**Recruitment Coordinator:**  
Clare Tyson Select Clear  
if name is not found, enter it here:

**\* Recruitment Coordinator Phone:**  
843-792-1534

**\* Recruitment Coordinator Email:**  
tysonc@musc.edu

**\* Edit/Add Keyword(s):**  
Add  
Alcohol Remove  
Anxiety Remove  
Depression Remove  
Mental Health Remove  
Psychiatry Remove