eIRB

Electronic Institutional Review Board

Medical University of South Carolina

User Guide

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

HEALTH SCIENCES SOUTH CAROLINA
A Collaborative To Advance Health Sciences

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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

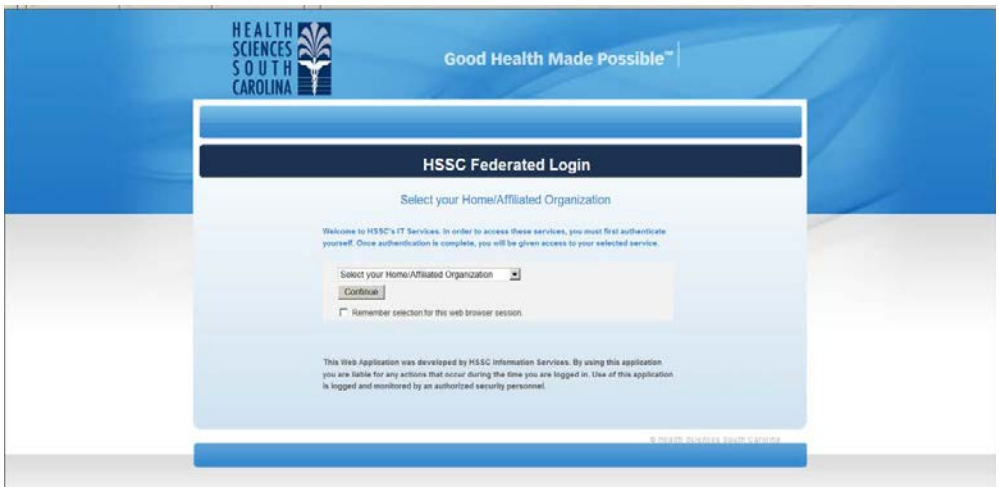
italicized NOTES and text boxes are designed to give you helpful hints as you use eIRB

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

GETTING STARTED

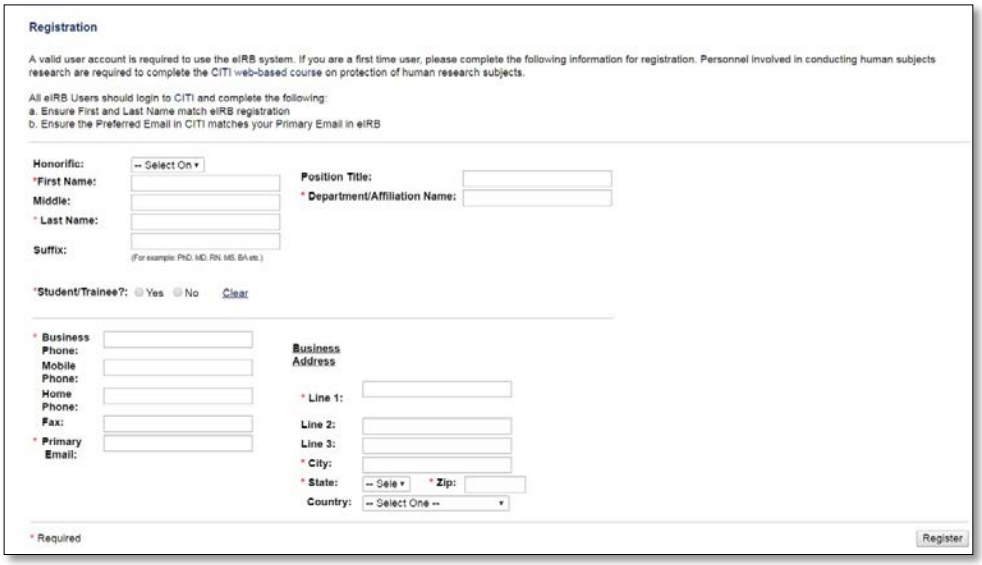
Logging in to eIRB

For additional assistance, view the recorded demonstration 'Getting Started' in the eIRB Education & Training section.

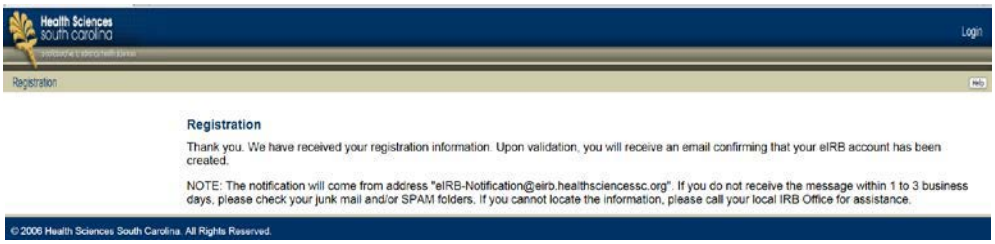
To begin utilizing the system, assess the internet site by clicking HERE. From the drop down list, select Medical University of South Carolina as your Organization. *If you are an External Affiliate member of MUSC (e.g., not an MUSC employee), select 'MUSC External Affiliate')* Click Continue.	
Enter 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.

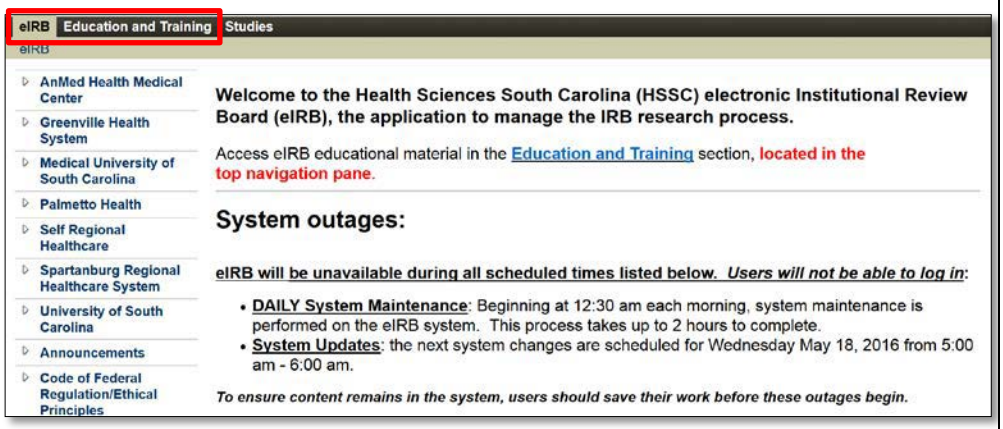


An e-mail will be sent to MUSC's eIRB administrator to activate your account, and you will receive an e-mail confirming that your registration is complete.



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.



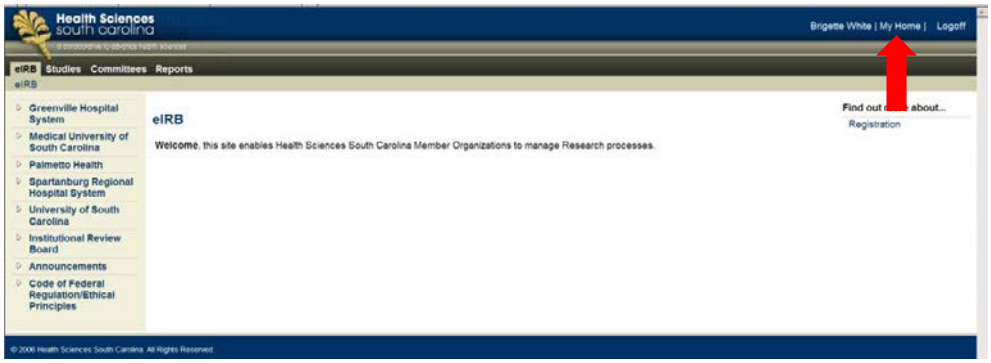
My Home

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.

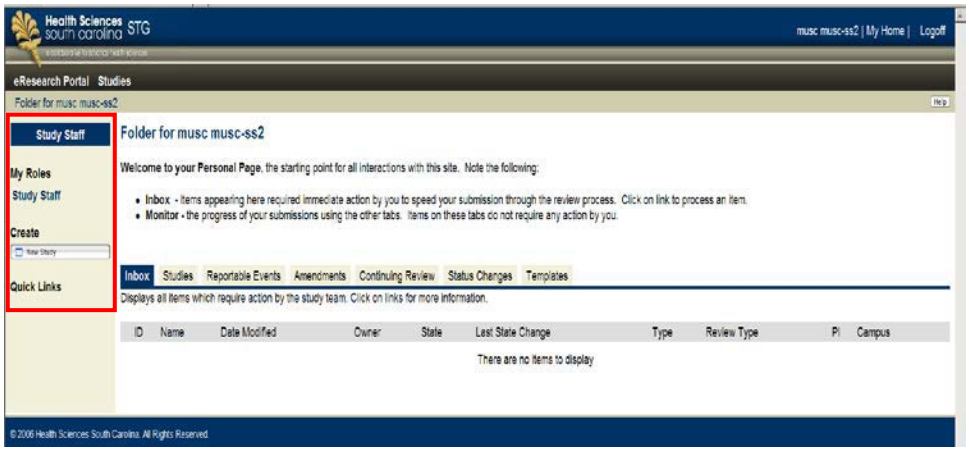
Select 'My Home' to view your personal workspace.



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.

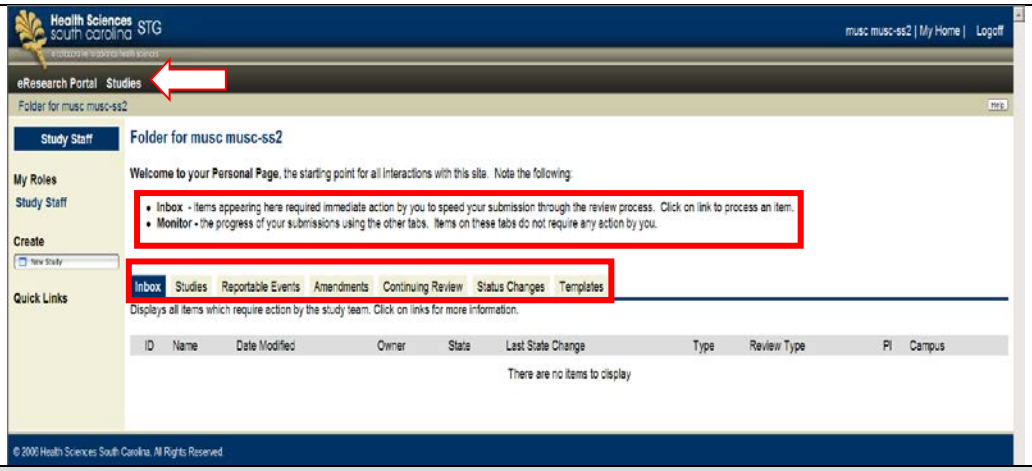
Note: click 'My Home' from any page to bring you back to your personal workspace to access studies and items that require action



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:

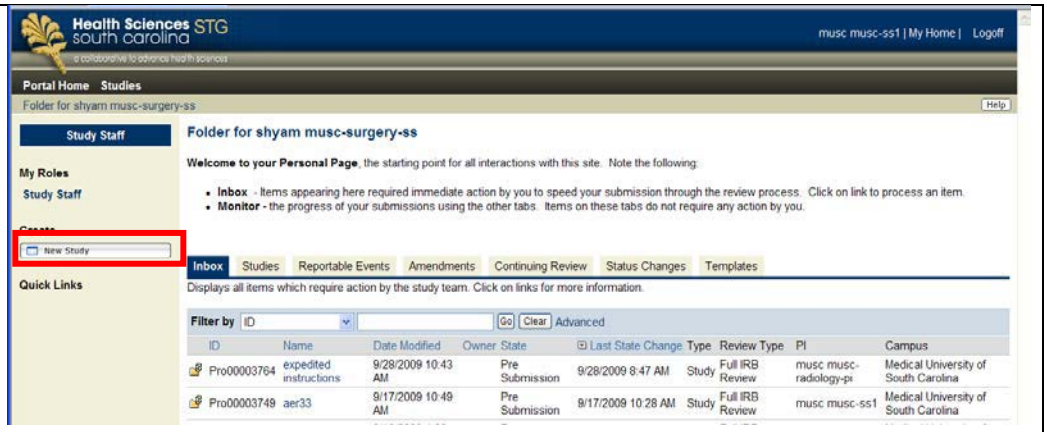
- The ‘Inbox’ tab contains activities that require some action on your part (for instance, new studies or amendments to finish that have not yet been submitted to IRB).
- The ‘Studies’ tab will show all studies of which you are associated. You can click on the ‘Name’ of a particular study to view the 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

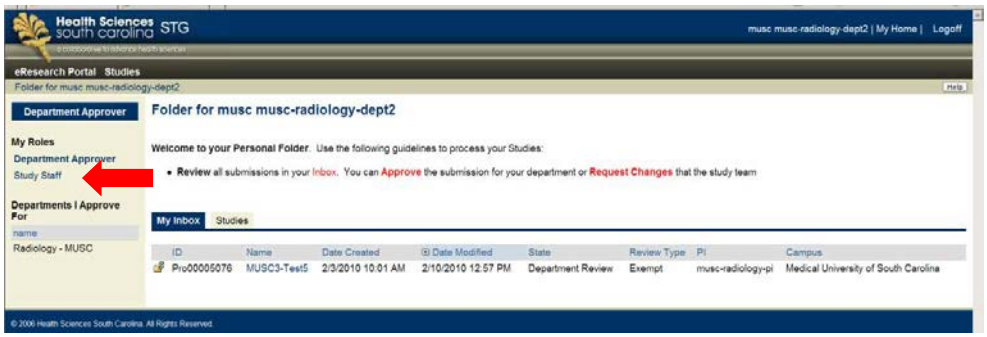
For additional assistance, view the recorded demonstration ''Created and Submitting New Studies' in the eIRB Education & Training section.

Beginning all application types

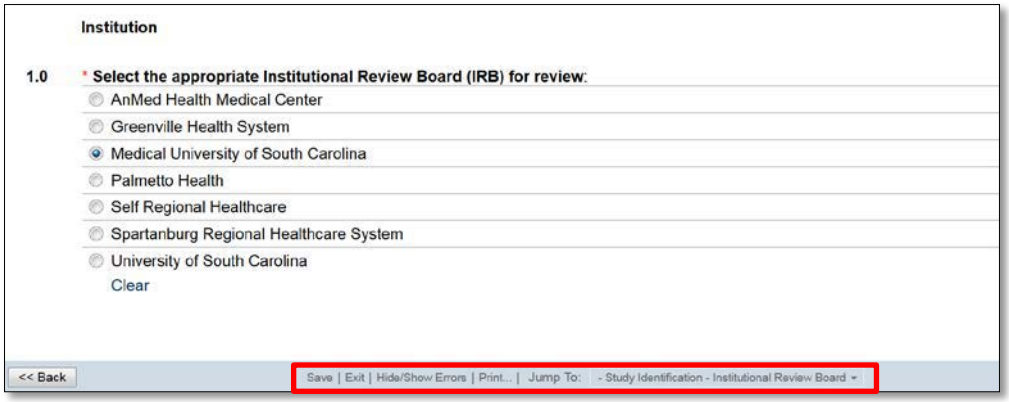
On your Personal Workspace screen, click New Study on the left Navigation column.

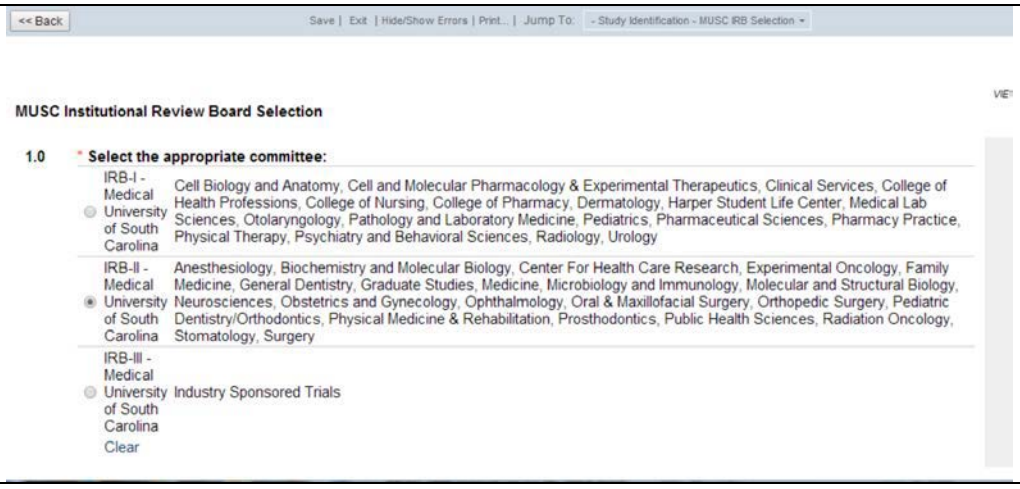


Note: If you don't see the option to create a new study, you may have multiple roles assigned in the system. If so, click on the 'Study Staff' role.



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***	
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***	

IRB Review Request	
Select whether study requests a different IRB Review process if it is a multi-site study. ***See SmartForm descriptions of these types of reviews.*** Only one type can be selected. If you select yes to any of these reviews, you will be routed to the appropriate SmartForm pages. **Click one of the links below to go to the section of this document that describes a review process on this page.* *Otherwise, continue within this section** Central Review Facilitated Review NCI CIRB Independent External Review	 IRB Review Request for Multi-site Studies The IRB of Record 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. If you are requesting one of these IRB reviews, indicate the type below. Otherwise, click Continue on this page. 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 IRB OF RECORD IS ANOTHER IRB Facilitated Review 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. All institutions allow this review in eIRB. * Is this a Facilitated Review (non-HSSC IRB, non-NCI CIRB, non-contracted IRB)? Yes No Clear Independent Review Model 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. The institutions that allow this review in eIRB are MUSC, GHS, PH, AnMed and Self Regional. * Is this an Independent Review (NCI CIRB)? Yes No Clear External IRB Review 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. The institutions that allow this review in eIRB are MUSC, GHS, SRHS, AnMed and Self Regional. * Is this an External IRB Review (e.g. WIRB, etc.)? Yes No Clear
Select the appropriate IRB Committee (IRB I, II or III). This selection of the appropriate board is the same as the current system. Click Continue.	 << Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Study Identification - MUSC IRB Selection - MUSC Institutional Review Board Selection 1.0 * Select the appropriate committee: IRB-I - Medical 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 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 University of South Carolina: Industry Sponsored Trials Clear

Adding Study Personnel

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

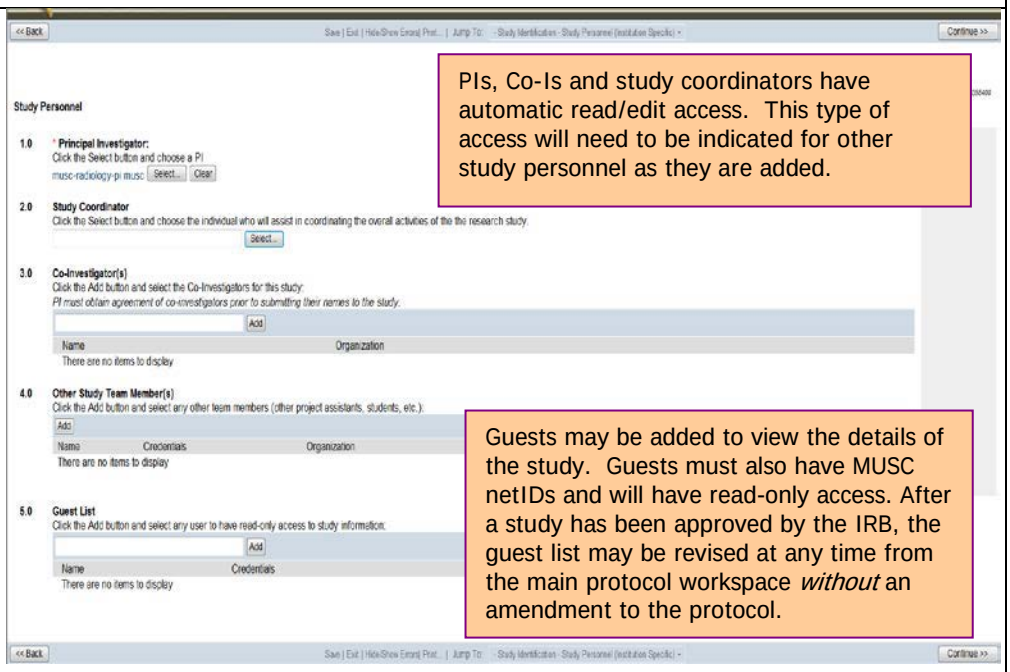
Click Continue.

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.*

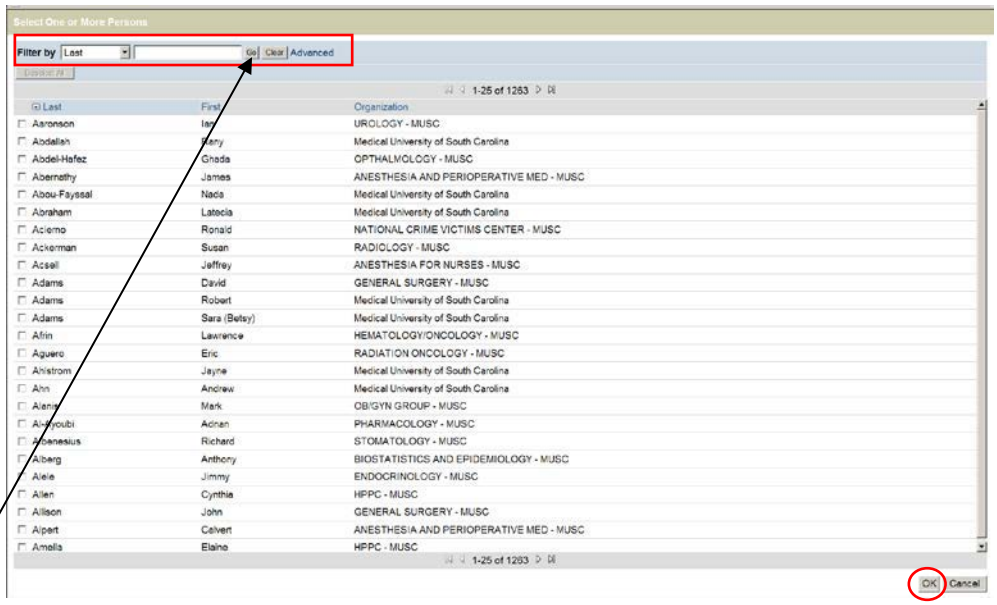
If you are changing your name from one personnel role to another, FIRST add your name to the new role and THEN delete yourself from the old role. This will let you to continue preparing the IRB application without being removed from the study.

*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.

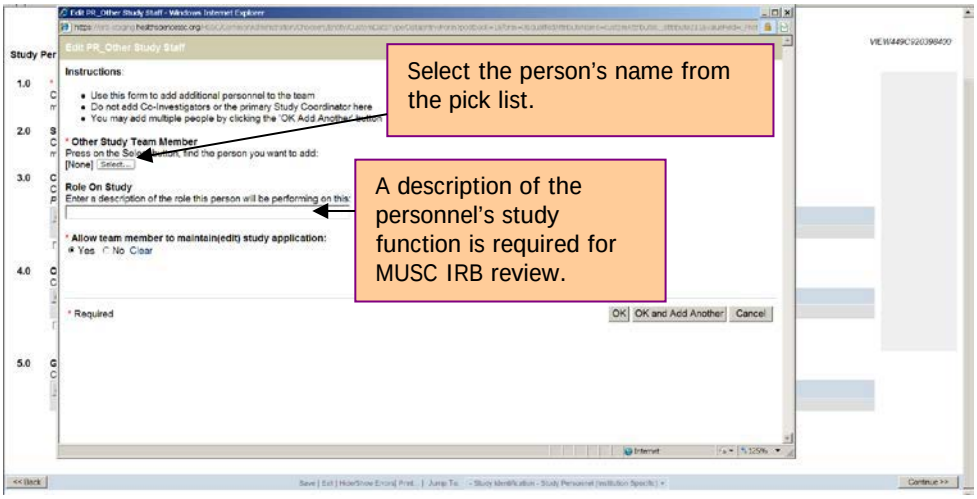
Click Ok when done adding all Co-Is.

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.

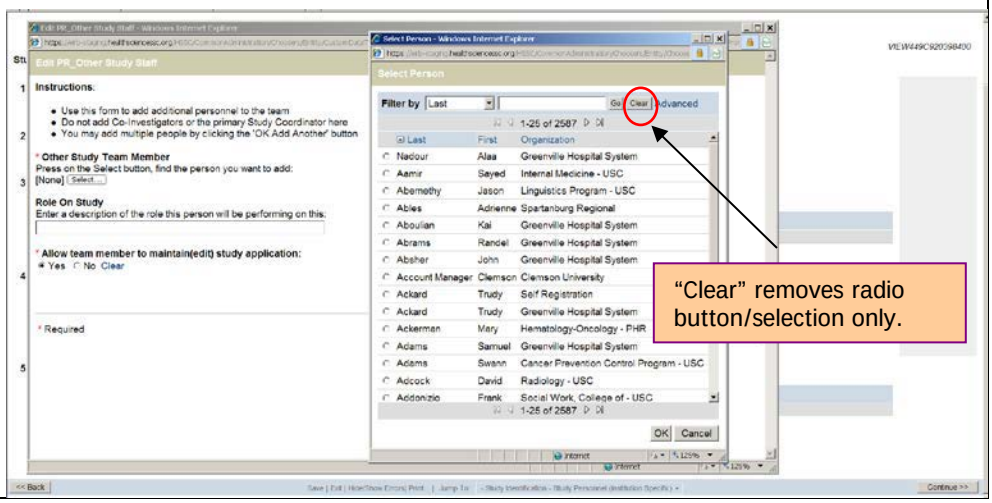


Other study team members must be added one at a time so that study roles can be identified.

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



***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.*

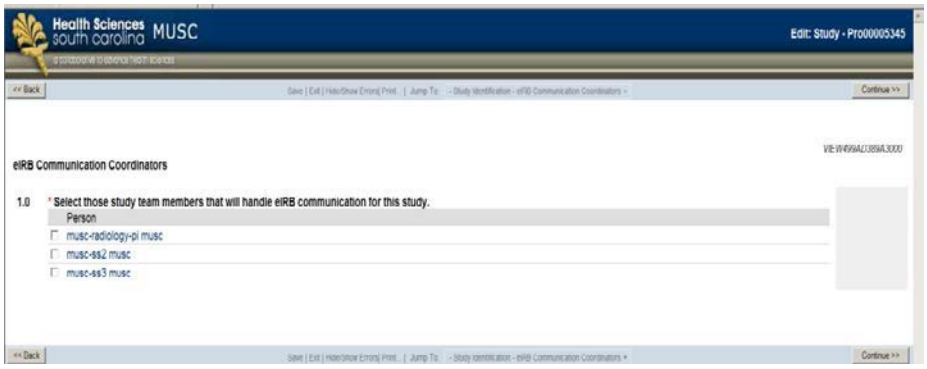


Indicate eIRB communication coordinator(s) for the study.

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.



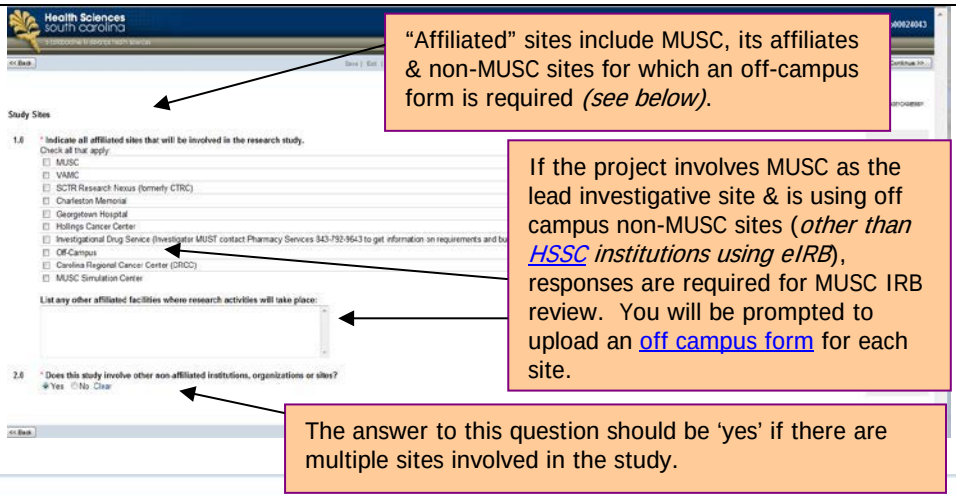
Study Locations

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.

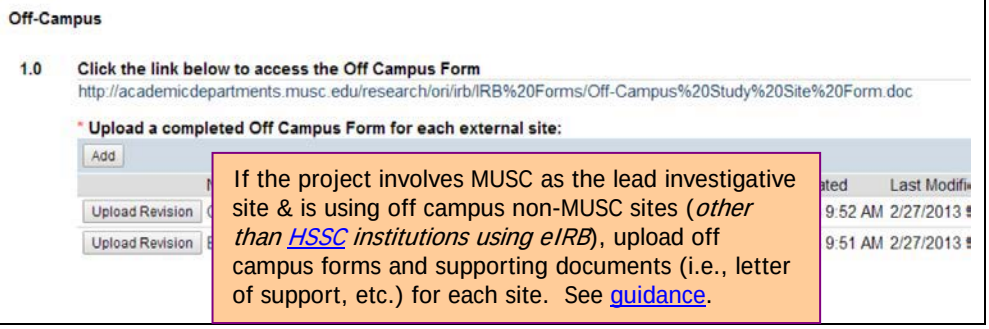
Note: if completing a Not Human Research Review application, click here to go to that section of this guide to finish completing the application



"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.



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.

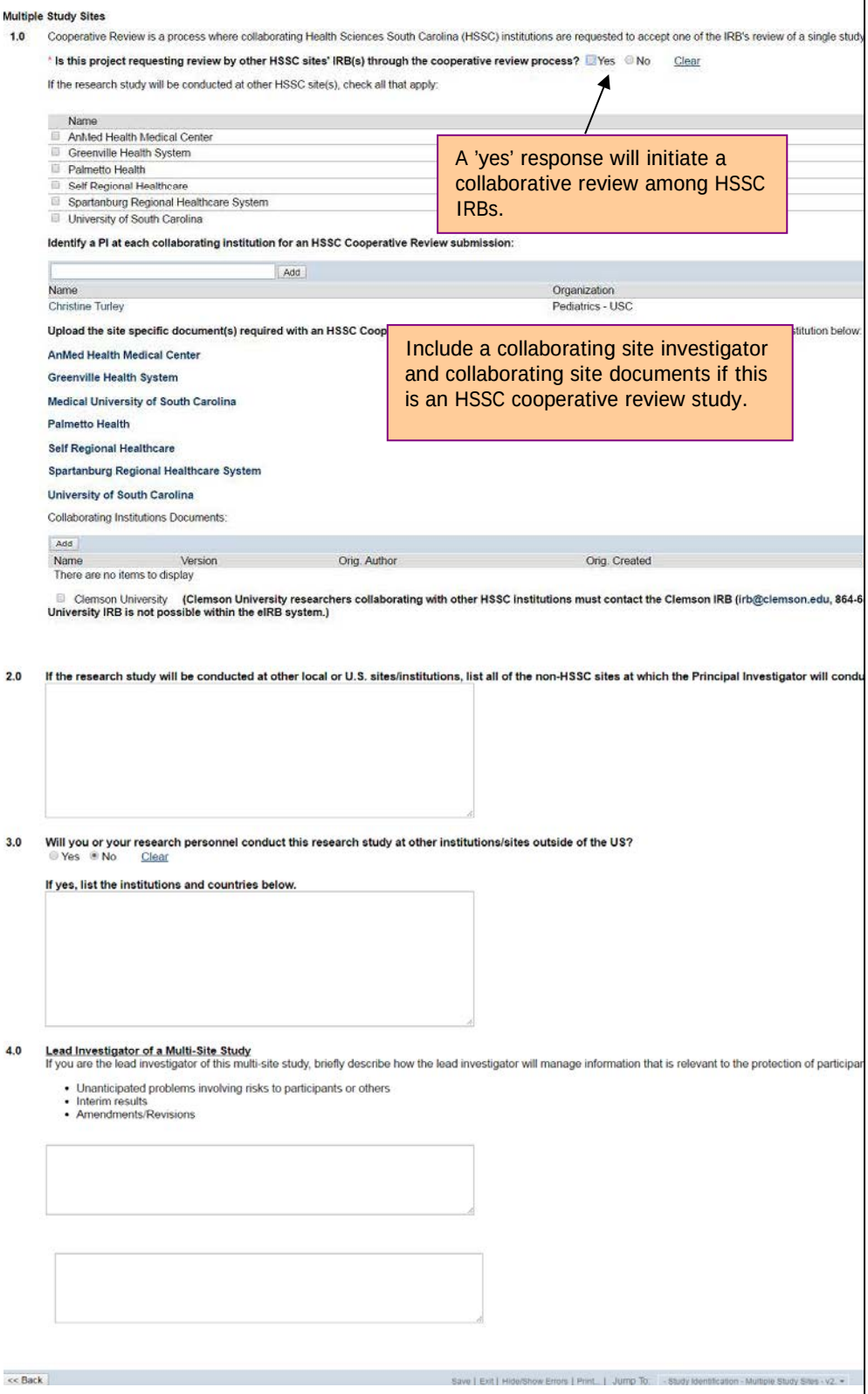
If multiple HSSC institutions are involved, include responses.

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.

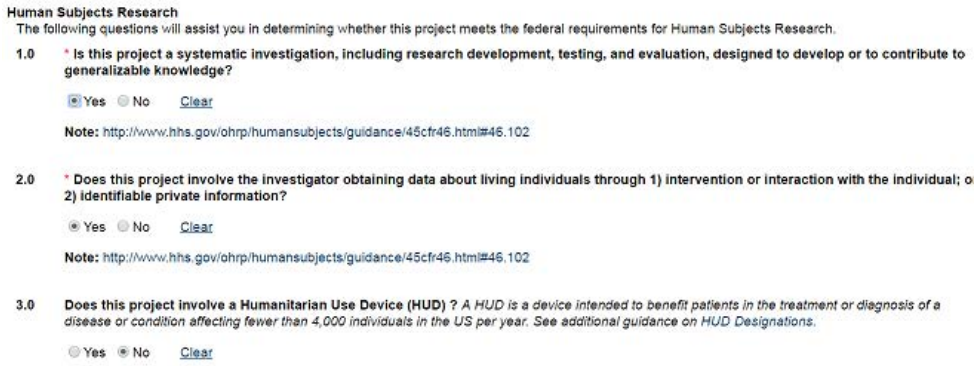


Human Research Requirements

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. P;ease contact your IRB for additional information and requirements for Humanitarian Use Device (HUD) submissions

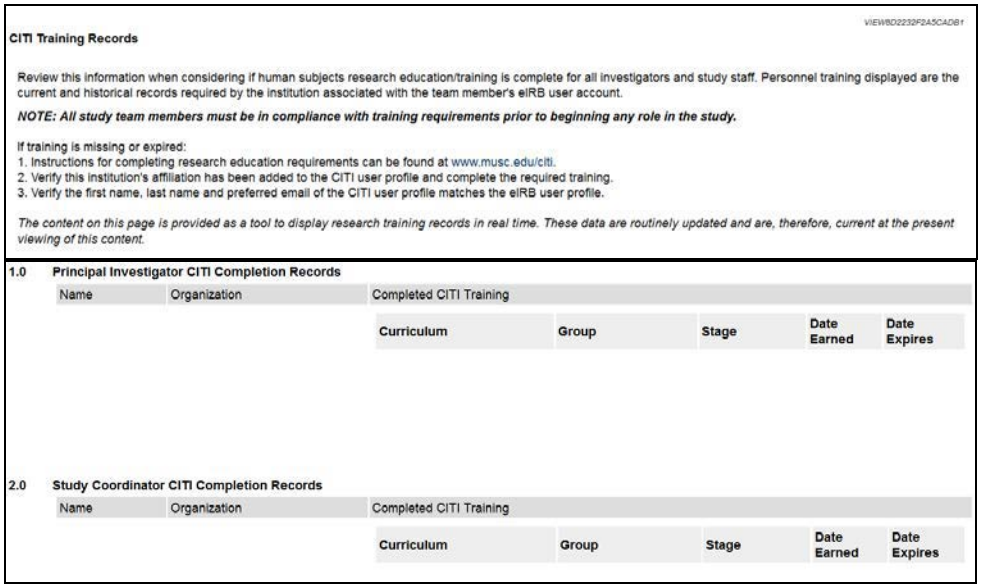


CITI Training Records

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.

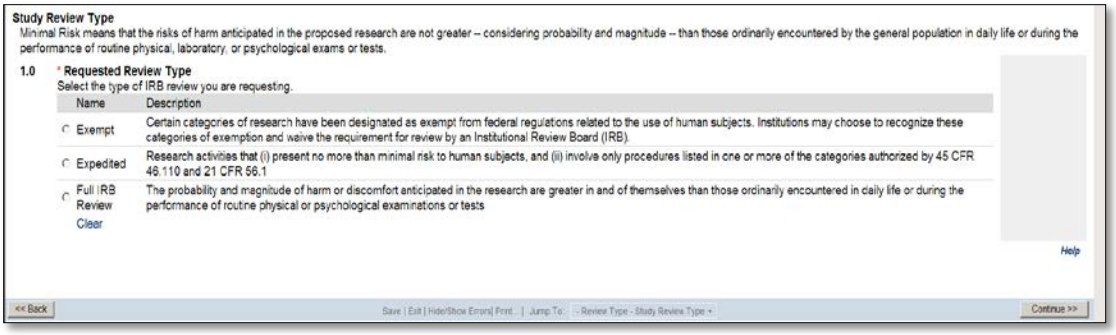
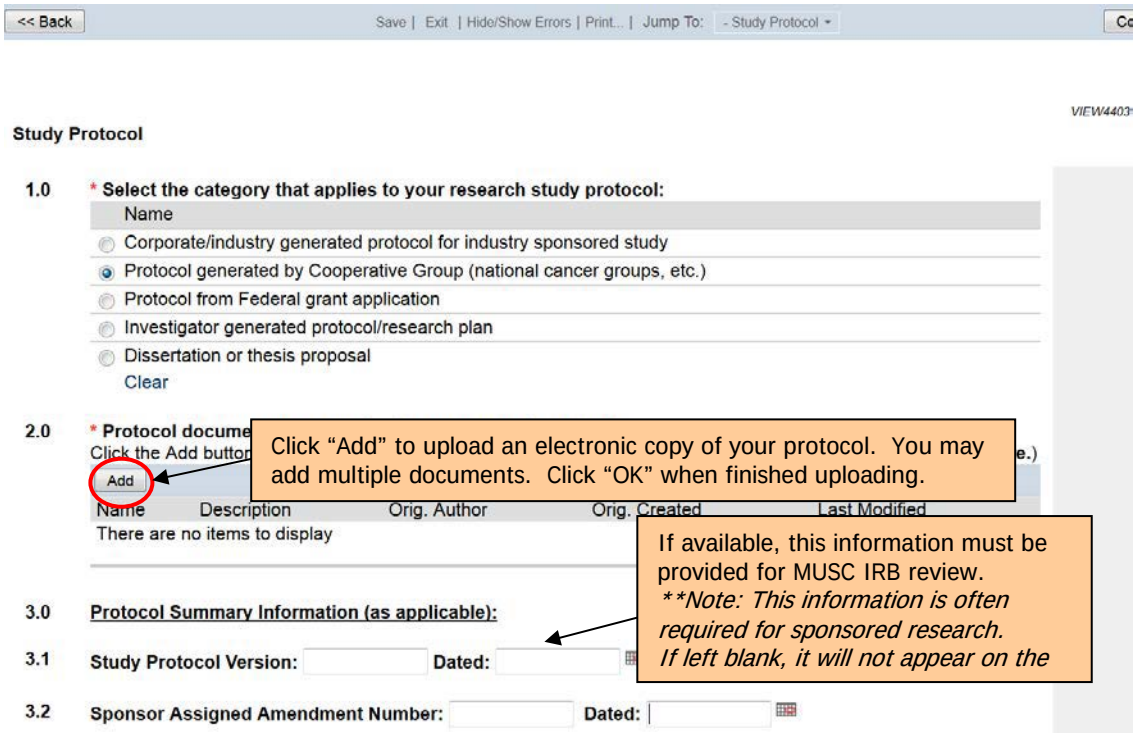


Click on the appropriate study review type below for guidance to finish completing the application:

- 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.

Indicate Study Review Type as "Full IRB Review". Click Continue.	
Protocol Information Enter Study Protocol Information. Click Continue. ***Note: a scientific protocol template is available at the IRB's website here***	

Study Subjects

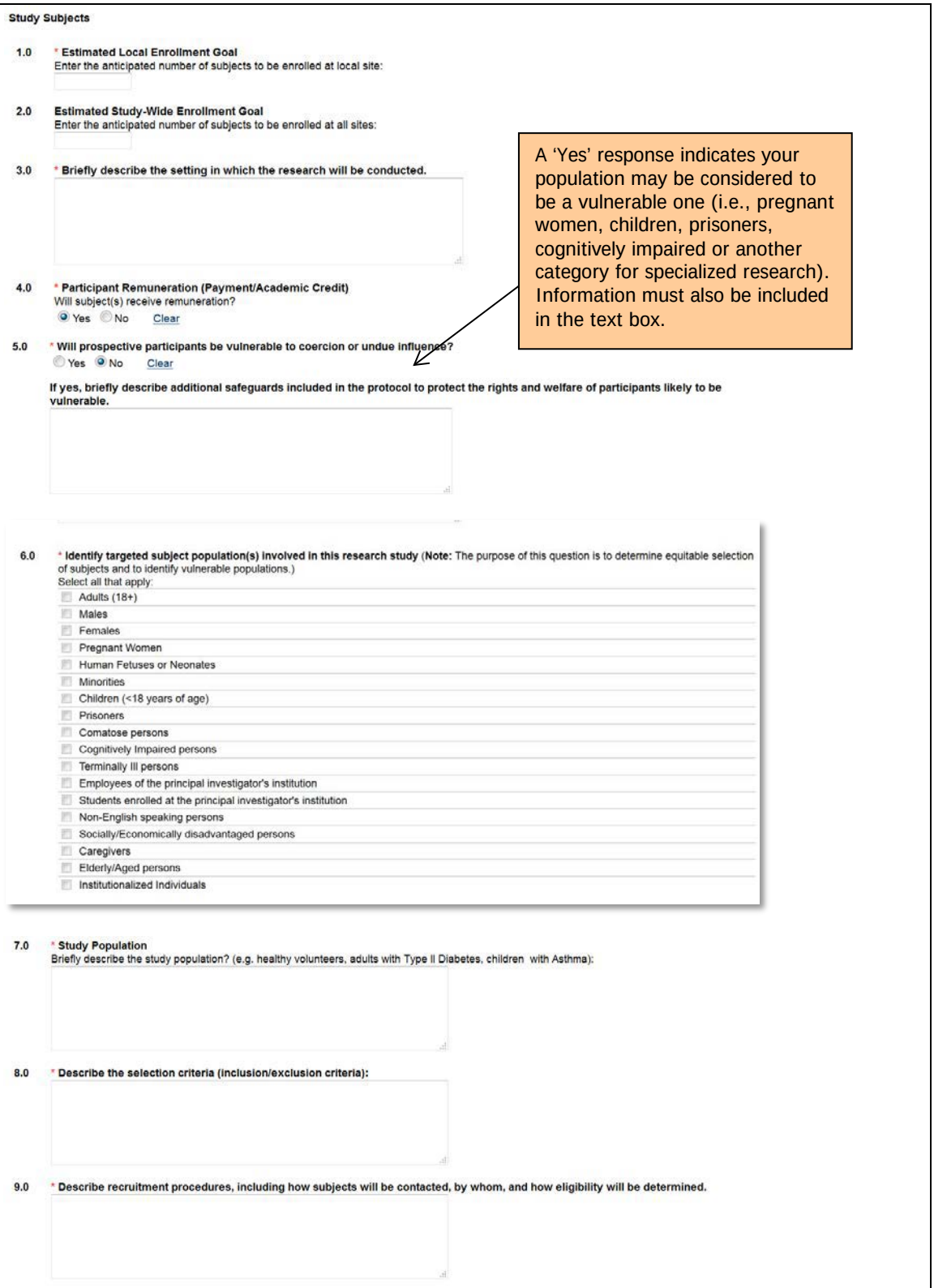
Enter information regarding the subjects you will include in the study.

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.



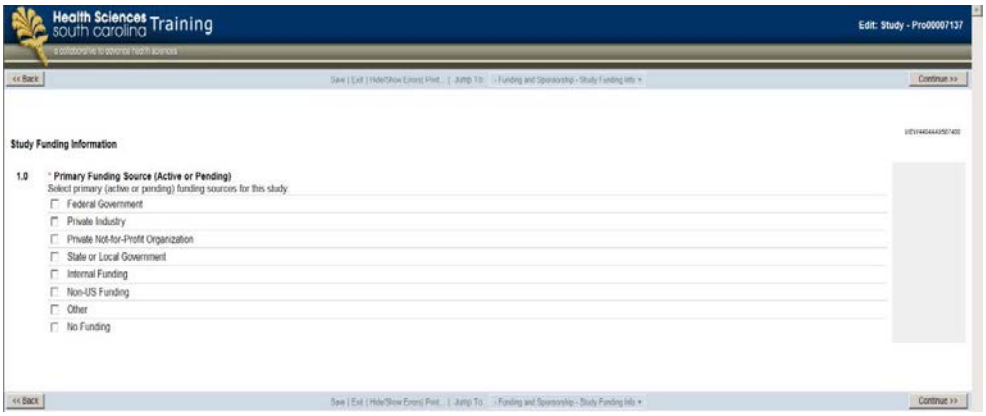
Study Funding

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.

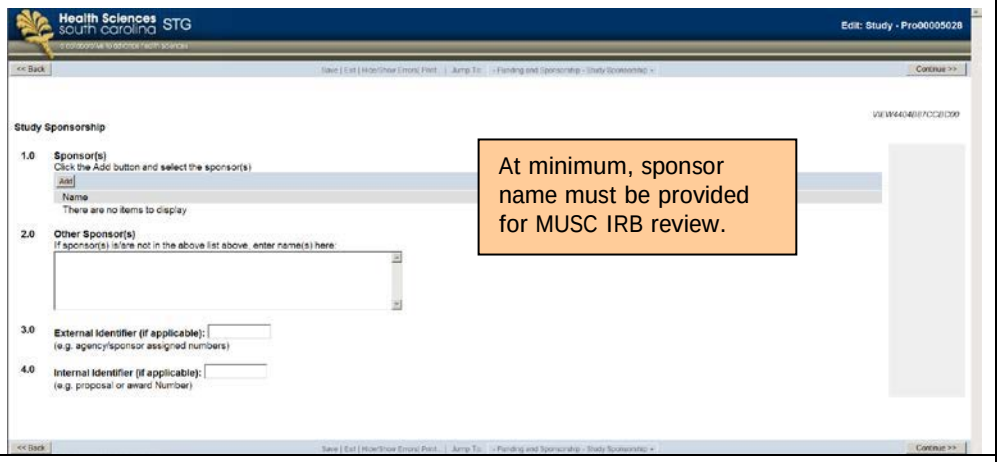
Click Continue.



Indicate details of study sponsorship.

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

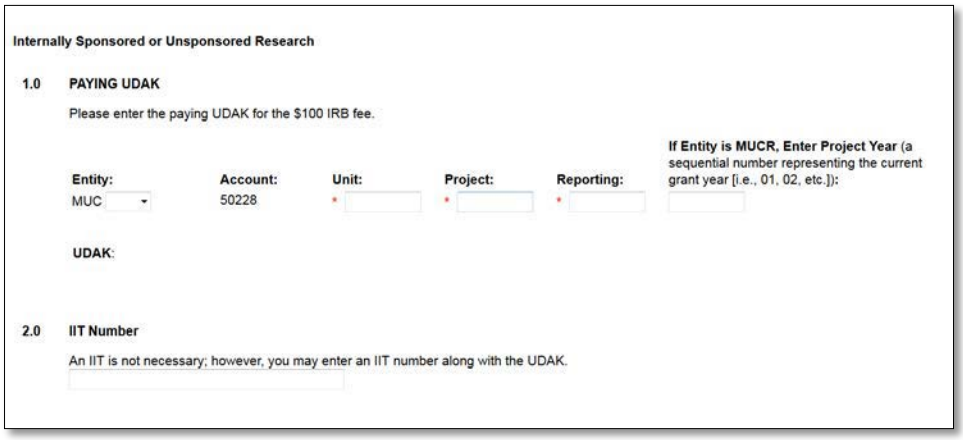
Click Continue.



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

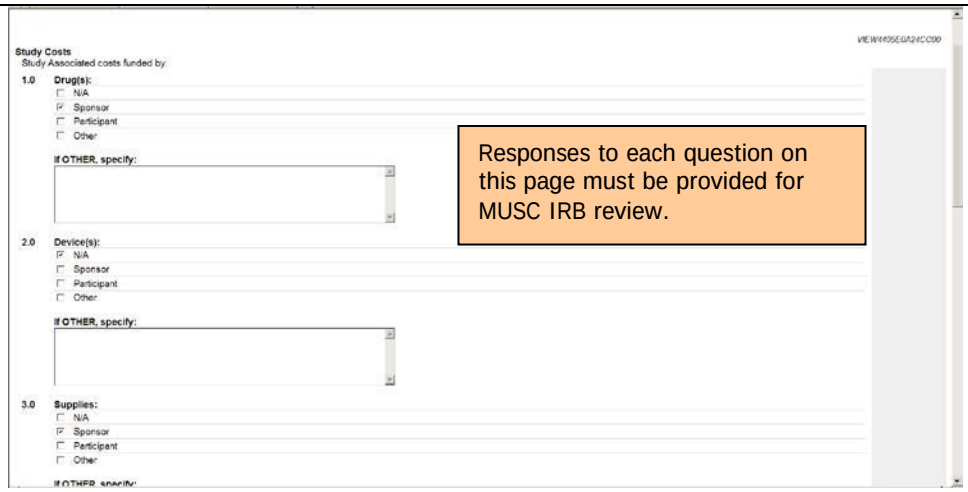
Please continue to consult with your business administrators to obtain the information required for IRB submission.

Click Continue.



Indicate the costs associated with the study.

Click Continue.

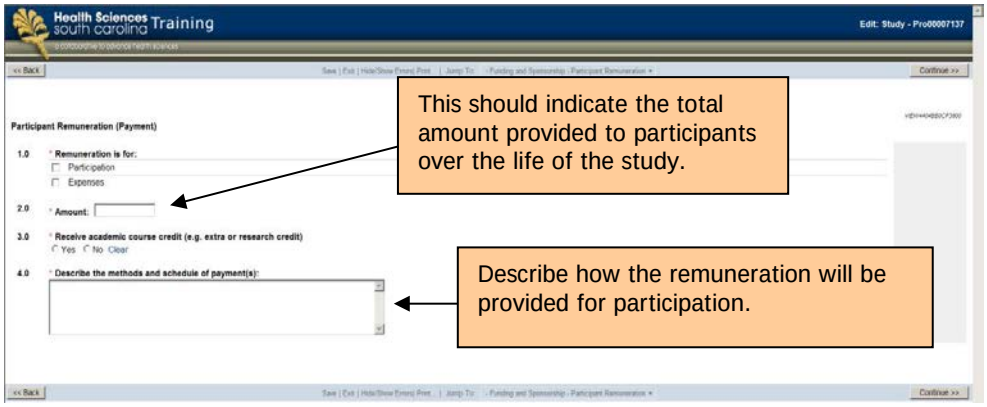


Subject Remuneration

Describe Participant Remuneration.

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

Click Continue.



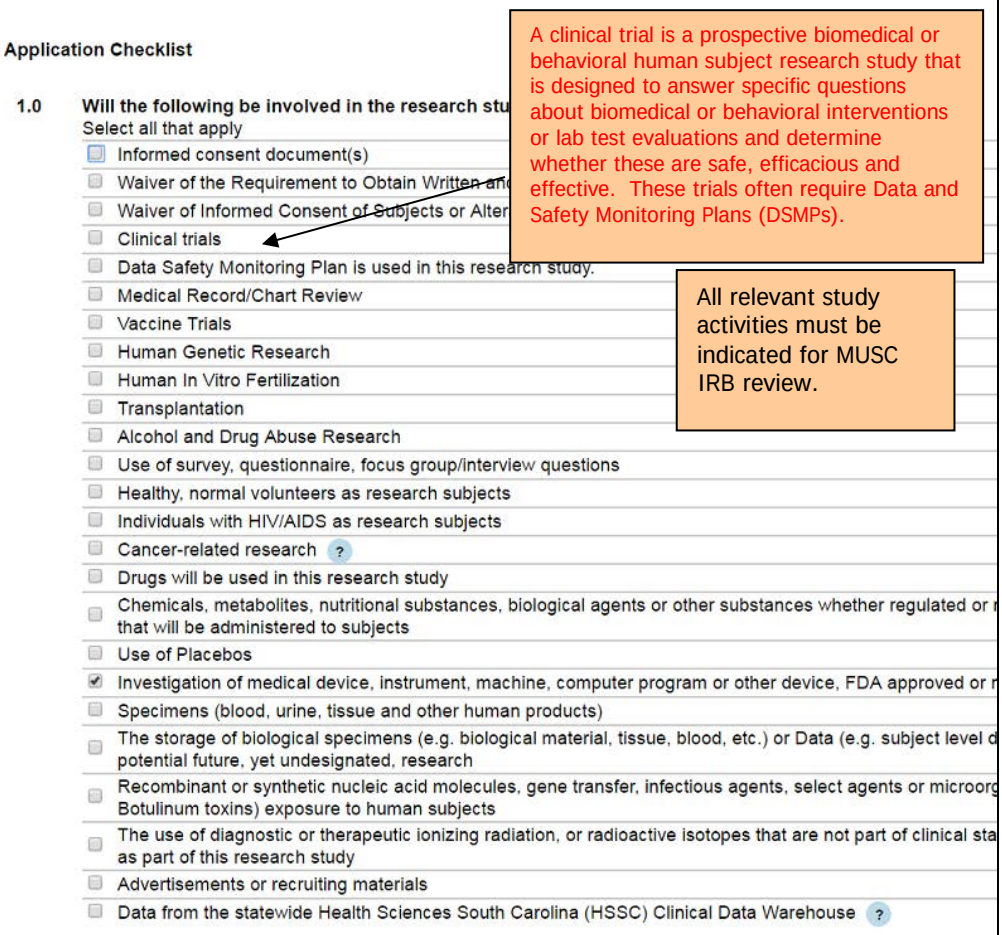
Application Checklist

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.).***

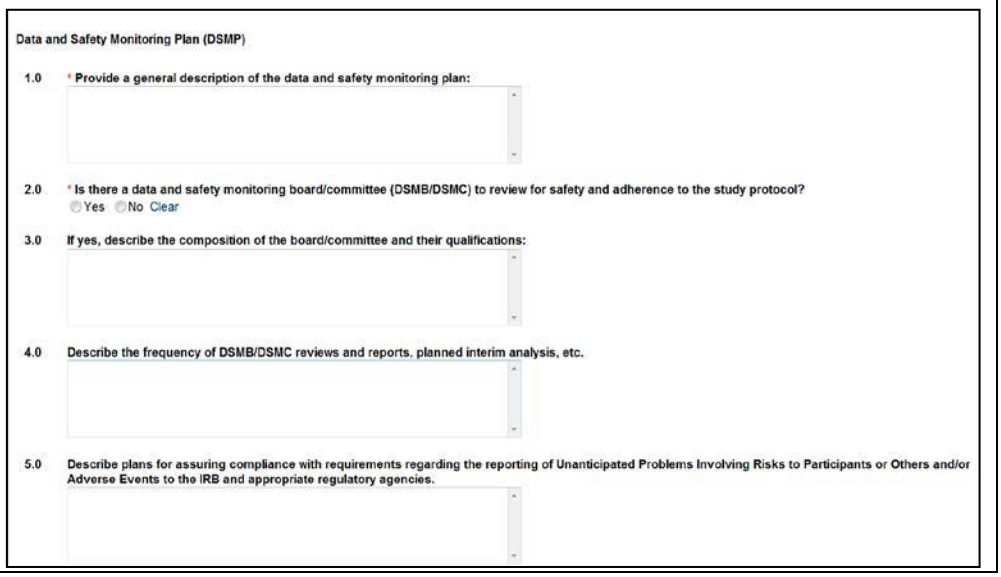
Click Continue.



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).

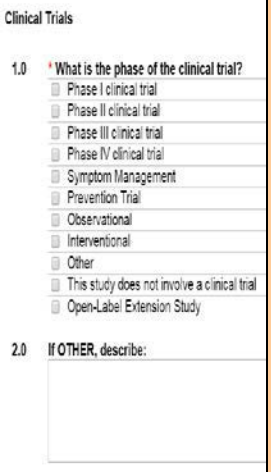
Click Continue.



Clinical Trials

Indicate the type of clinical trial applicable for the project.

Click Continue.



Visit 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.

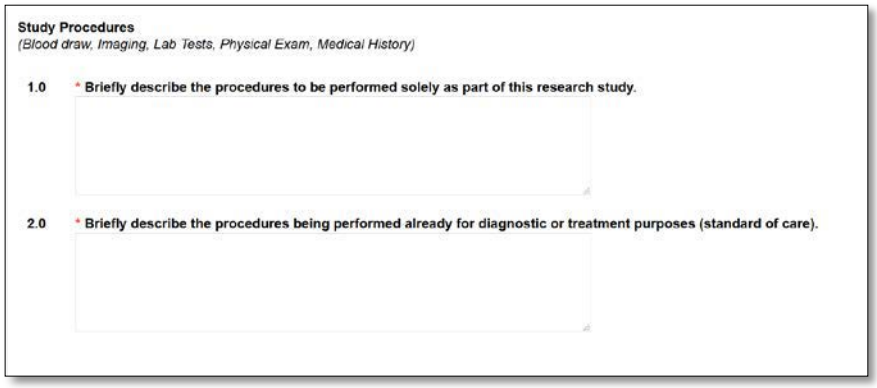
Open-Label Extension Studies are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.

ClinicalTrials.gov

Study Procedures

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

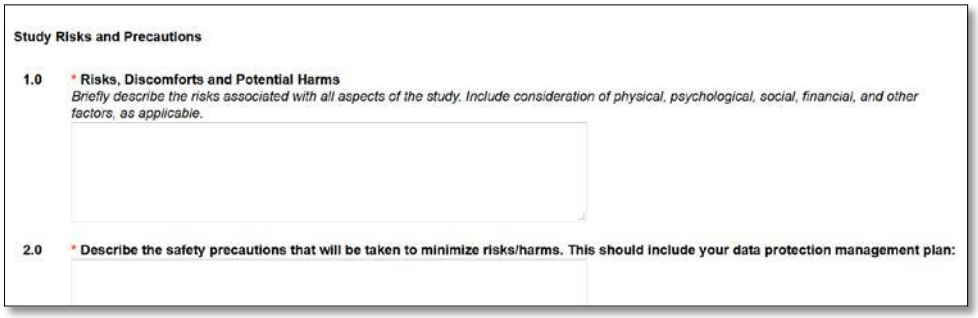
Click Continue.

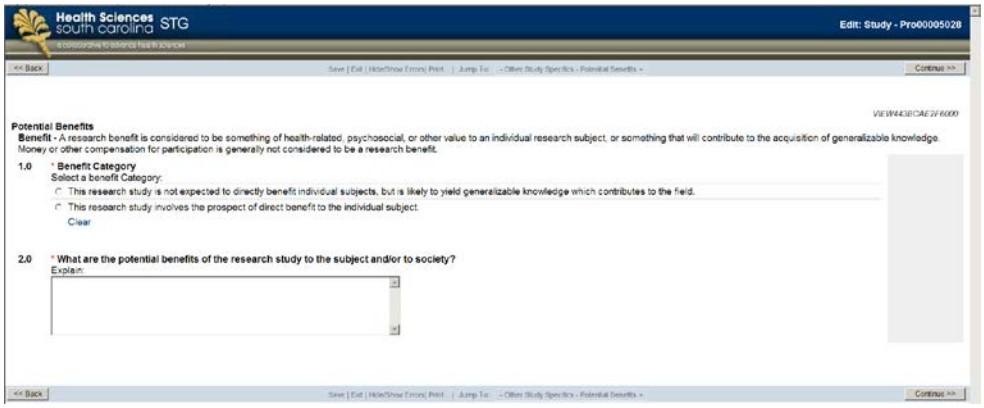
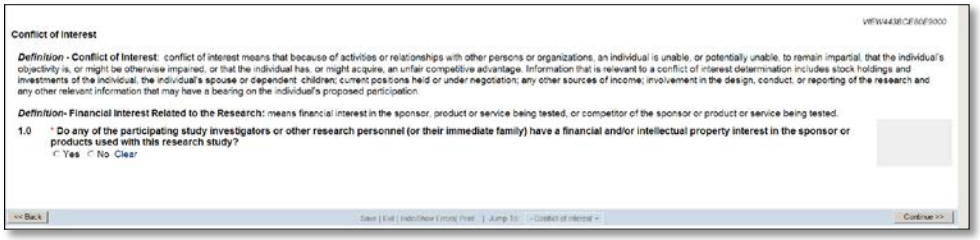


Risks

Describe all potential risks and discomforts and precautions to minimize risks.

Click Continue.



Potential Benefit Select the potential benefit category and explain potential benefits to the subject and/or society. Click 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.***	

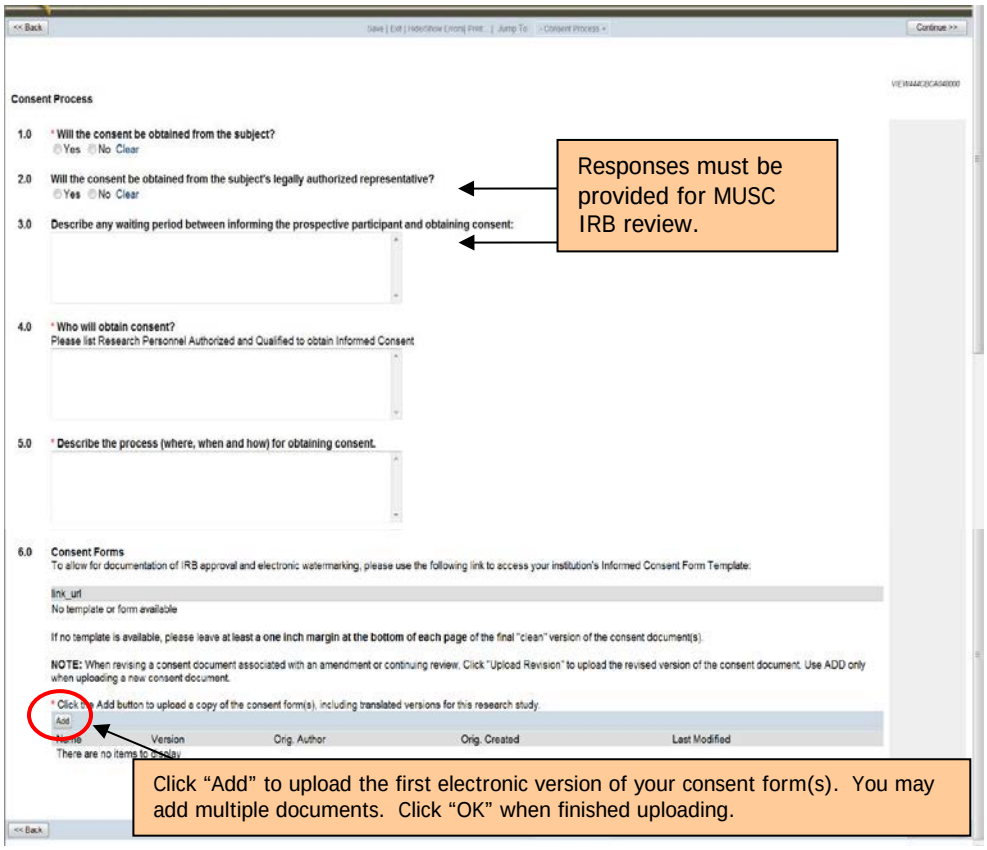
Consent Process

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.



Privacy and Confidentiality

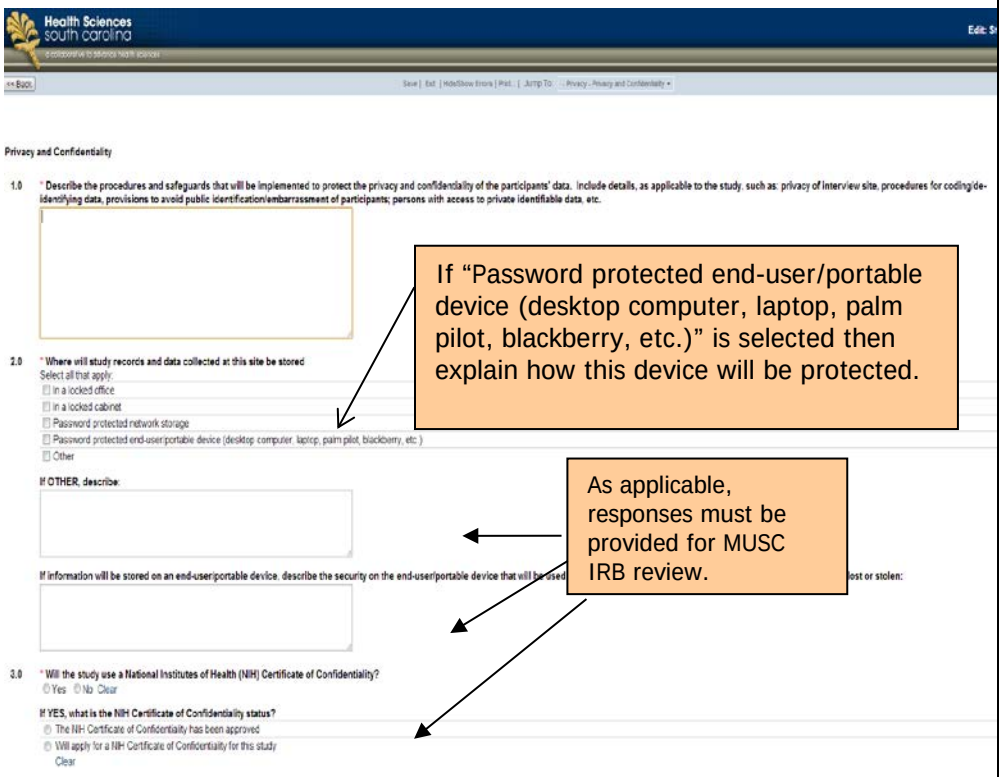
Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

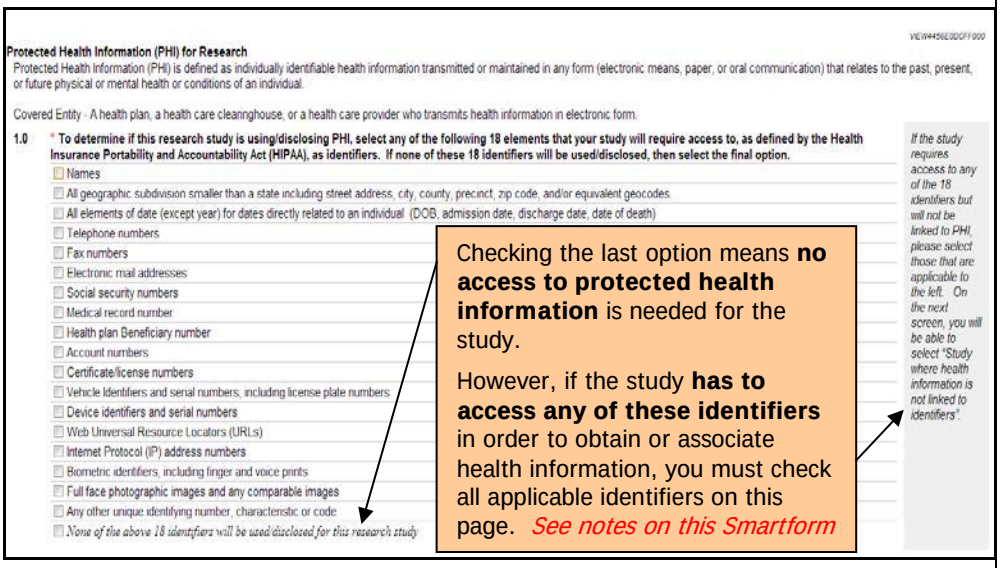
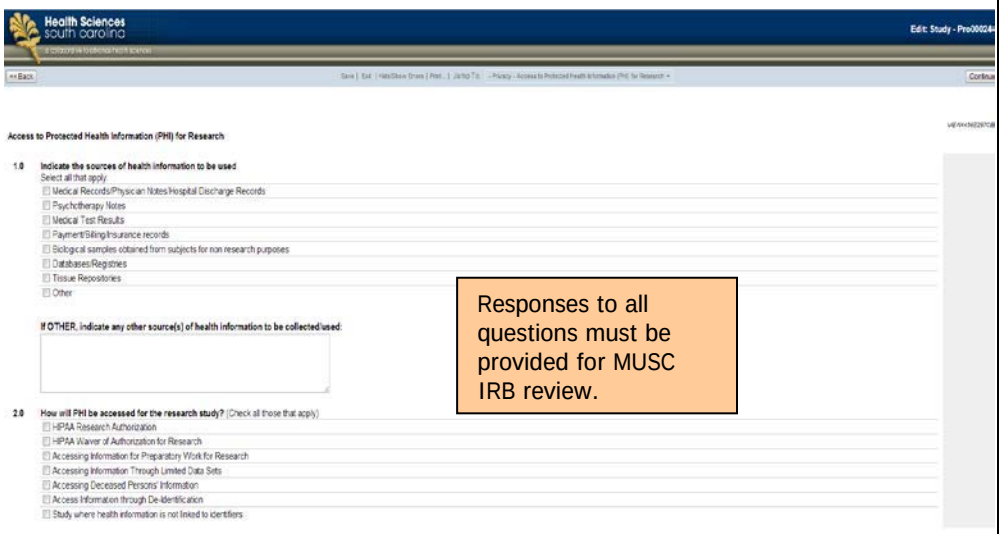
Select where study records and data collected will be stored. If "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)" is selected then explain how this device will be protected.

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).



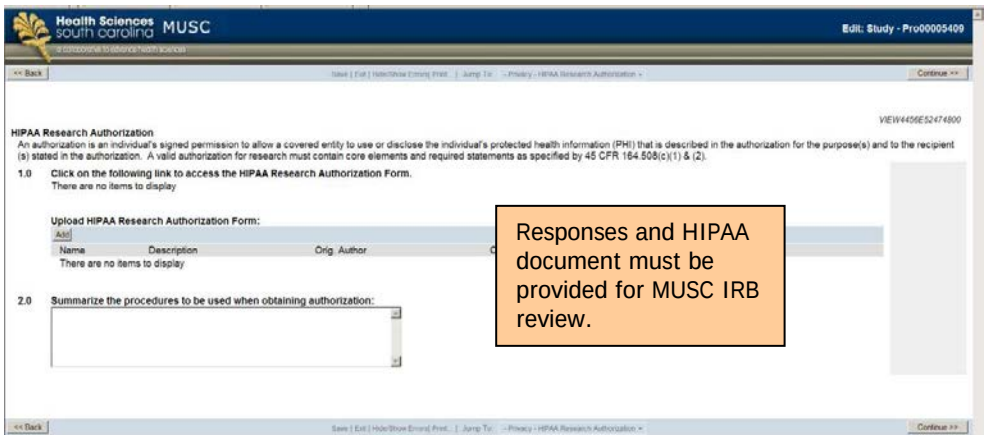
Protected Health Information (PHI) Indicate if the study will access (view, obtain or use) participant protected health data. Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI). Click Continue.	 **Protected Health Information (PHI) for Research** 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* *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*
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 Edit: Study - Pro00024 Back 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/Physican 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.

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.****

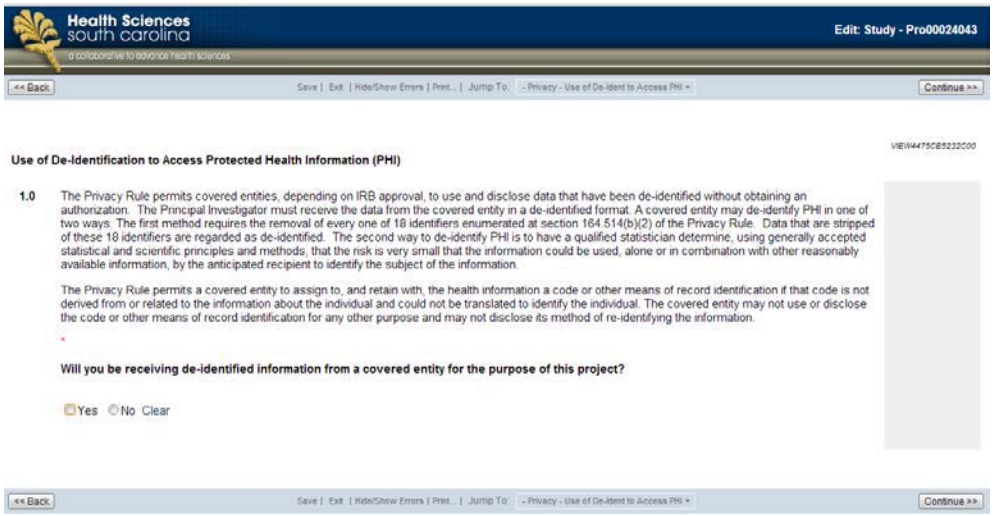
Click Continue.



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

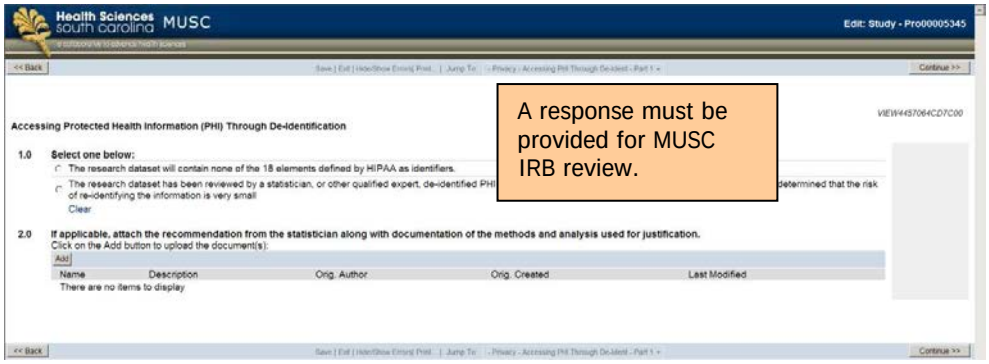
Note: The intent of this question is to document whether study data is received through a de-identification method (i.e., via a de-identified database warehouse).

Click Continue.



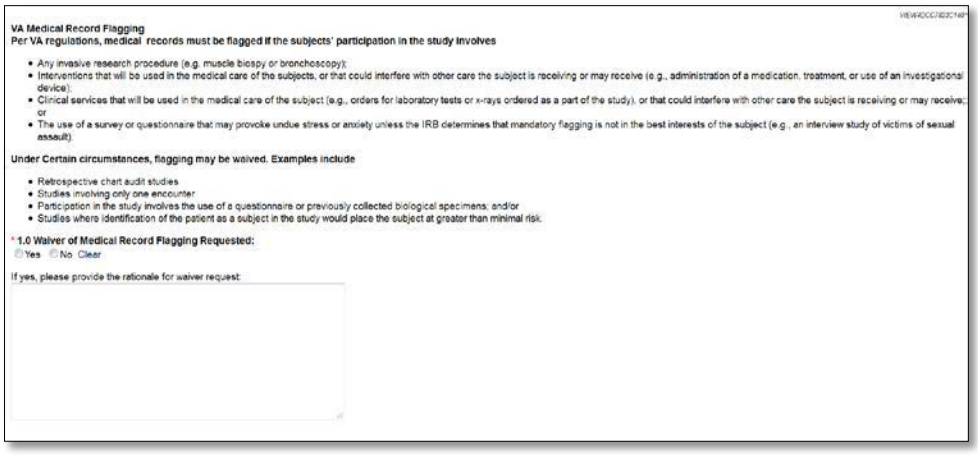
If the answer is "yes" to the question above, indicate how the data will be de-identified.

Click Continue.



For VA studies, indicate medical record flagging waiver requests.

Click Continue.

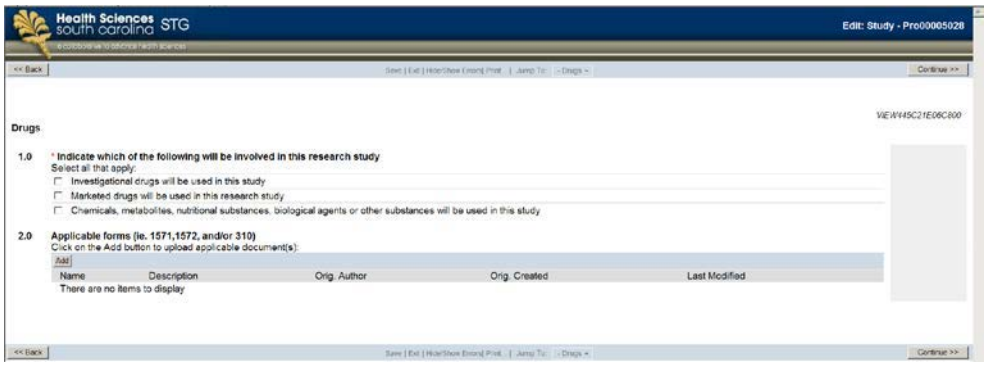


Drugs

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

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

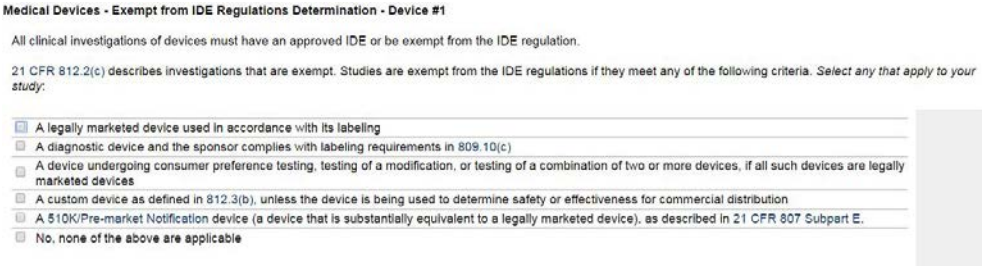
Click Continue.



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.

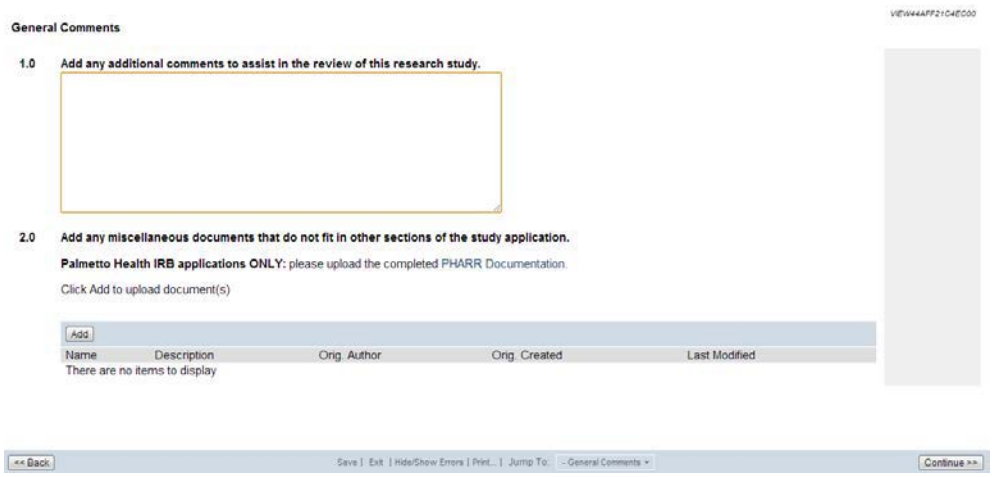


General Comments

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.

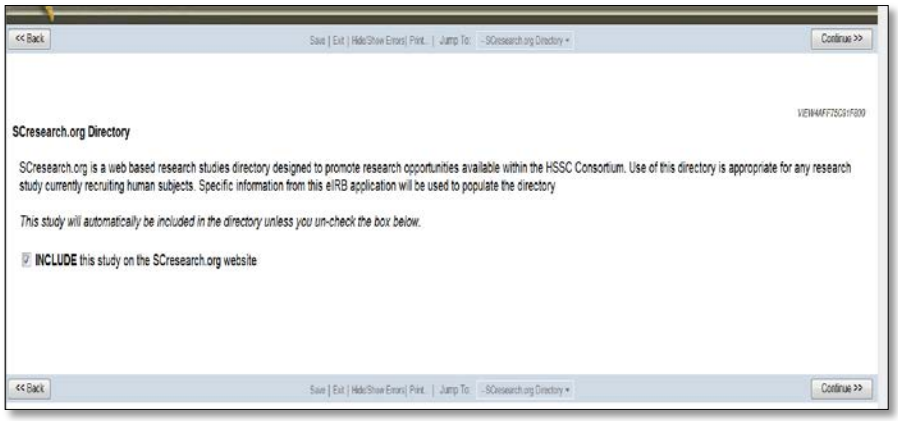
Click Continue.



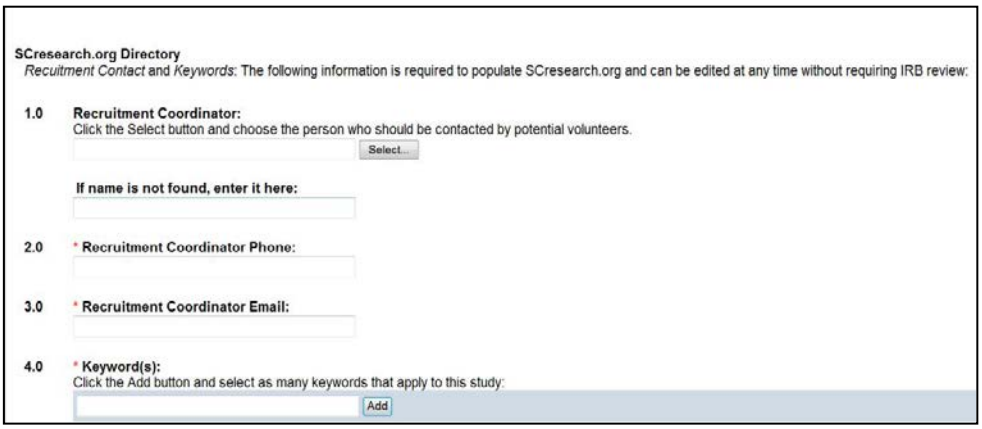
S.C. Research Studies Directory Online Posting

The study will be included on 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

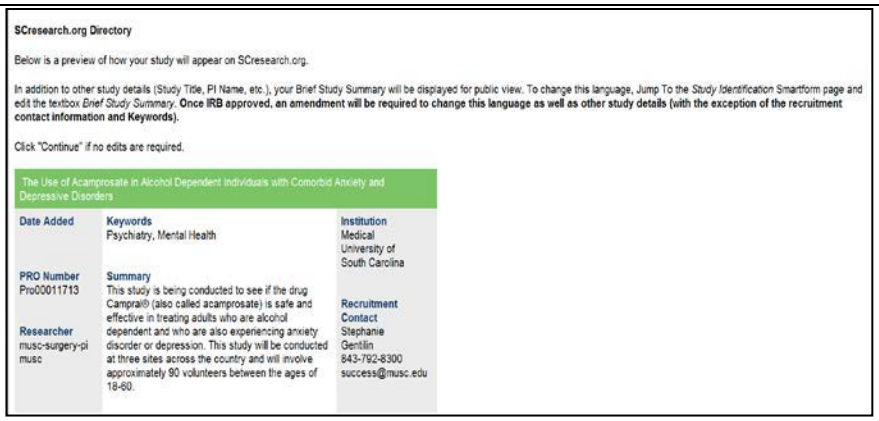


Continue to the next screen to enter in the recruitment coordinator's name, phone & e-mail and select from a list of keywords to associate with the study.

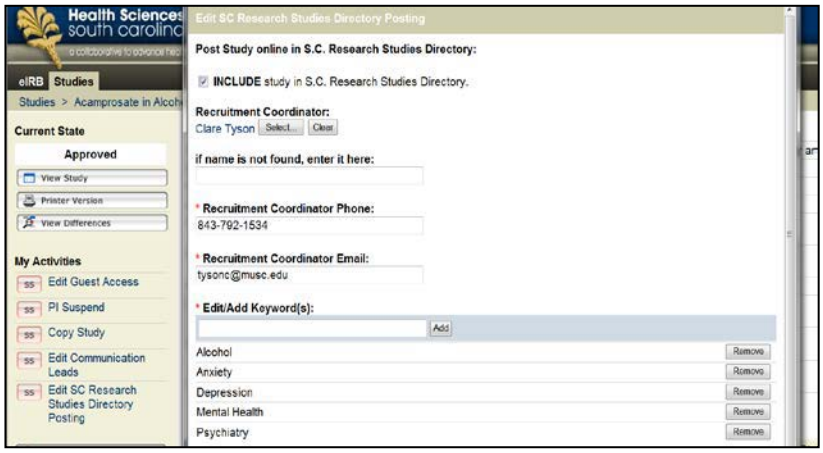


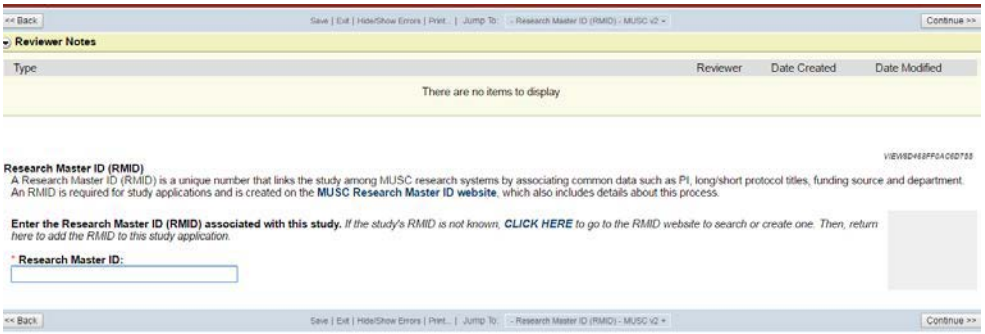
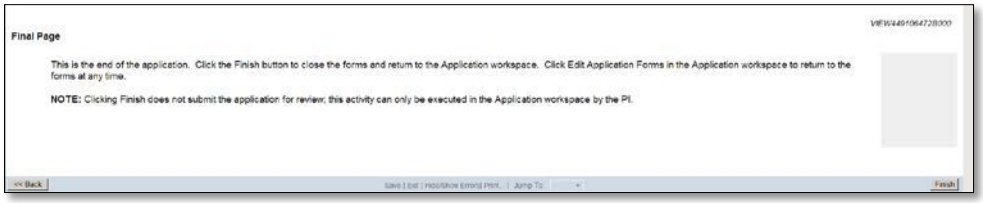
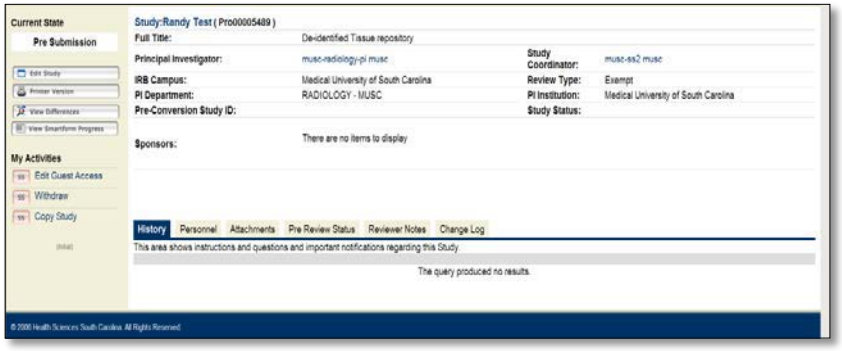
Review a preview of how the study will appear on SCResearch.org.

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



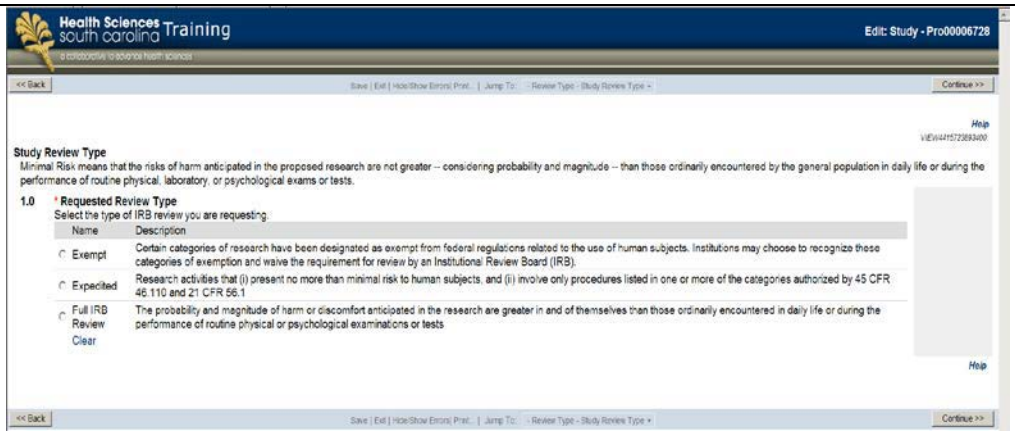
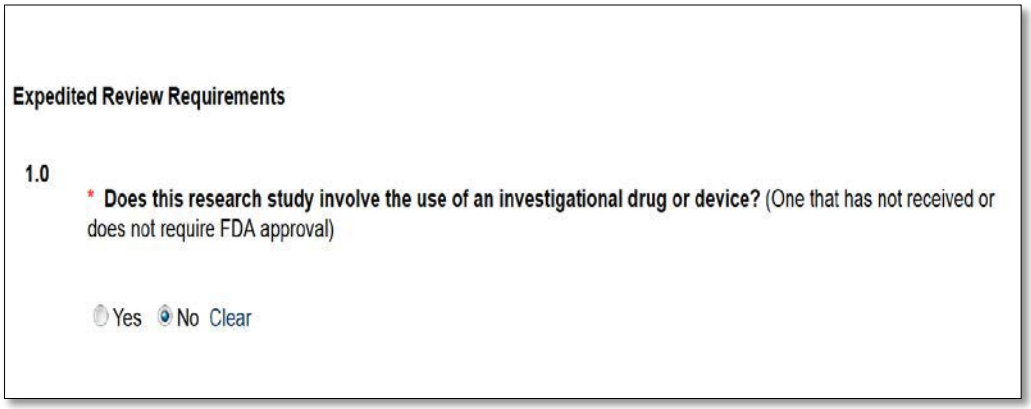
Posting the study on the registry & the information in this section can be revised at any point by accessing the 'Edit SC Research Studies Directory Posting' option on the protocol's main page.



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 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.***	

Request for Expedited Review

If not already done, complete steps in the 'Beginning the Application' section.

Study Review Type Indicate Study Review Type as "Expedited". Click Continue.	
Expedited Review Requirements You will be routed to the Expedited Review Requirements page. Indicate if the study uses an investigational drug or device. ***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. *** Click Continue.	

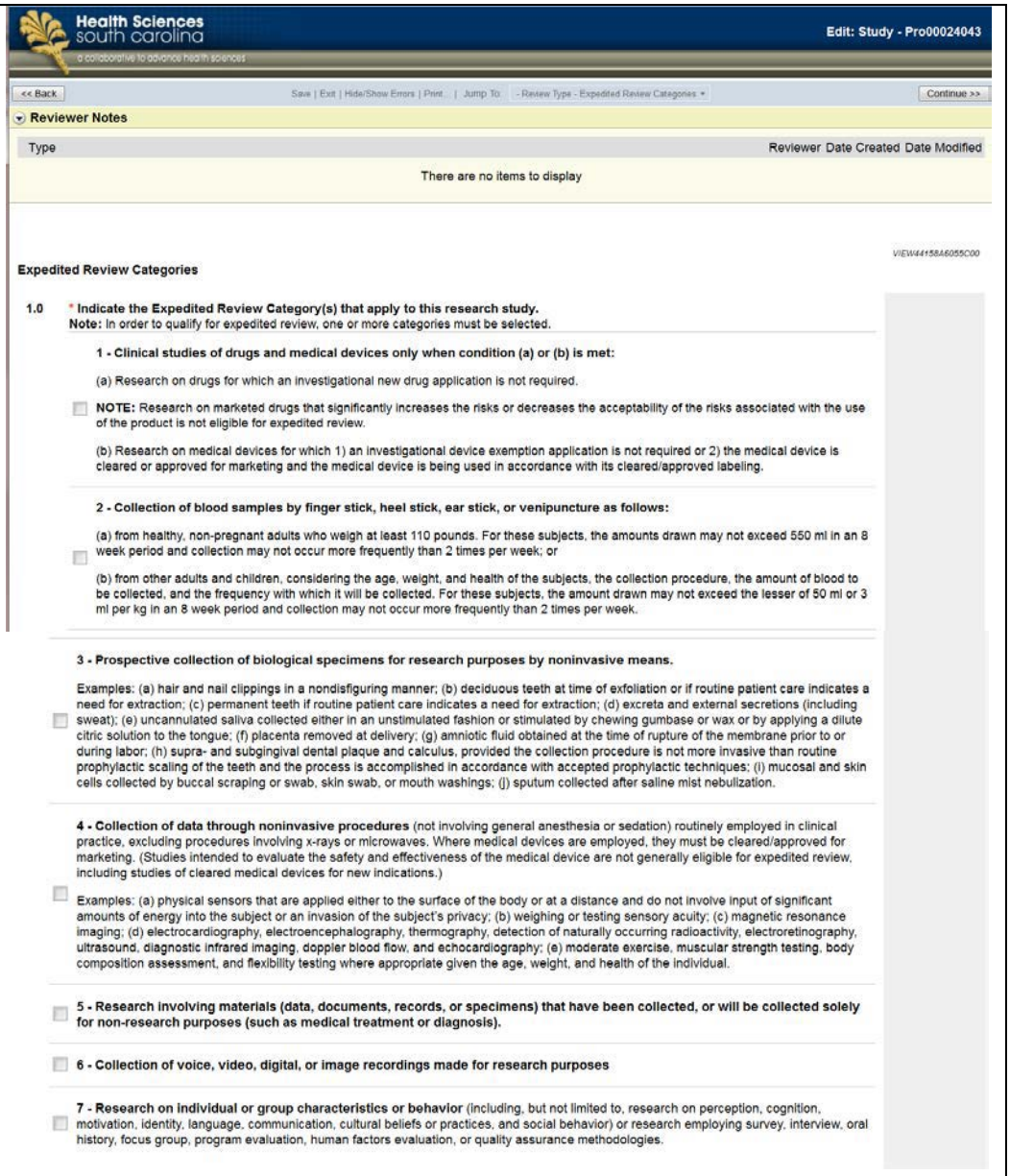
Expedited Review Categories

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.

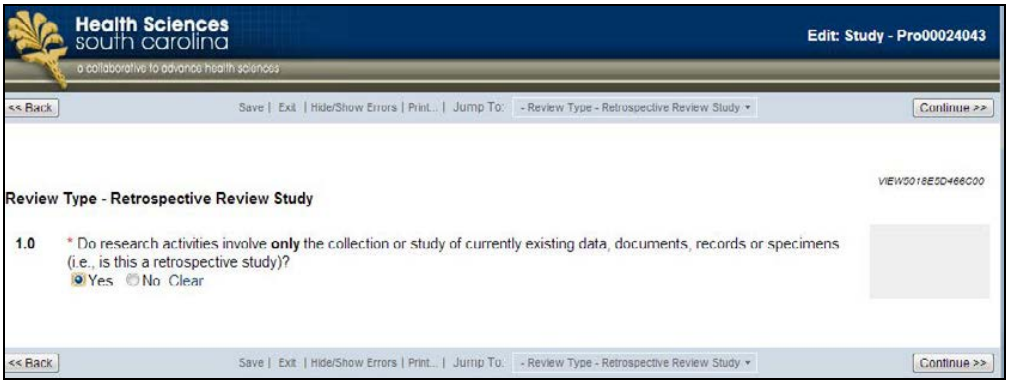


Retrospective Review Study

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 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.

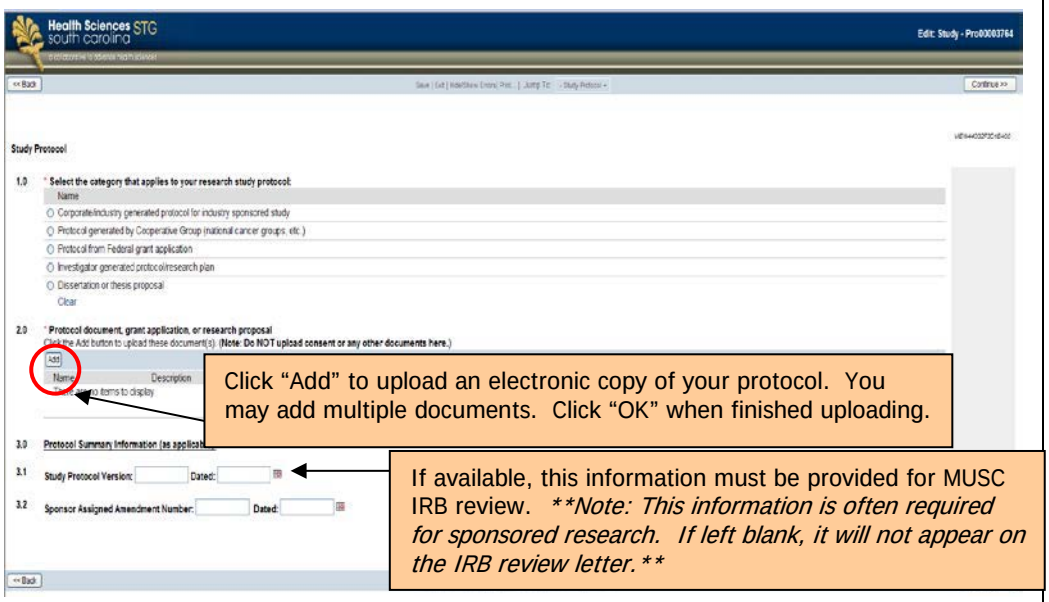
Click Continue.

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.



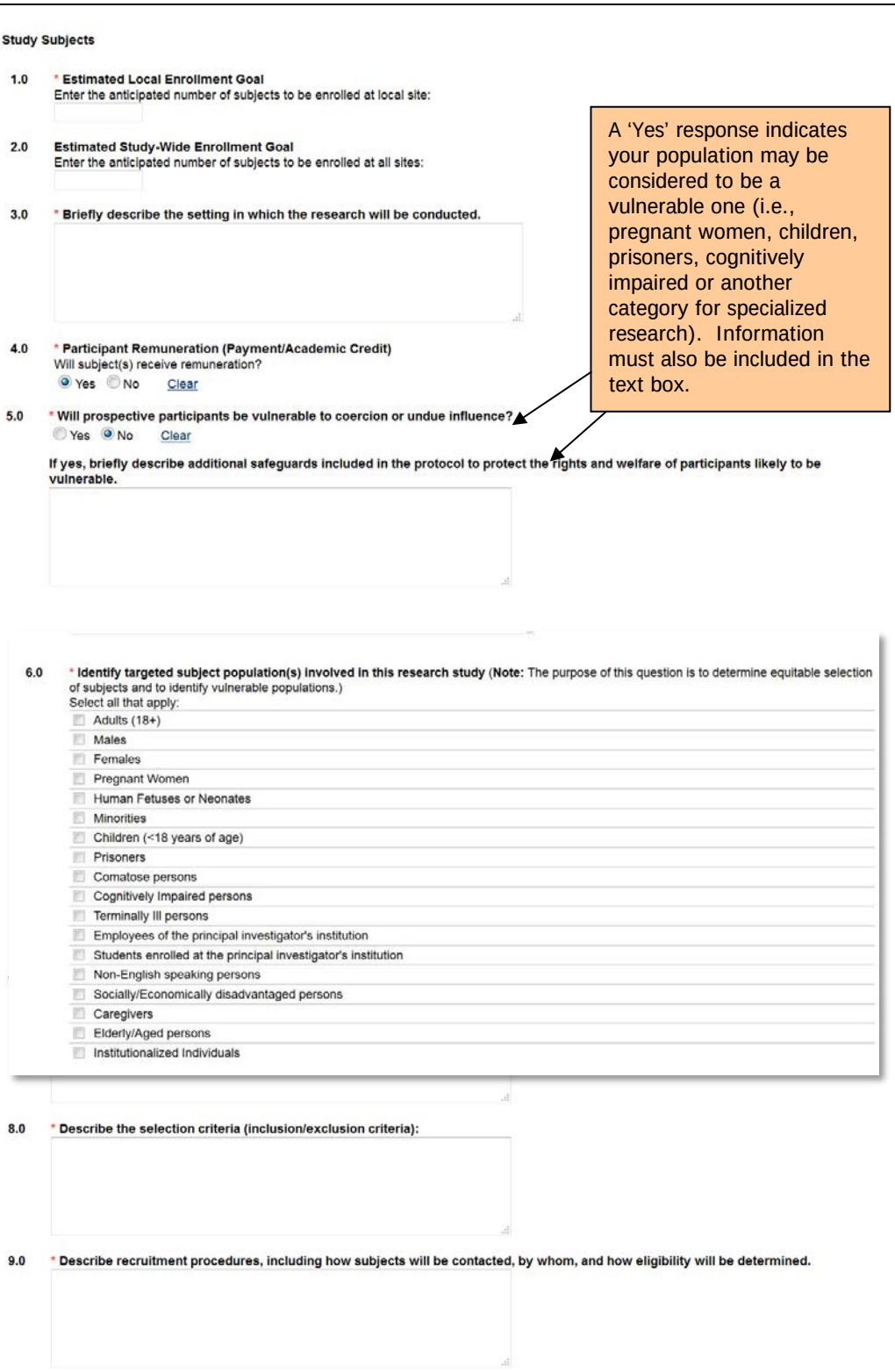
Study Subjects
Enter information regarding the subjects you will include in the study.

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.



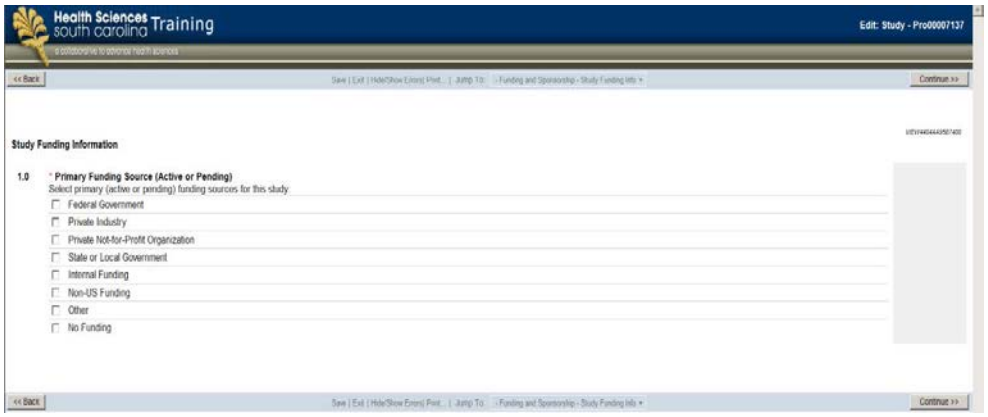
Study Funding

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.

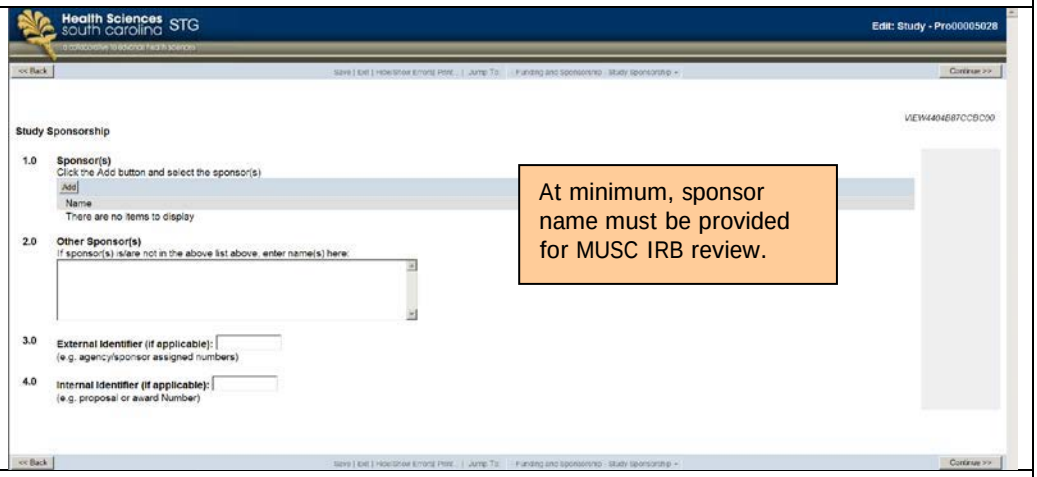
Click Continue.



Indicate details of study sponsorship.

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

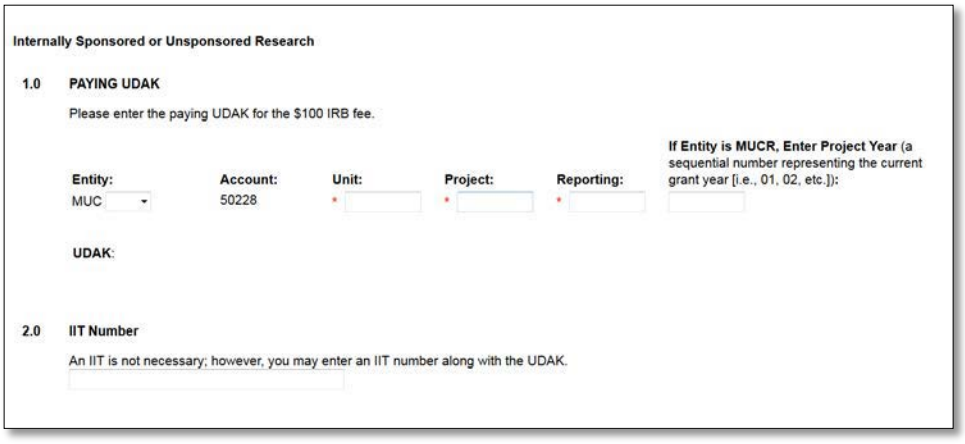
Click Continue.



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

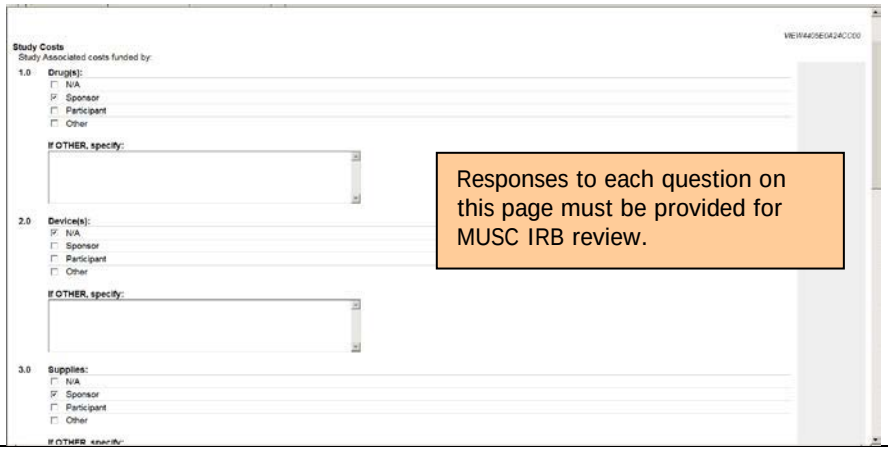
Please continue to consult with your business administrators to obtain the information required for IRB submission.

Click Continue.



Indicate the costs associated with the study.

Click Continue.

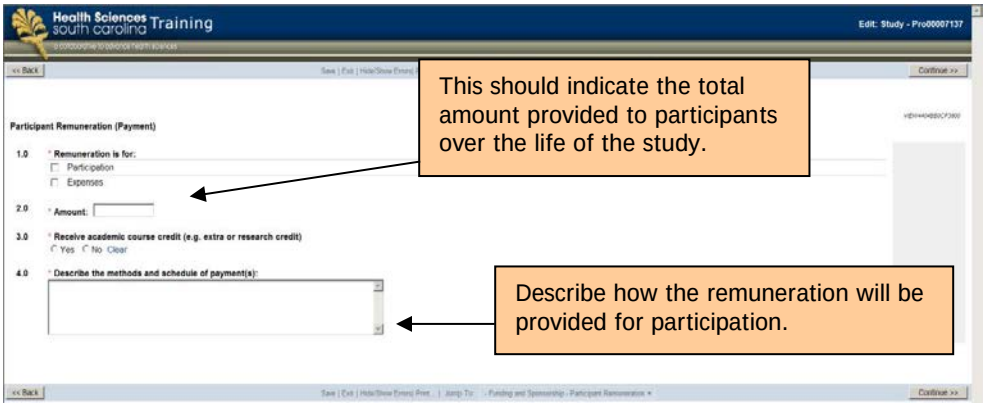


Subject Remuneration

Describe Participant Remuneration.

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

Click Continue.



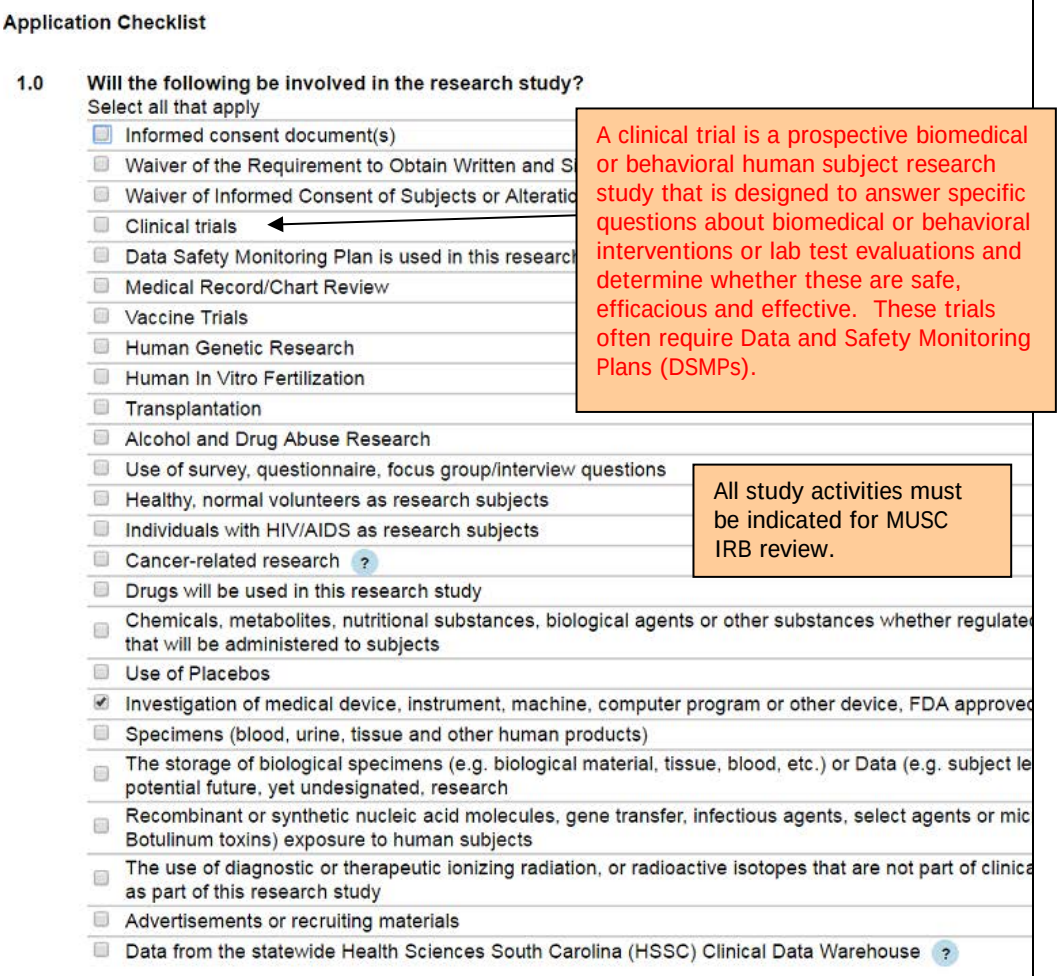
Application Checklist

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.).****

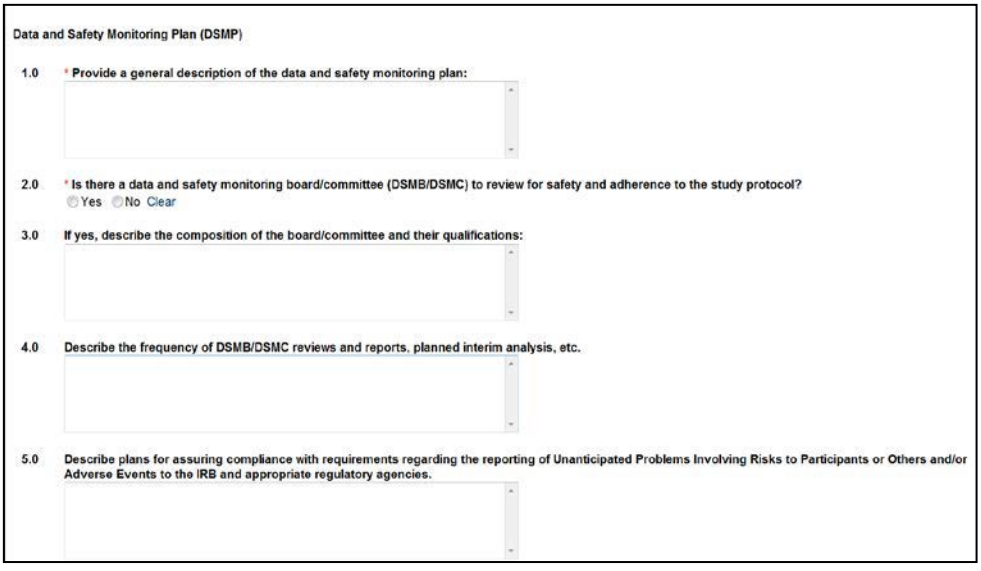
Click Continue.



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).

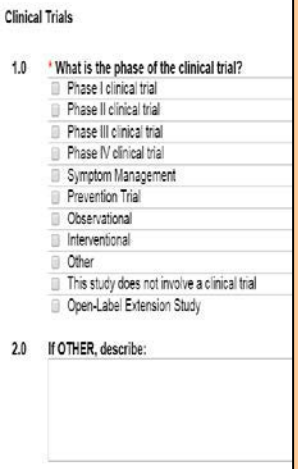
Click Continue.



Clinical Trials

Indicate the type of clinical trial applicable for the project.

Click Continue.



Visit 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.

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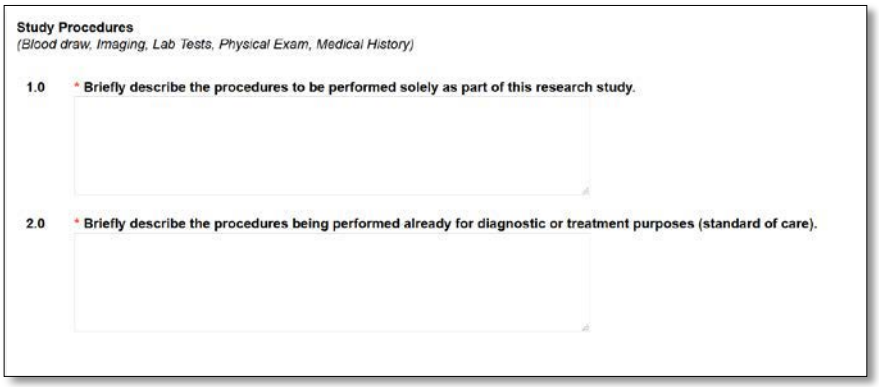
Open-Label Extension Studies are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.

ClinicalTrials.gov

Study Procedures

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

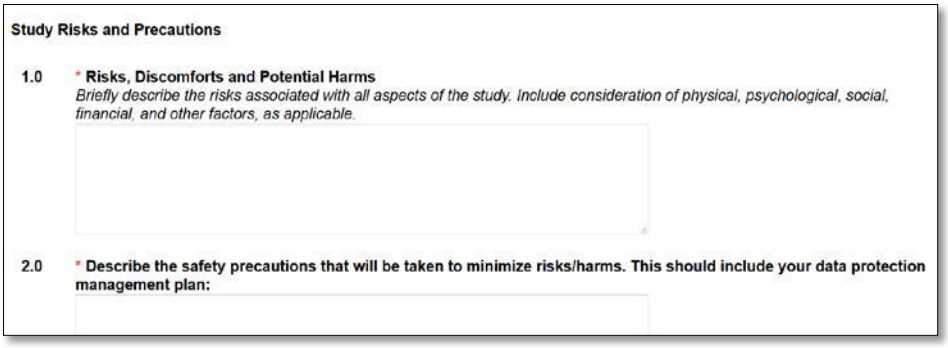
Click Continue.

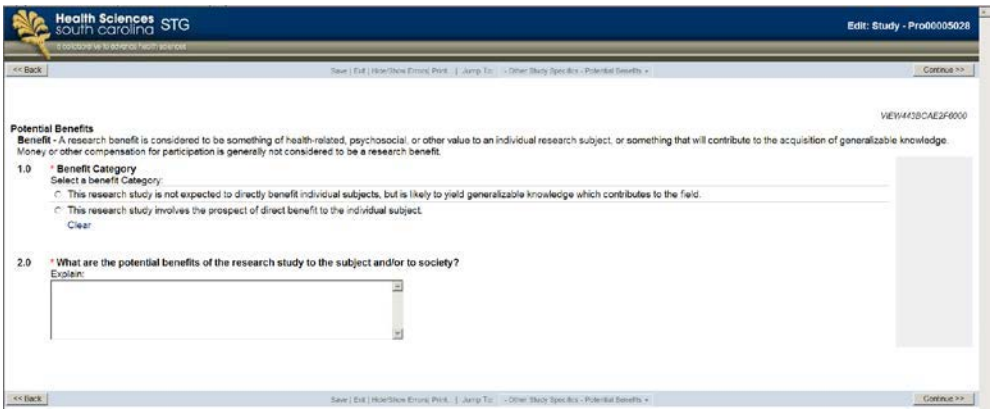
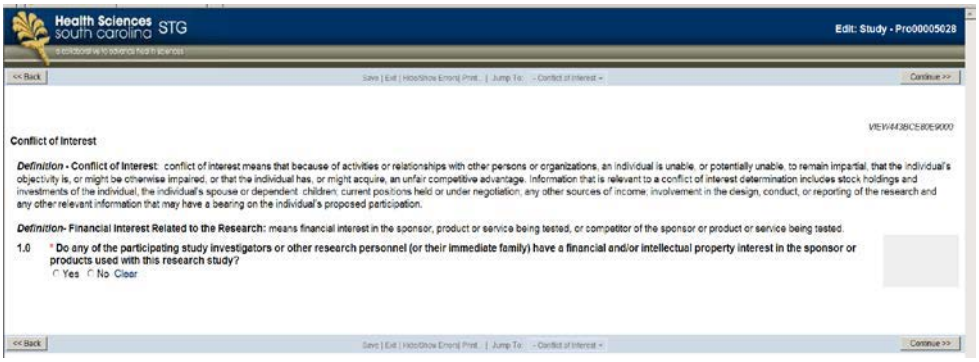


Risks

Describe all potential risks and discomforts and precautions to minimize risks.

Click Continue.



Potential Benefit Select the potential benefit category and explain potential benefits to the subject and/or society. Click 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.***	

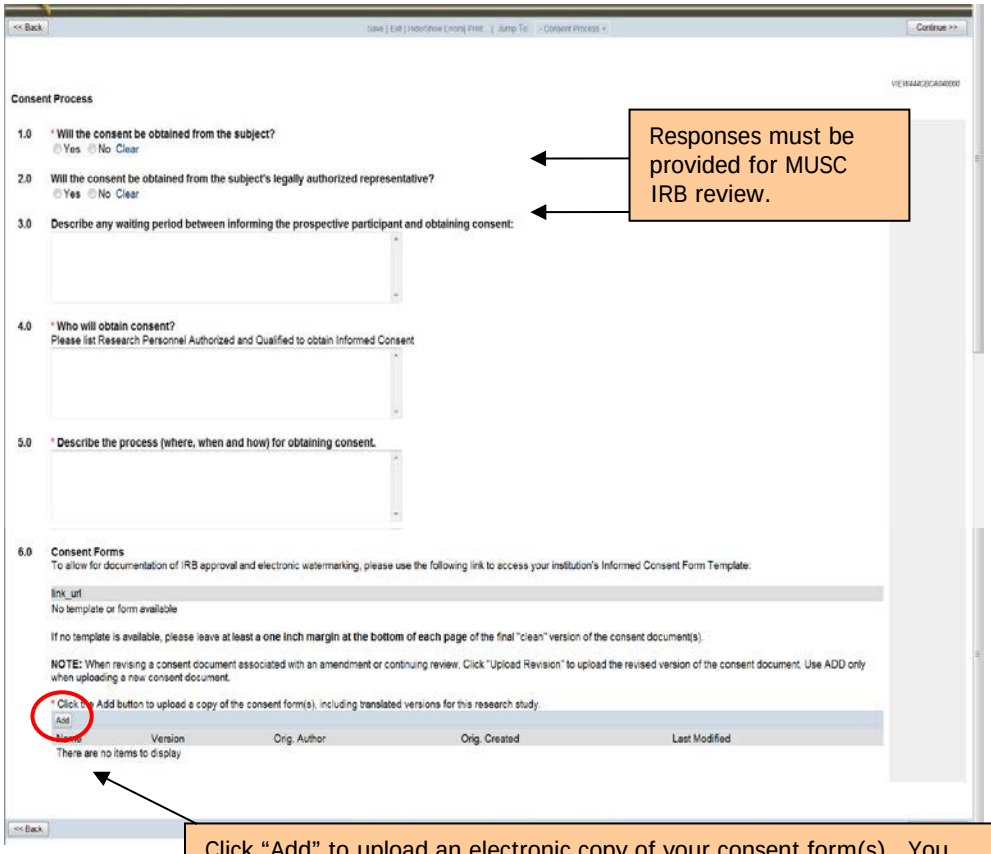
Consent Process

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.



Privacy and Confidentiality

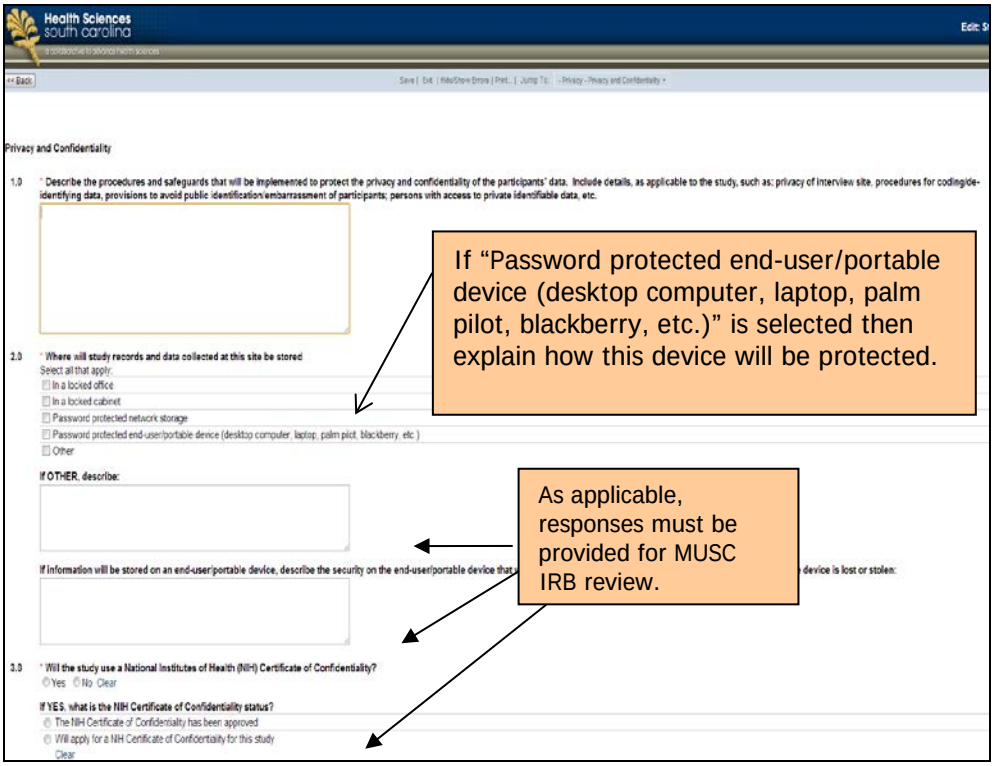
Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

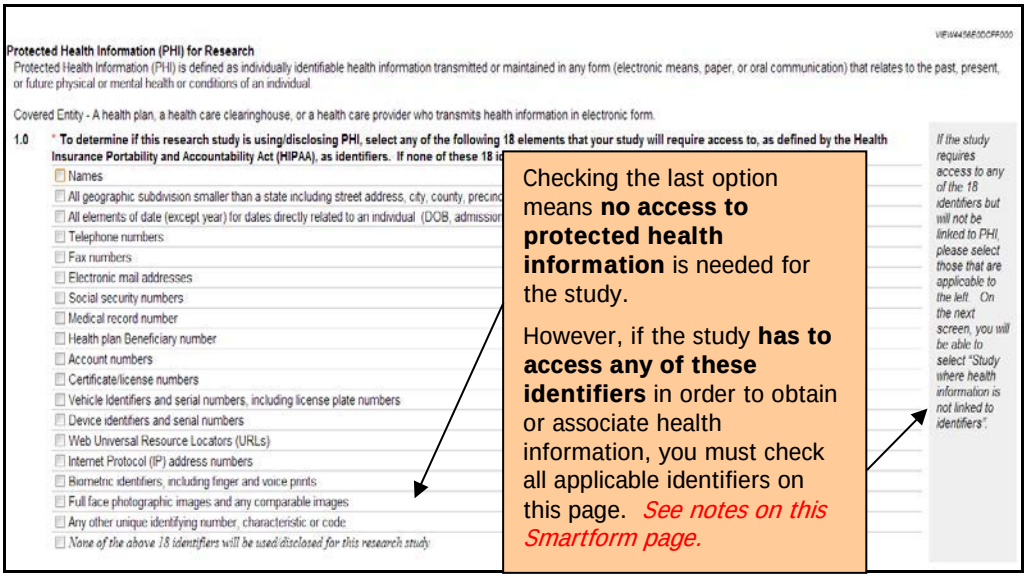
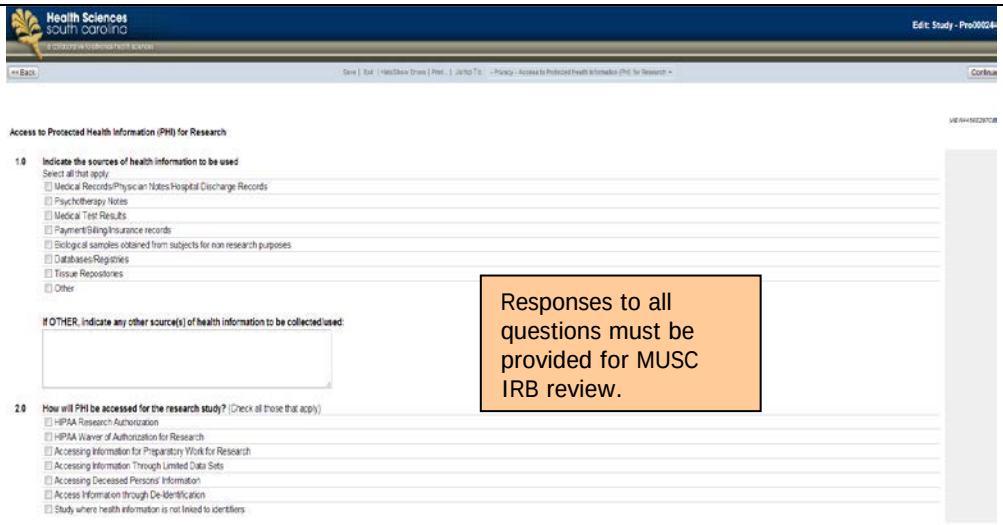
Select where study records and data collected will be stored. If "Password protected end-user/portable device (desktop computer, laptop, palm pilot, blackberry, etc.)" is selected then explain how this device will be protected.

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).



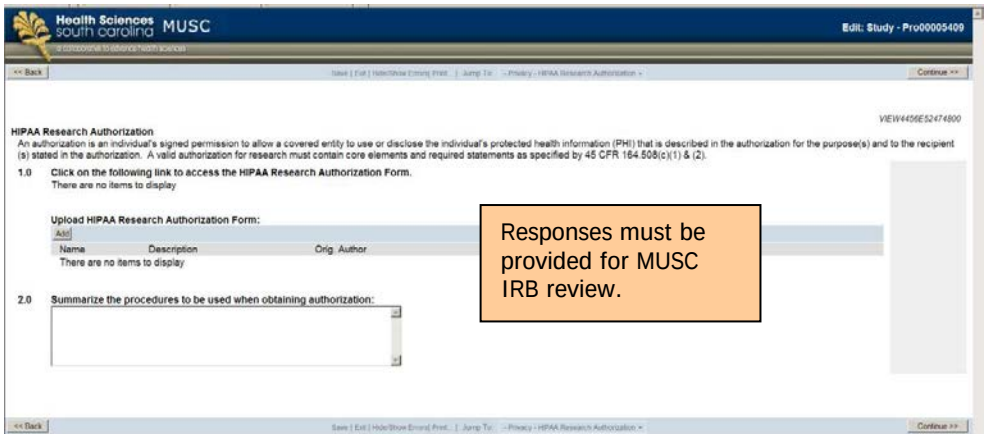
Protected Health Information (PHI) Indicate if the study will access (view, obtain or use) participant protected health data. Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI). Click Continue.	 **Protected Health Information (PHI) for Research** 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 id** Names All geographic subdivision smaller than a state including street address, city, county, precinc All elements of date (except year) for dates directly related to an individual (DOB, admissio 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 Edit: Study - Pro00024 Back 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.

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.***

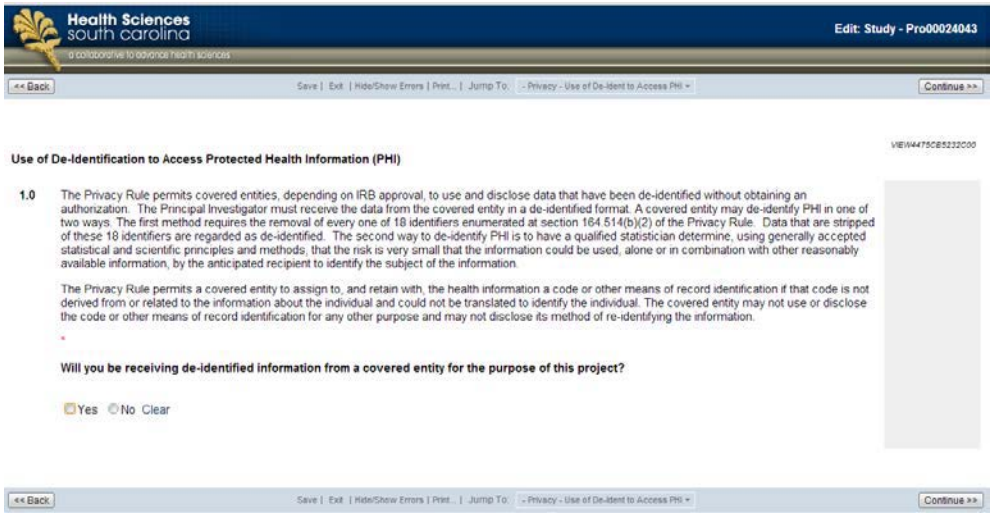
Click Continue.



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

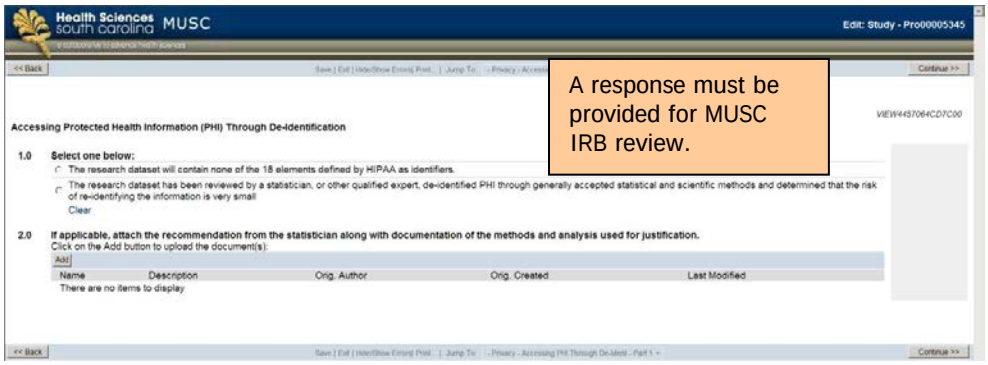
Note: The intent of this question is to document whether the study data is received through a de-identification method (i.e., via a de-identified database warehouse).

Click Continue.



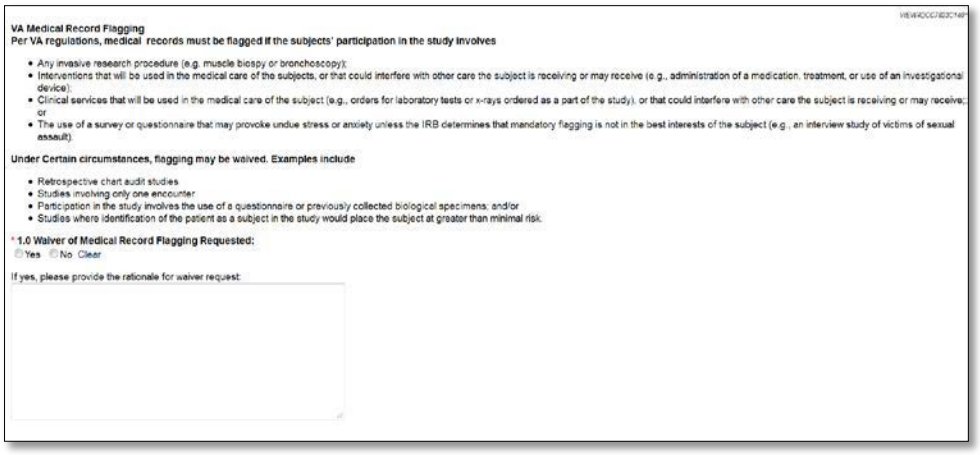
If the answer is "yes" to the question above, indicate how the data will be de-identified.

Click Continue.



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.

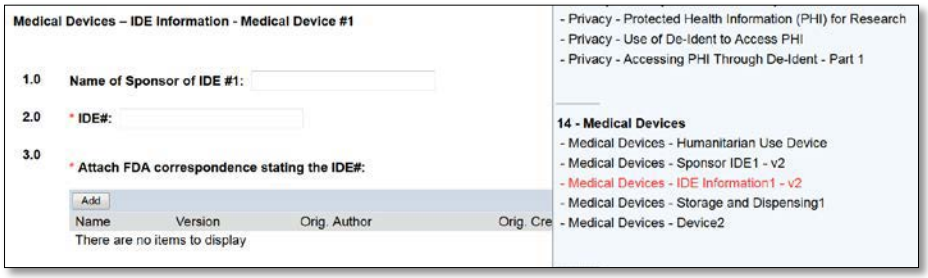
***Note: Depending on your responses, you will be required to answer questions specific to investigational drugs, marketed drugs or other types of drugs.*

Click Continue.

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.

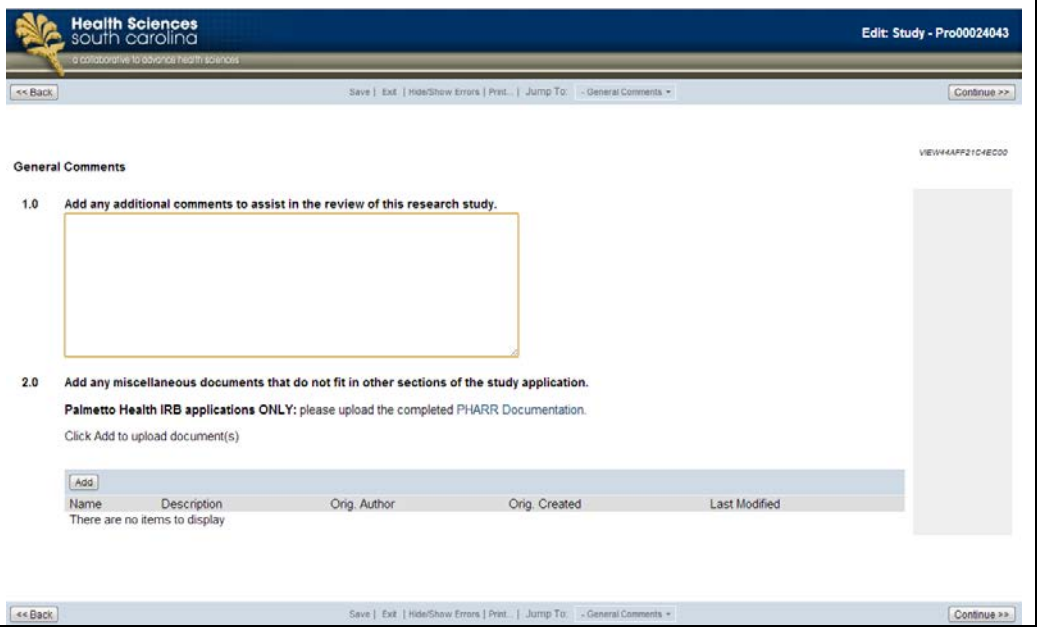


General Comments

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, requires an IND or IDE application to FDA, or as requested by IRB.

Click Continue.

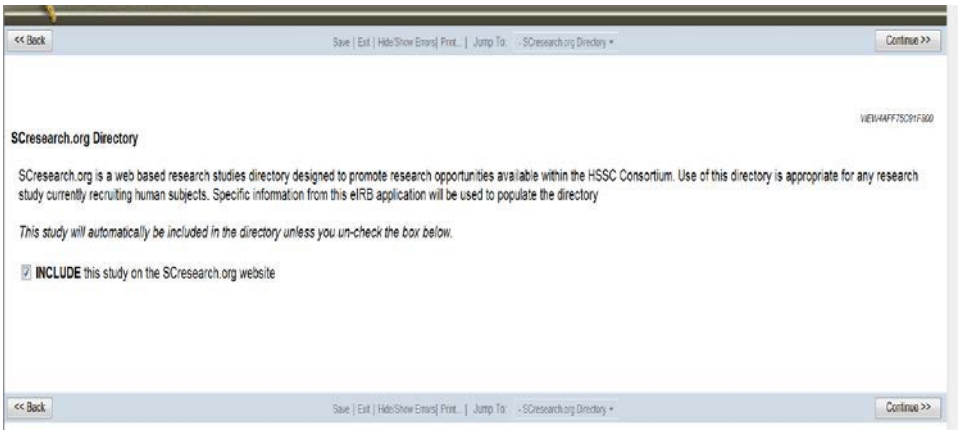


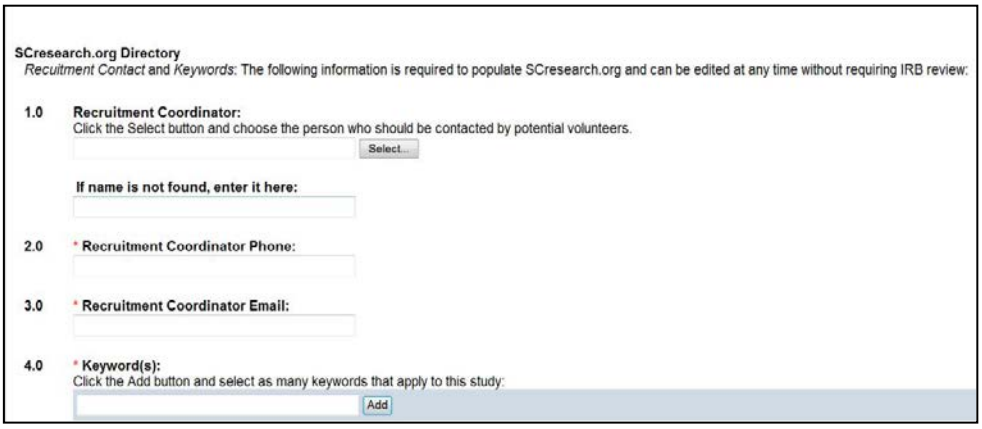
S.C. Research Studies Directory Online Posting

The study will be included on 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

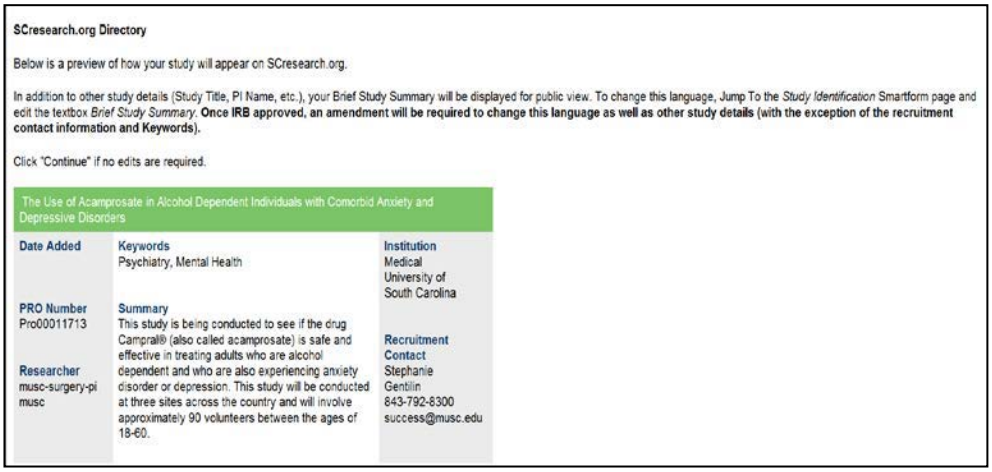
Continue to the next screen to enter in the recruitment coordinator's name, phone & e-mail and select from a list of keywords to associate with the study.



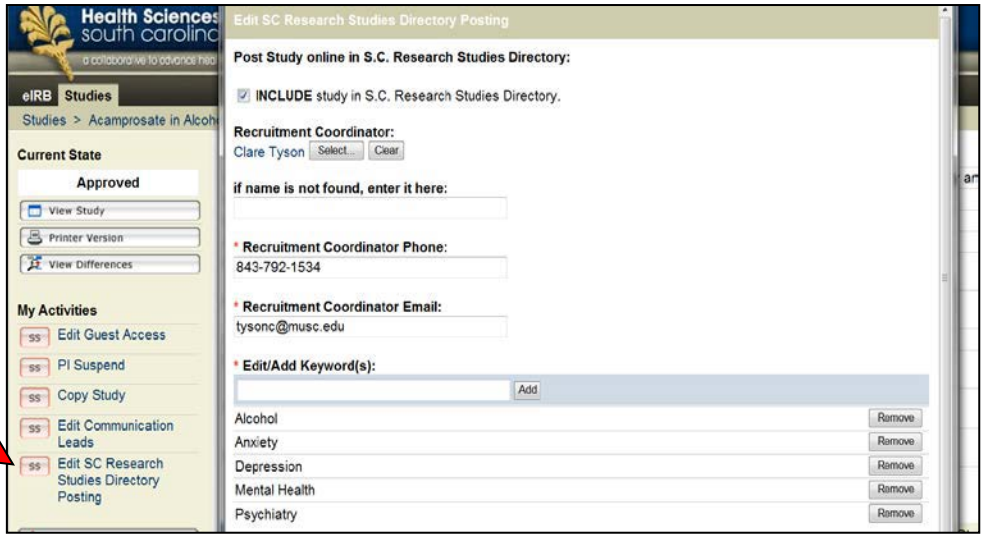


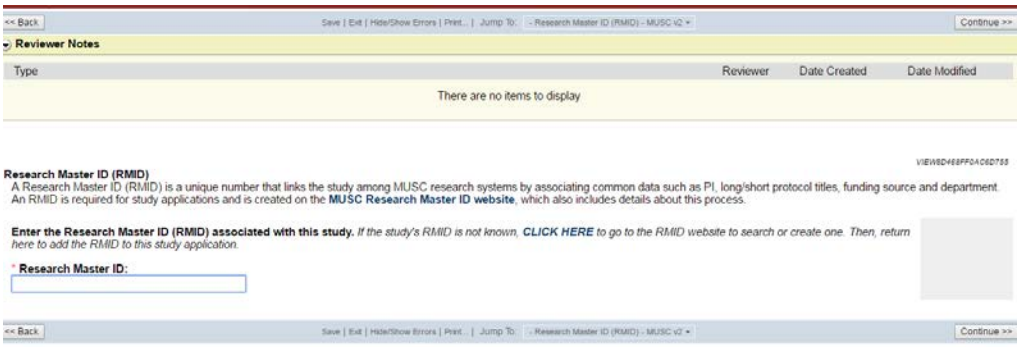
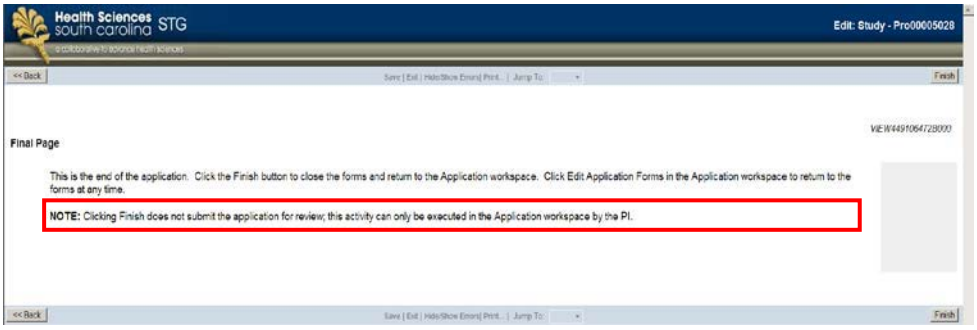
Review a preview of how the study will appear on SCResearch.org.

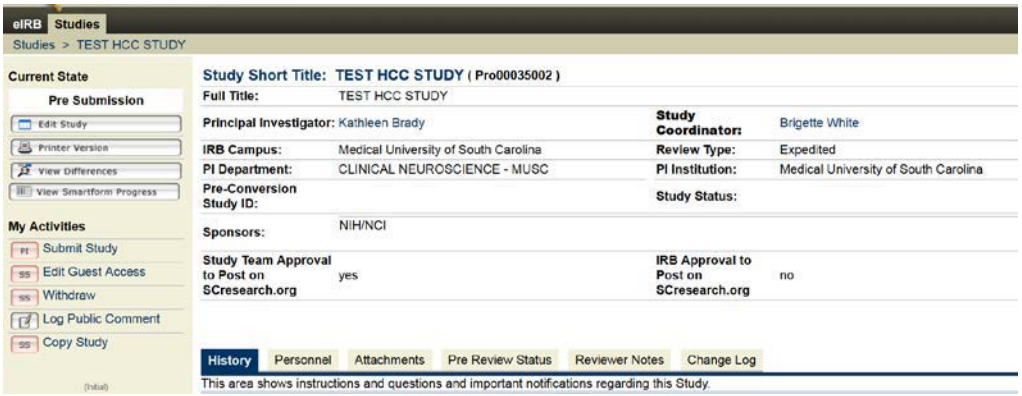
Follow the instructions on this screen to make changes and finalize the study application.



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.

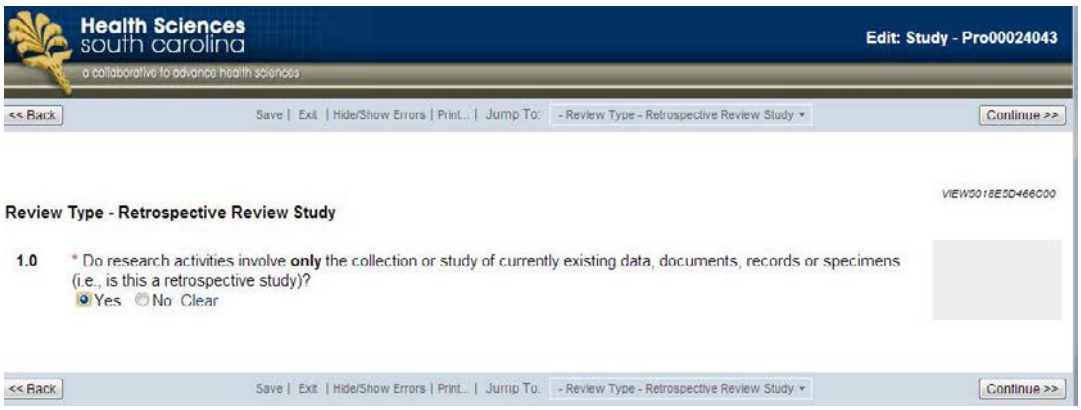
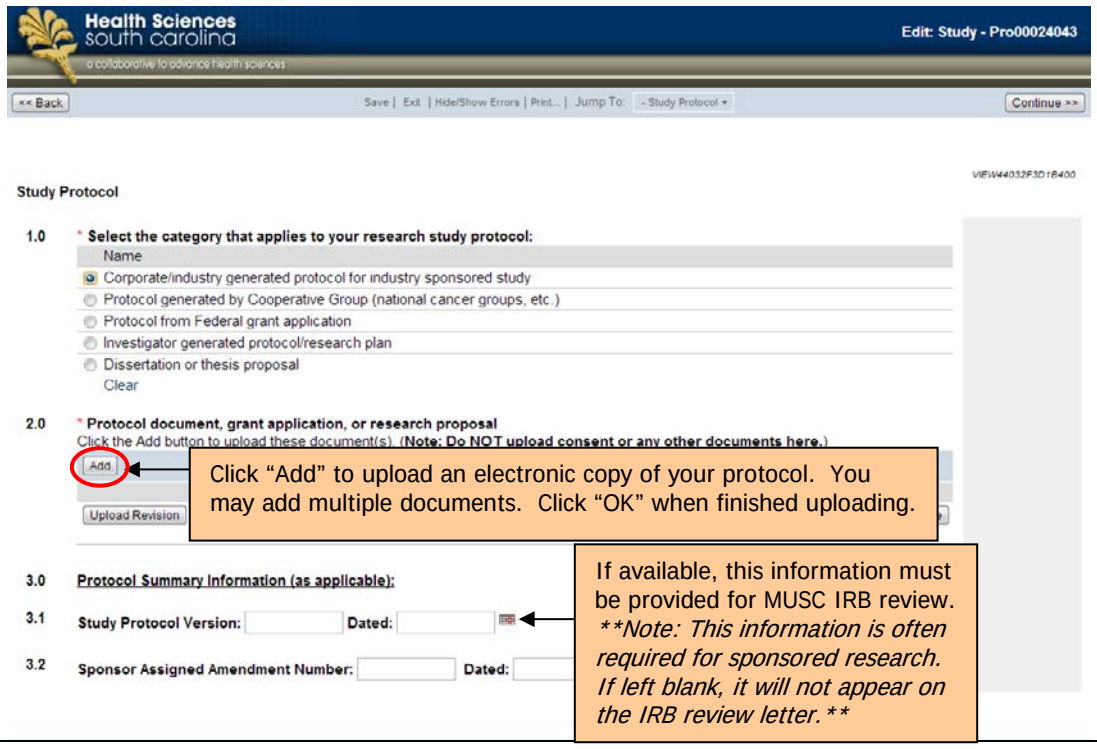


Research Master ID (RMID) A Research Master ID (RMID) is a unique number that links the study among MUSC research systems by associating common data such as PI, long/short protocol titles, funding source and department. An RMID is required for all study applications and is created on the MUSC Research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

Request for Expedited Review (Category 5 Retrospective Studies)

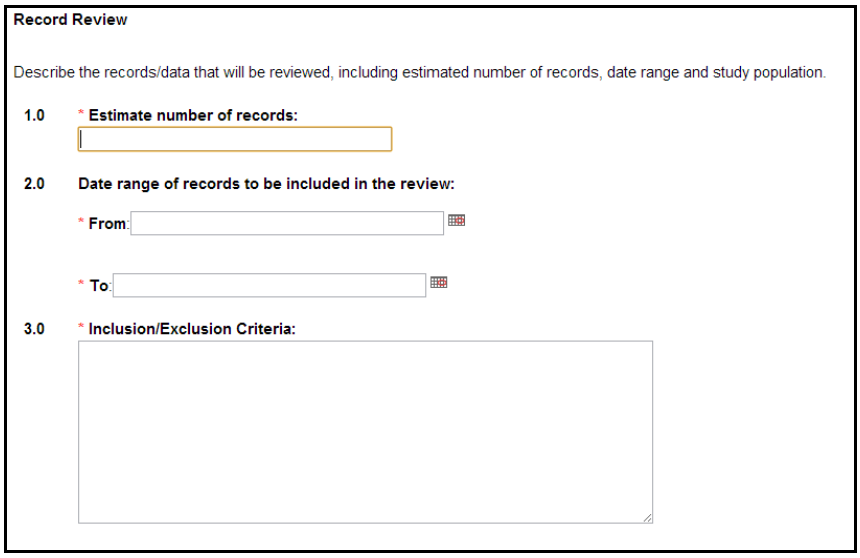
*These steps are expedited review for category 5 retrospective only studies. Complete steps in the 'Expedited Review' section if this is not a study that includes **only** data that existed before this study's IRB application.*

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.	
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.	

Record Review

Enter the estimated number of records, date ranges and inclusion and exclusion criteria for the study.

Click Continue.



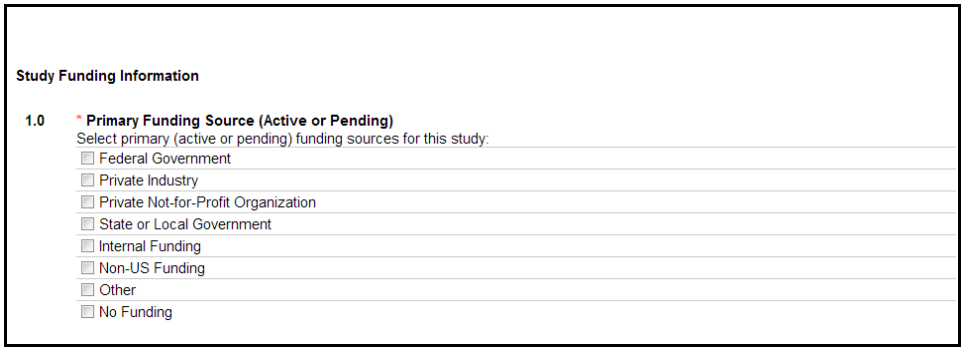
Study Funding

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.

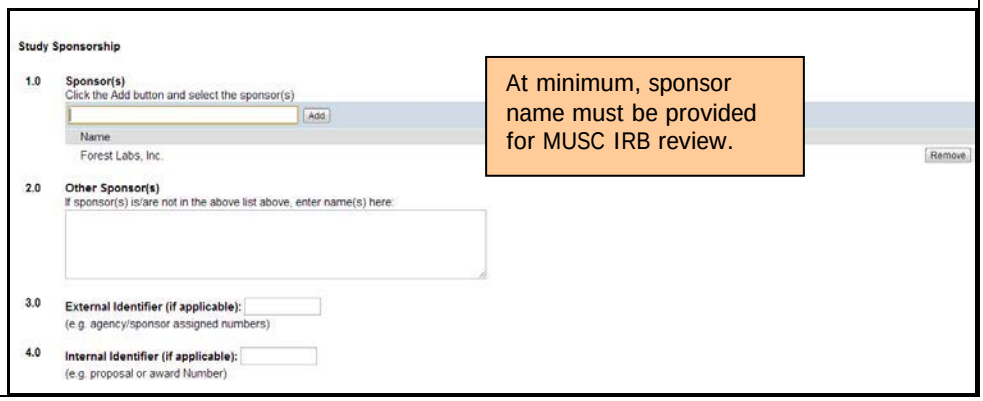
Click Continue.



Indicate details of study sponsorship.

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

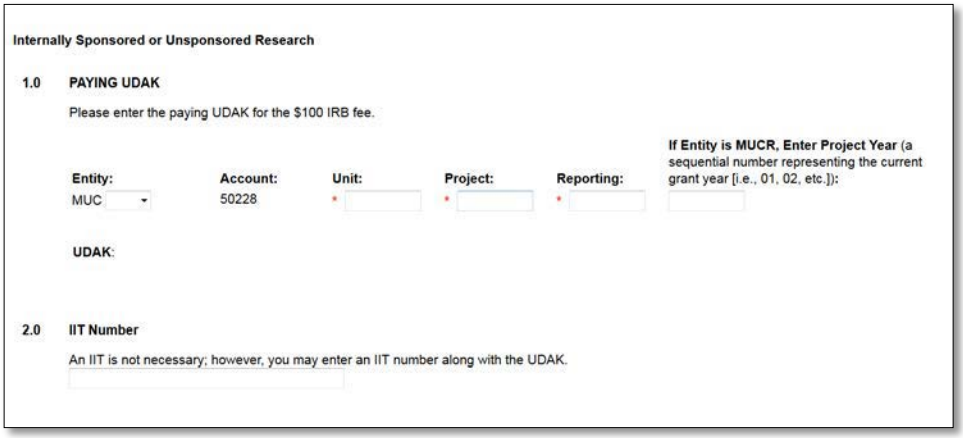
Click Continue.



The 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.

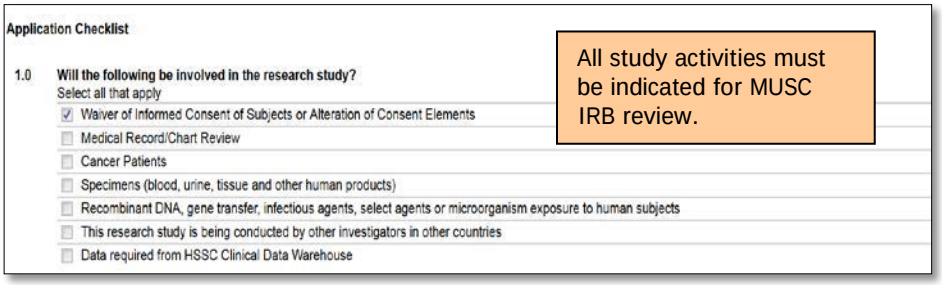


Application Checklist

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

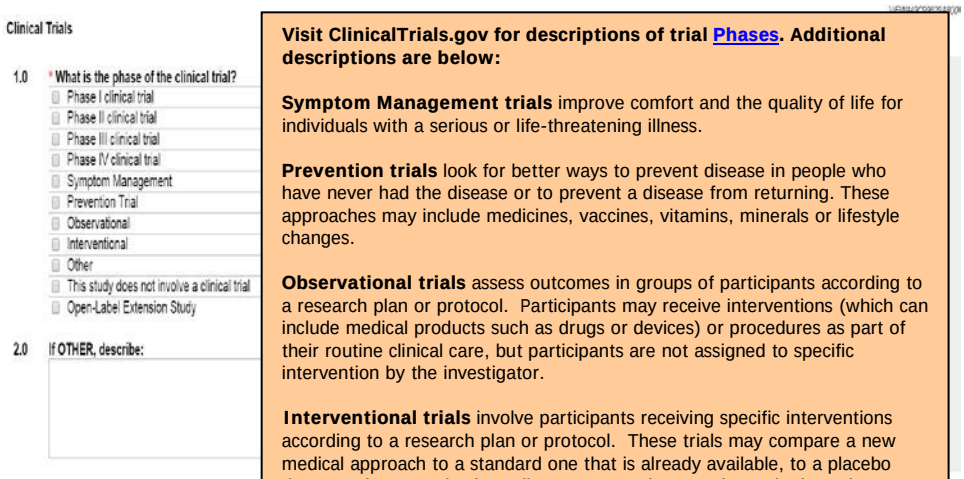
Click Continue.



Clinical Trials

Indicate the type of clinical trial applicable for the project.

Click Continue.



Visit 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.

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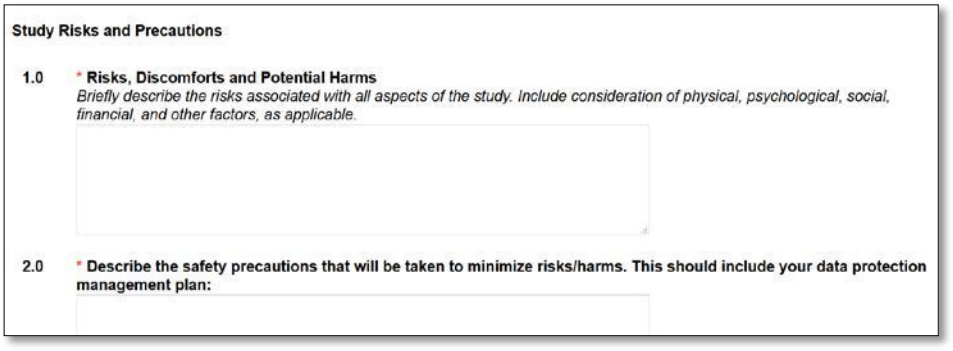
Open-Label Extension Studies are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.

Risks

Describe all potential risks and discomforts and precautions to minimize risks.

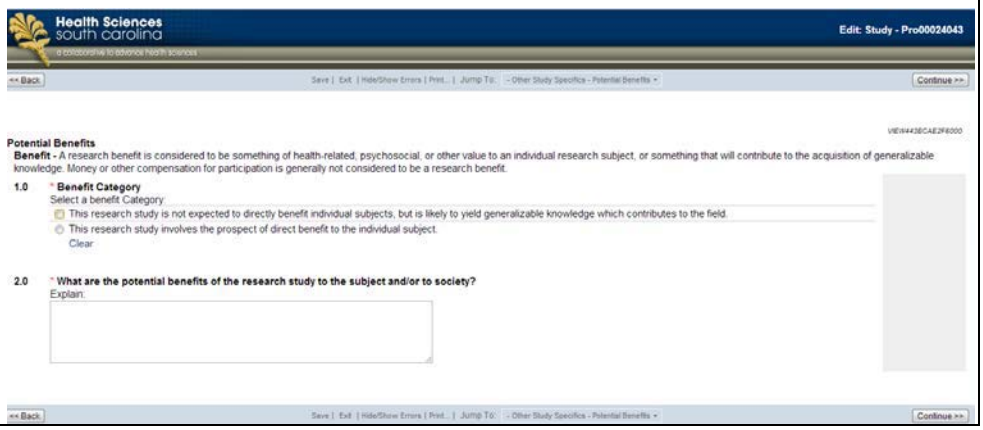
Click Continue.



Potential Benefit

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

Click Continue.

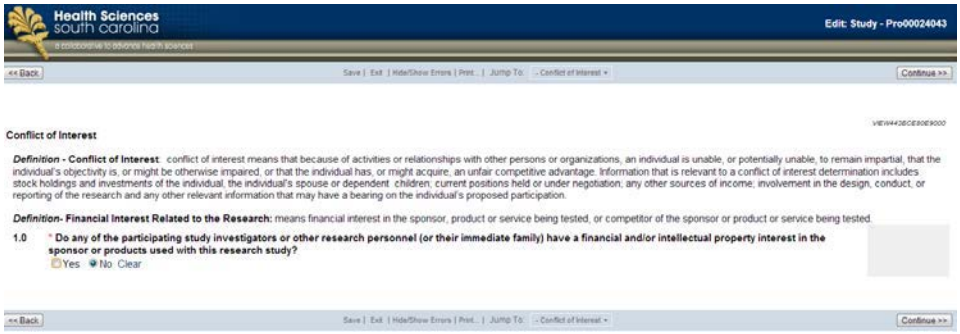


Conflict of Interest

Indicate potential Conflict of Interest.

Click Continue.

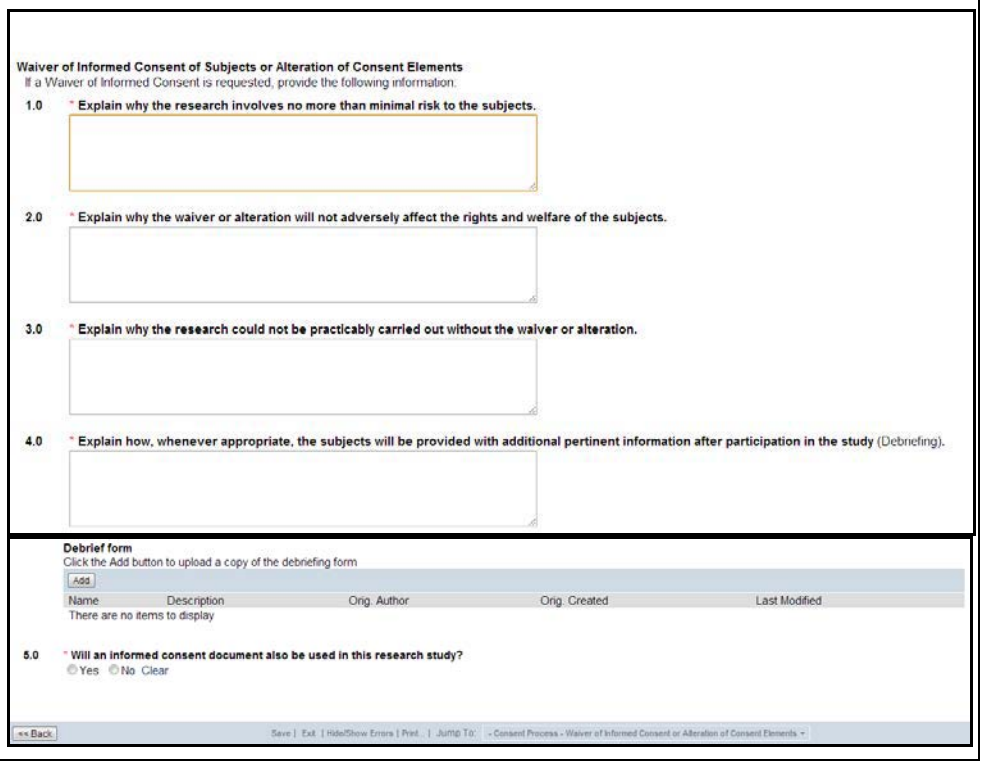
Note: A 'Yes' or privately funded studies response will require responses on the next screen in the system to disclose the interest. In addition, conflicts of interest must be verified at the time of continuing review.



Waiver of Informed Consent or Alteration of Consent Elements

Describe why a Waiver of Informed Consent is being requested.

Click Continue.



Privacy and Confidentiality

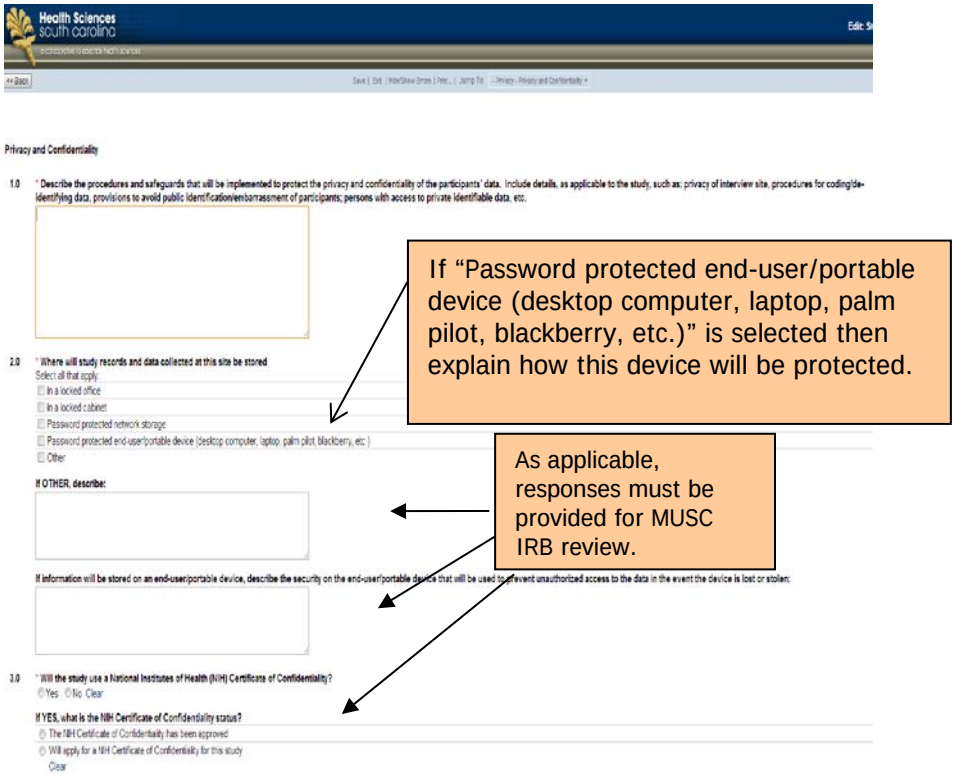
Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

Select where study records and data collected will be stored.

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

Click Continue.

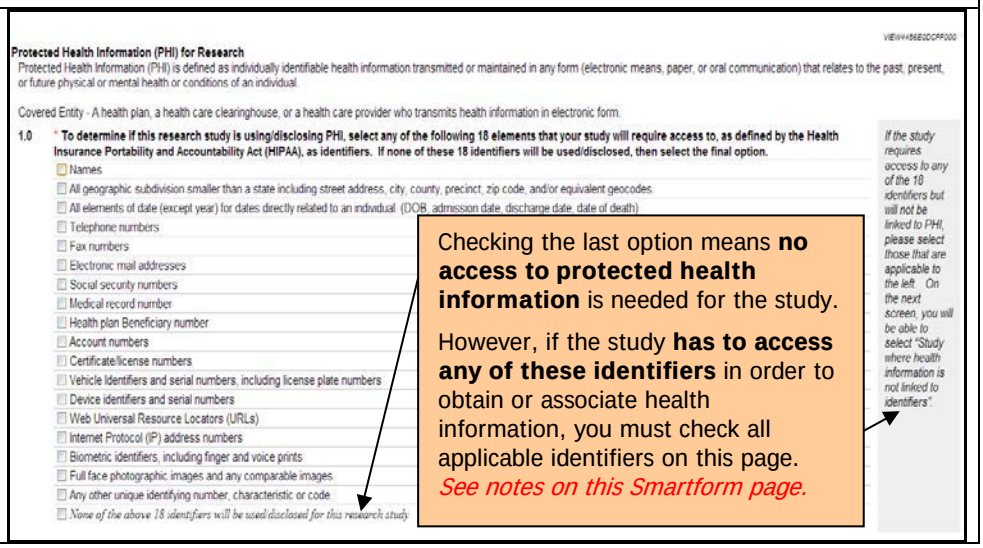
Note: A NIH Certificate of Confidentiality protects investigators and institutions from being forced to disclose research participants' identifying information in research projects with 'sensitive' topics (studies in which disclosure can have adverse consequences for the participant).



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).

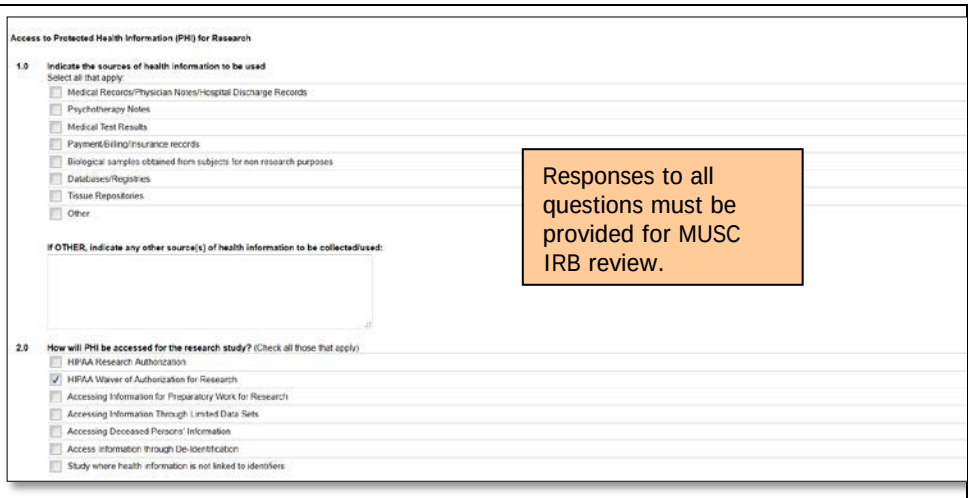
Click Continue.



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.

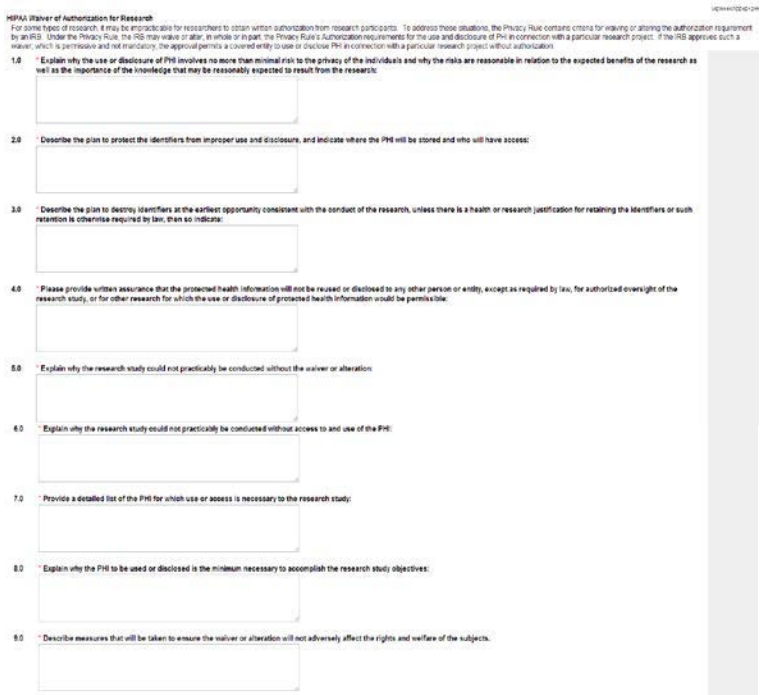


Responses to all questions must be provided for MUSC IRB review.

HIPAA Waiver of Authorization for Research

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

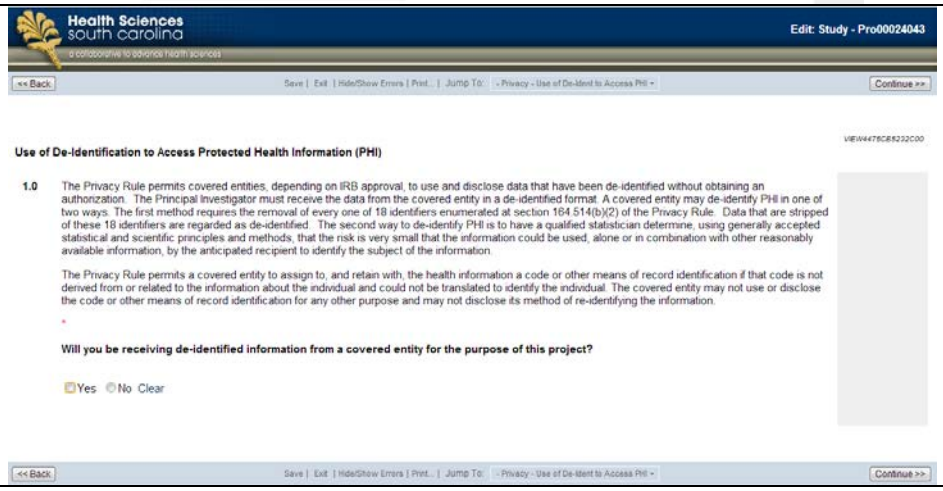
Click Continue.

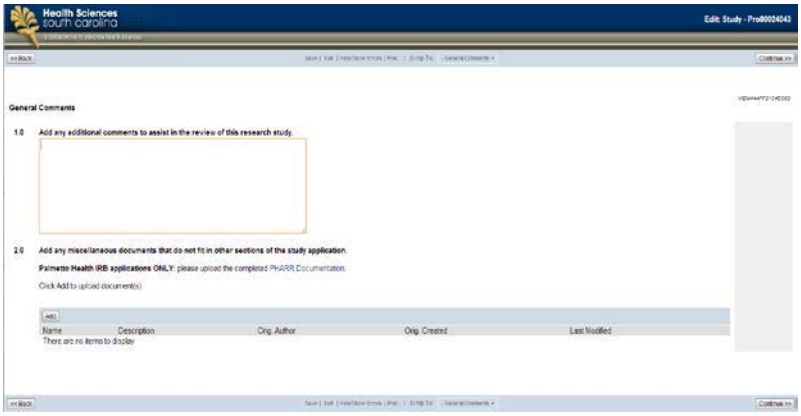
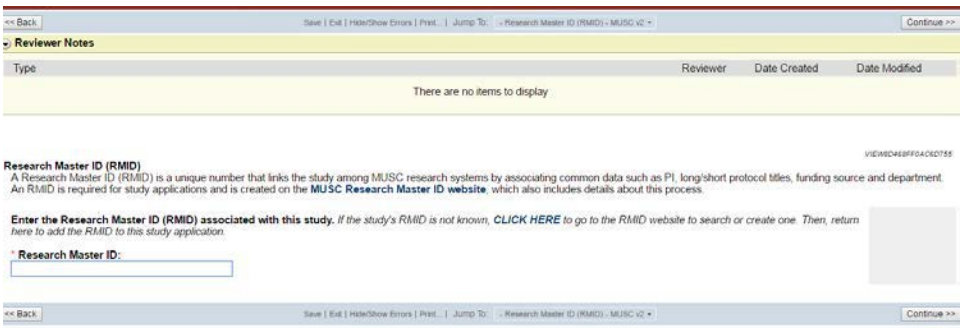


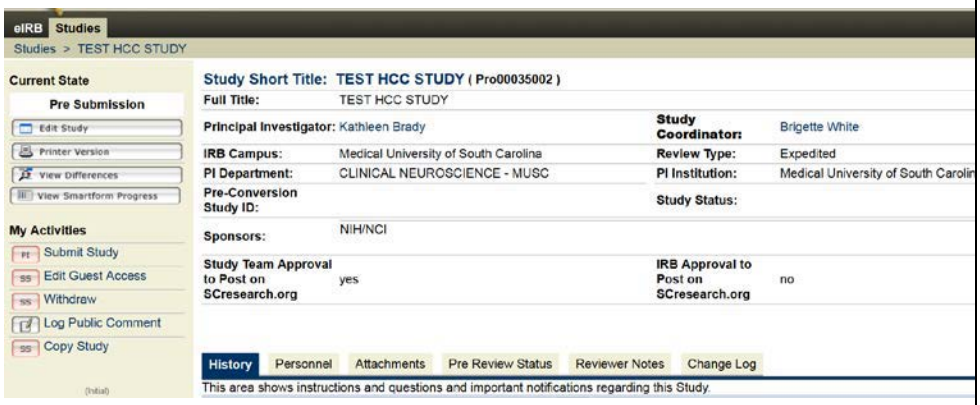
Indicate whether de-identified information will be accessed (viewed, obtained or used) for this study.

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.



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.***	

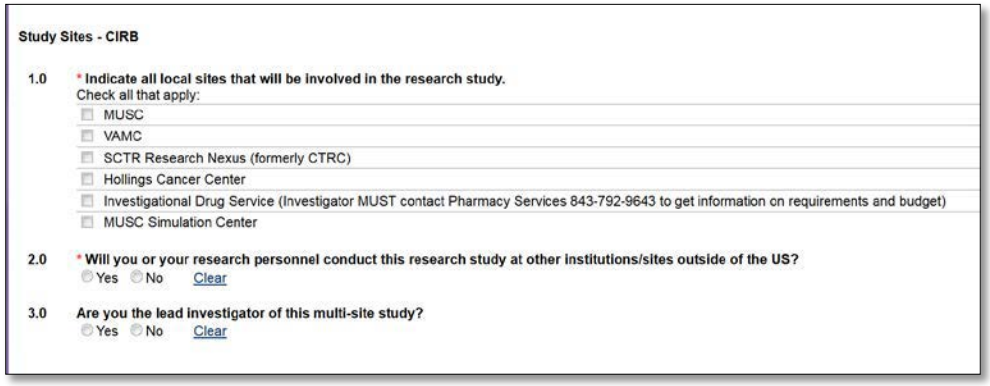
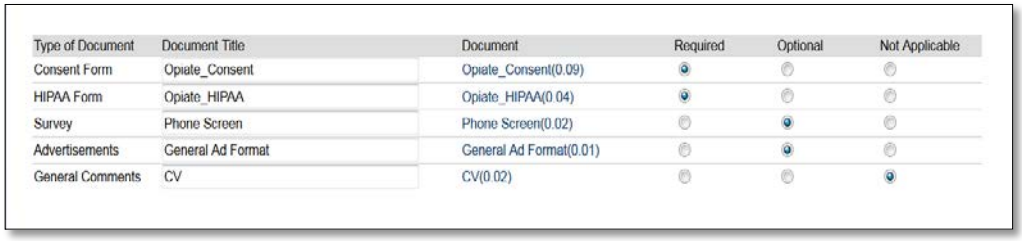
The system will return to the protocol workspace. ***Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the application, the PI must be notified through routine communication that a new study is pending submission.* *To send application, complete steps in the Submission to Mentor/Departmental Review section of this guidance document.***	
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.

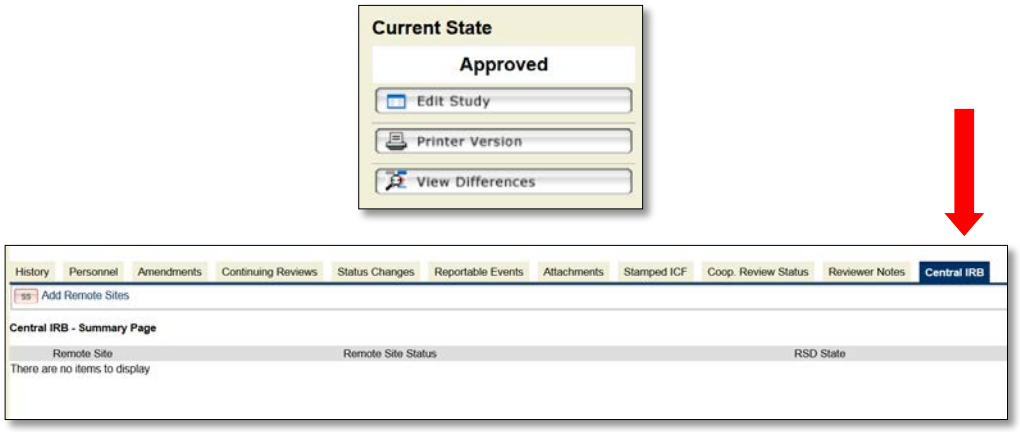
Central IRB Review is indicated early in the application, as described in the 'IRB Review Request' section of this document. These types of studies are completed as other review types (Full Board Review, Expedited Review, Exempt Review) and include additional application pages to complete for the CIRB 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.	
On a new Study Sites page, record the local sites, if there are foreign locations and whether the PI is the lead study investigator.	
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.	

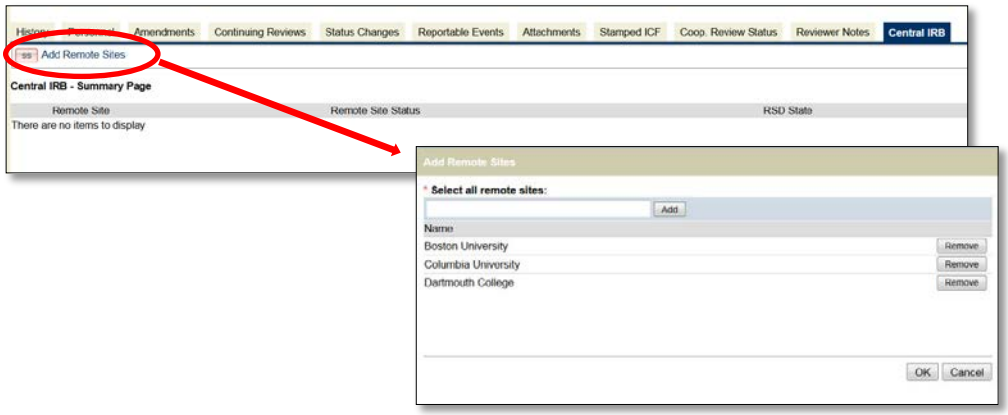
The Lead PI submits the study to IRB for review via the existing review processes *(see the Human Subjects Research Requirements section of this document to complete an application for the applicable study review type).*

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



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.

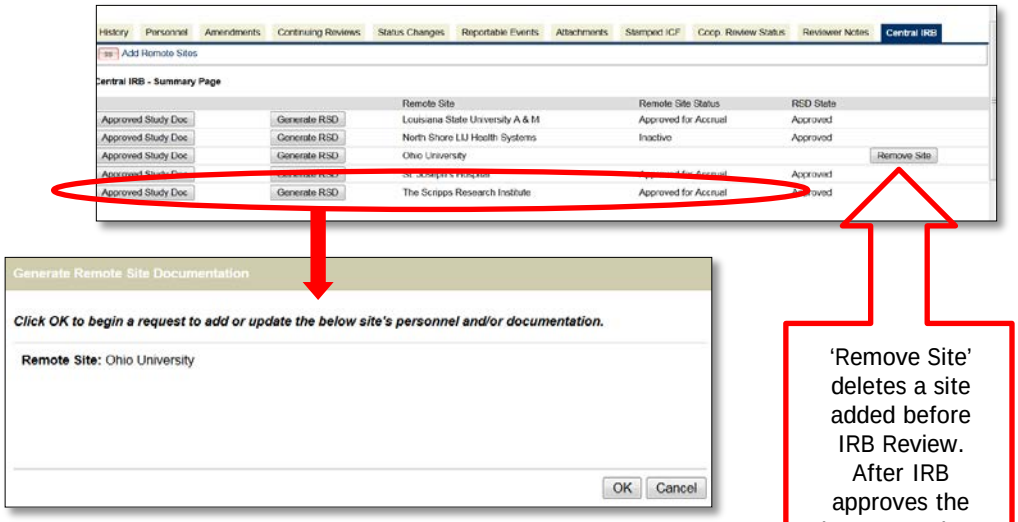


Select the 'Generate RSD' button to begin the request to add the site.

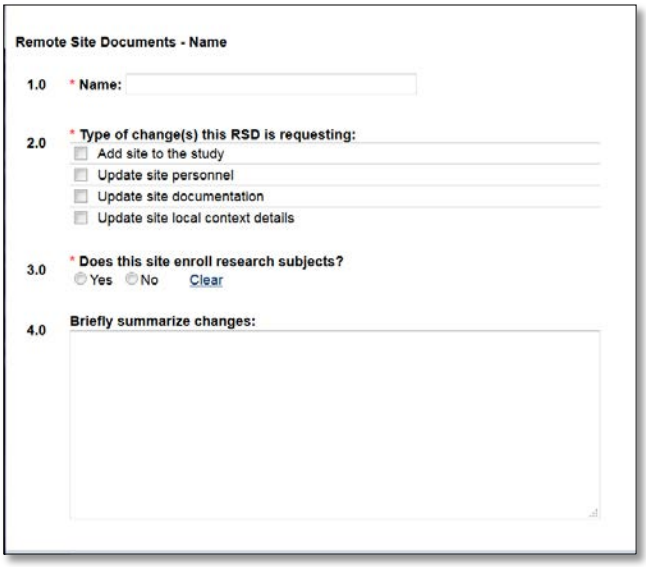
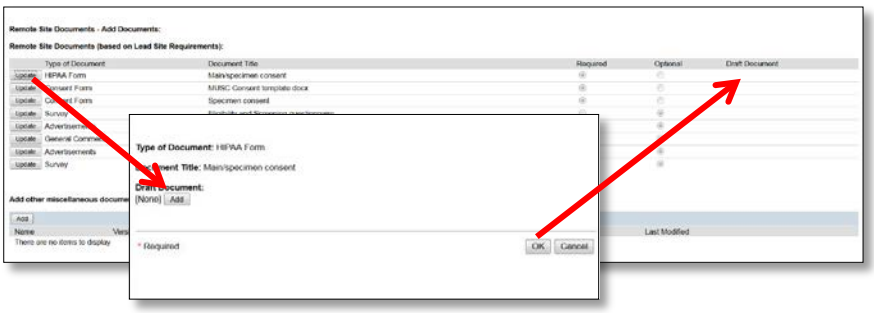
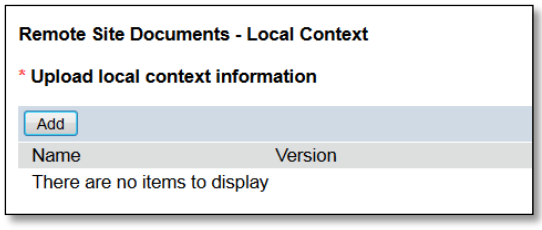
RSD = Remote Site Documentation. This is the mechanism for adding and updating sites, its personnel and site specific documentation for submission to IRB. RSDs be created and submitted independent of study amendments.

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.



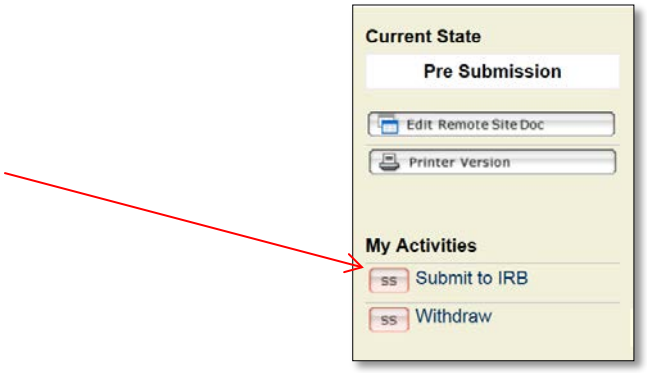
'Remove Site' deletes a site added before IRB Review. After IRB approves the site, removal can occur during an annual review

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.

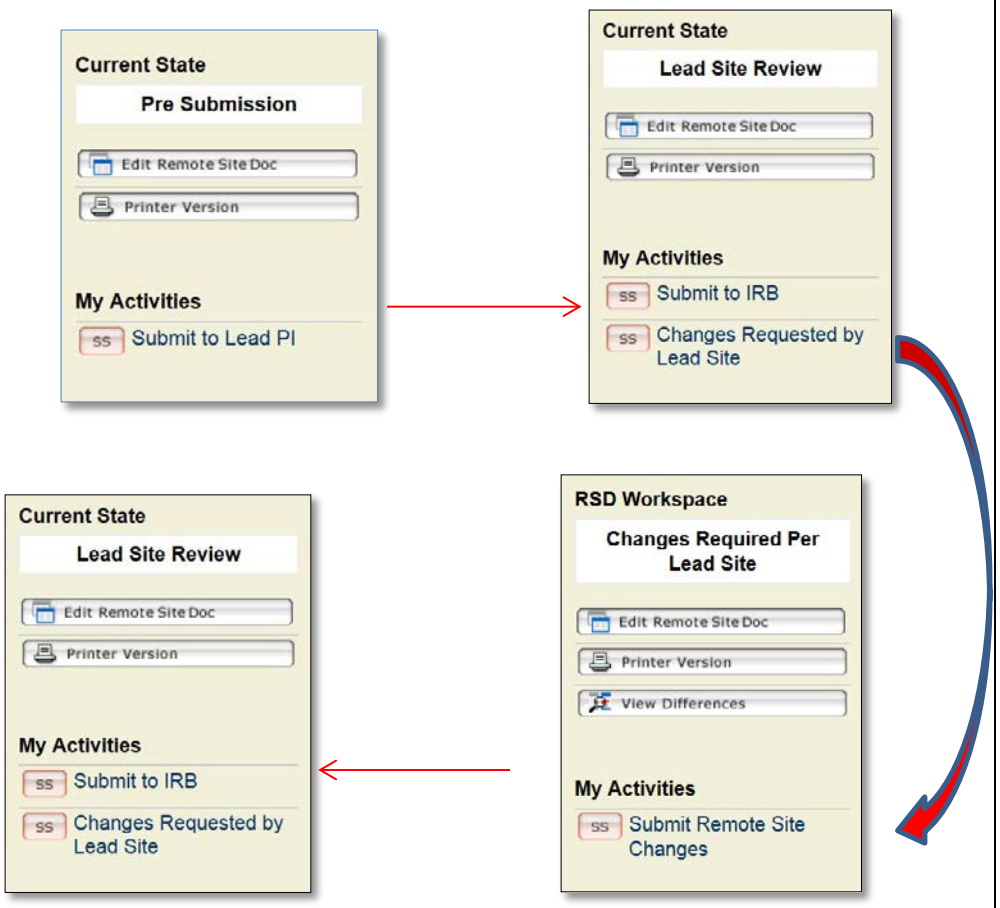
This is usually the next step when the Lead Site personnel has completed the RSD application on behalf of the Remote Site.



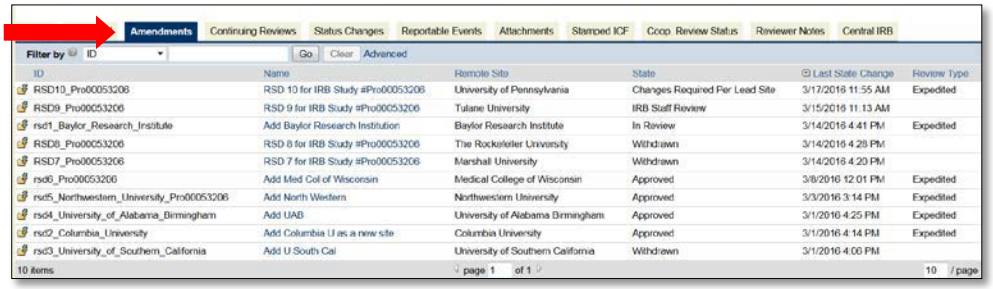
Alternatively, the system also supports a process where:

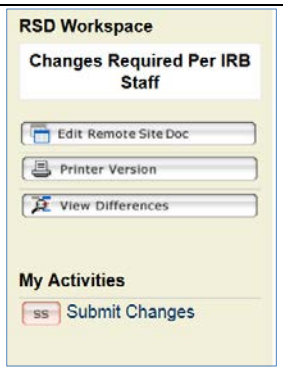
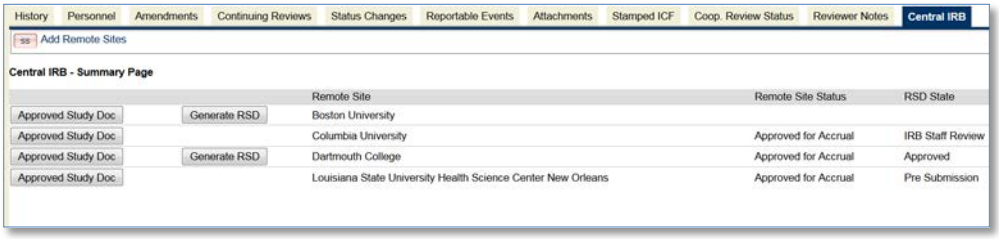
1) the Remote Site personnel completes the RSD application and submits it to the Lead site for review before IRB submission.

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, afterwhich the Lead site personnel can submit to IRB



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



Respond to IRB change requests in the same manner for study amendments. *Both the Lead site personnel and Remote site personnel have the ability to respond to comments.*	
Upon RSD review, approved personnel and documents (along with the draft document versions) appear in the *Central IRB* tab, *Approved Site Docs* button	
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. *The Central IRB tab is also the location where:* *1) the Lead Site personnel can add more sites and create new RSDs to update site details and create new remote site Reportable Events* *2) current Remote Site personnel can create new RSDs and Reportable Events*	

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

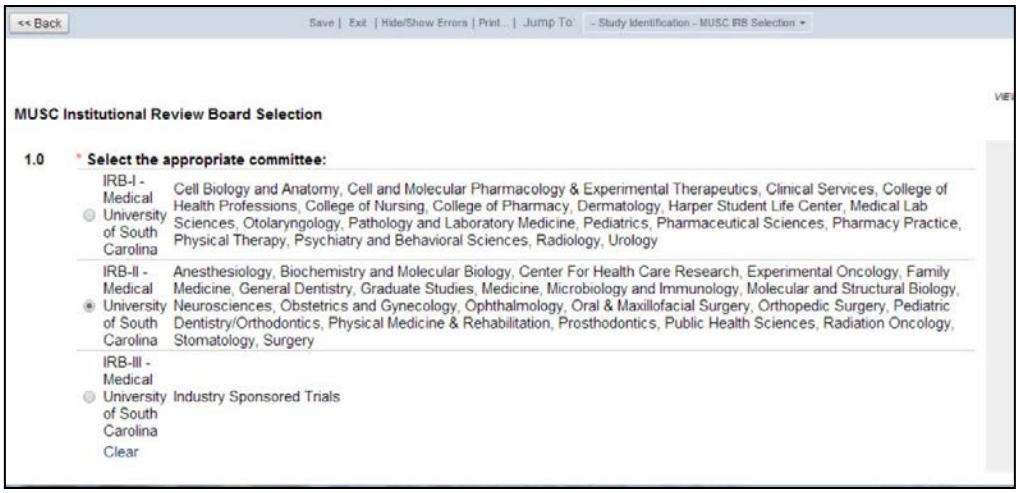
Provide documentation supporting the approval of the study.

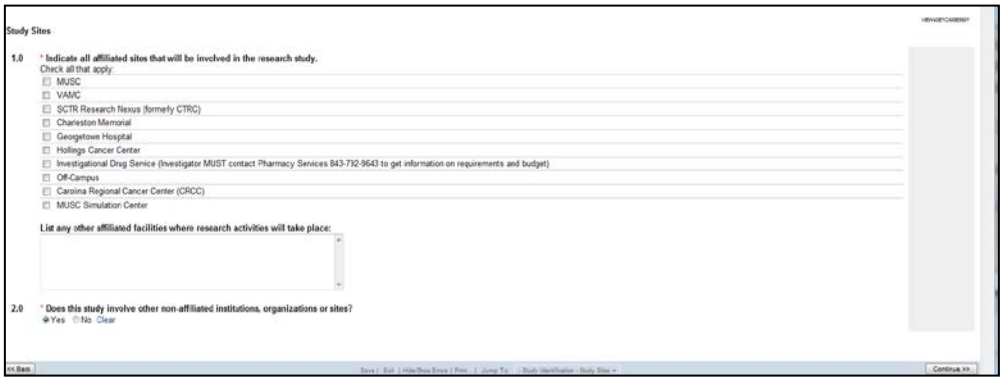
Note: The Protocol and HIPAA authorization form (if applicable) will be uploaded here instead of separate sections within the application.

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.

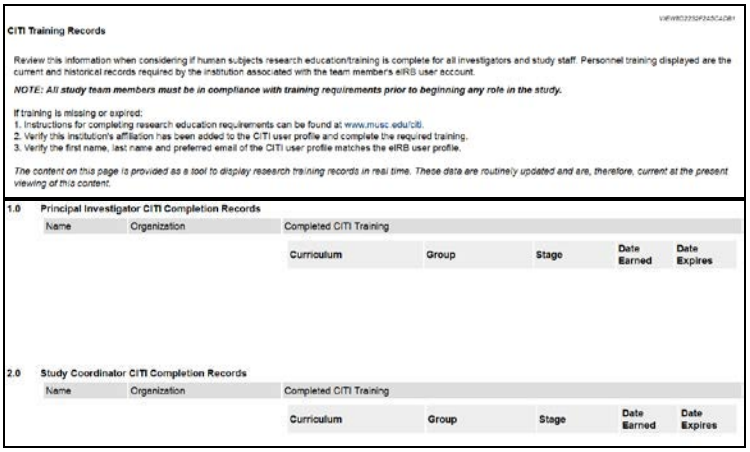




CITI Training Records

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.



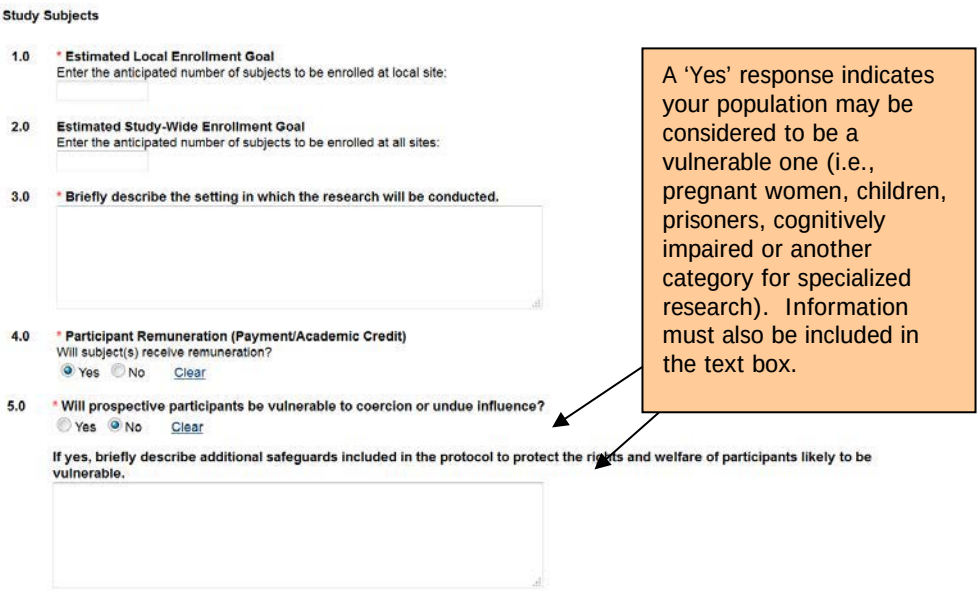
Study Subject
Enter information regarding the subjects you will include in the study

Check all subject populations that are involved in this study.

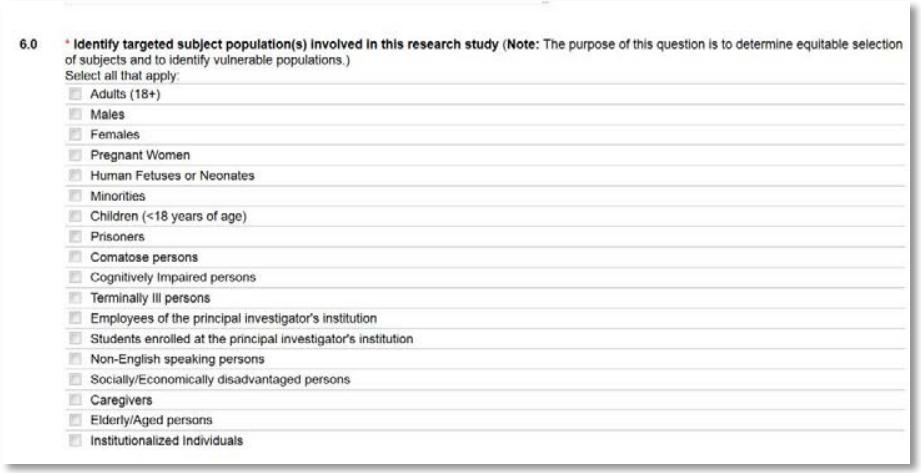
Note: The system will prompt you to answer questions regarding vulnerable populations if they are a part of your study or if there is no intent to include set groups.

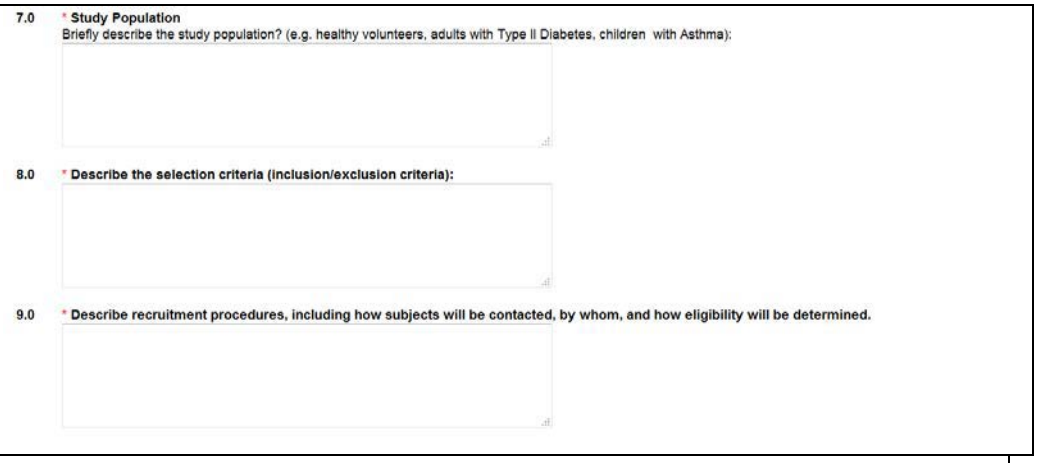
Describe the population, inclusion/exclusion & recruitment procedures.

Click Continue.

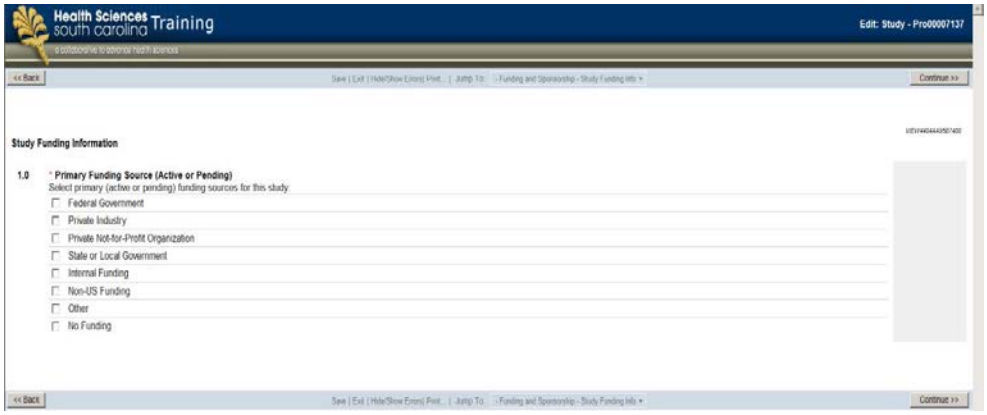


A 'Yes' response indicates your population may be considered to be a vulnerable one (i.e., pregnant women, children, prisoners, cognitively impaired or another category for specialized research). Information must also be included in the text box.

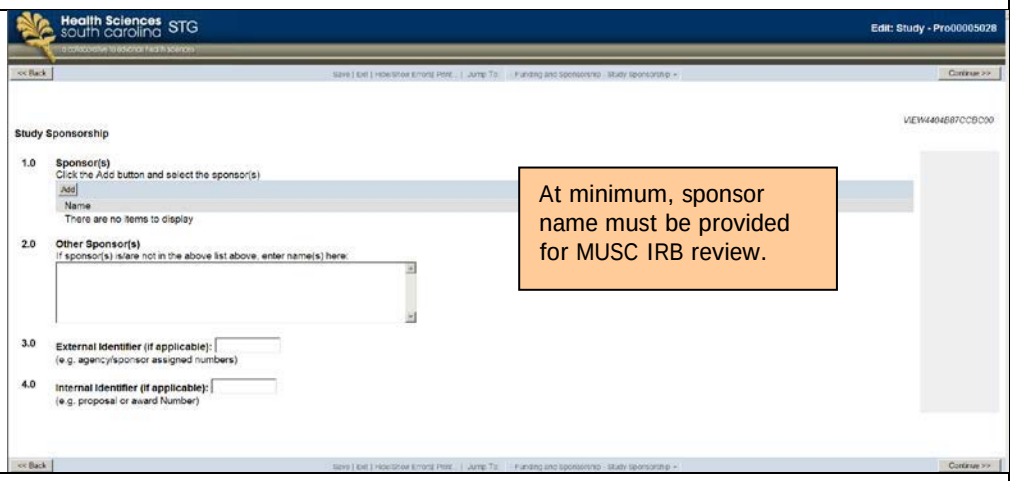


<table>
<tr><td></td><td> 
</td></tr>
<tr><td>Study Funding
Indicate study funding sources.

**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.

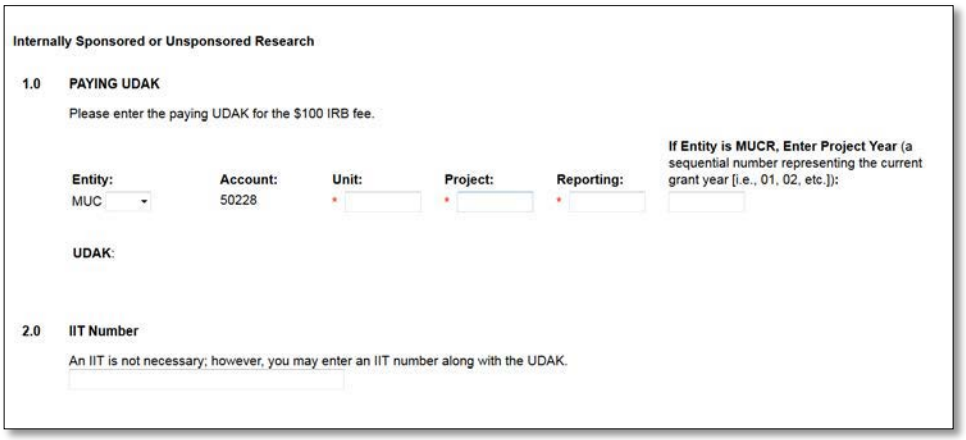
Click Continue.</td><td> 
</td></tr>
<tr><td>Indicate details of study sponsorship.

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

Click Continue.</td><td> 
</td></tr>
<tr><td>The Intra-Institutional Transfer (IIT) Smartform is required for faculty researchers of unfunded or internally funded IRB studies.</td><td></td></tr>
</table>

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

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 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 W
- ☐ Waiver of Informed Consent of Subjects
- ☐ Clinical trials
- ☐ Data Safety Monitoring Plan is used in t
- ☐ 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 reg that will be administered to subjects
- ☐ Use of Placebos
- ☑ Investigation of medical device, instrument, machine, computer program or other device, FDA app
- ☐ Specimens (blood, urine, tissue and other human products)
- ☐ The storage of biological specimens (e.g. biological material, tissue, blood, etc.) or Data (e.g. subj potential future, yet undesignated, research
- ☐ Recombinant or synthetic nucleic acid molecules, gene transfer, infectious agents, select agents c Botulinum toxins) exposure to human subjects
- ☐ The use of diagnostic or therapeutic ionizing radiation, or radioactive isotopes that are not part of as part of this research study
- ☐ Advertisements or recruiting materials
- ☐ Data from the statewide Health Sciences South Carolina (HSSC) Clinical Data Warehouse ?

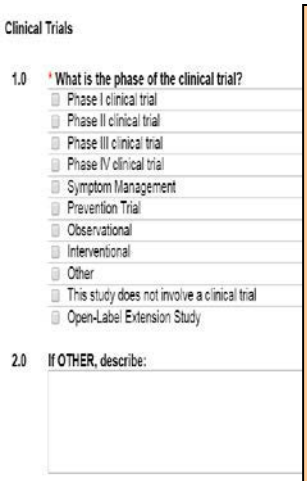
A clinical trial is a prospective biomedical or behavioral human subject research study that is designed to answer specific questions about biomedical or behavioral interventions or lab test evaluations and determine whether these are safe, efficacious and effective. These trials often require Data and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



Visit 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.

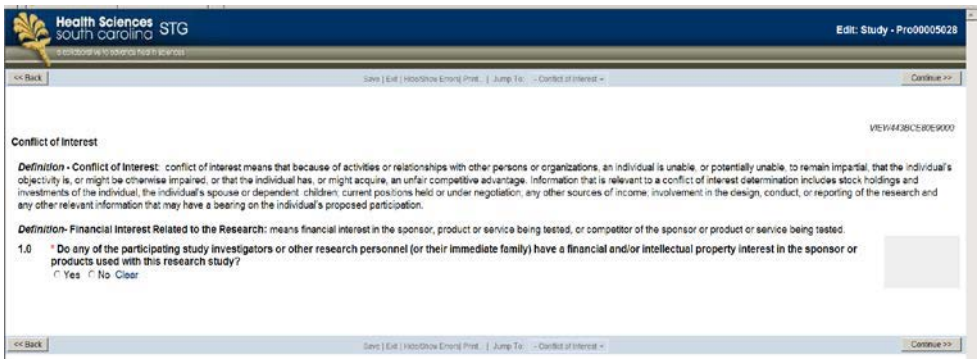
ClinicalTrials.gov

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.

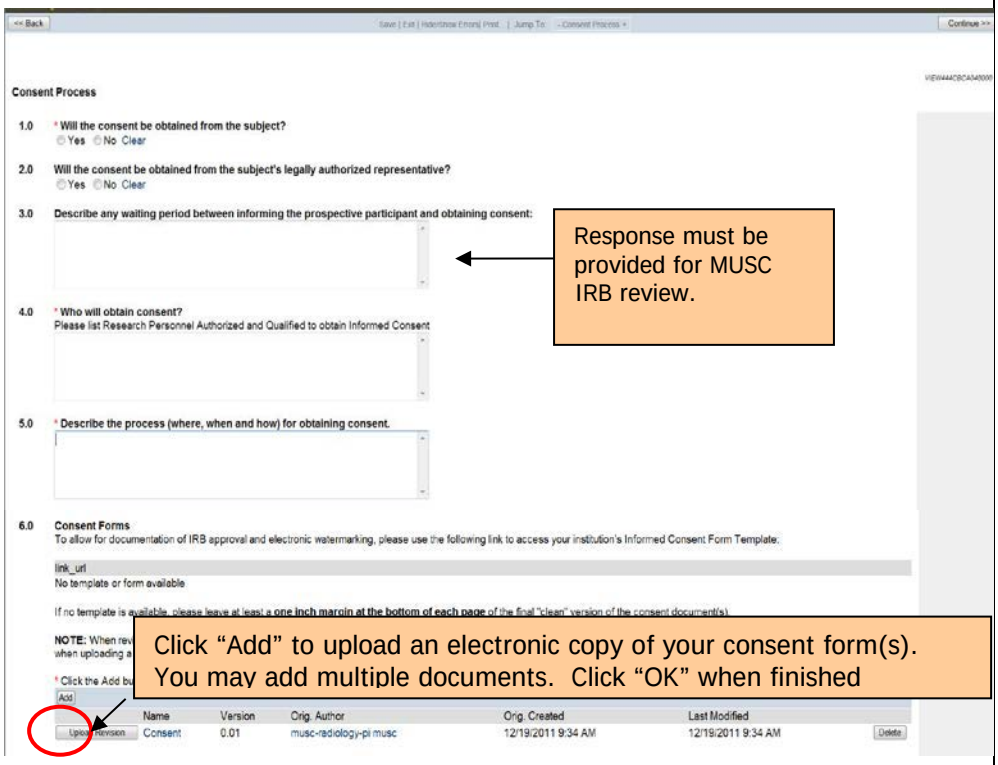


Consent Process

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.



Privacy and Confidentiality

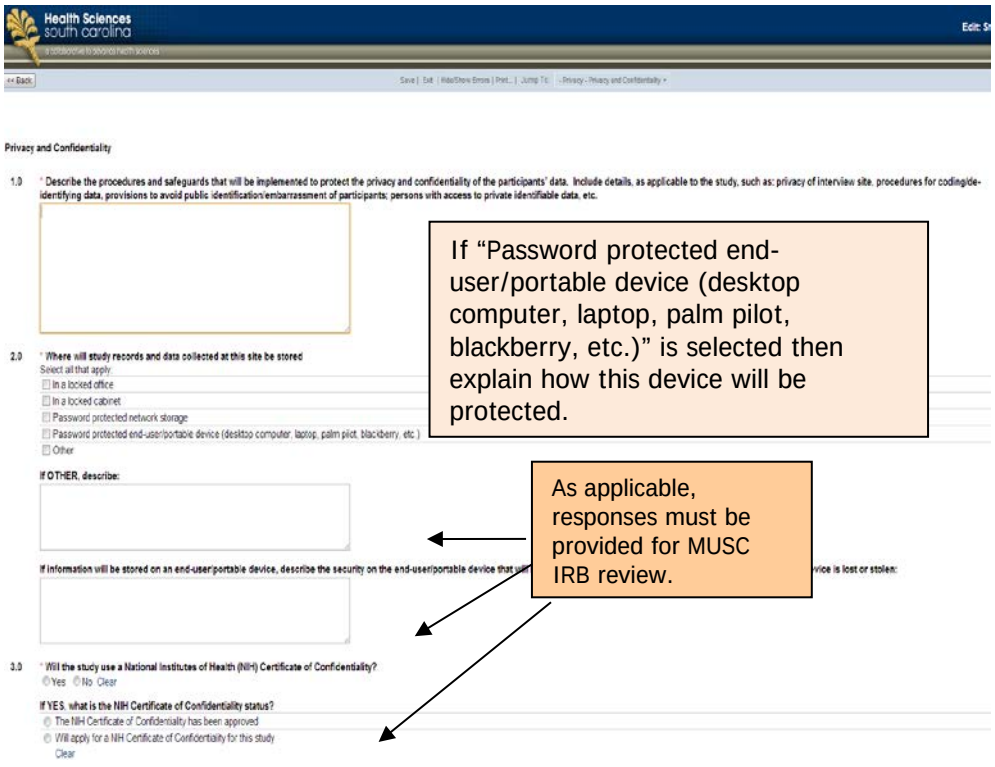
Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

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).

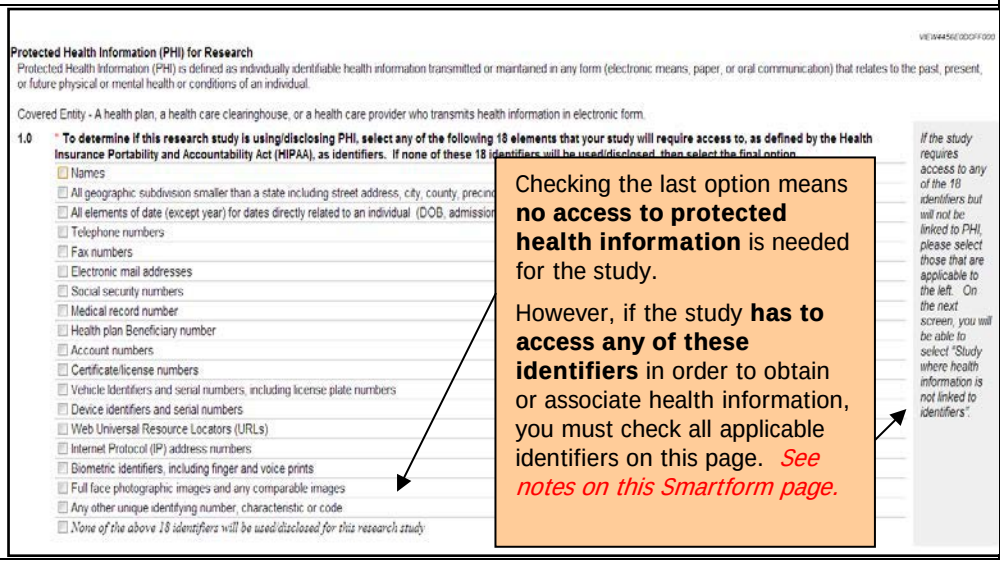
Click Continue.



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

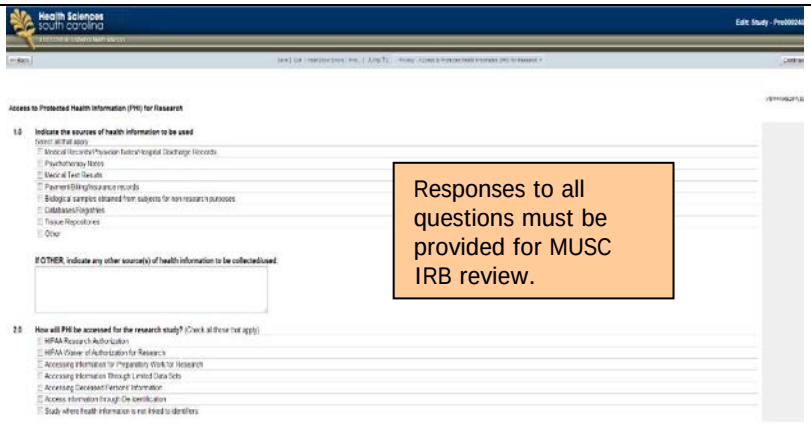
Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI).

Click Continue.



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

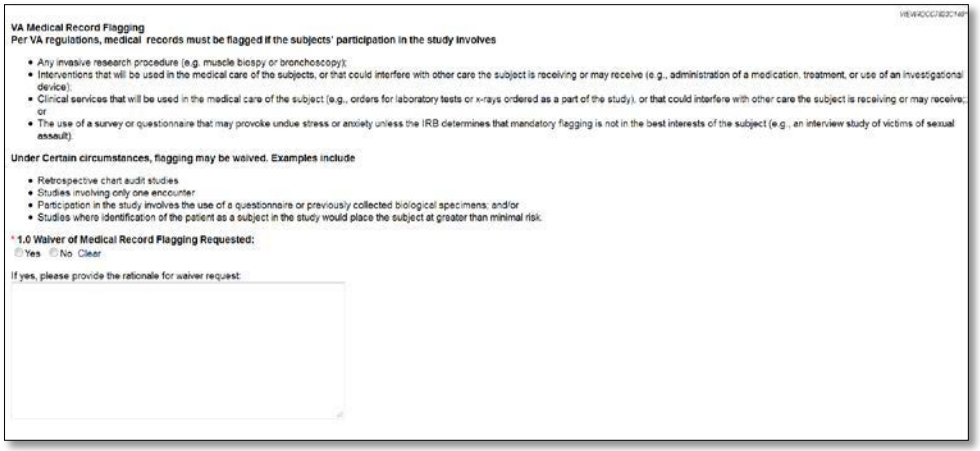
Click Continue.



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

For VA studies, indicate medical record flagging waiver requests.

Click Continue.

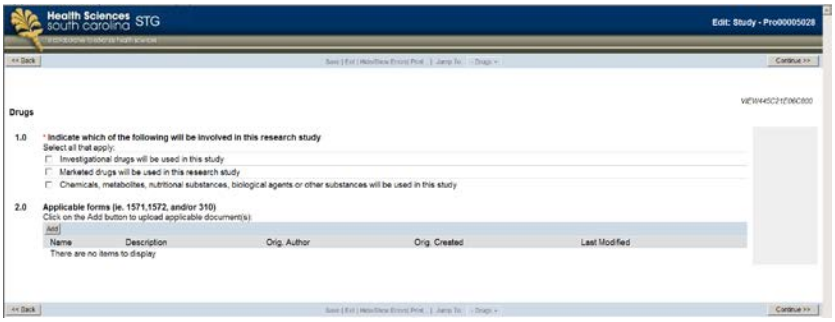


Drugs

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

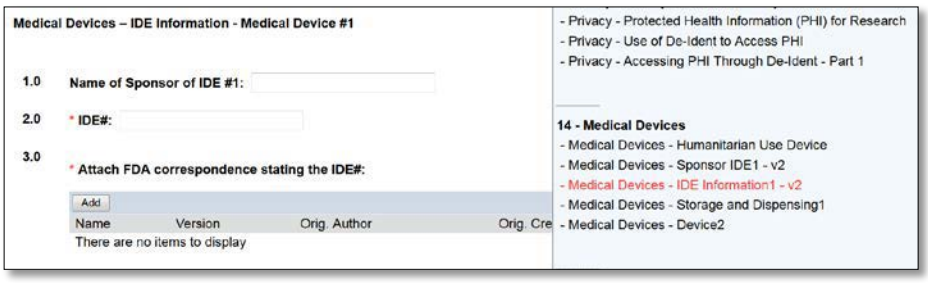
Click Continue.

***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.

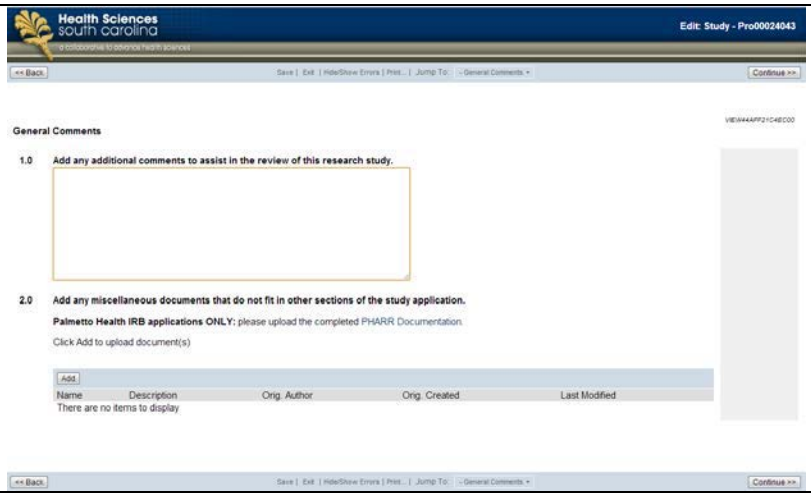


General Comments

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

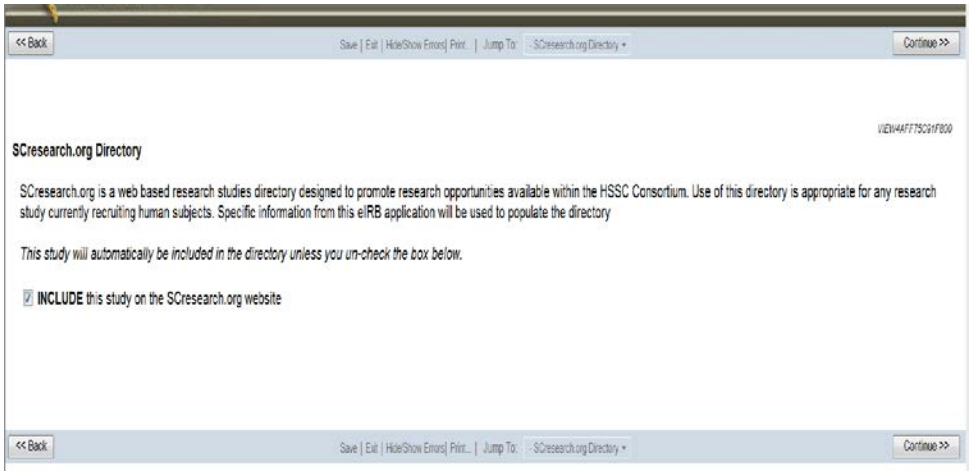
Click Continue.



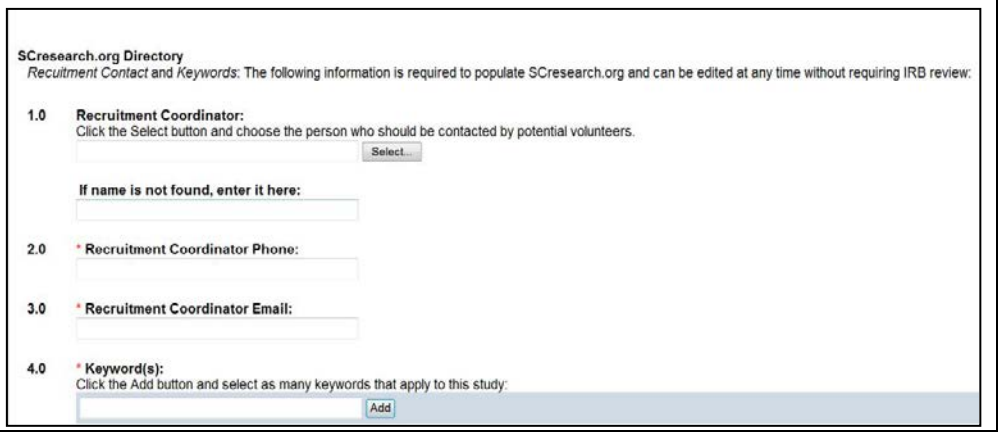
S.C. Research Studies Directory Online Posting

The study will be included on 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

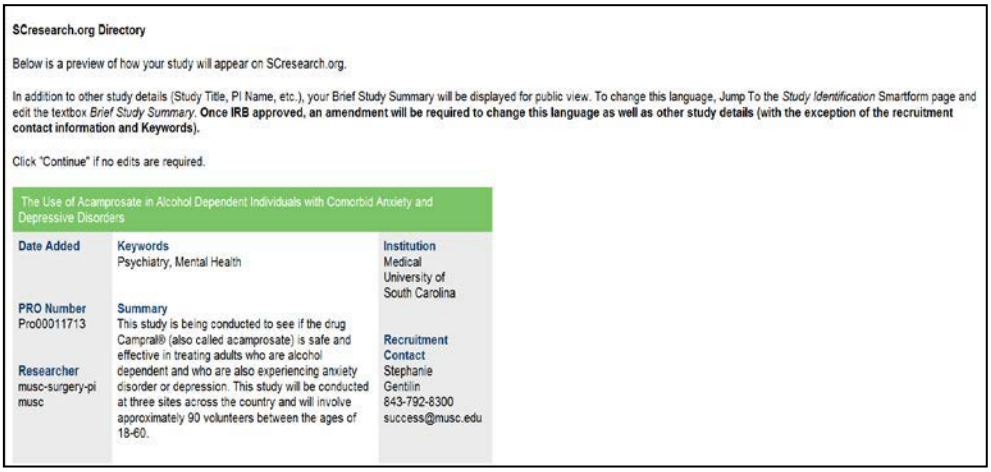


Continue to the next screen to enter in the recruitment coordinator's name, phone & e-mail and select from a list of keywords to associate with the study.

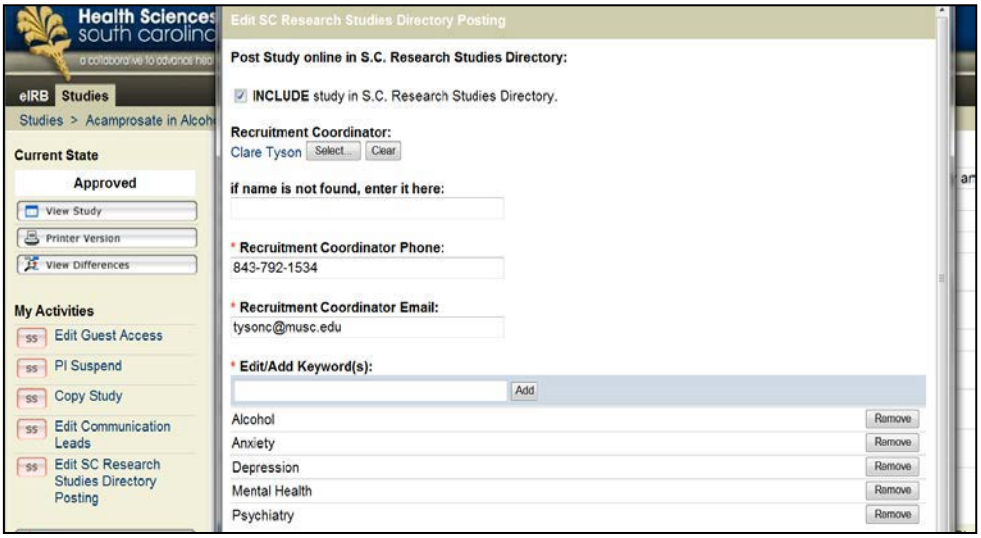


Review a preview of how the study will appear on SCResearch.org.

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



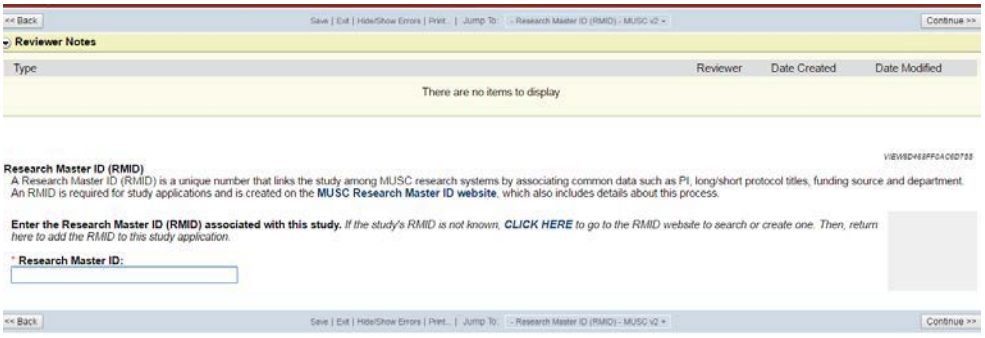
Posting the study on the registry & the information in this section can be revised at any point by accessing the 'Edit SC Research Studies Directory Posting' option on the protocol's main page.



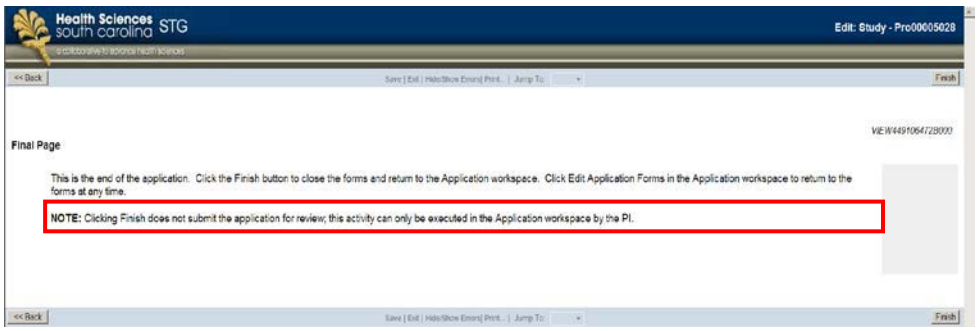
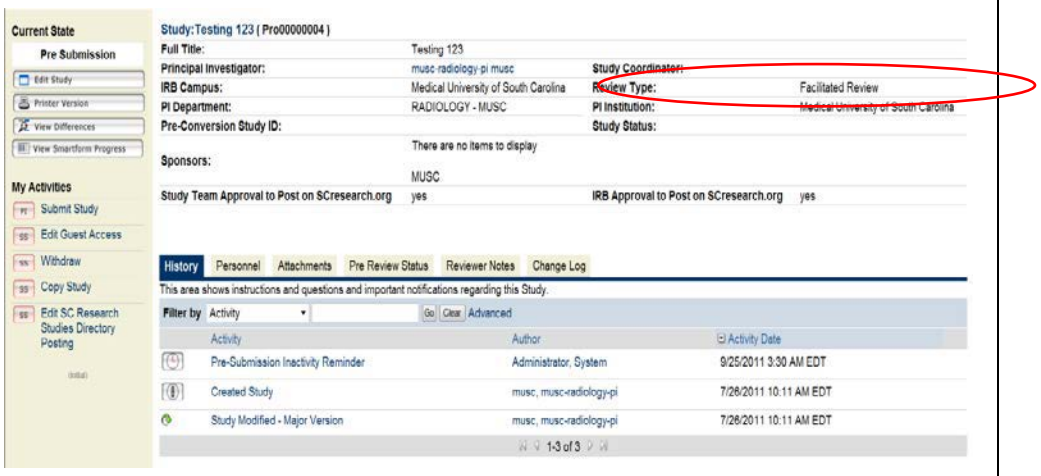
Research Master ID (RMID)

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.



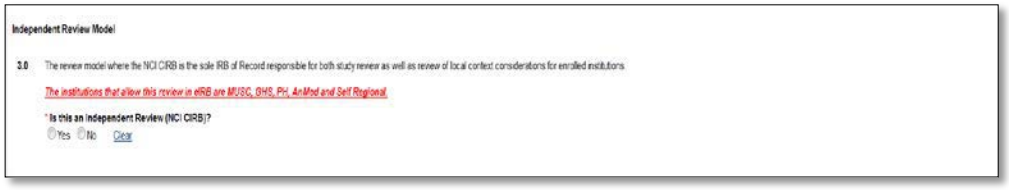
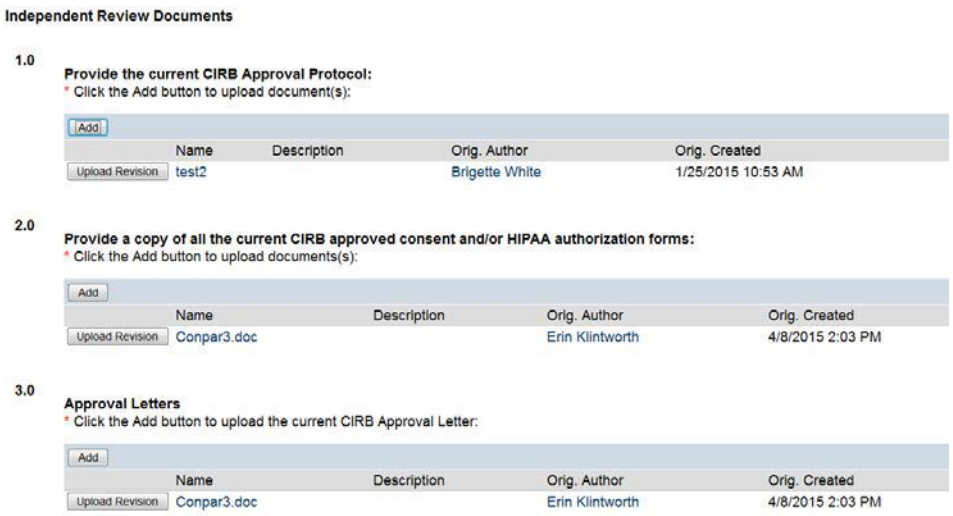
Enter the study's Research Master ID. Click Continue.	

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. 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.***	

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.

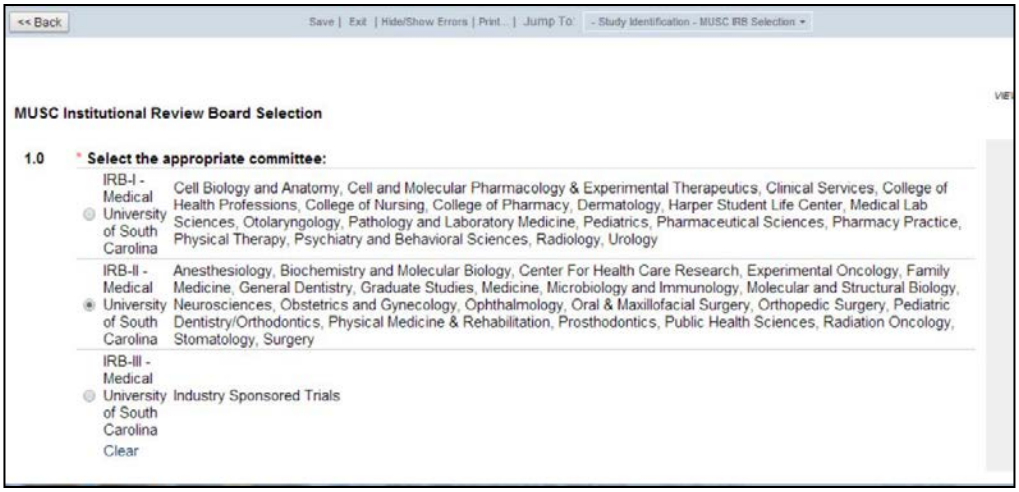
If not already completed, follow the steps in the 'Beginning the Application'.

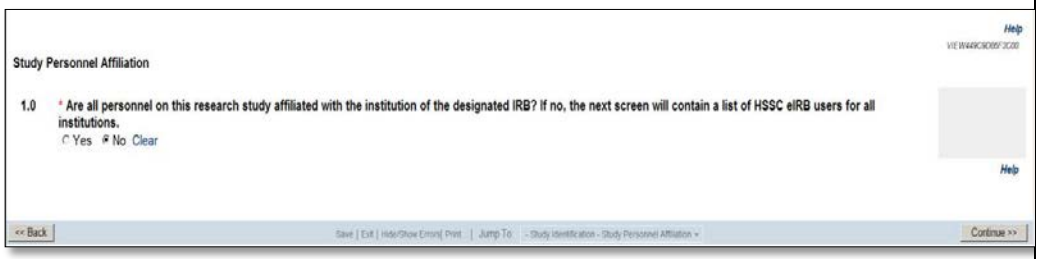
IRB Review Request Indicate Study Review Type as "Independent Review (NCI CIRB)". Click Continue.	
NCI CIRB documents Upload the NCI CIRB approval documents where indicated. Click Continue.	

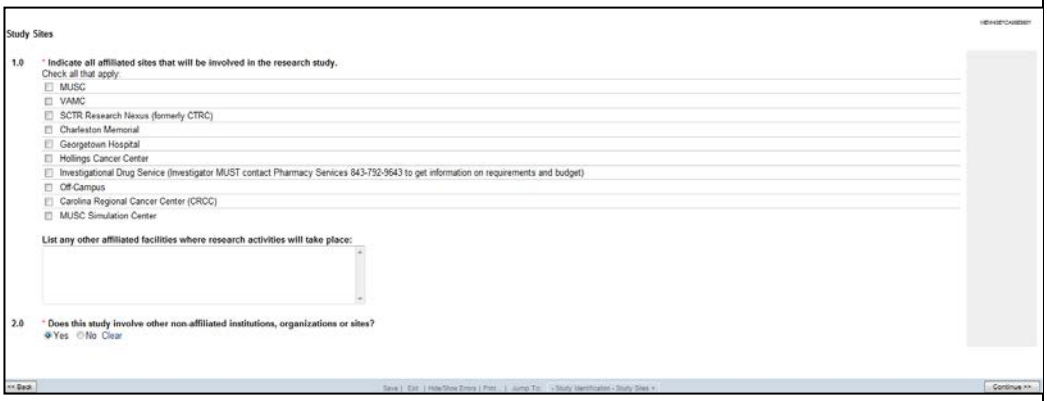
Study Identification

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.



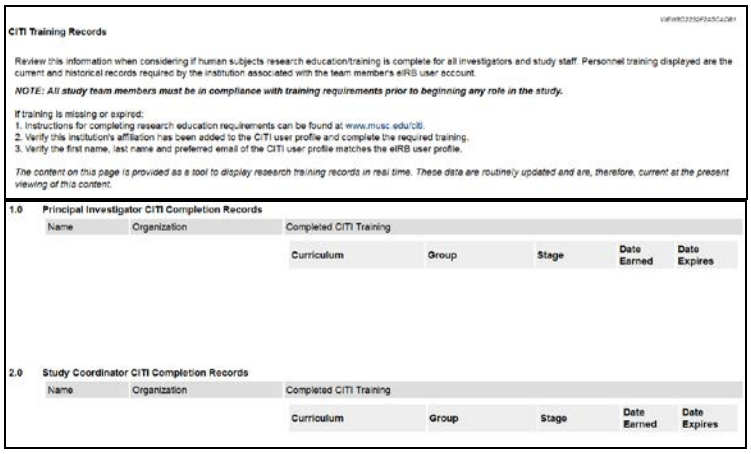




CITI Training Records

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

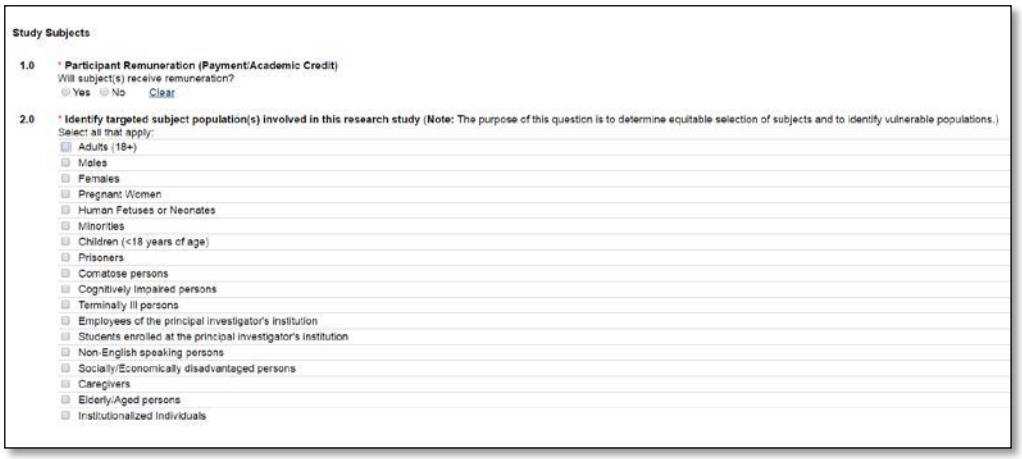
For additional guidance for this feature is located in the Education & Training section of eIRB.



Study Subjects

Check all subject populations that are involved in this study.

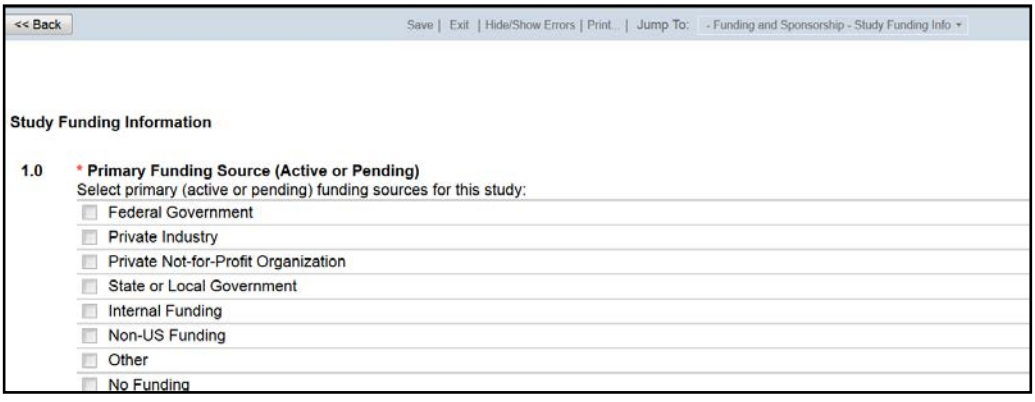
Click Continue.



Study Funding

Indicate study funding sources.

Click Continue.

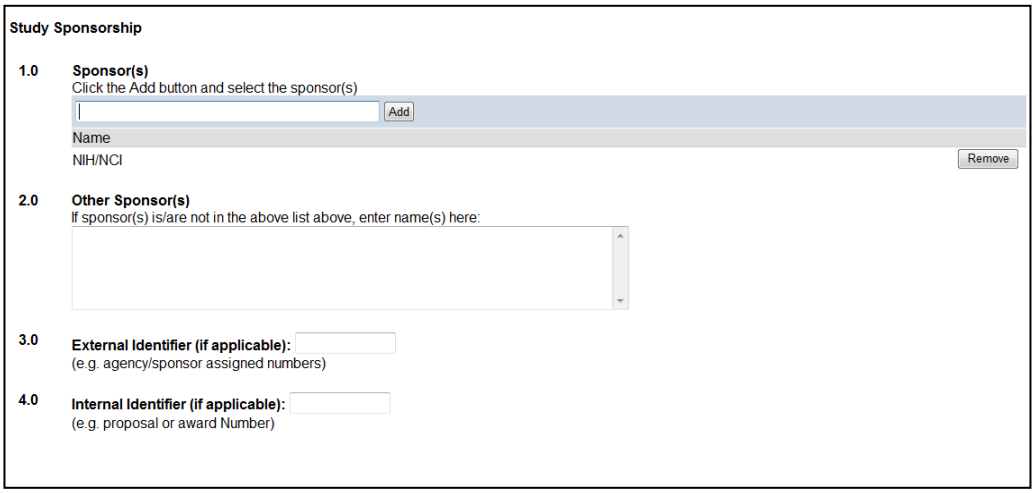


Study Sponsorship

Indicate details of study sponsorship.

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

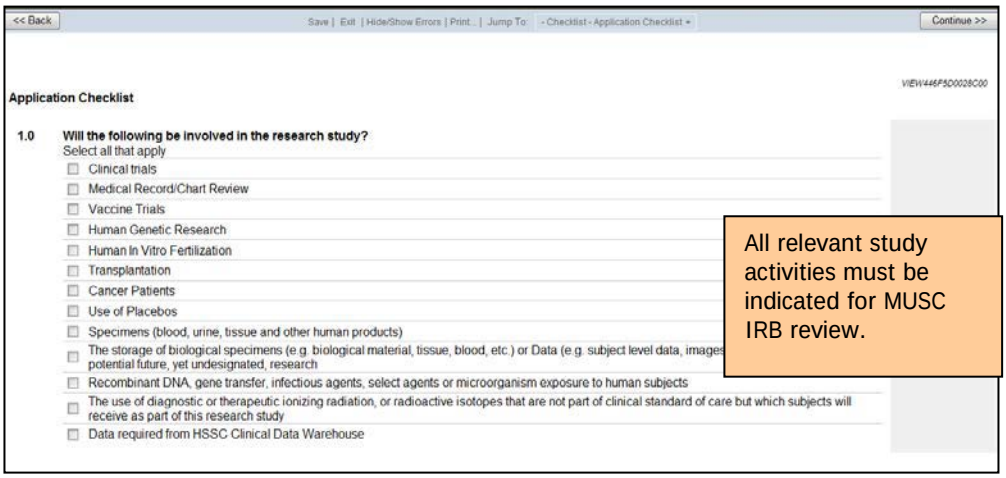
Click Continue.



Application Checklist

Check all applicable items for this project.

Click Continue.



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

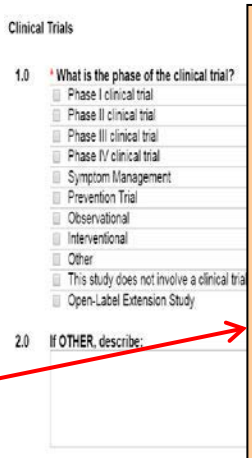
Clinical Trials

Indicate the type of clinical trial applicable for this project.

Click continue.

Visit ClinicalTrials.gov for descriptions of trial Phases.

Descriptions of the other listed trial types are included here



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.

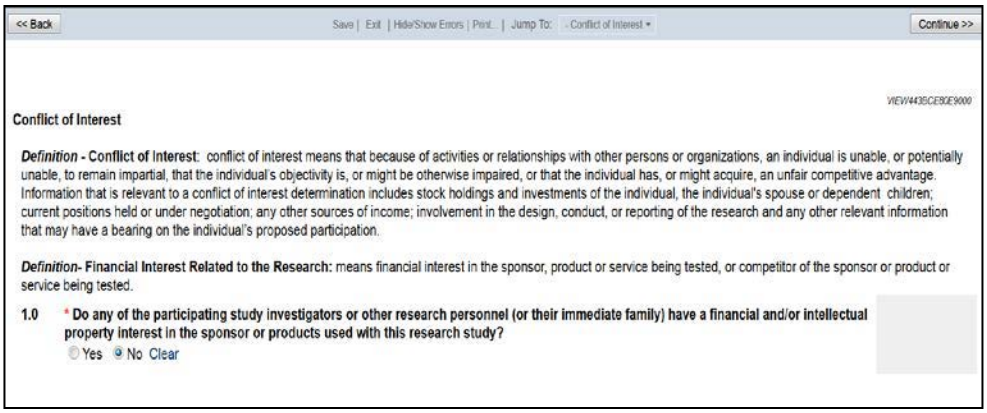
Open-Label Extension Studies are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.

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.



Privacy and Confidentiality

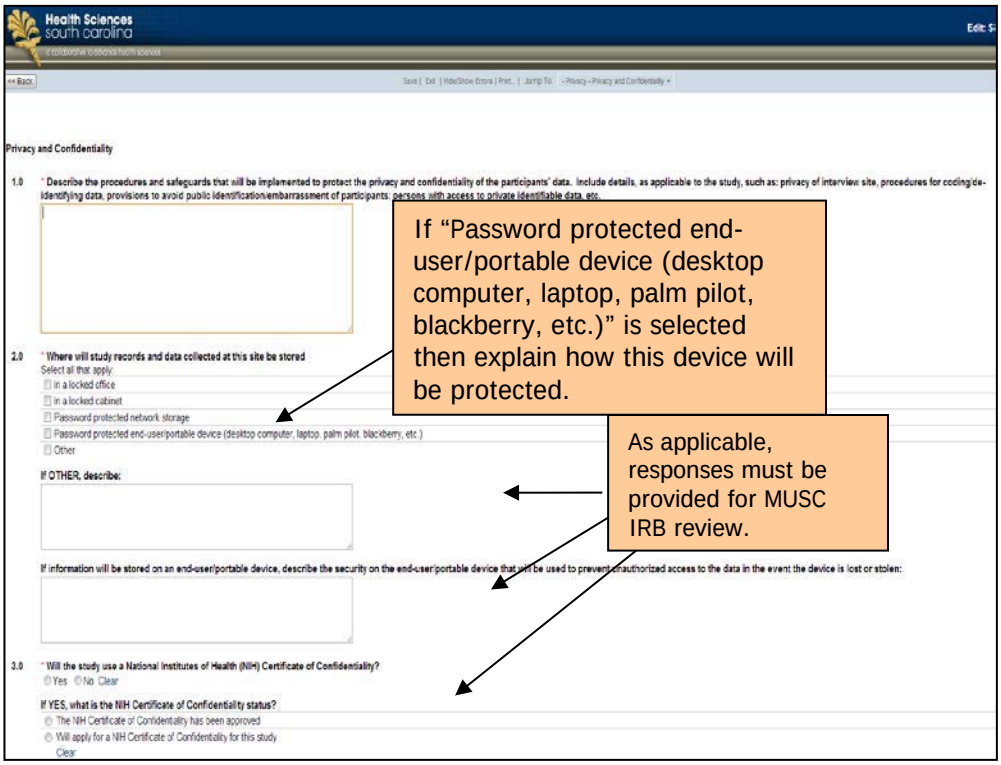
Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

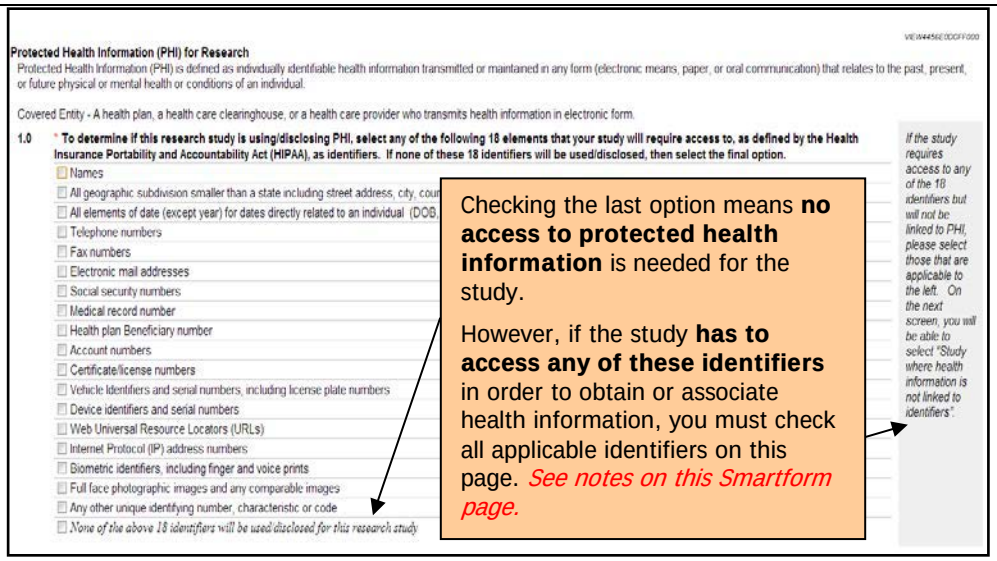
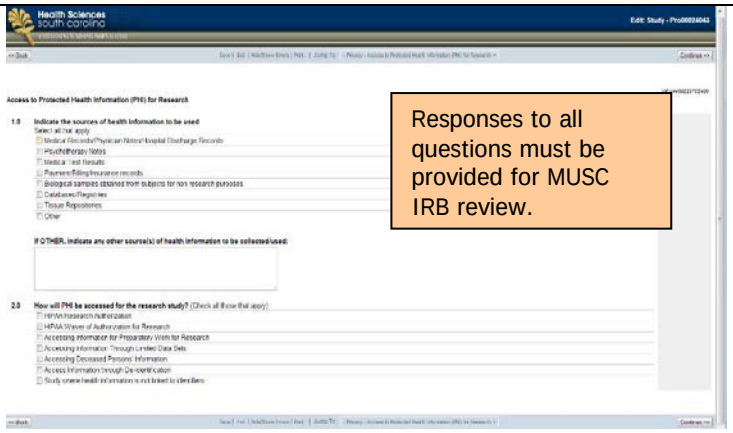
Select where study records and data will be collected and stored.

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.



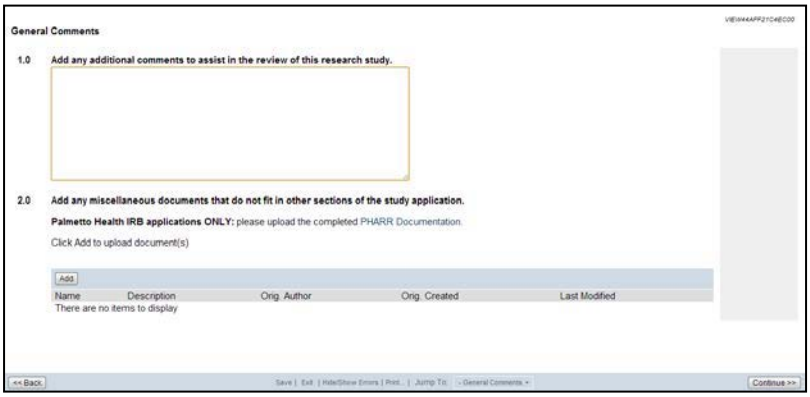
Indicate if the study will access (view, obtain or use) participant protected health data. Subsequently, the system will ask questions regarding accessing and sources of Protected Health Information (PHI). Click Continue.	 **Protected Health Information (PHI) for Research** Protected Health Information (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, cou ☐ All elements of date (except year) for dates directly related to an individual (DOB, ☐ 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 this access. Click Continue. If the study application indicates that no identifiers are used/accessed then this page will not populate.	 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/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.

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.

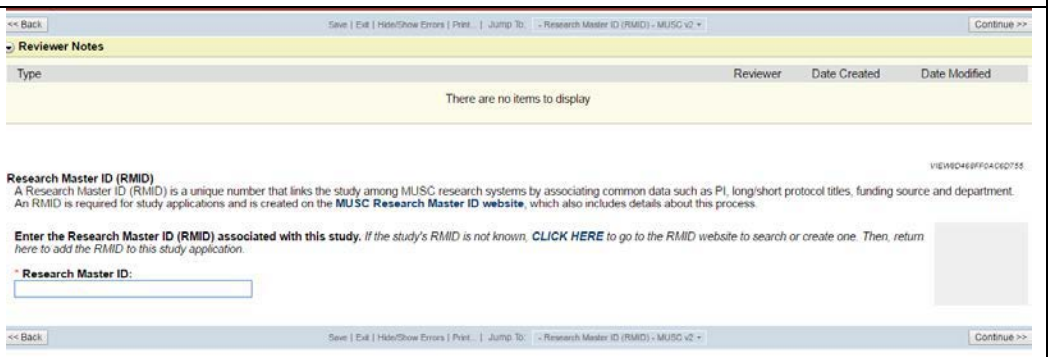


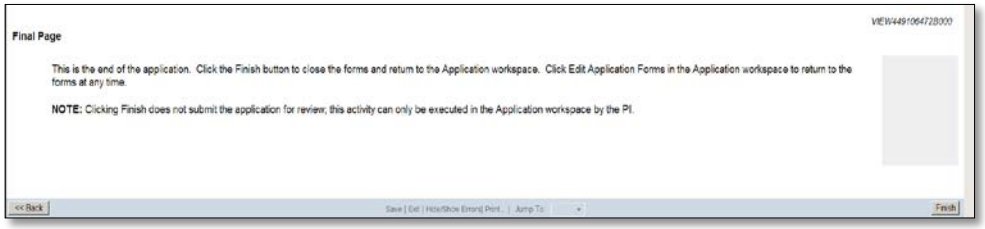
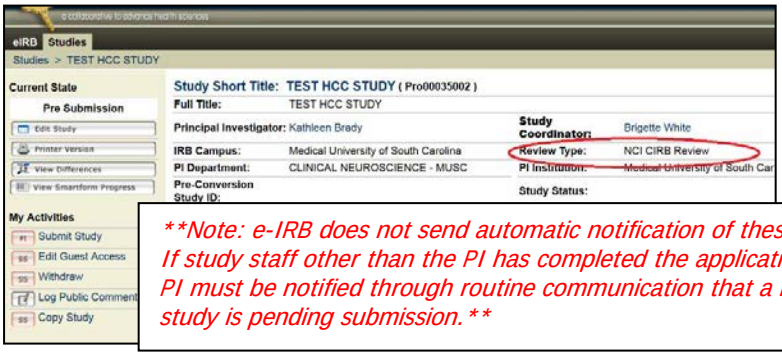
Research Master ID (RMID)

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.



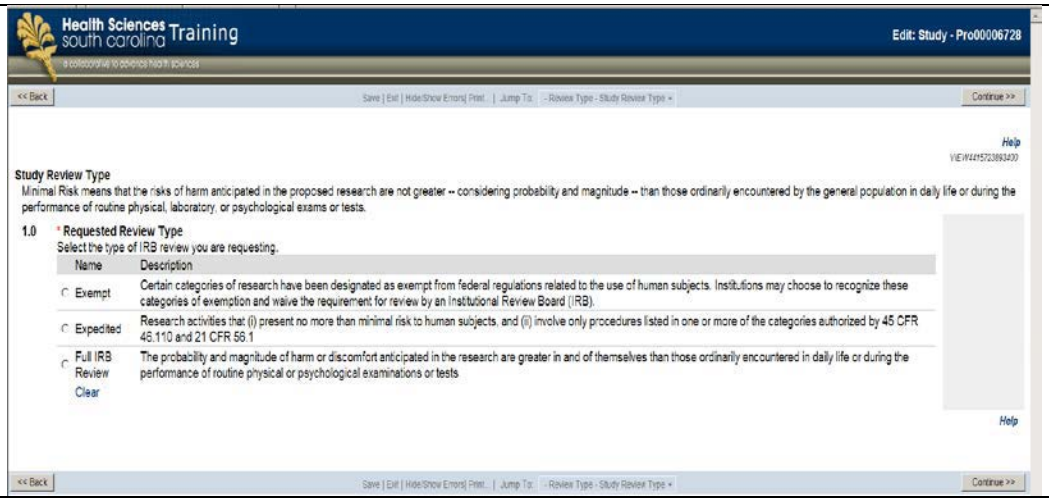
End of Application Click "Finish" to close the forms and return to the Application workspace. ***Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB.*	
The system will return to the protocol workspace. *To send application, complete 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.

Indicate Study Review Type as "Exempt".

Click Continue.

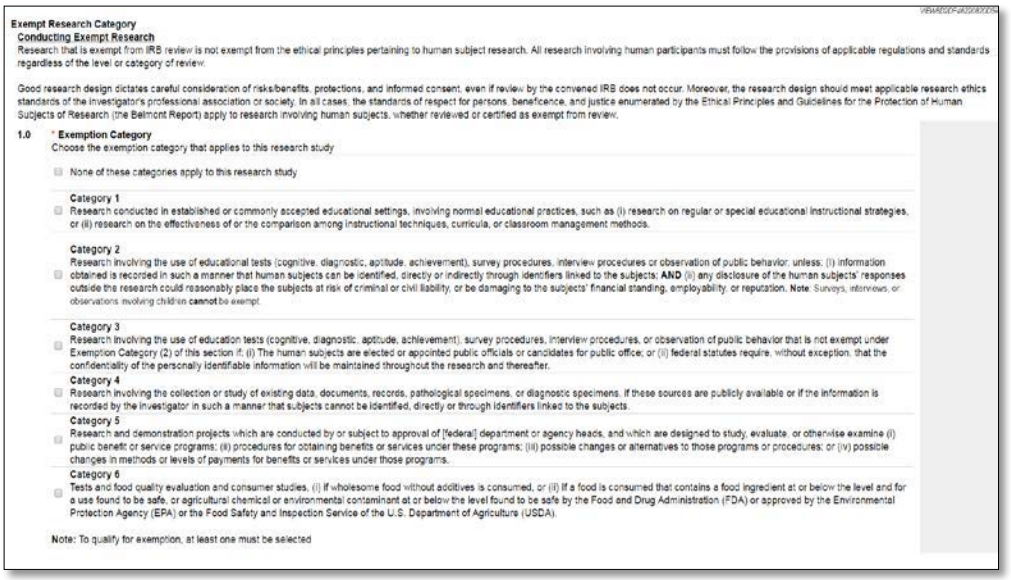


Category

Select the exempt research category(ies) most applicable to the study.

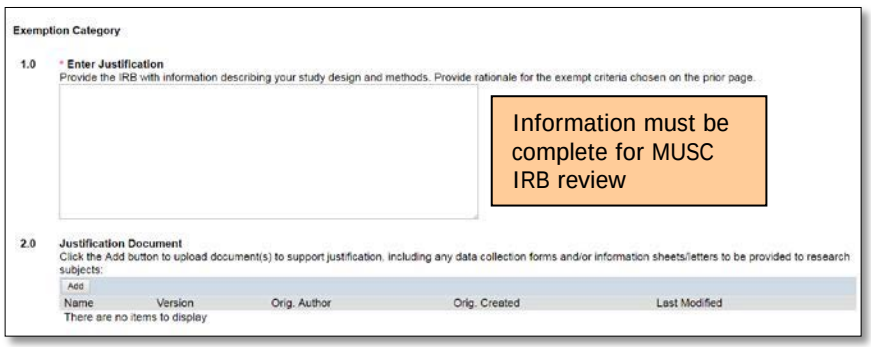
If none of these categories apply, you will be routed to select another type of review.

Click Continue.



Describe the study design and methods and upload supporting documentation.

Click Continue.

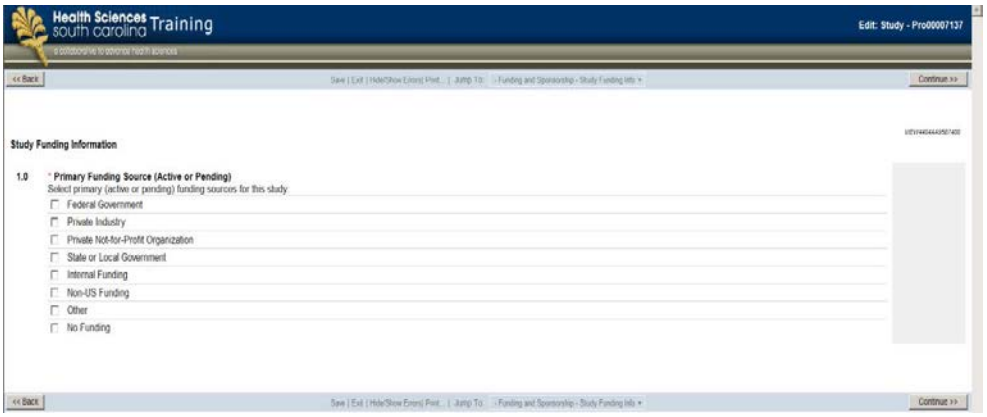


Study Funding

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.*

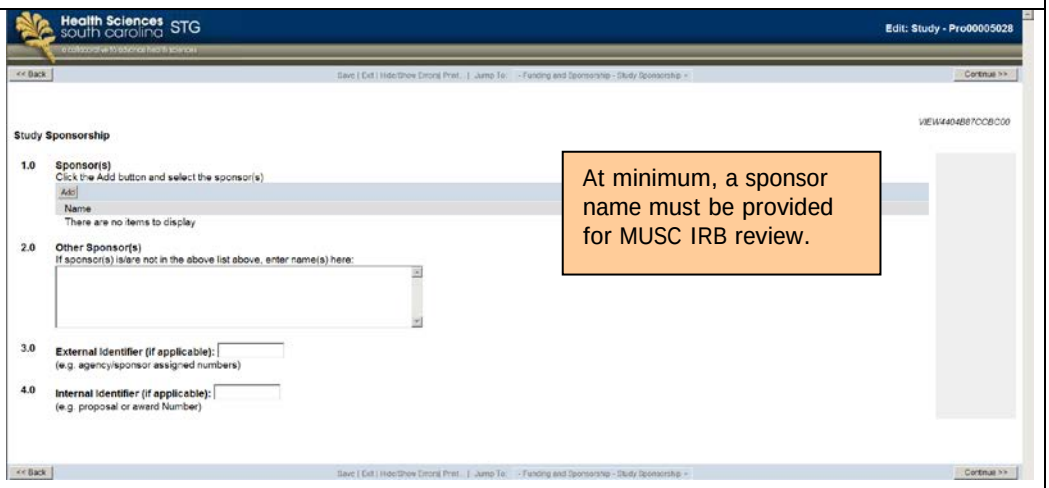
Click Continue.



Indicate details of study sponsorship.

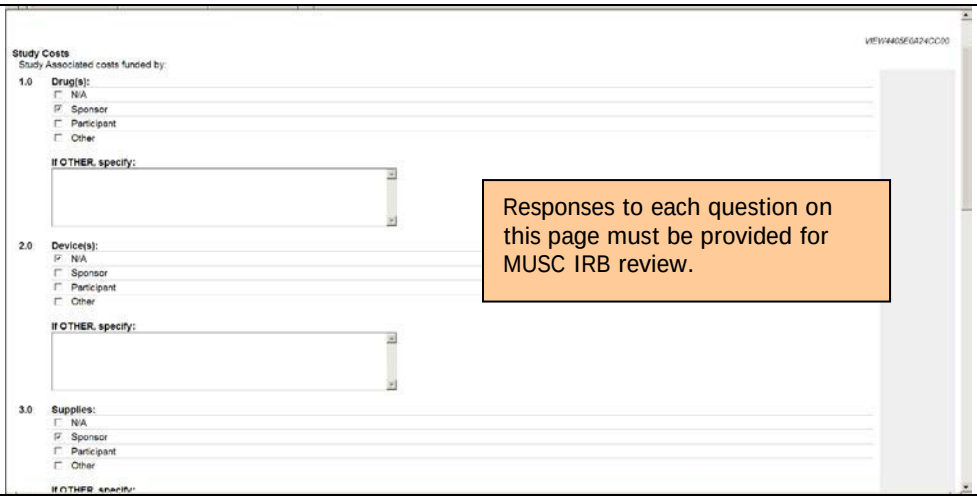
Note: If any of this information is omitted, it will not appear on the IRB review letter.

Click Continue.



Indicate the costs associated with the study.

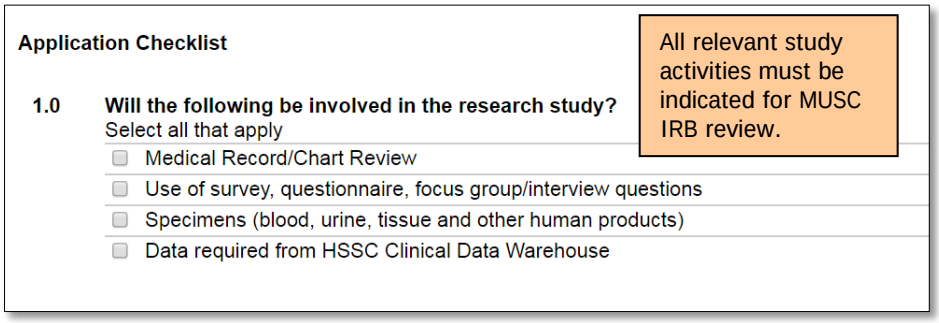
Click Continue.



Application Checklist

Check all applicable items for this project.

Click Continue.

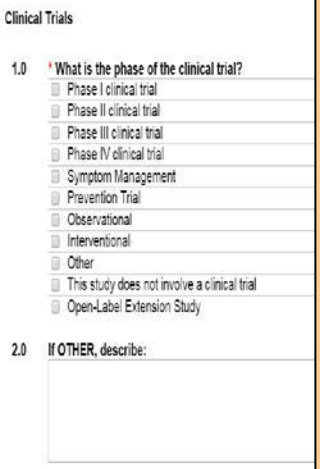


Clinical Trial

Indicate the type of clinical trial applicable for the project.

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.

Click Continue.



Visit 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.

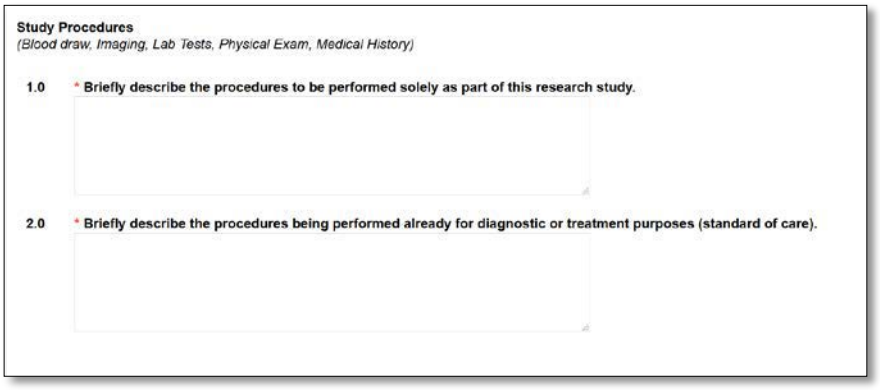
Open-Label Extension Studies are follow-up to randomized, blinded well-controlled main studies where the previously enrolled subjects continue receiving treatment to assess long-term safety and tolerability.

ClinicalTrials.gov

Study Procedures

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

Click Continue.



Privacy and Confidentiality

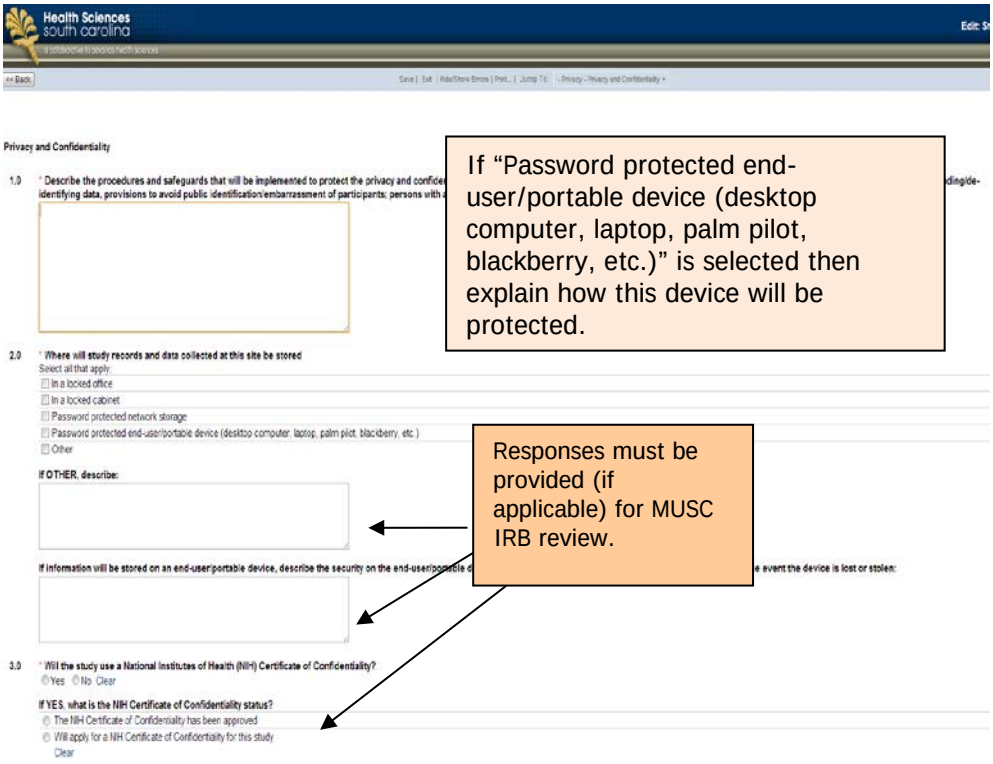
Describe the procedures and safeguards for protecting subject privacy and data confidentiality.

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).



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

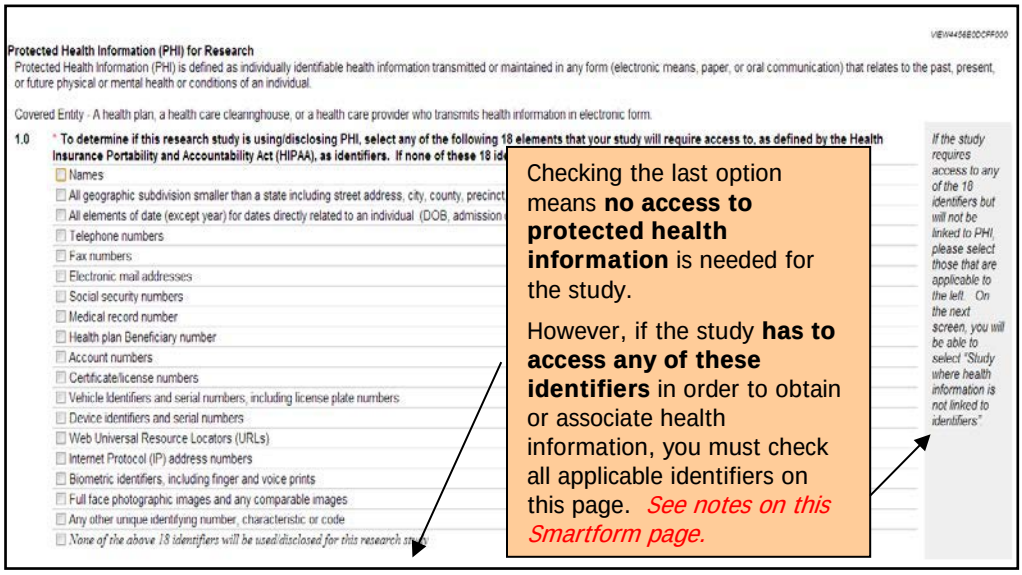
Responses must be provided (if applicable) for MUSC IRB review.

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.

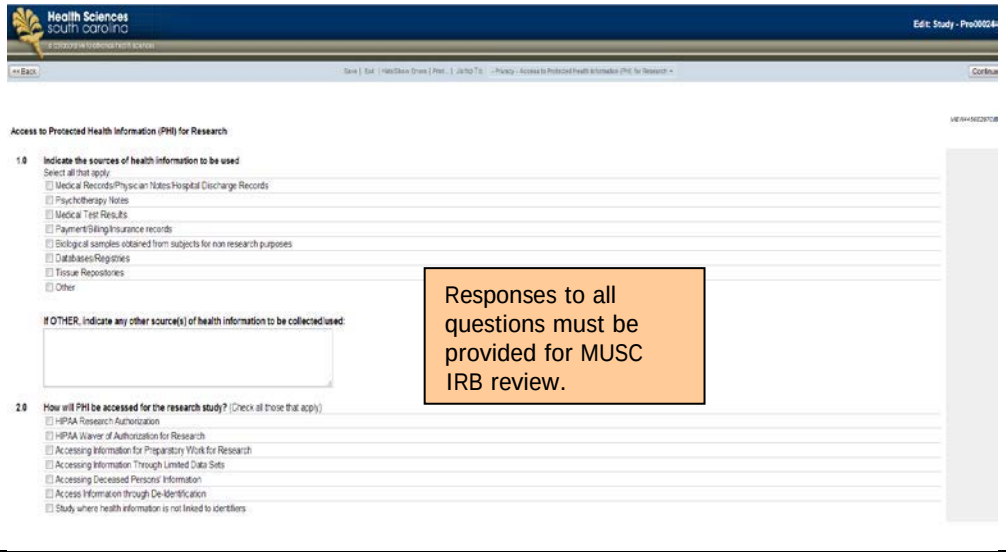


Checking the last option means **no access to protected health information** is needed for the study.

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 this.

Click Continue.

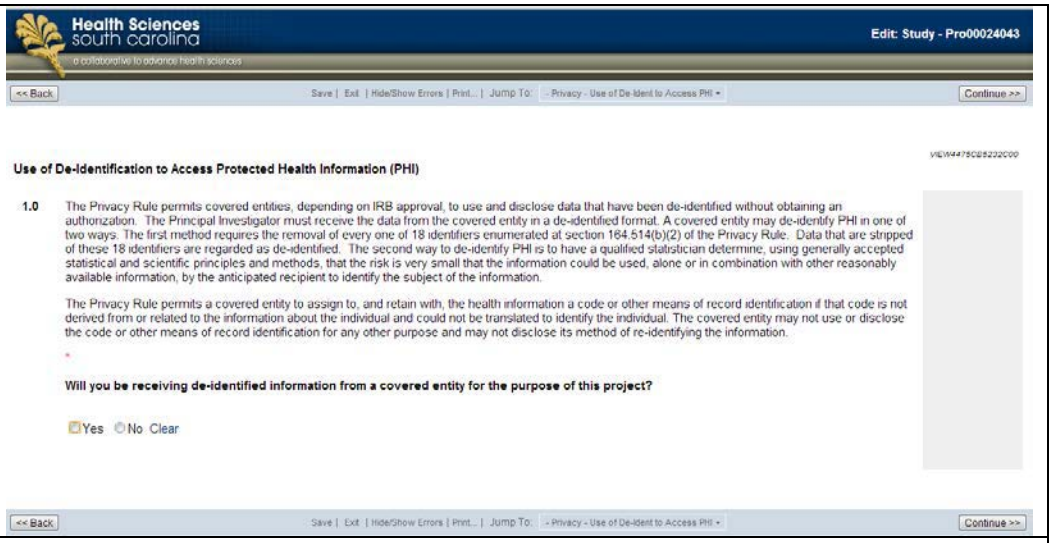


Responses to all questions must be provided for MUSC IRB review.

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

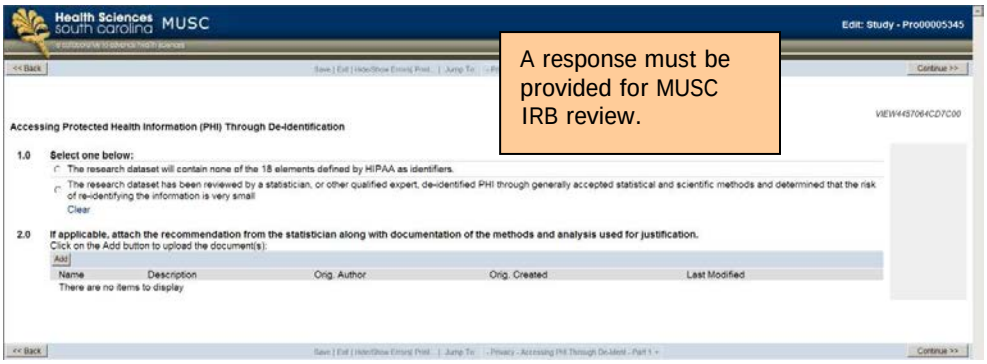
Note: The intent of this question is to document whether the study data is received through a de-identification method (i.e., via a de-identified database warehouse).

Click Continue.



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

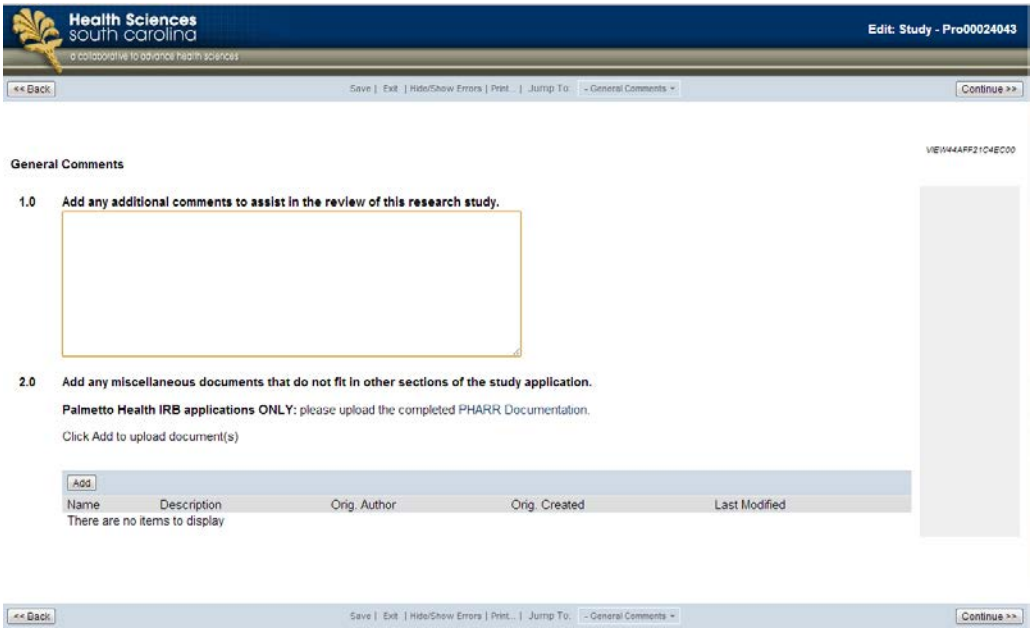
Click Continue.



General Comments

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

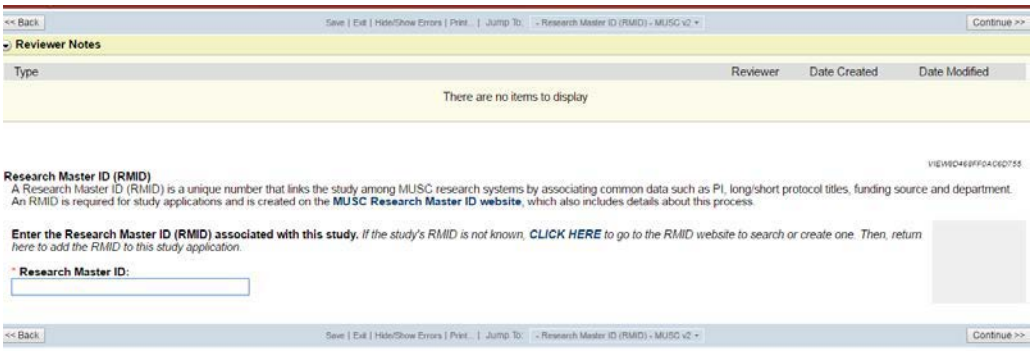
Click Continue.



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.

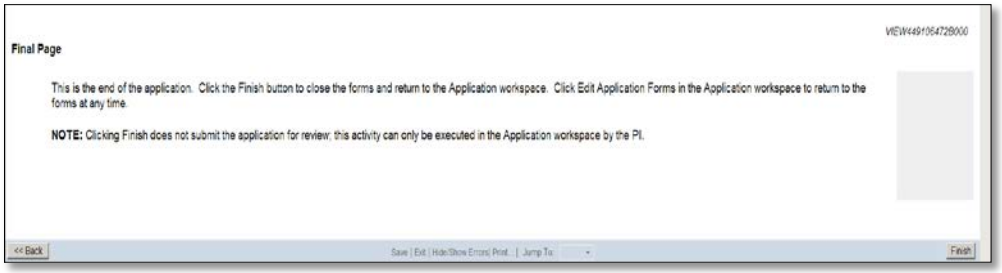
Click Continue.



End of Application

Click “Finish” to close the forms and return to the Application workspace.

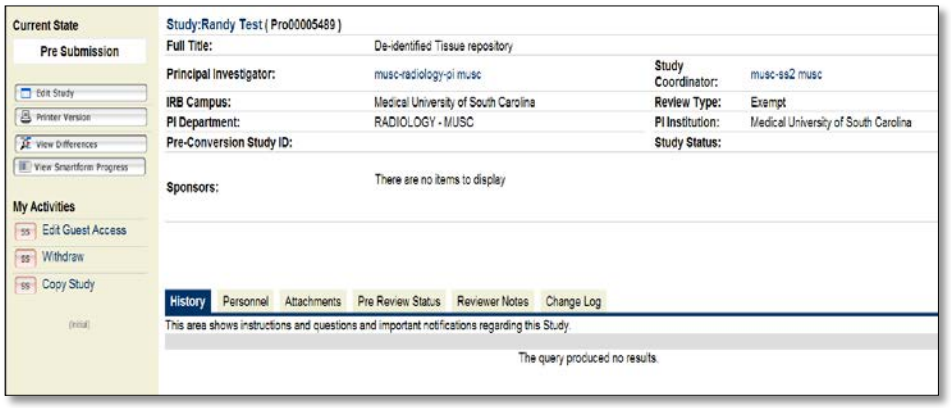
Note: Clicking “Finish” does not submit the application for review. Only the PI can submit the initial application to IRB.



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.***



Request for Not Human Research Review

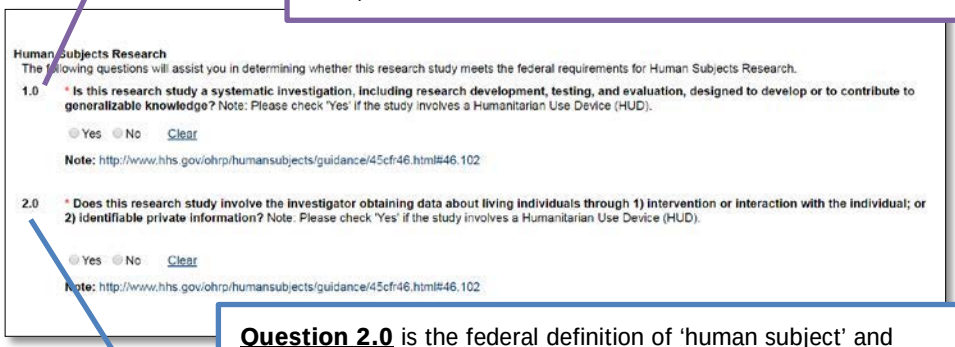
If not already completed, follow the steps in the 'Beginning the Application' section through Study Locations.

<table>
<tr>
<td>Indicate if this study is considered research involving human subjects.

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 here for steps to submit a full review application

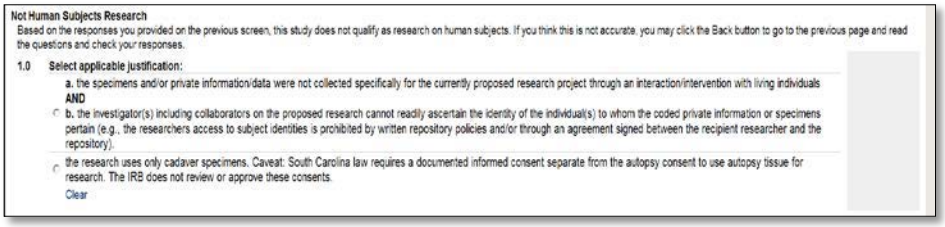
Click Continue if proceeding with a Not Human Subjects Research request.</td>
<td><u>Question 1.0</u> is the federal definition of 'research' and captures whether the proposal fits this definition. If the proposal is not research (i.e., response to Q1.0 is 'No'), then submission to IRB is not required and you should exit and withdraw the application.

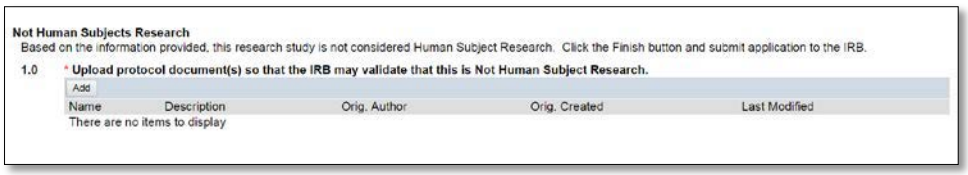
An exception to this response is if the project involves a HUD, as instructed on the screen.

<u>Question 2.0</u> 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'), then you can proceed with this section of the document to submit an application for Not Human Subject Research. Otherwise, you must continue through the application to select the correct review type, as described in the Human Subjects Research Requirements section.

As with Q1.0, the exception to this is if the project involves a HUD, as instructed on the screen.</td>
</tr>
<tr>
<td>Indicate a justification for submission as not human research.

Click Continue.</td>
<td> 
</td>
</tr>
<tr>
<td>The system will confirm your response based on what you selected on the previous page and ask that you upload a protocol.

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.</td>
<td> 
</td>
</tr>
</table>

Research Master ID (RMID)

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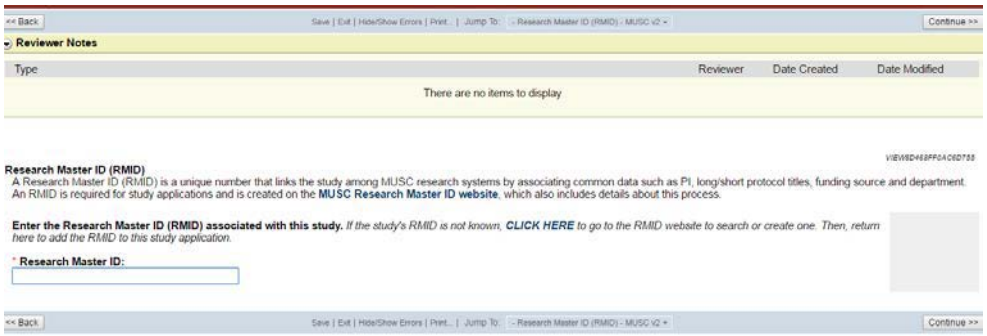
Resources and trainings on the RMID process are available online. The Office of Clinical Research (OCR) can also provide guidance about this process.

Enter the study's Research Master ID.

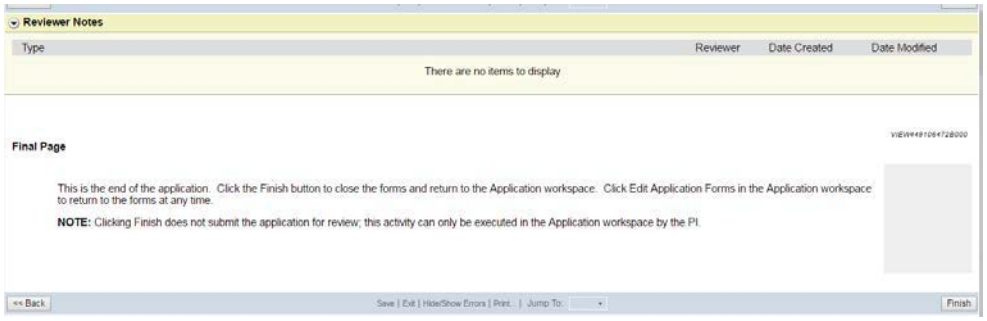
Click Continue.



Final Page

Click Finish

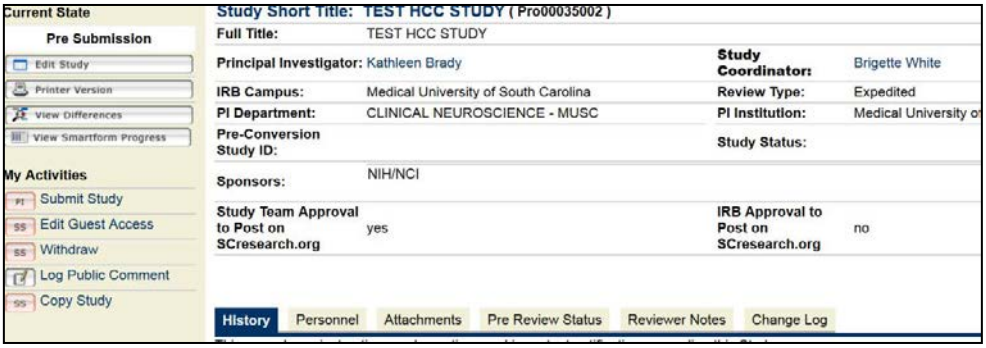
Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to the IRB



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

Select the PI of the study. ***Note: All other study team members should be listed on the Request for Submission WIRB Form.*	
Upload external IRB review documents and all associated approvals and attachments, as required by your institution. ***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 IRB's website.* *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.***	

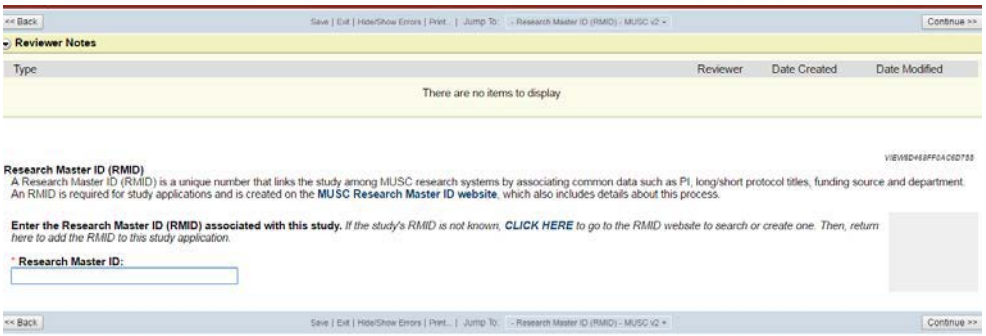
Research Master ID (RMID)

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.



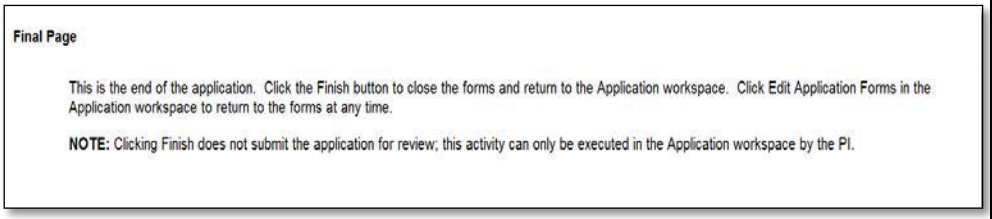
The application is complete for system required Smartforms.

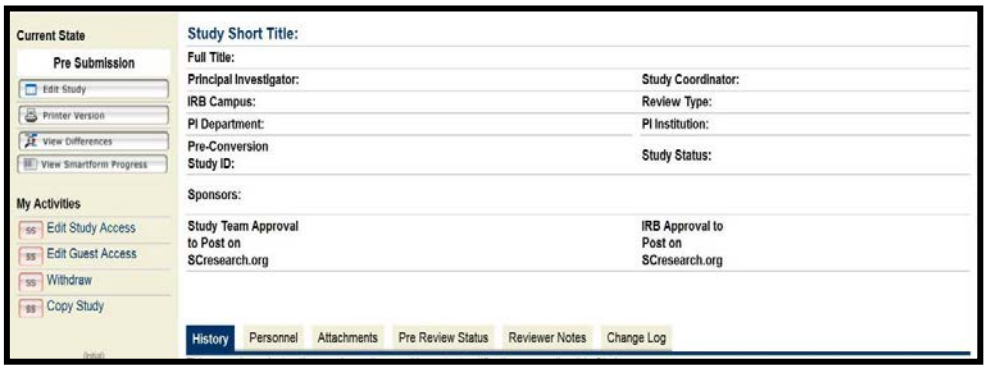
Note: Clicking "Finish" does not submit the application for review. Only the PI can submit the initial application to IRB.

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.***





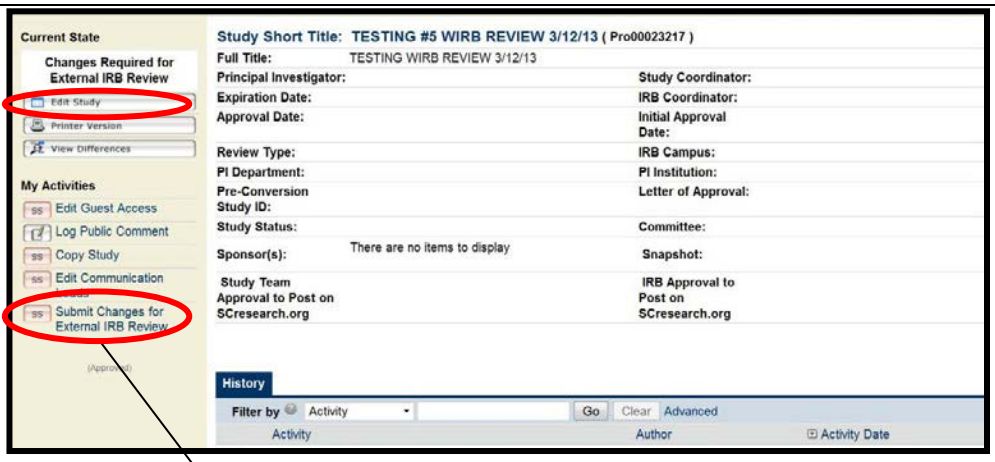
When the study is received in the IRB office, it will move into the External IRB Review state, initiating IRB review of the request.	

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.

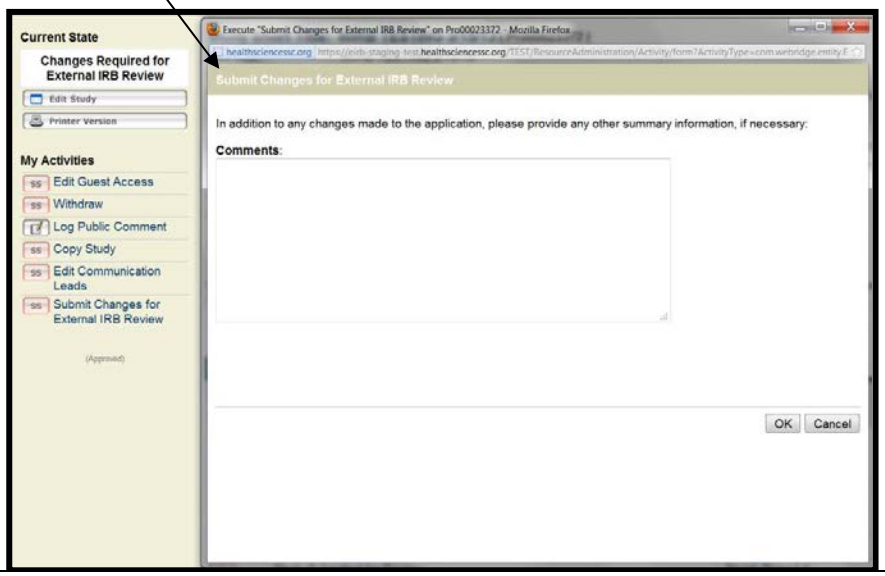
To make changes, select 'Edit Study' and go to the necessary study page to make changes.

When done, return to the study's main page and select 'Submit Changes for External IRB Review'.



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.



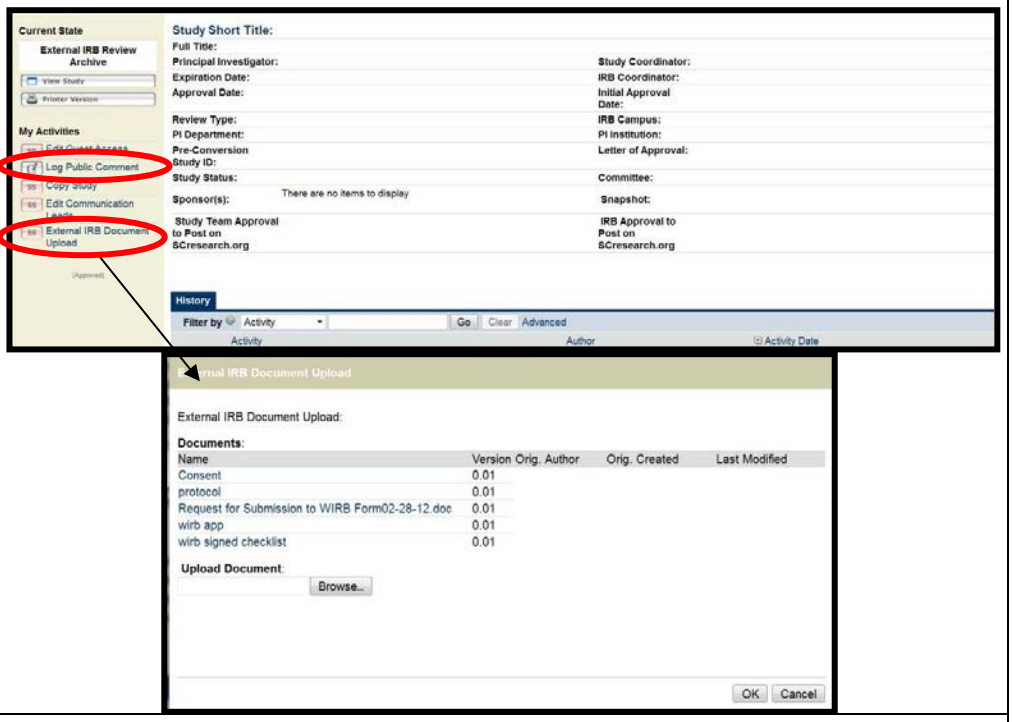
IRB Acceptance of the External IRB Review Application

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.

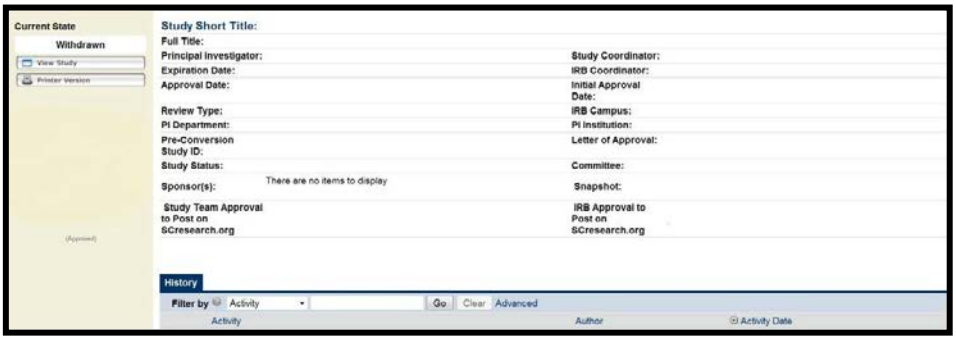
While there is not a study maintenance function, comments can be logged and additional documents uploaded into the system.

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

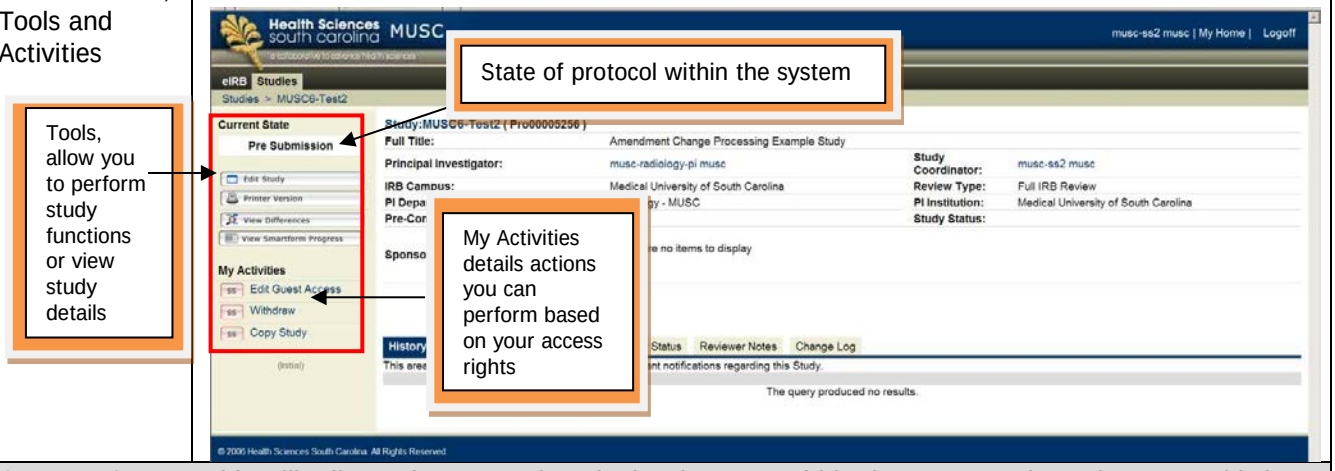
If the study is not eligible for external IRB review, the IRB will issue a non-acceptance review and the study will enter into the 'Withdrawn' state. **Researchers planning to proceed with the study a must create a new application and submit it for IRB review.**	
The withdrawn study will be accessible from the All Studies and Archived tabs available at login.	

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.

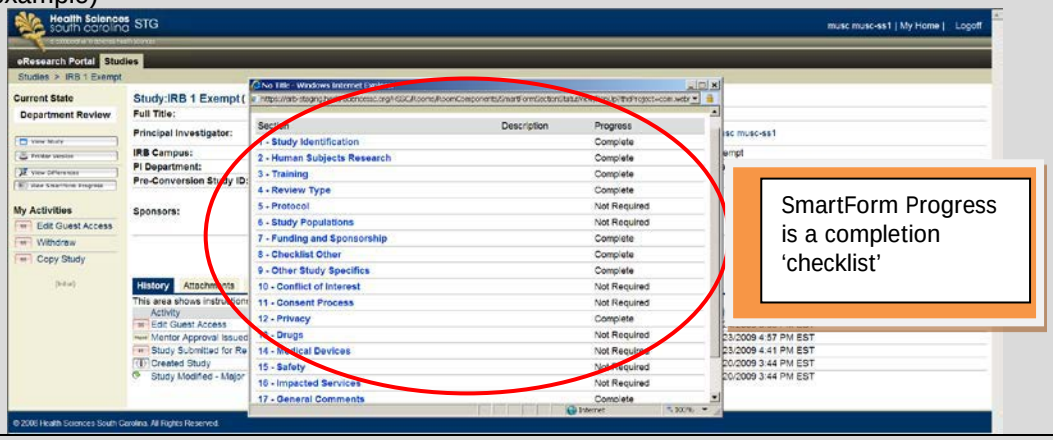
Protocol State, Tools and Activities



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)



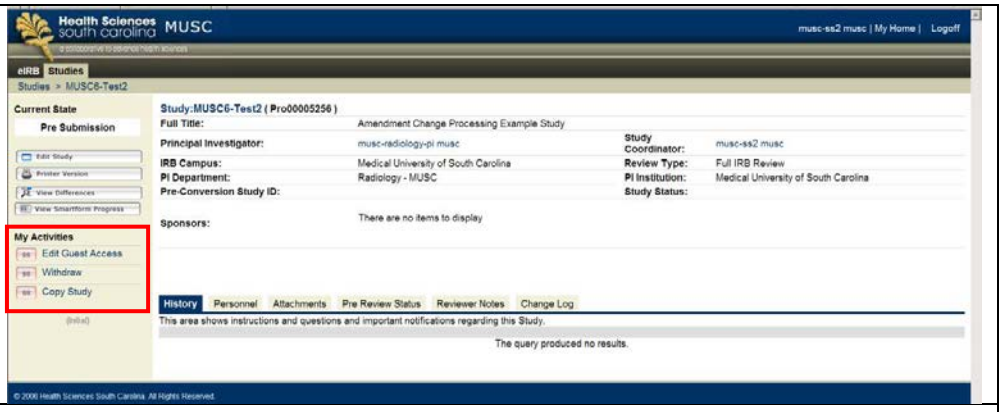
Activities: A list of actions that can be taken within the submission process. The types of actions permissible are specific to the state of the protocol. The types of actions permissible are managed by roles, for example:

- 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.

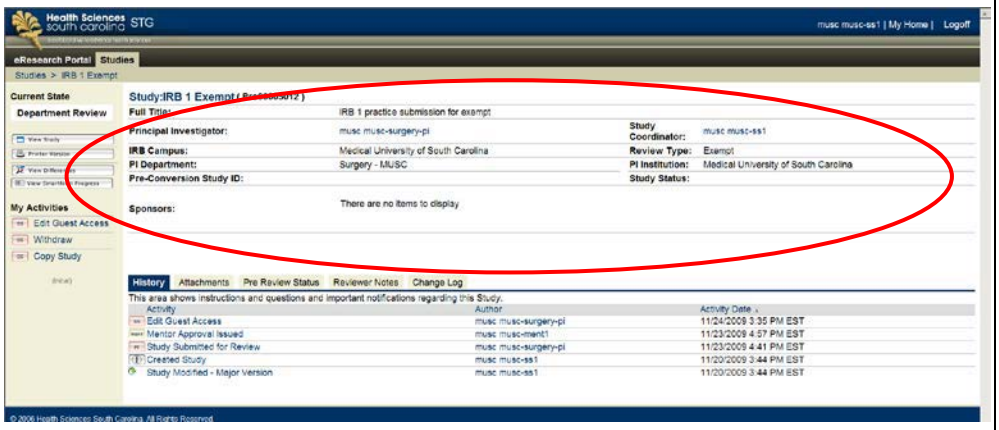
In this example, the activities as study staff include:

- 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



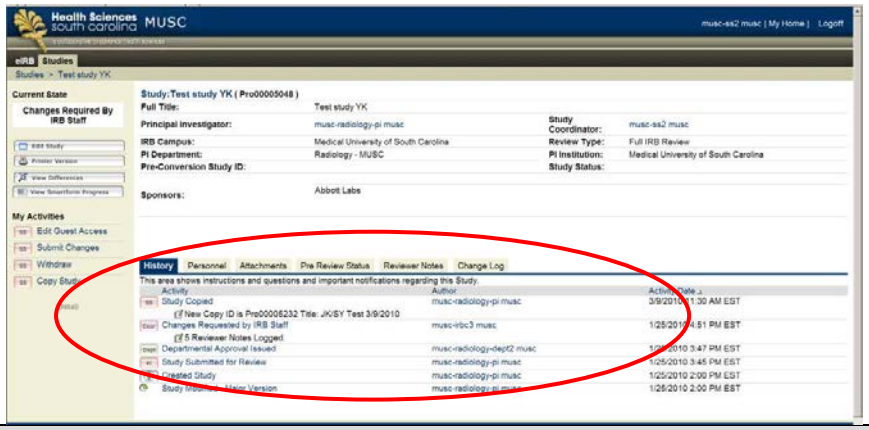
Protocol Information

The top middle section of the workspace shows a synopsis of the study, such as title, PI, department, coordinator, study status, etc.



Protocol details

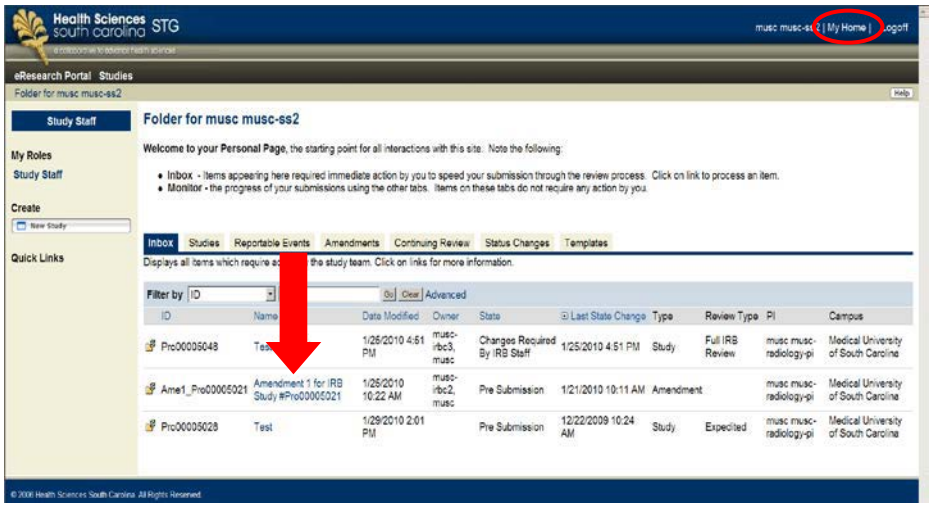
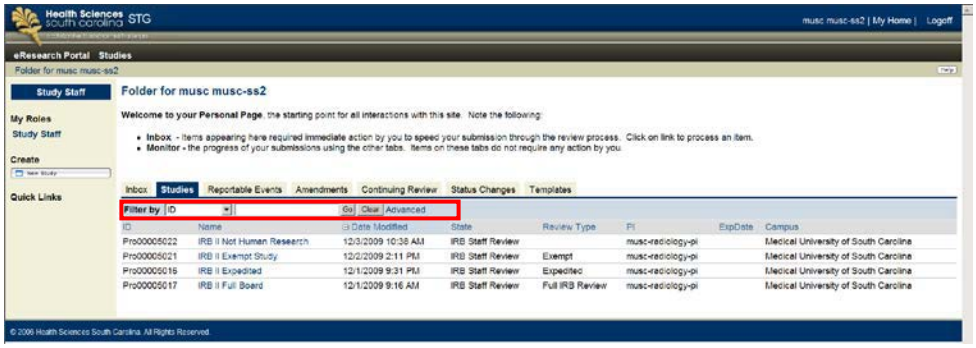
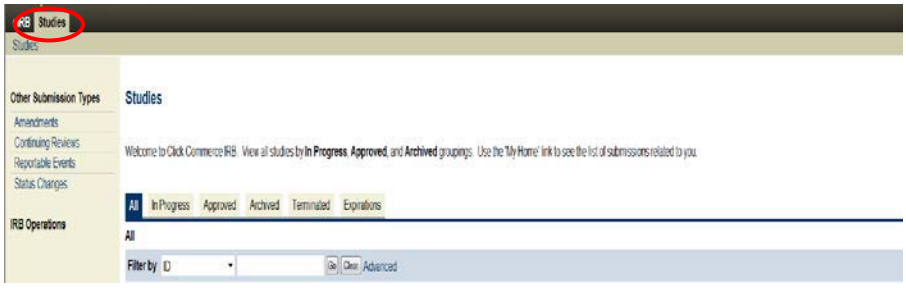
The lower portion of the workspace shows Workspace Tab.



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.	
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	
View Studies by Protocol States From your homepage, select the 'Studies' link.	

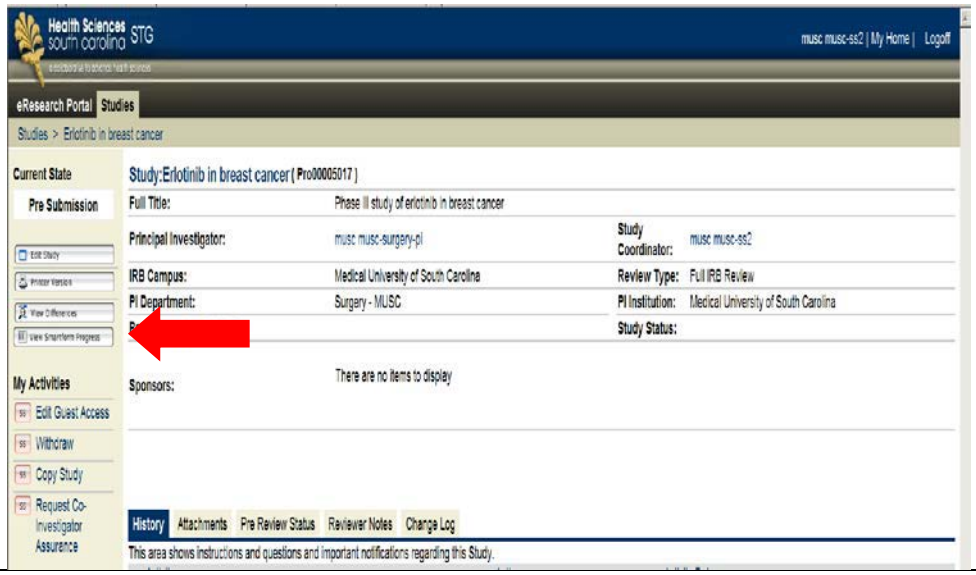
The tabs on the Studies link include:

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

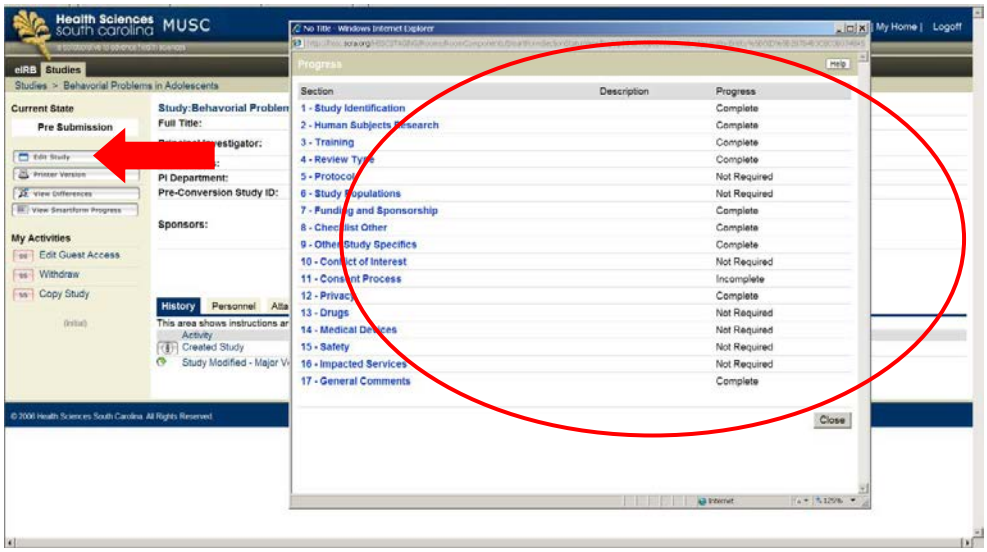
Select the study by following steps in the Retrieving Pre-Submission Study section.

Select 'View SmartForm Progress'



View the details of the SmartForm Progress completion 'checklist'.

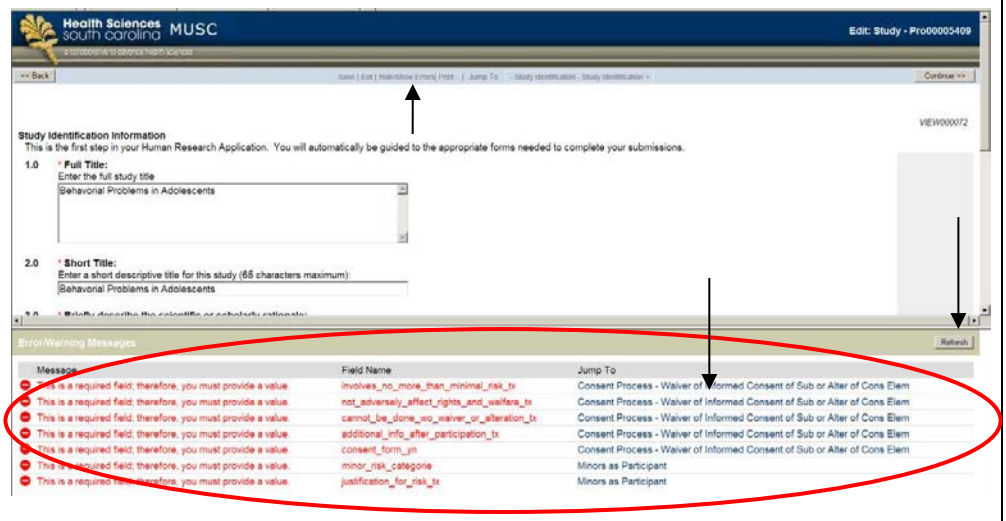
If any sections are incomplete, edit the study as described in the 'Edit Study' section of this manual and finalize the application questions.



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.

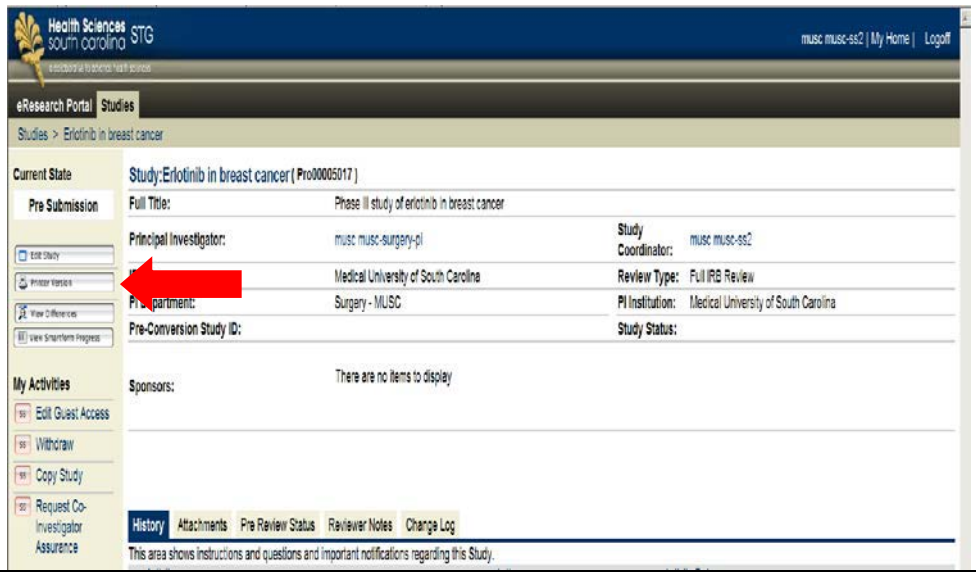
Select 'Refresh' to update the Hide/Show Errors list. To exit this view, click on the 'Hide/Show Errors' link again.



Edit Study

Select the study by following steps in the Retrieving Pre-Submission Study section.

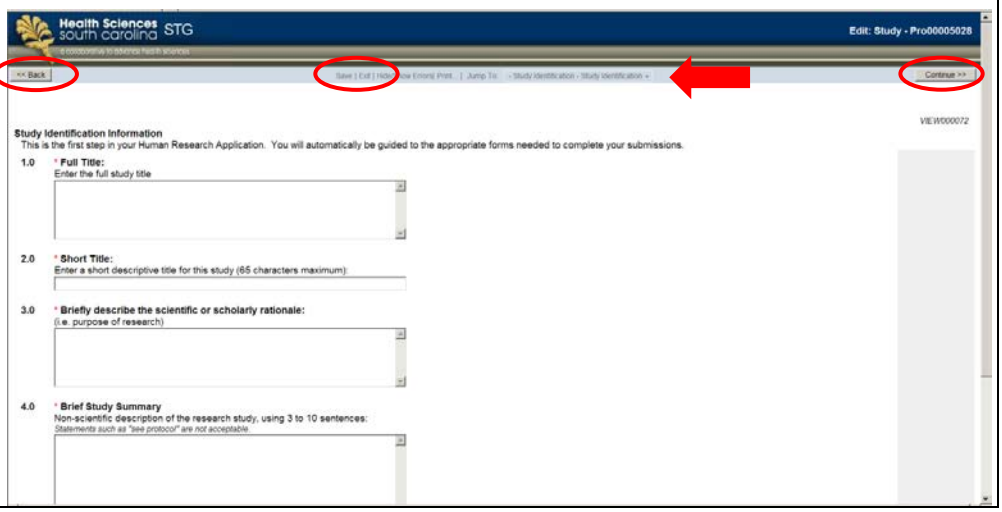
Click 'Edit Study'



Use the 'Jump To' feature to select the section to edit.

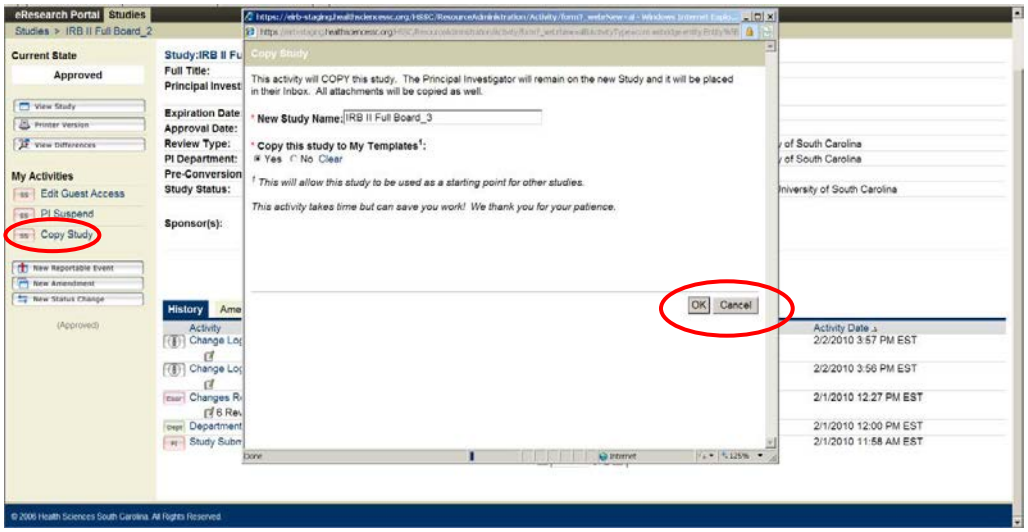
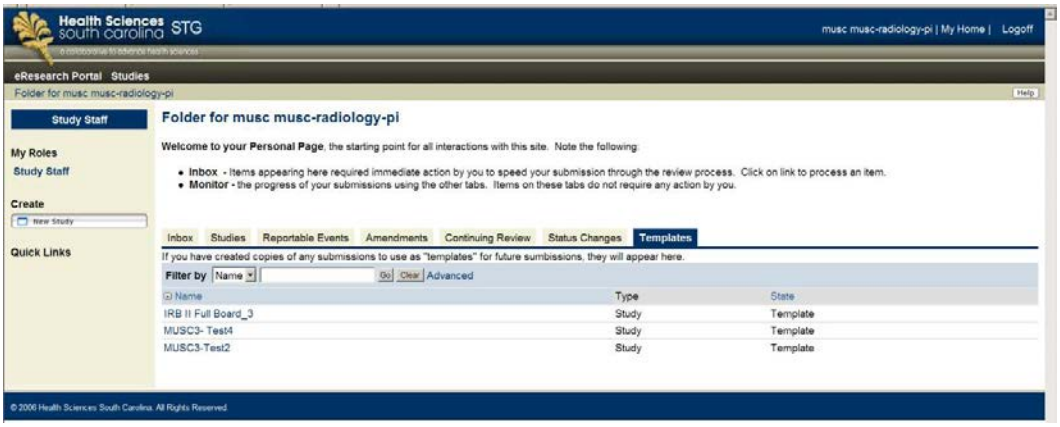
Select the Back and Continue button to make changes to the application.

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 Template' 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.

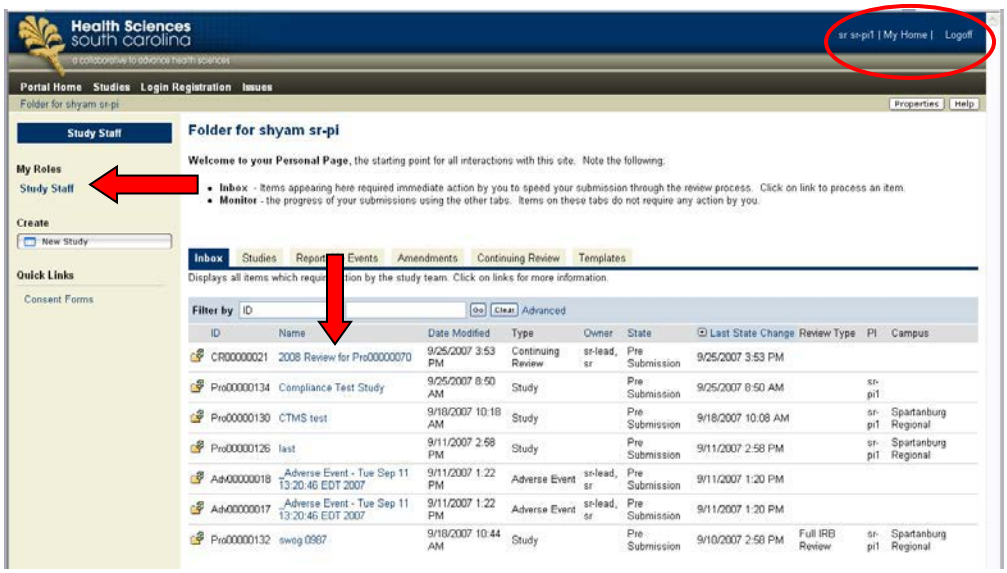
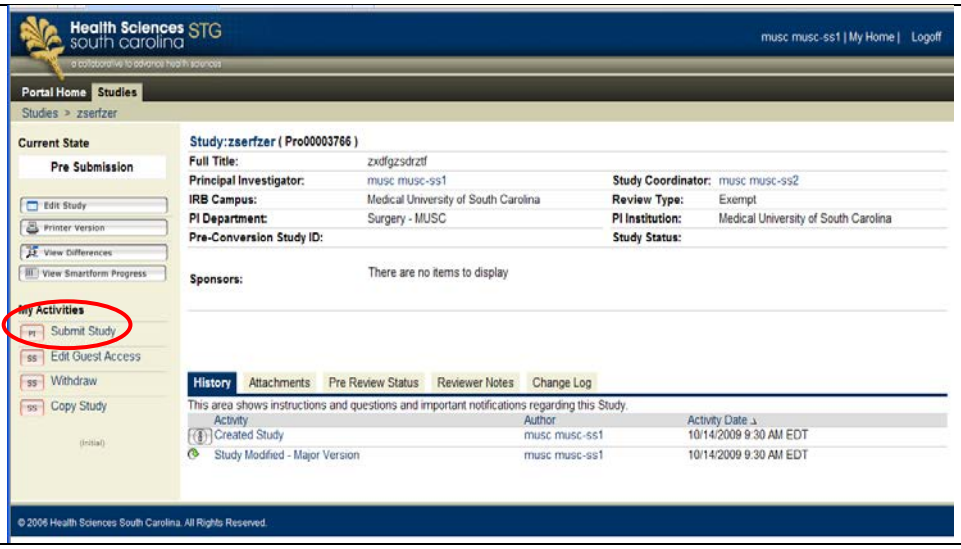
SUBMITTING APPLICATIONS

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.

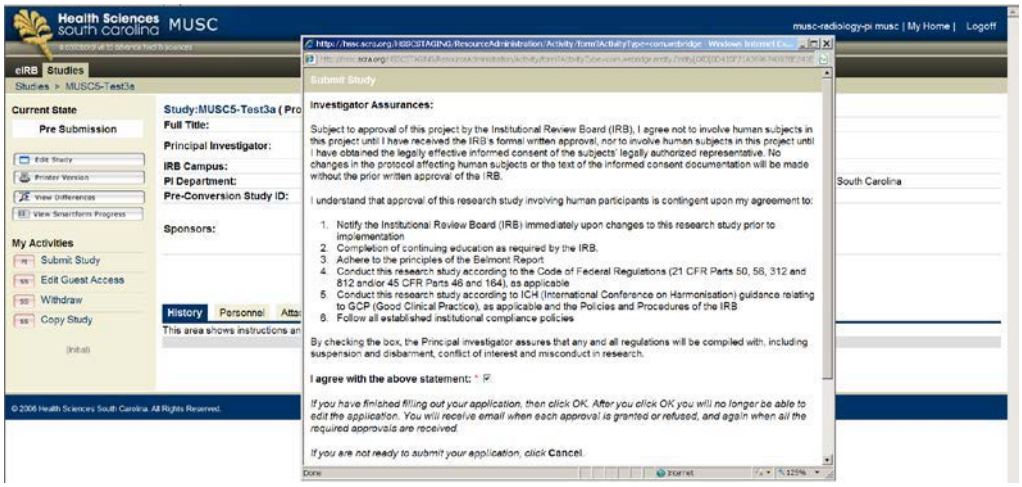
Note: study staff **can not send the application to any department on behalf of the PI. The PI must log in and send the study to a mentor (if the PI is a student) and the Department.*

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.***	
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.***	

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.



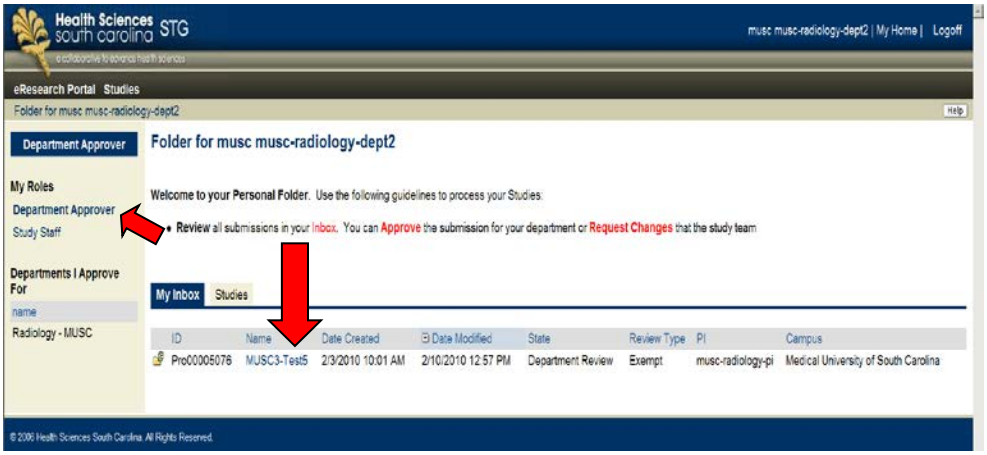
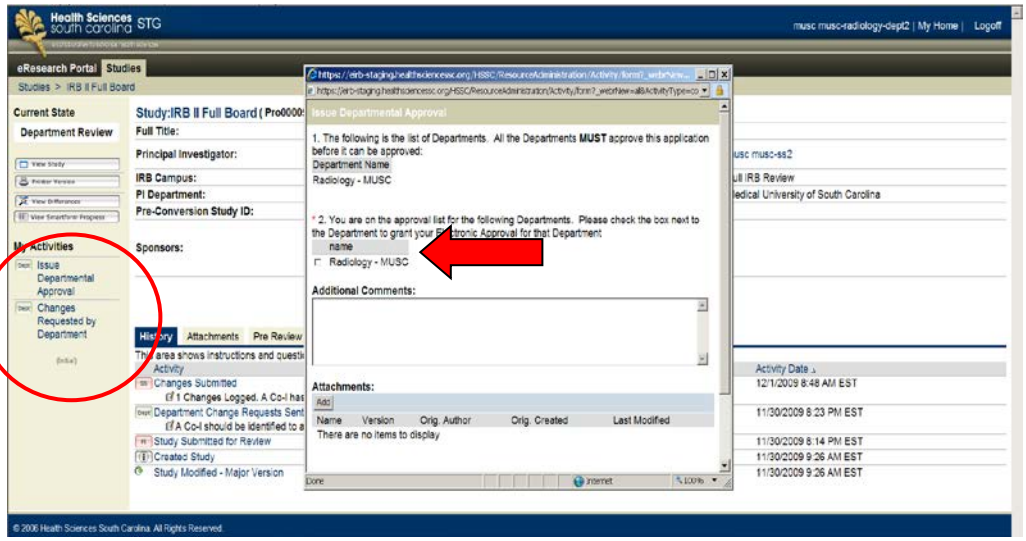
The study is now accessible under the "Studies" tab on the home page and the study state has changed to **"Department Review"** (or "Mentor Review" if the PI is a student).

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.

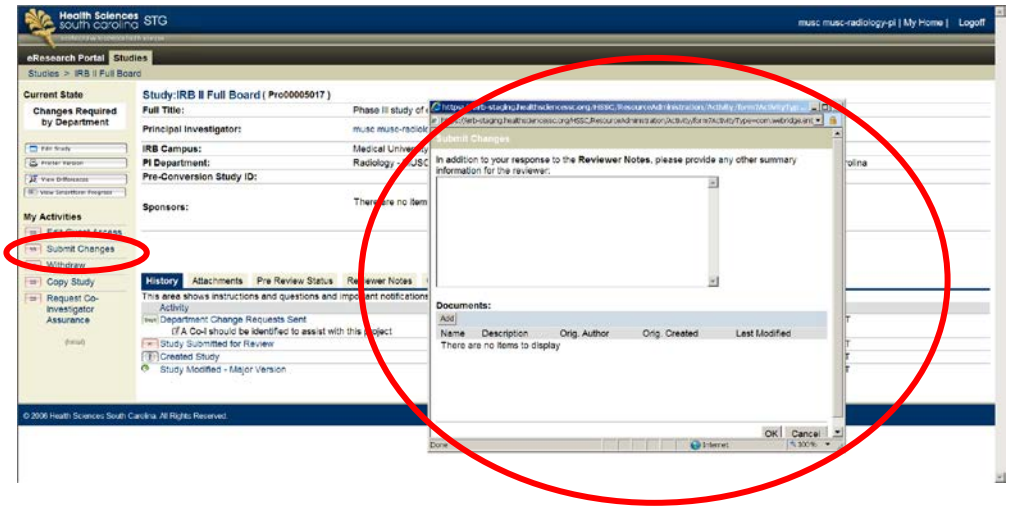
Mentor/Departmental Review

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.

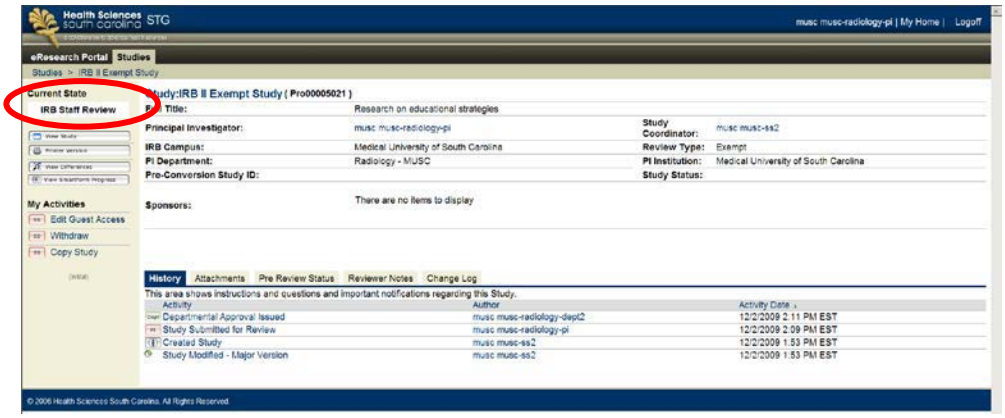
Responding to Departmental Review Comments

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 '<u>Edit Pre-Submission Study</u>' in this guidance document.	
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 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.



Responding to IRB Comments

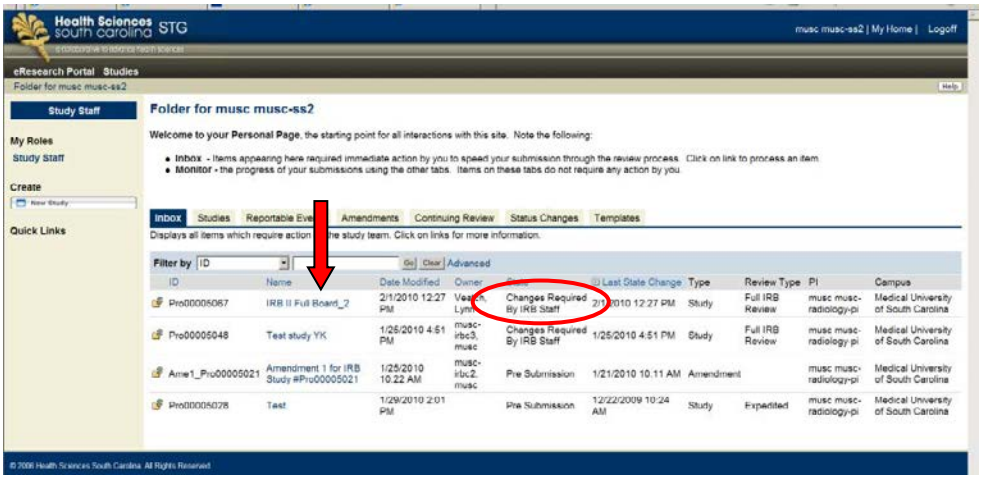
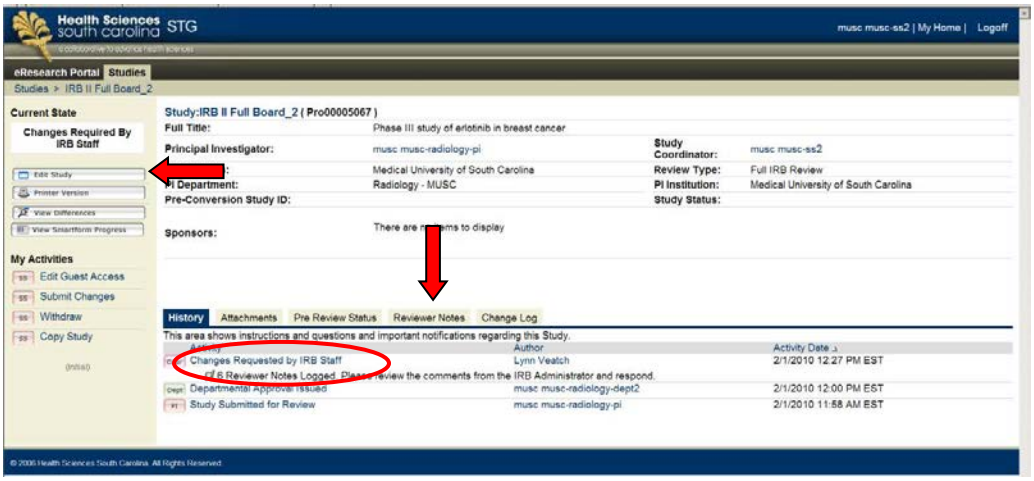
For additional assistance, view the recorded demonstration 'Responding to IRB Reviewer Comments' in the eIRB Education & Training section.

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.

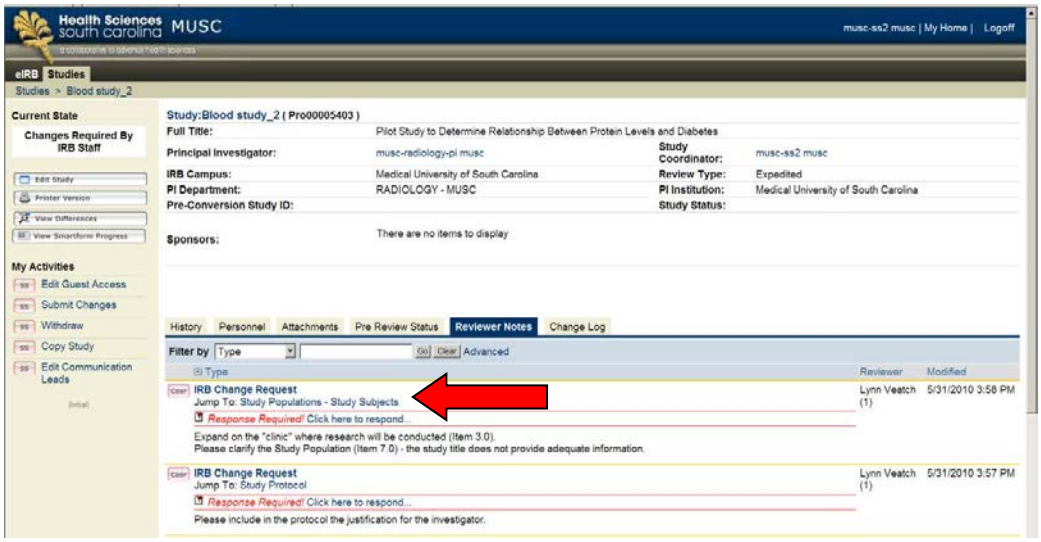
1. The changes must first be made within the study application; and
2. The changes must be documented as completed, not completed or for information only and include a summary of the responses.

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

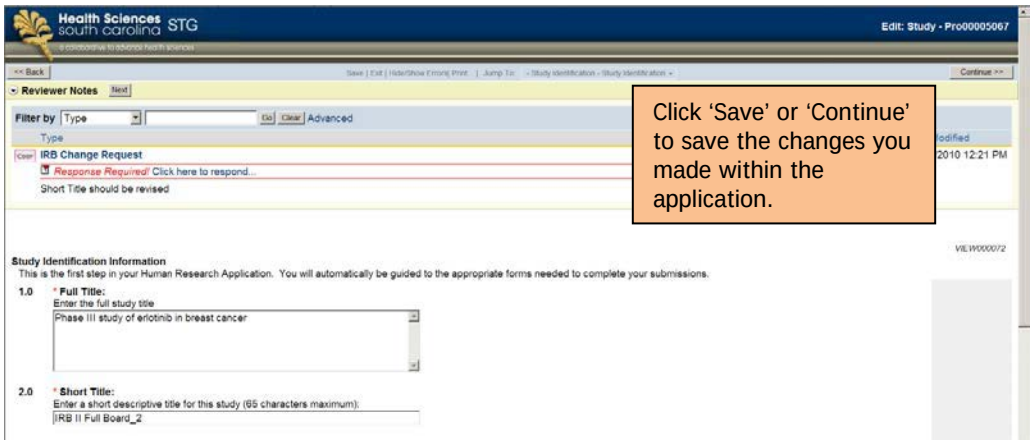


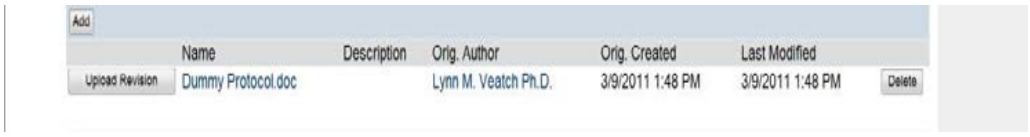
The system will navigate to the question and form.

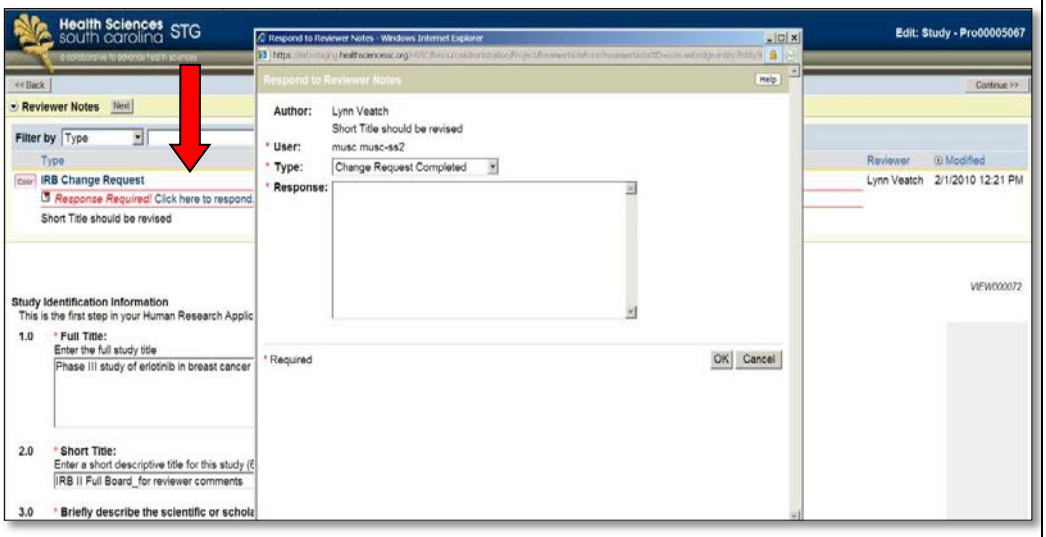
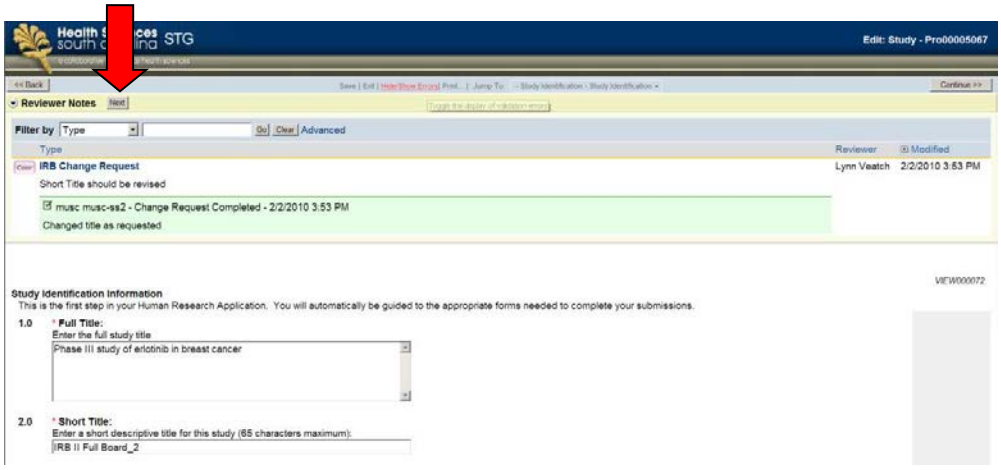
Make the requested changes to question within the application.

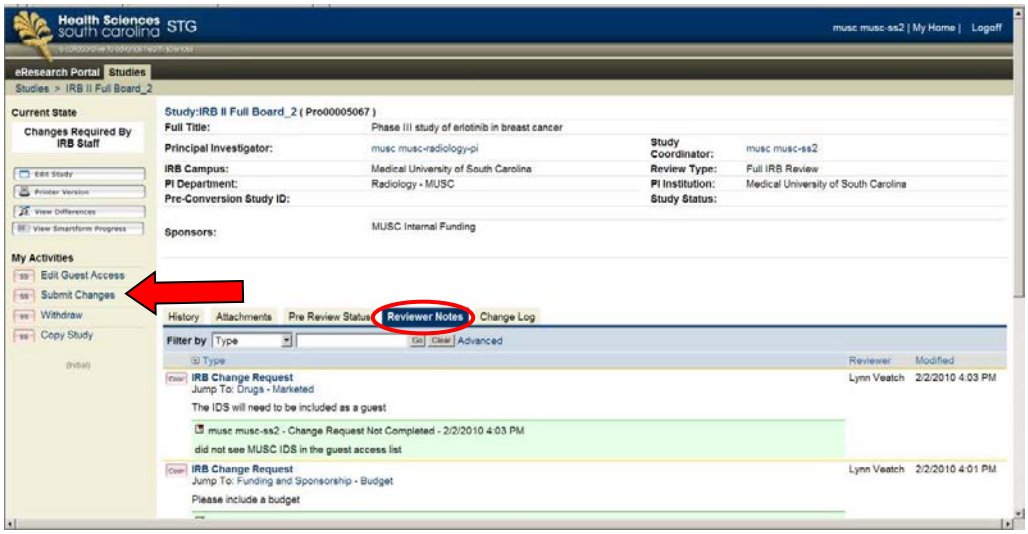
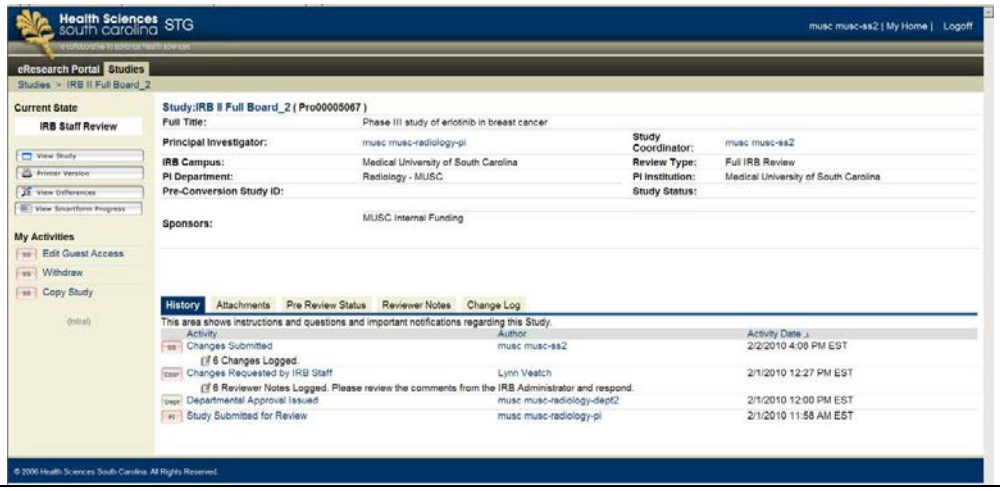
***Note: If previously submitted documents are required to be revised & uploaded, select 'Upload Revision' next to the document's name & locate the file from your computer. DO NOT use 'Add' or 'Delete' button unless this is the first time that document is included.*

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.





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'.	
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.	

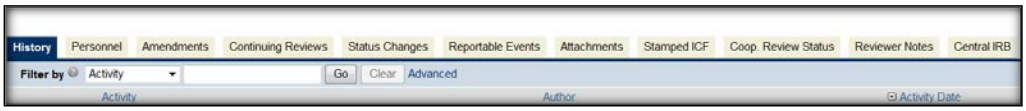
Click on the 'Reviewer Notes' tab to ensure that all comments have been addressed in step #2 (i.e., a green bar appears indicating you have completed the final step in responding to that question). Click on 'Submit Changes'. A pop-up window will allow you to enter in any other summaries or upload additional documents. Click 'Ok' when done. This will send the response to the IRB.	
The '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'.	

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:

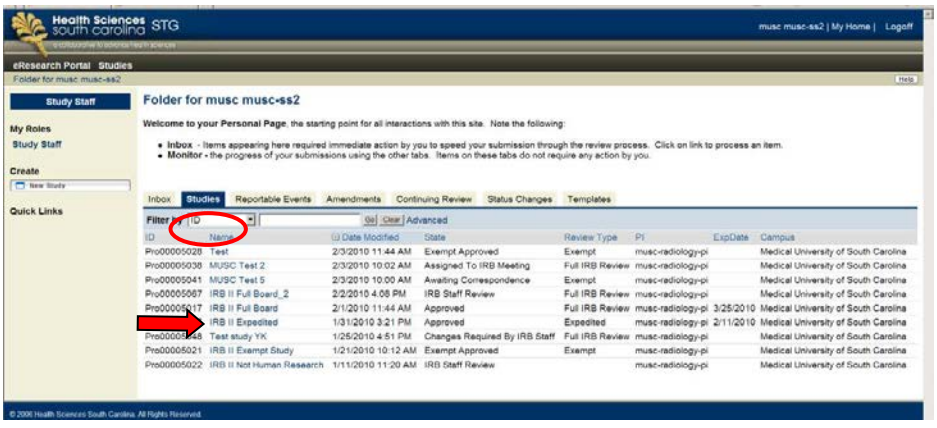
- **Amendments** include any study revision requests entered into the system
- **Continuing Review** includes all renewals entered into the system
- **Status Changes** include all requests to change the study subject accrual status (requests not included as a part of the continuing review) entered into 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.

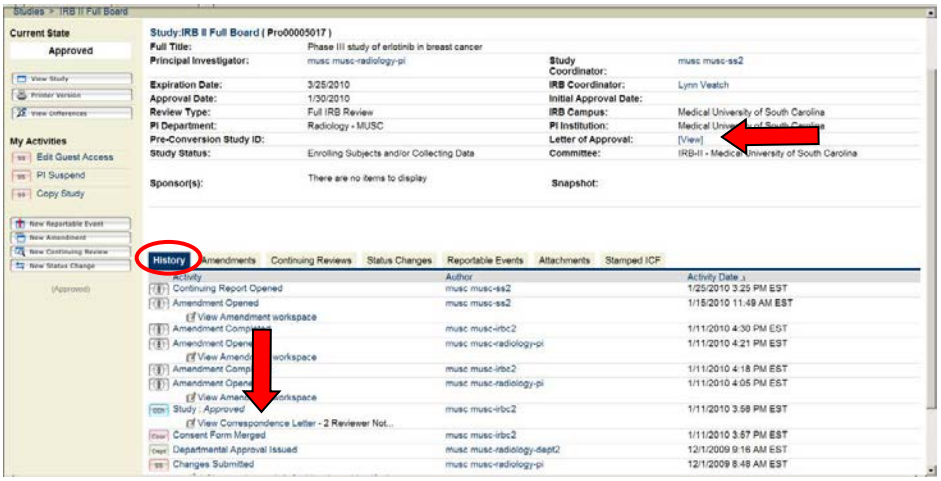


The ‘History’ tab on the study’s home page will include a line indicating that the study is approved and an option to view the IRB review letter.

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.

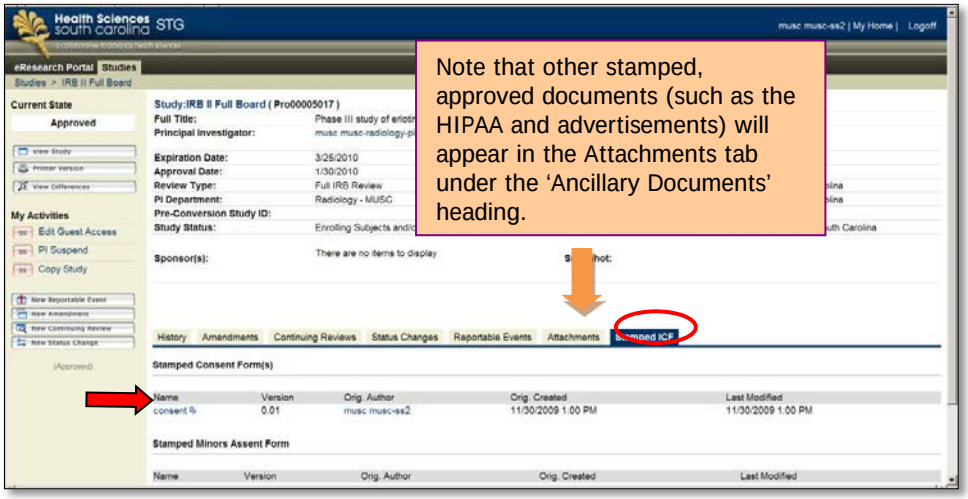


To view the approved consent document(s), select the ‘Stamped ICF’ tab.

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

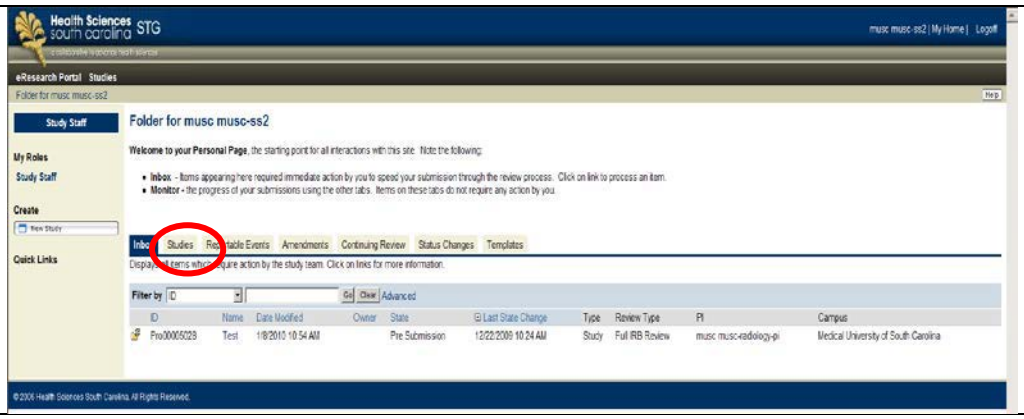
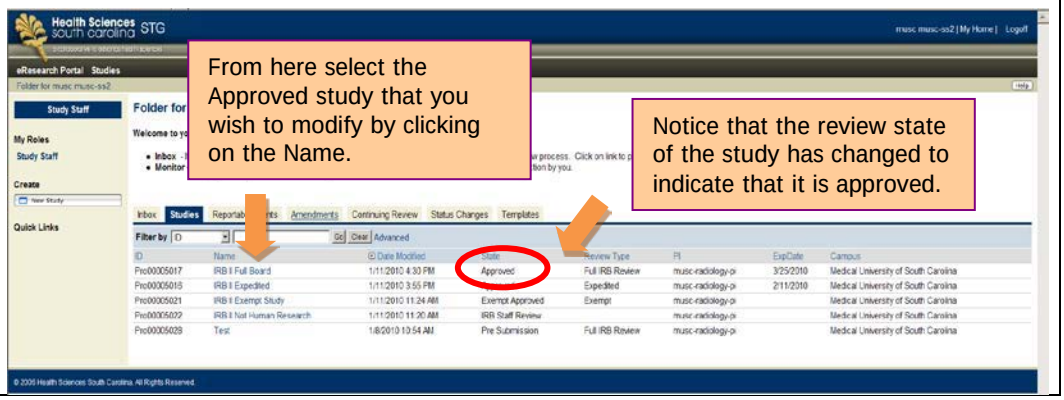
For additional assistance, view the recorded demonstrations 'Amendment Design' and 'Creating and Submitting Amendments' in the eIRB Education & Training section.

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

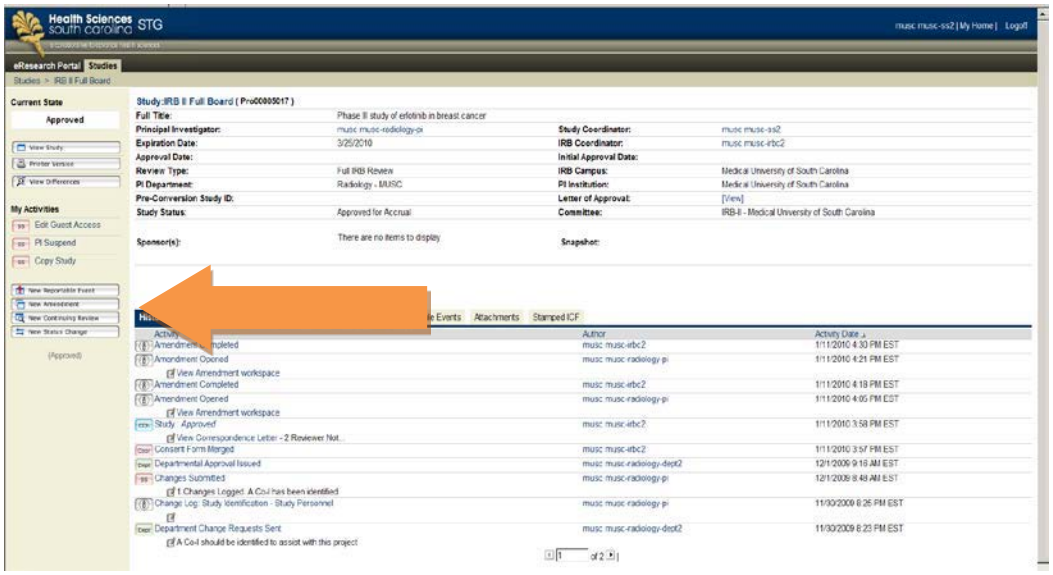
Note: only the PI can submit an amendment to IRB

Log into eIRB and select the 'Studies' tab.	
Select the study for which you would like to submit an amendment. ***Note: The study must be IRB approved before an amendment can be completed.***	

Under My Activities, select 'New Amendment'

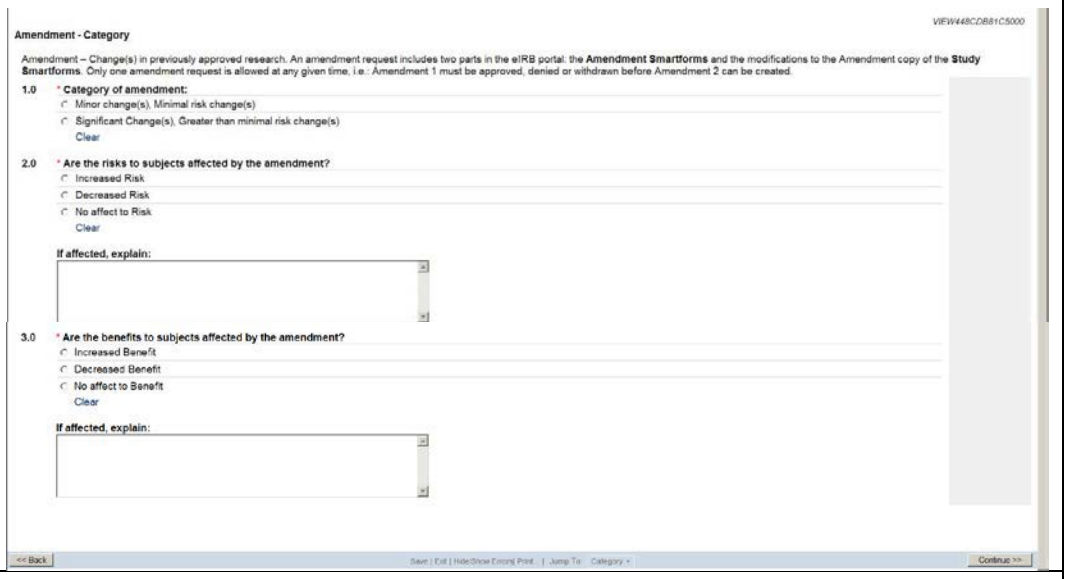
***Note: Only one amendment request at a time can be sent to IRB. However, several amendments can be combined within one request.*

*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.***



Select whether it's a minor or major amendment and the changes in risks and benefits.

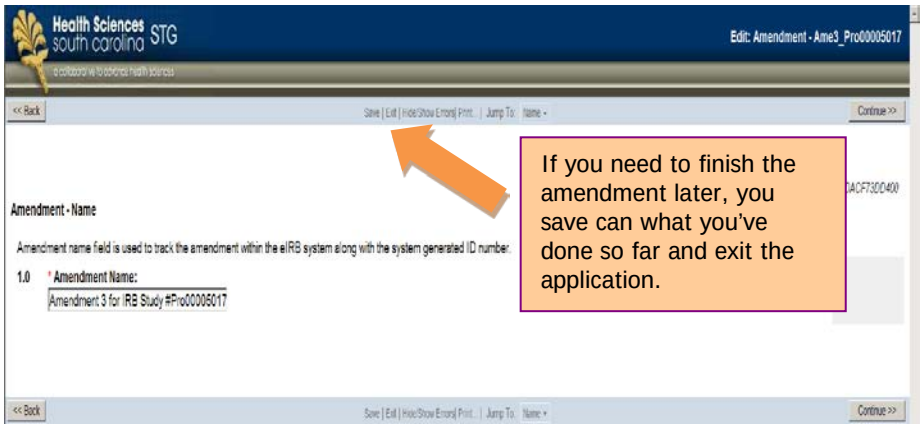
Click Continue



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.*

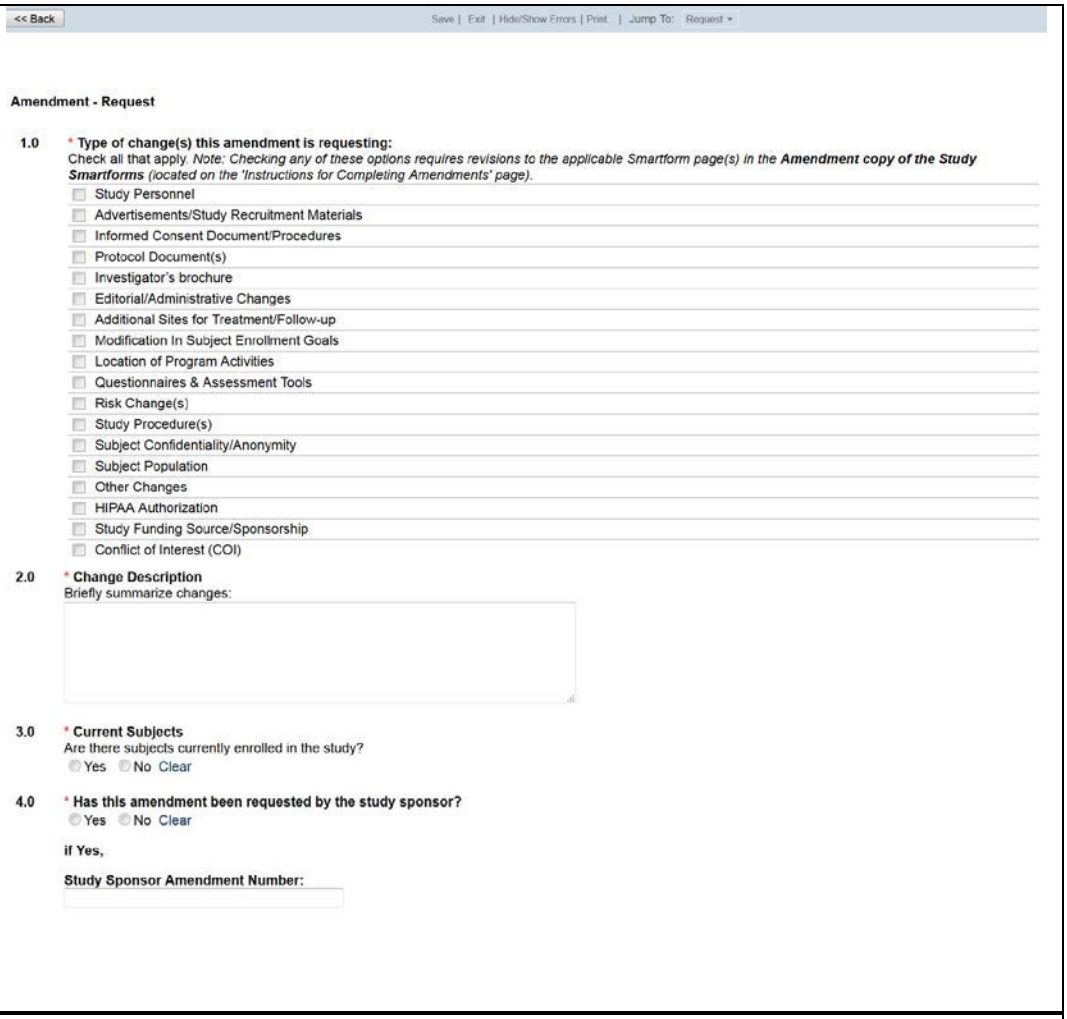


Select the type of amendment and enter in a description of the change.

Indicate if subjects are currently enrolled and if the amendment is at the request of the study sponsor.

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.

Click Continue.



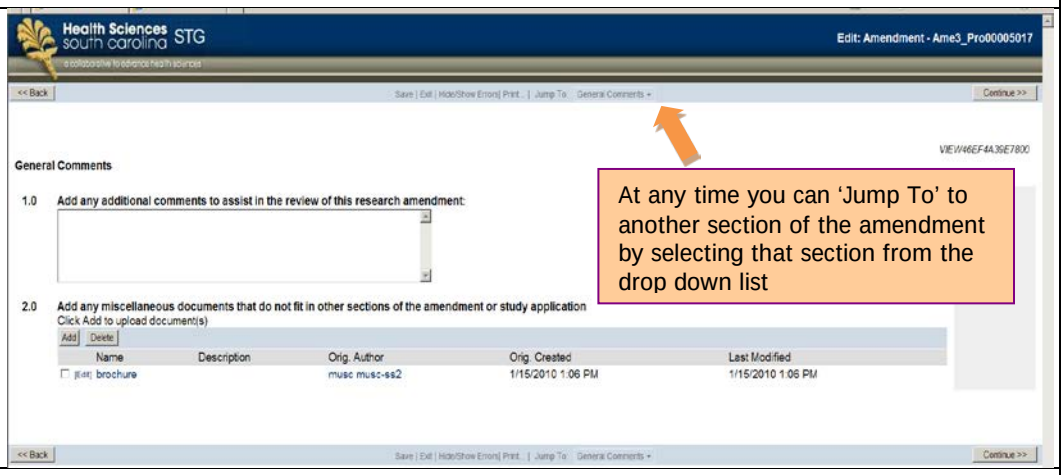
If desired, select an amendment type below for specific submission details. Otherwise, continue through the manual for General Completion guidance.

Change personnel	Investigator's Brochure	Sites/locations of Activities
Protocol Changes	Editorial/Administrative Changes	Subject Information
Informed Consent		

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.



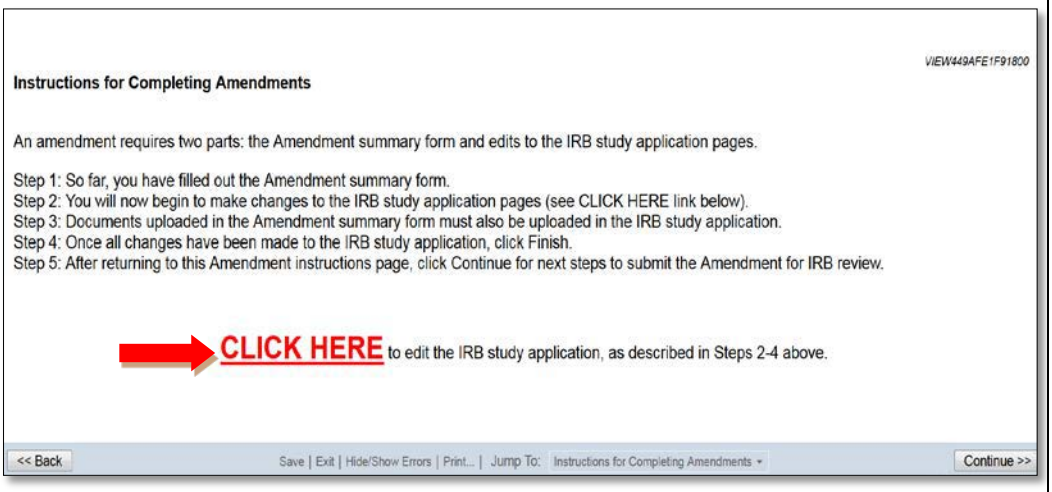
A Summary of the amendment changes will be presented.

Verify the information and click 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.



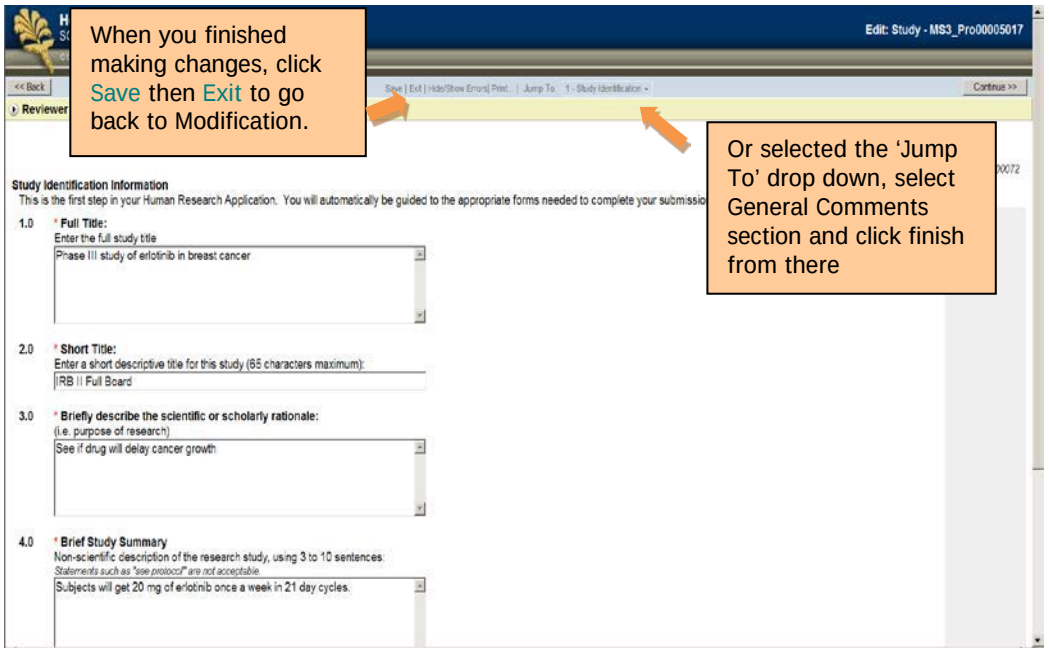
Make changes to the appropriate section so that it reflects what has changed in the amendment.

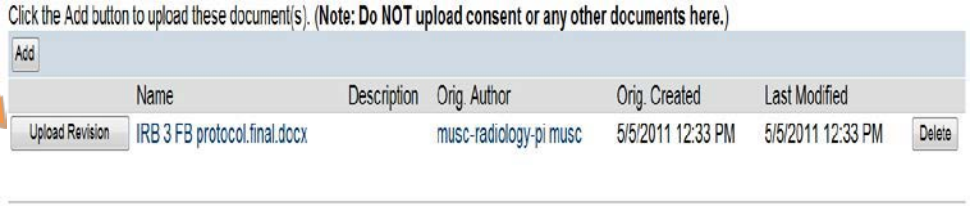
Click on the 'Jump To' drop down list to see which sections of the application require changes.

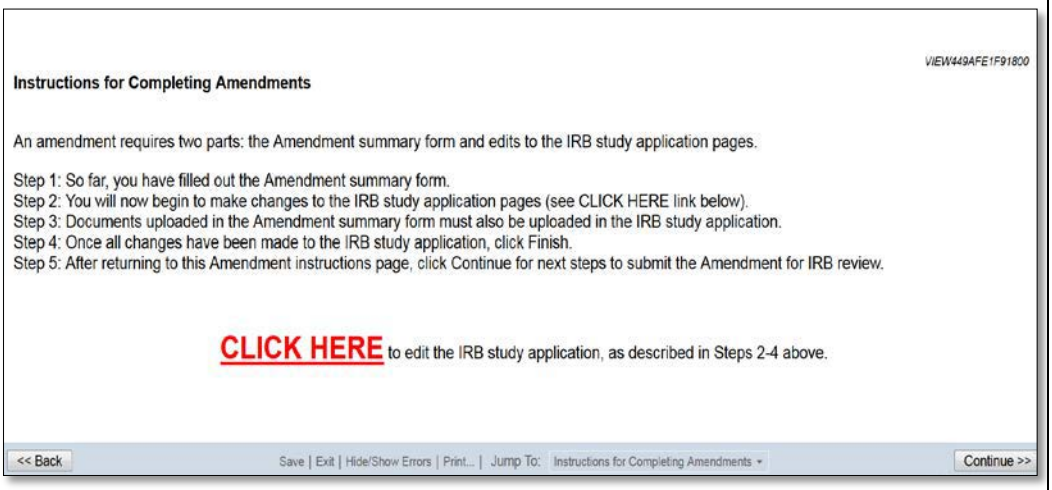
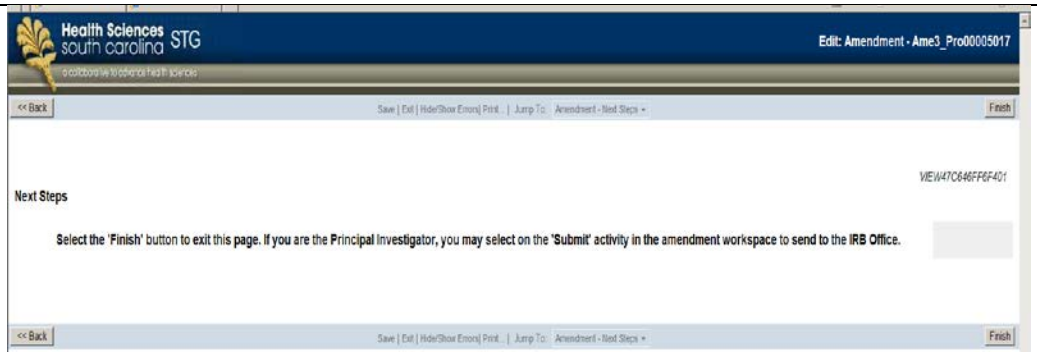
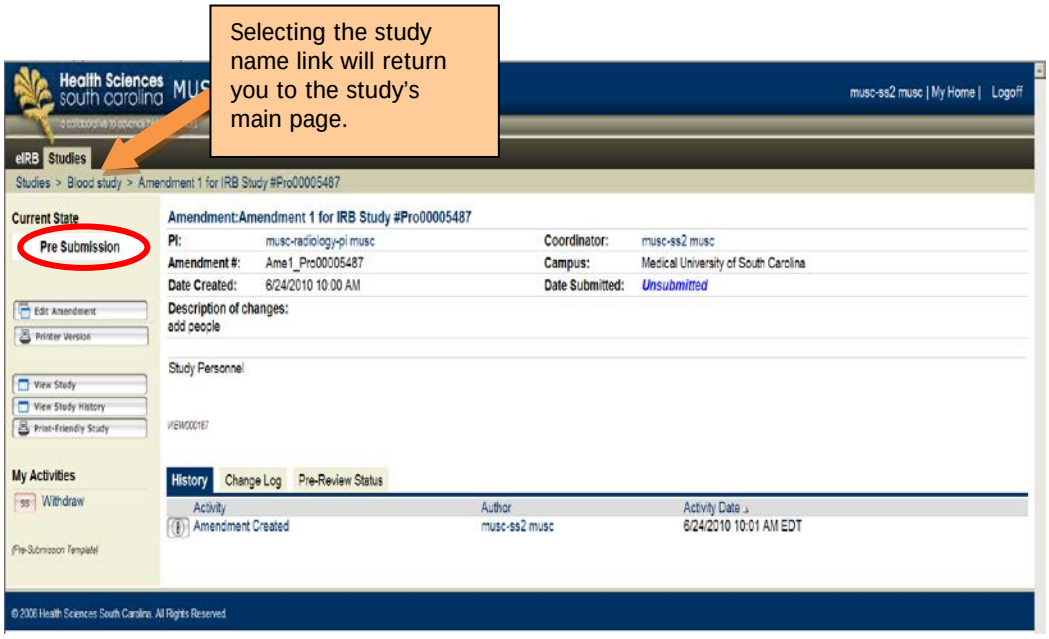
Upload any final documents that are a part of the amendment.

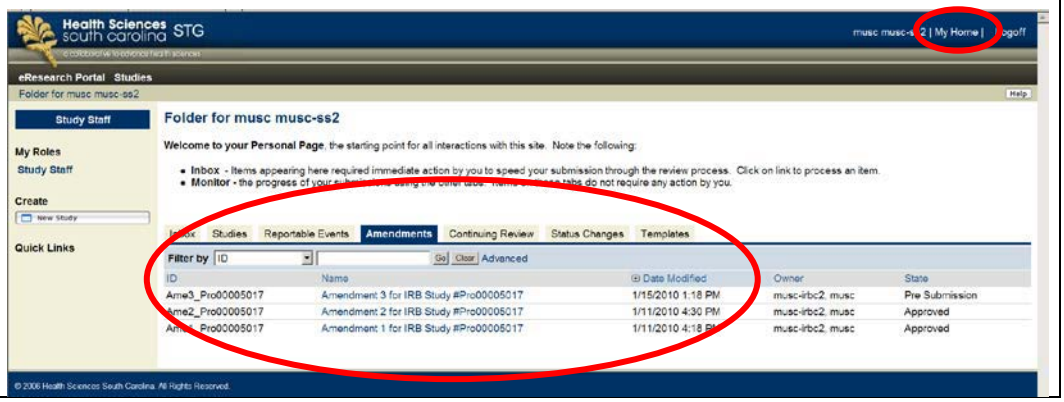
***Note: Upload revised documents (i.e., protocol, consent, ads, etc.) in the applicable section by clicking on the 'Upload Revision' button (NOT the 'Add' or 'Delete'). ***

When you have finished making the changes, save the information. You can then exit the application.



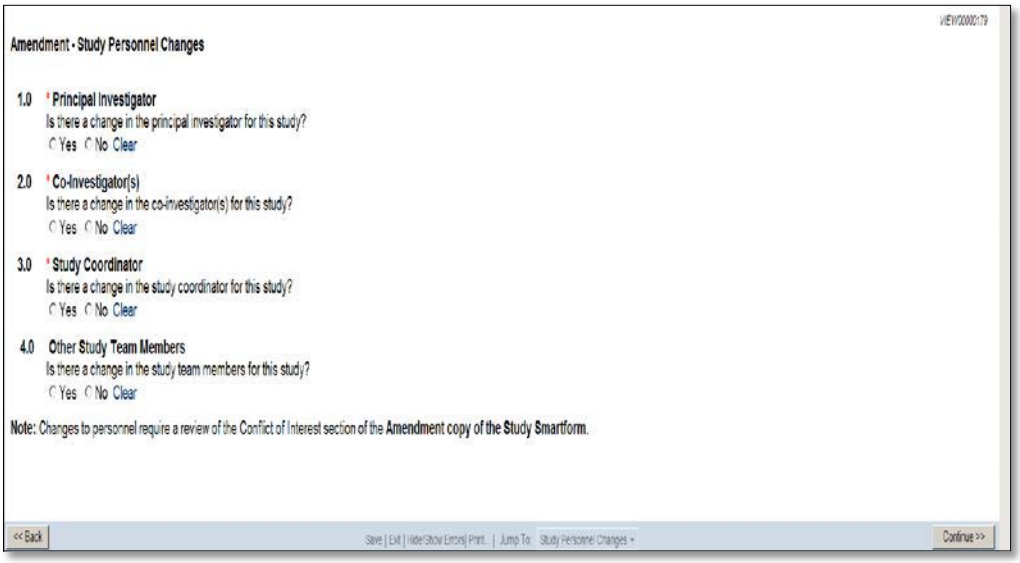


The 'Instructions for Completing Amendments' screen will re-appear. Click Continue.	
Select 'Finish' to complete the amendment in the system. ***Reminder: only the Principal Investigator can send the amendment to the IRB***	
The system will return to the protocol amendment workspace. ***Note: e-IRB does 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.	

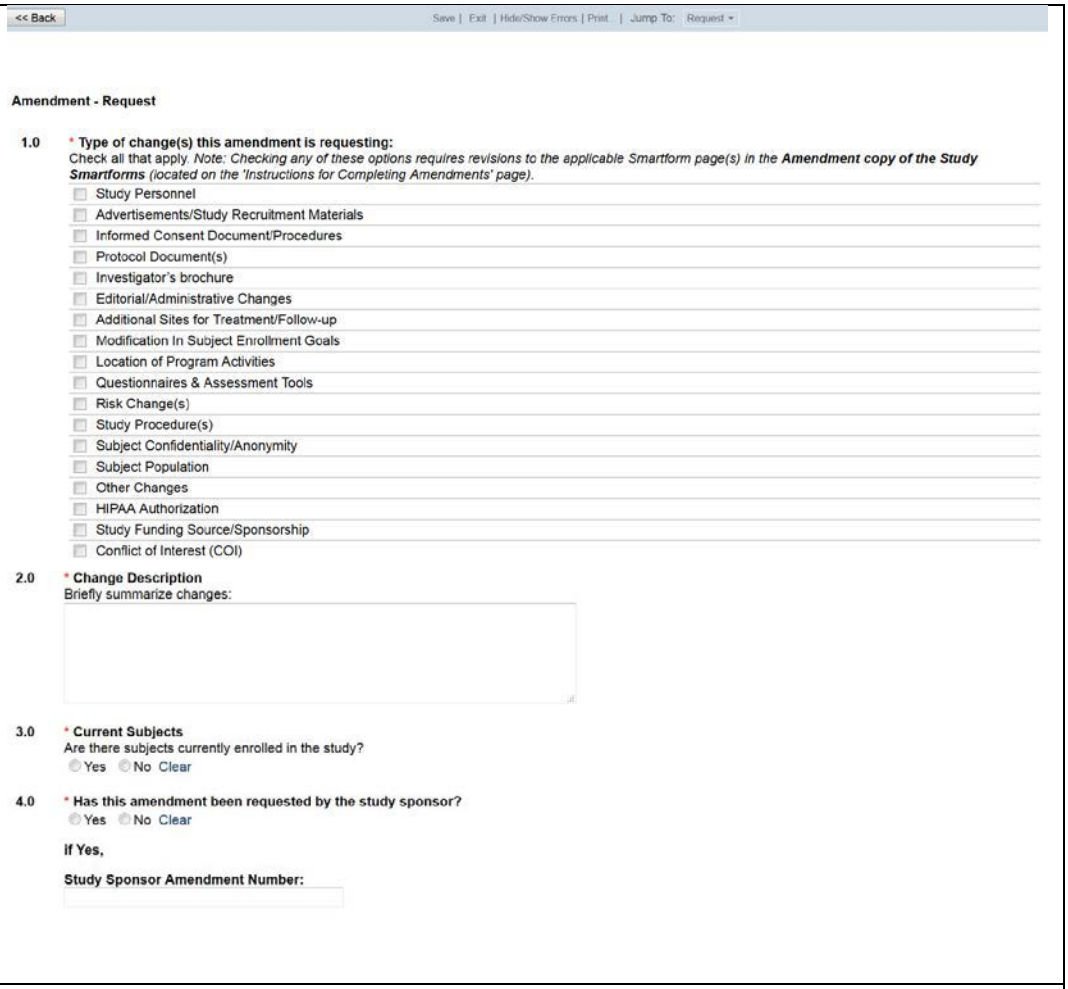
Change in personnel

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.	

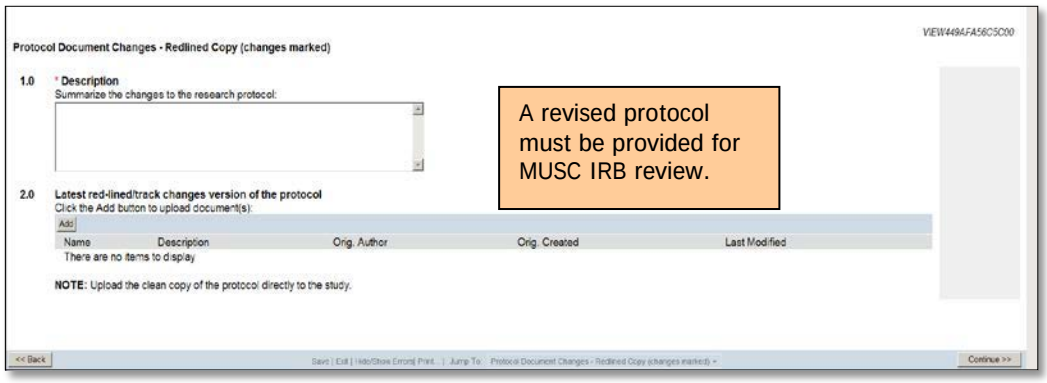
Protocol changes

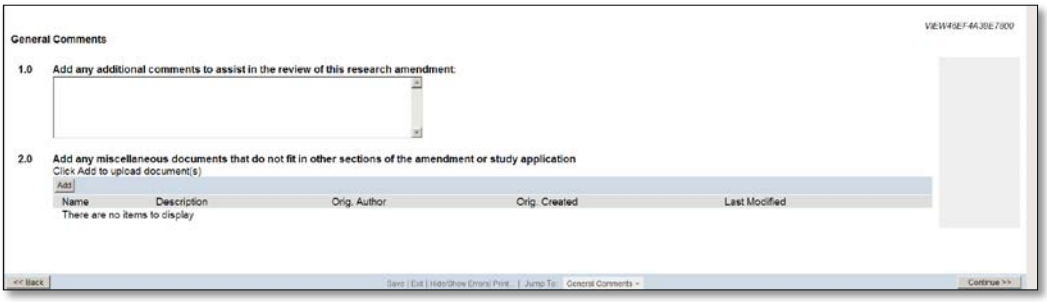
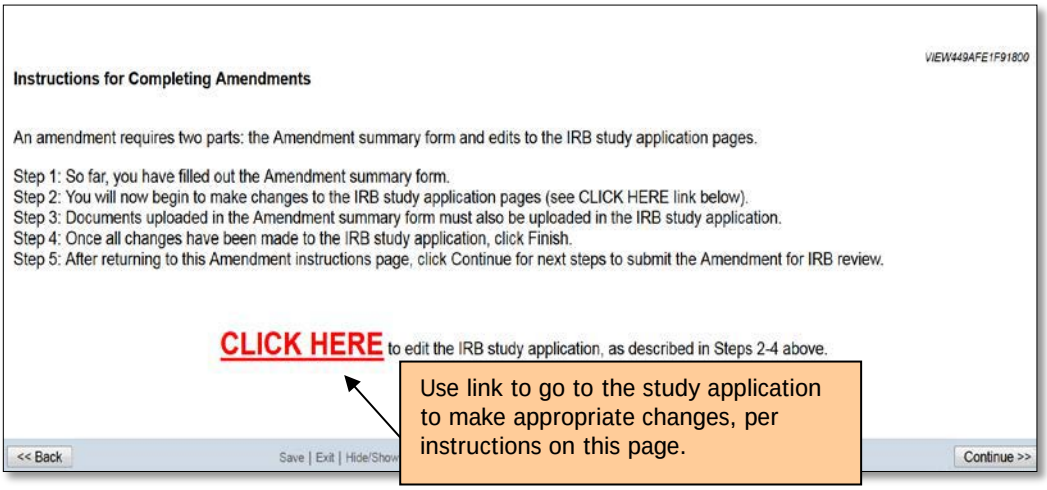
If not already completed, follow steps in the *General Completion Guidelines* section, selecting 'Protocol Document' as the amendment type.



Summarize the changes and click 'Add' to upload the tracked changes version of the protocol.

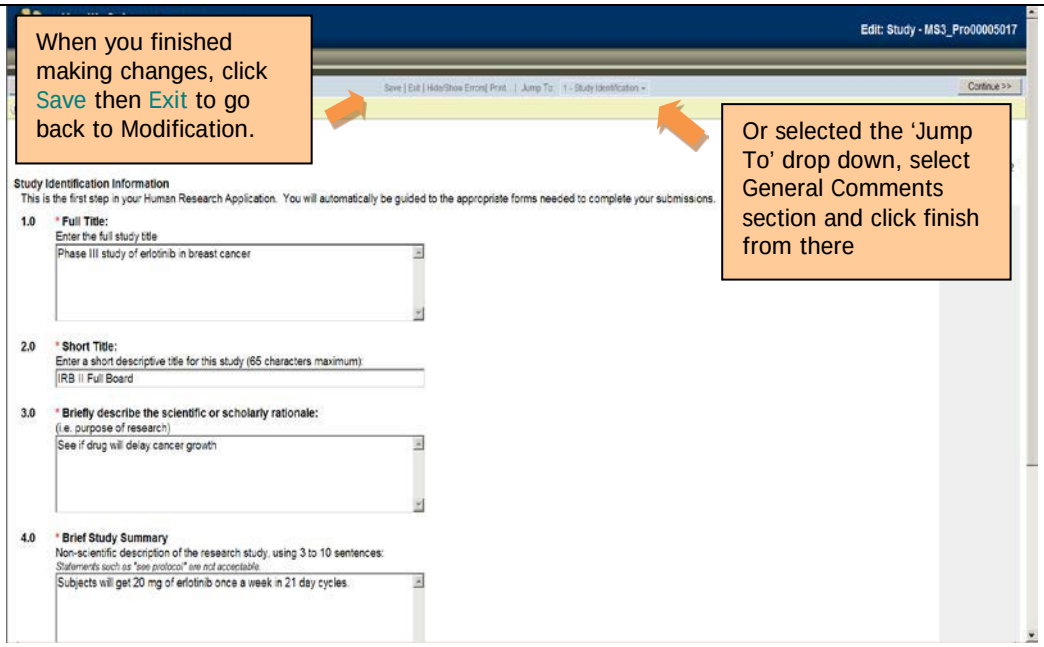
Note: you will upload the clean copy document directly into the current IRB application part of the amendment request



Add any additional comments and upload relevant documents that aren't uploaded in another section of the amendment request.	
The next screen will show a summary of changes you selected. Verify the information and click Continue.	
You must manually enter into the current IRB application the information that changed with this amendment. Review the steps on the page and click the CLICK HERE text to open up the currently approved application and incorporate the changes. ***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.***	

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.



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.*

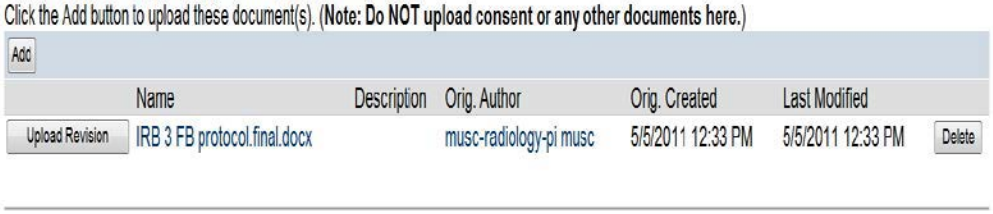
DO NOT select the 'Add' button unless this is an additional protocol document that was not previously approved.

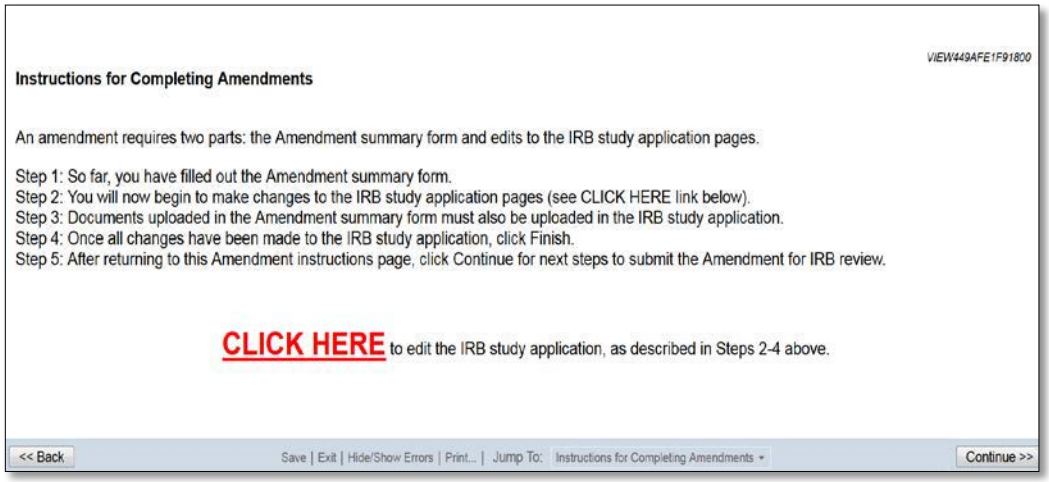
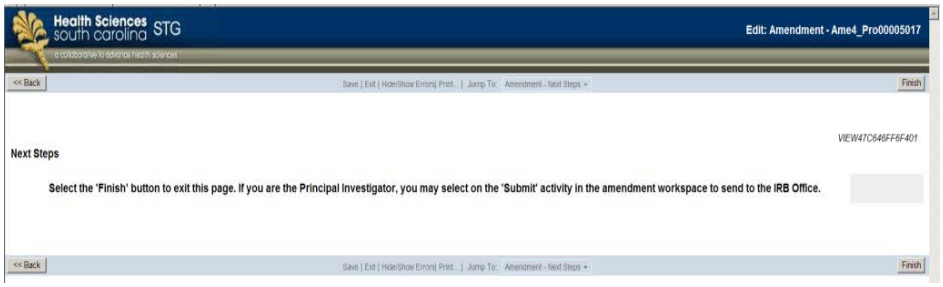
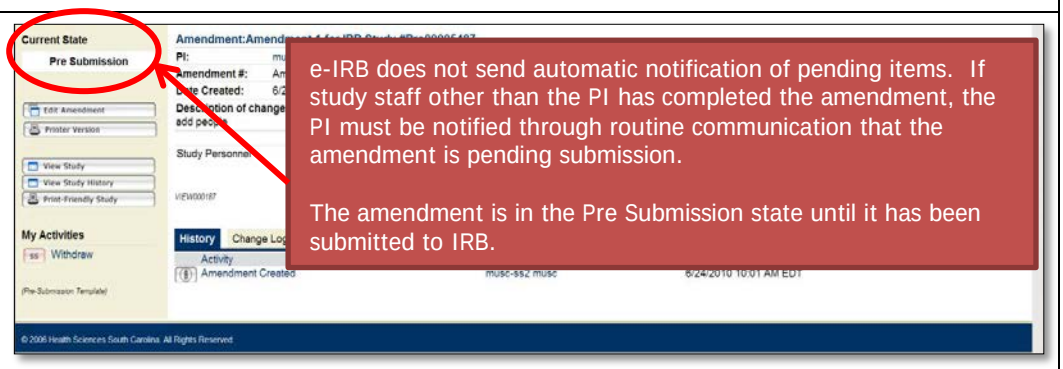
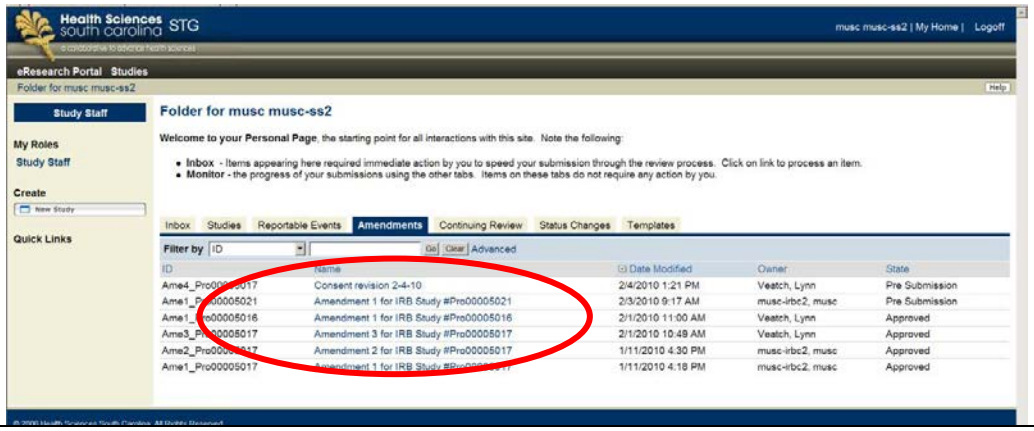
*DO NOT click 'Delete' button unless an incorrect document that has not yet been IRB approved was uploaded in error***

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.***

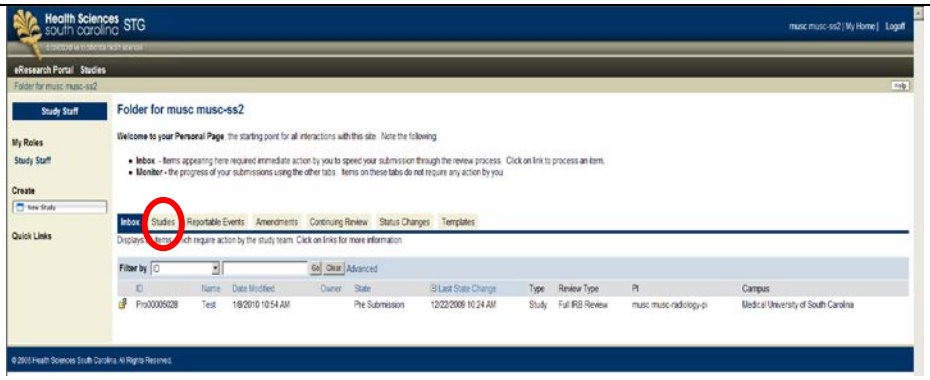
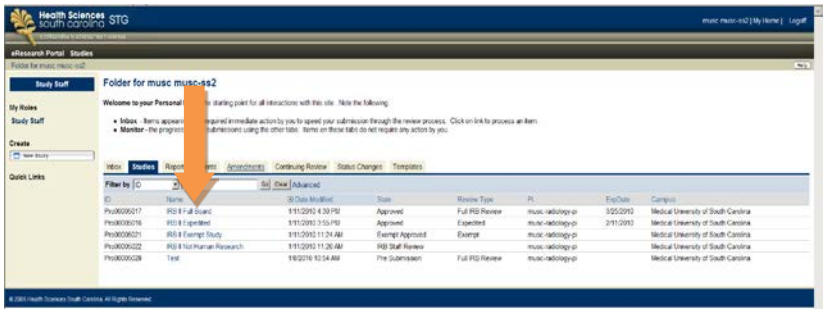
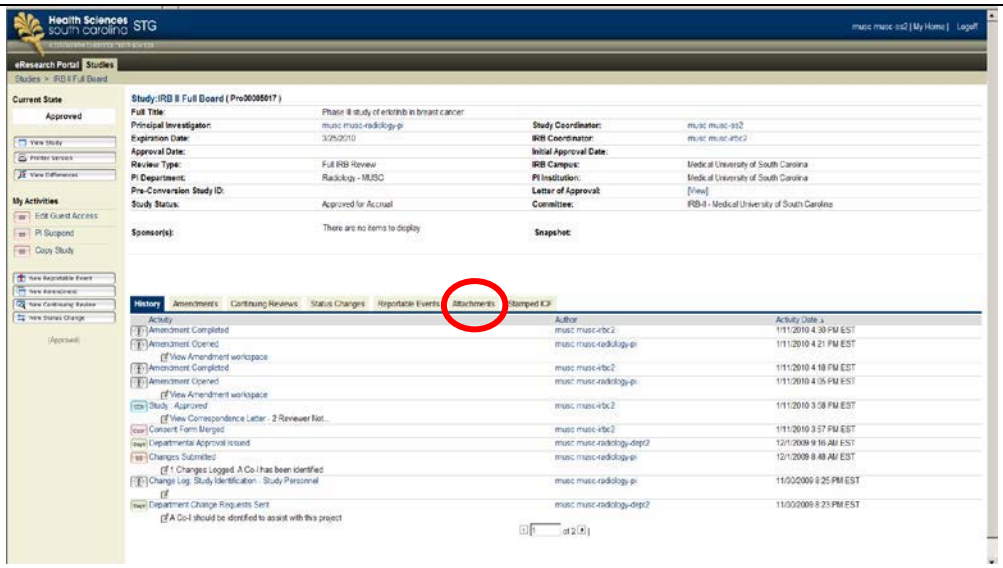


The system will take you back to the Amendment Summary to complete the submission. Click Continue.	
Click 'Finish' ***NOTE: only the Principal Investigator can send the amendment to the IRB***	
The system will return to the protocol amendment workspace.	
The amendment shows up in the 'Amendment' tab on your Home page and on the 'Amendment' tab in the study's details. Follow the steps in the 'Sending Amendment to IRB' section.	

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.

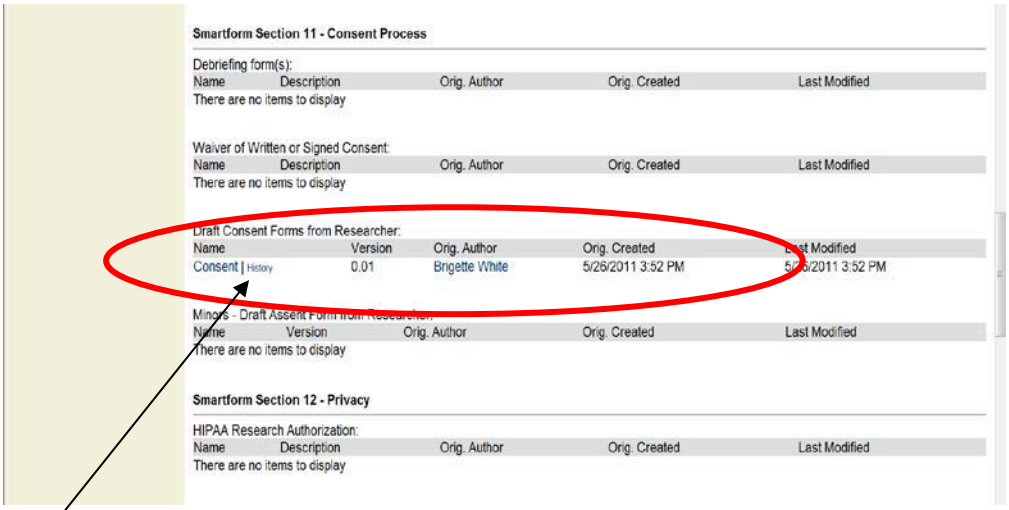
To locate the most recent consent form in eIRB, log into eIRB and select the 'Studies' tab.	
Click on the study the name of the study.	
Select the 'Attachments' tab.	

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.

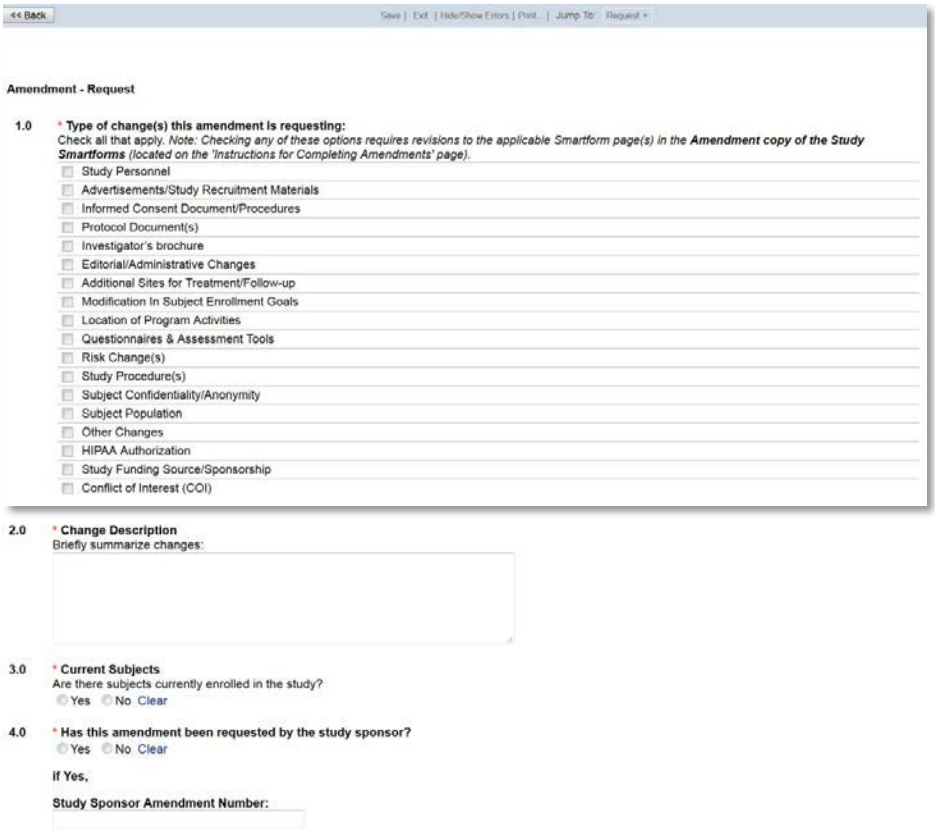
Click on the name of the document to open it. The document should have the shell of the date-stamped watermark.

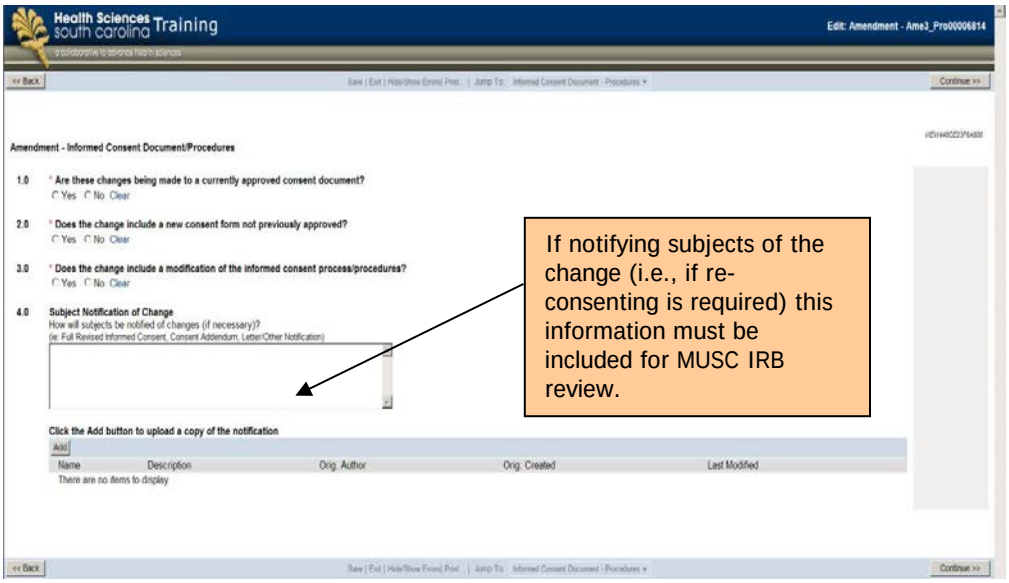
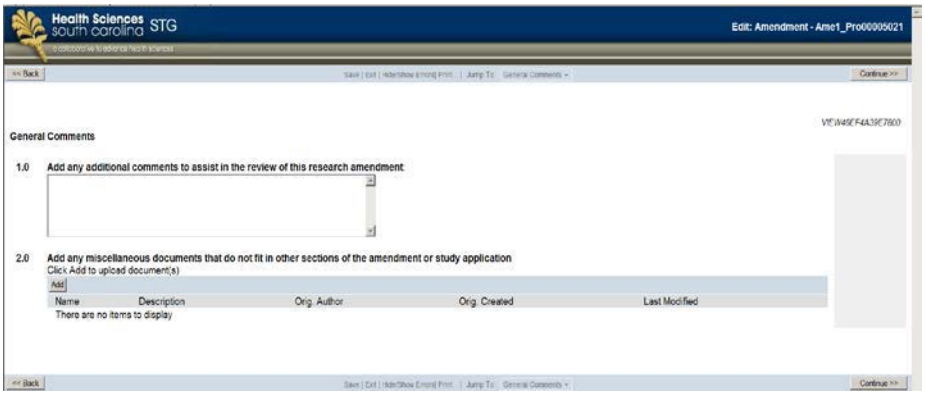
Note: to review previous versions of the consent form(s), select the 'History' link next to the document's name

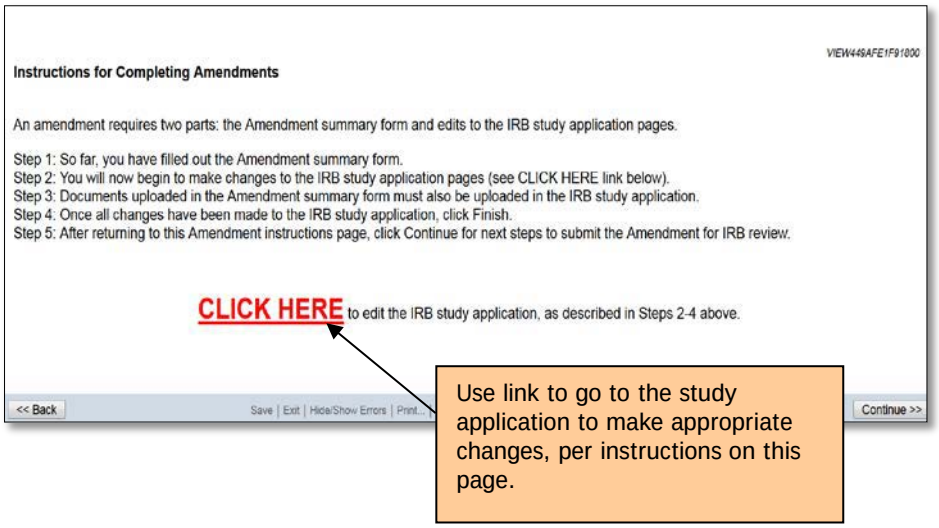
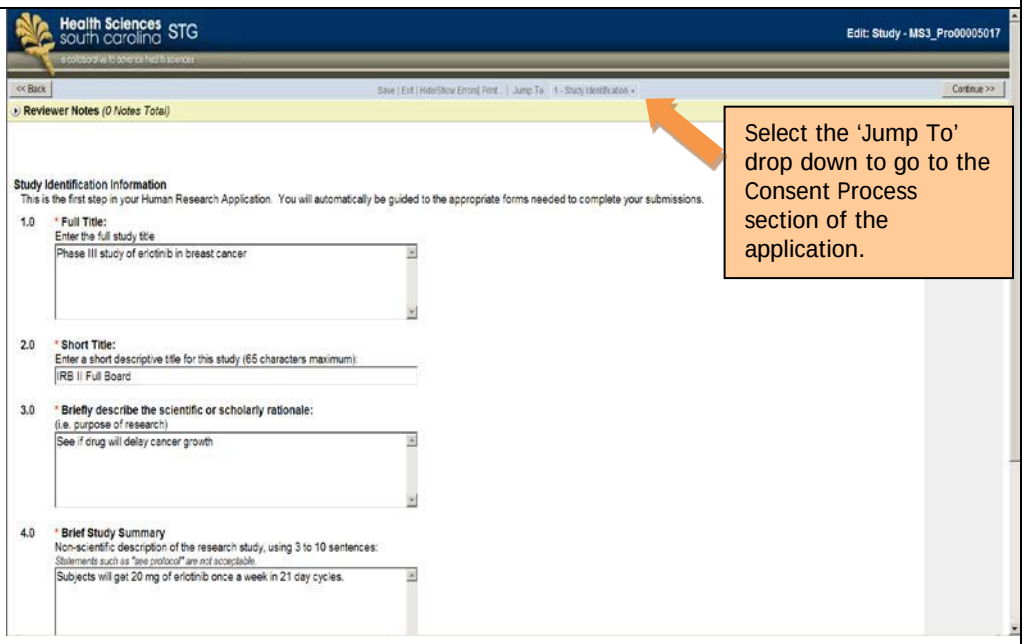


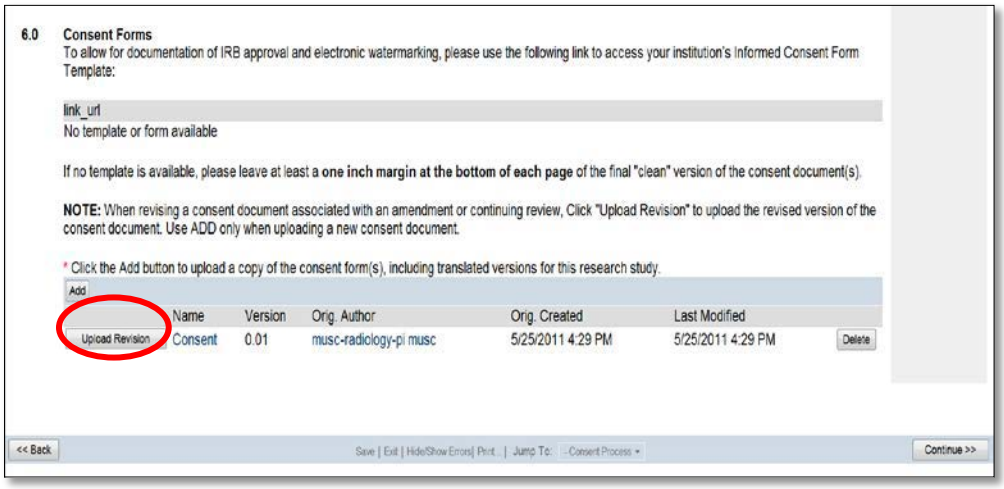
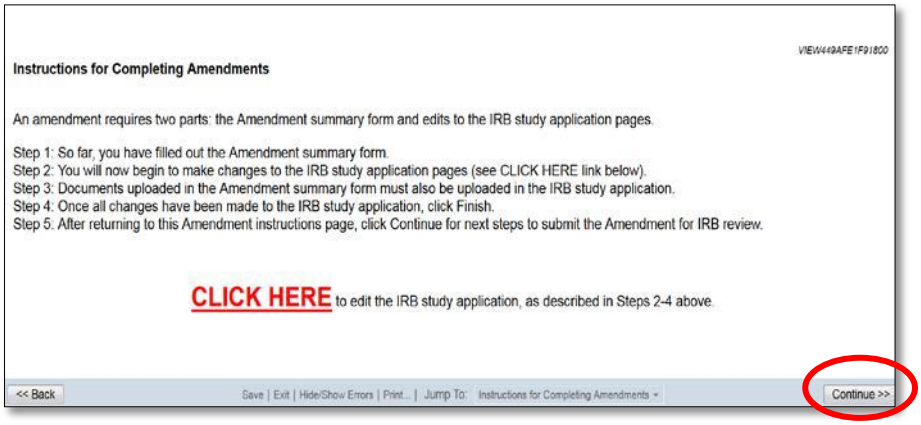
Completing Consent Amendment

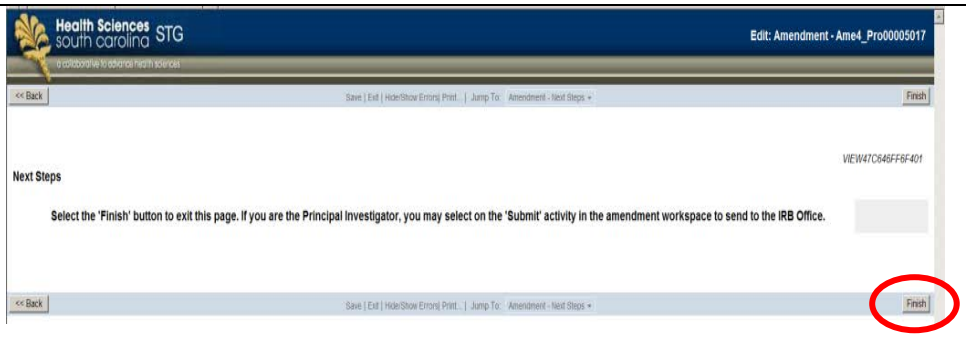
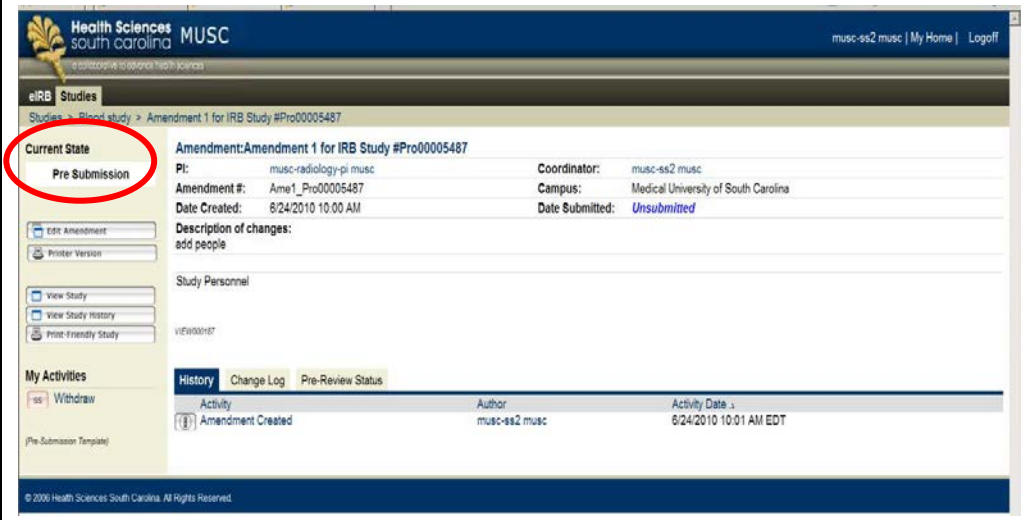
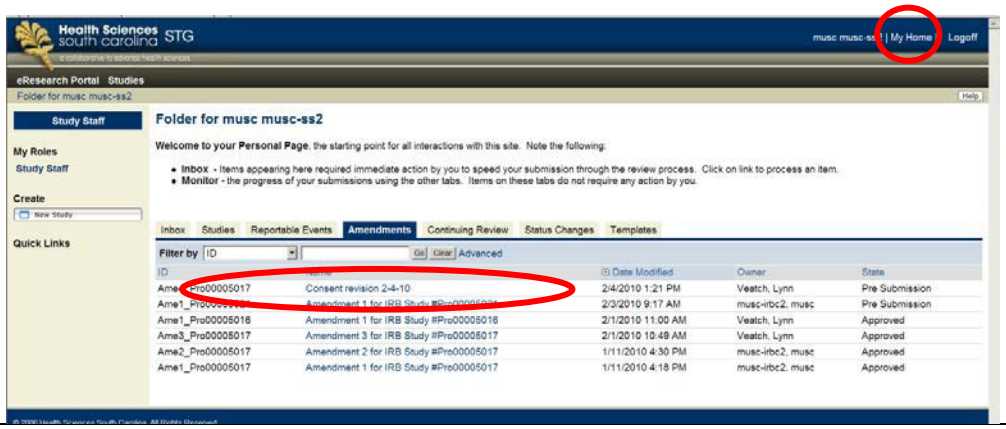
If not already completed, follow steps in the *General Completion Guidelines* section, selecting 'Informed Consent Document/Procedures' as the amendment type.



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.	
If the change is for a currently IRB approved consent form, summarize the changes.	
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***	
The next screen will show a summary of changes you selected. Verify the information and click Continue.	

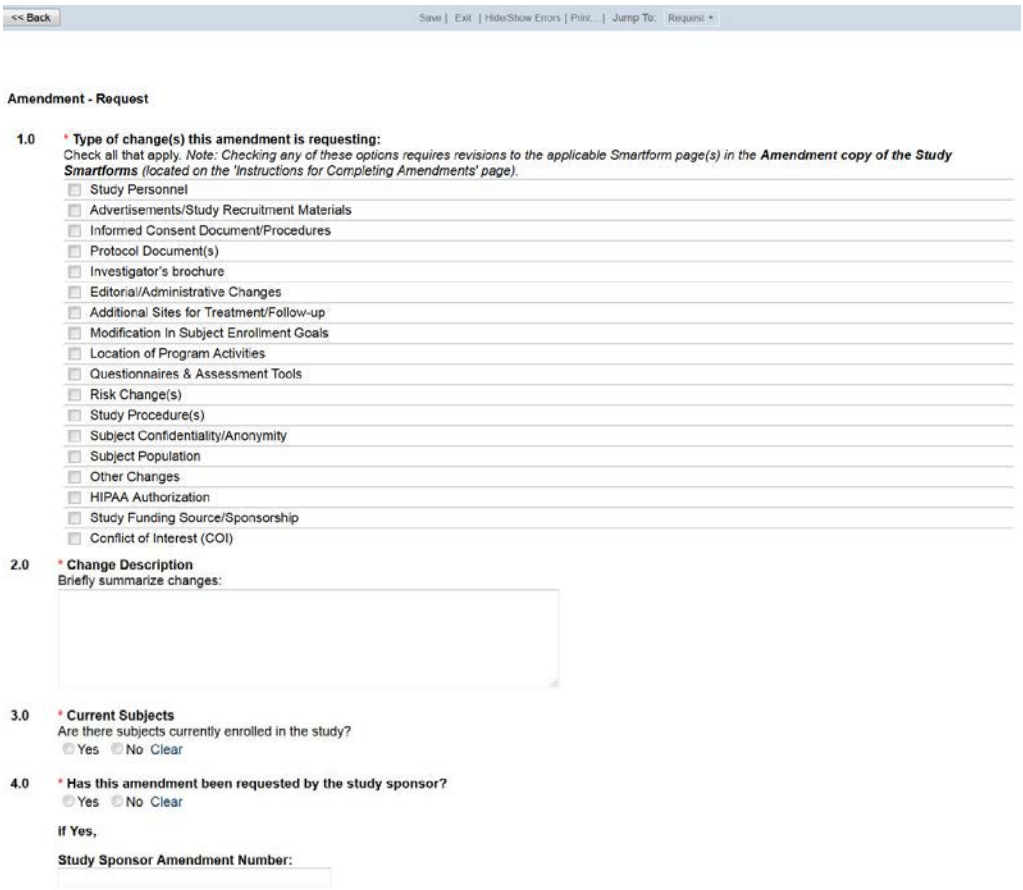
You must manually enter into the original/current IRB application the information that changed with this amendment. Review the steps and click on the CLICK HERE text to incorporate the changes in the study application. ***Note: the final/unmarked consenting documents will be uploaded in the current IRB application, which will appear after clicking on the 'Smartform' link***	
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.	

Edit all information in this section that has changed as a result of the amendment. To upload the un-tracked (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.	
The system will return to the Amendment Summary to finalize the amendment Click 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 '<u>Sending Amendment to IRB</u>' section.	

Investigator's Brochure

If not already completed, follow steps in the *General Completion Guidelines* section, selecting 'Investigator's Brochure' as the amendment type

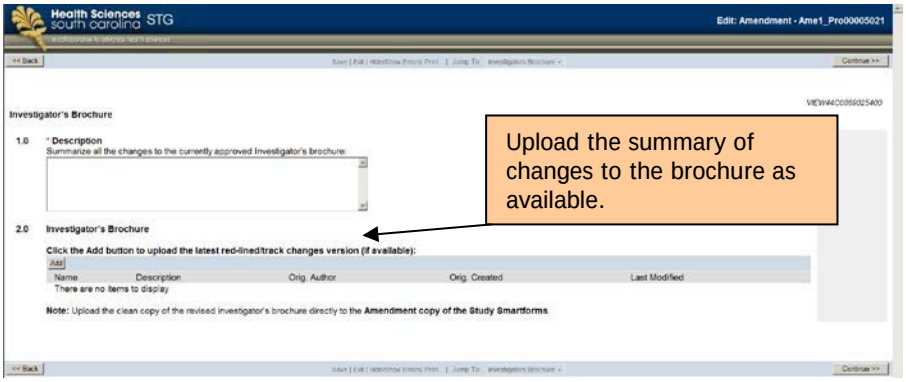


Provide a summary of the changes and tracked changes of the brochure (if available).

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.



Editorial / Administrative Changes

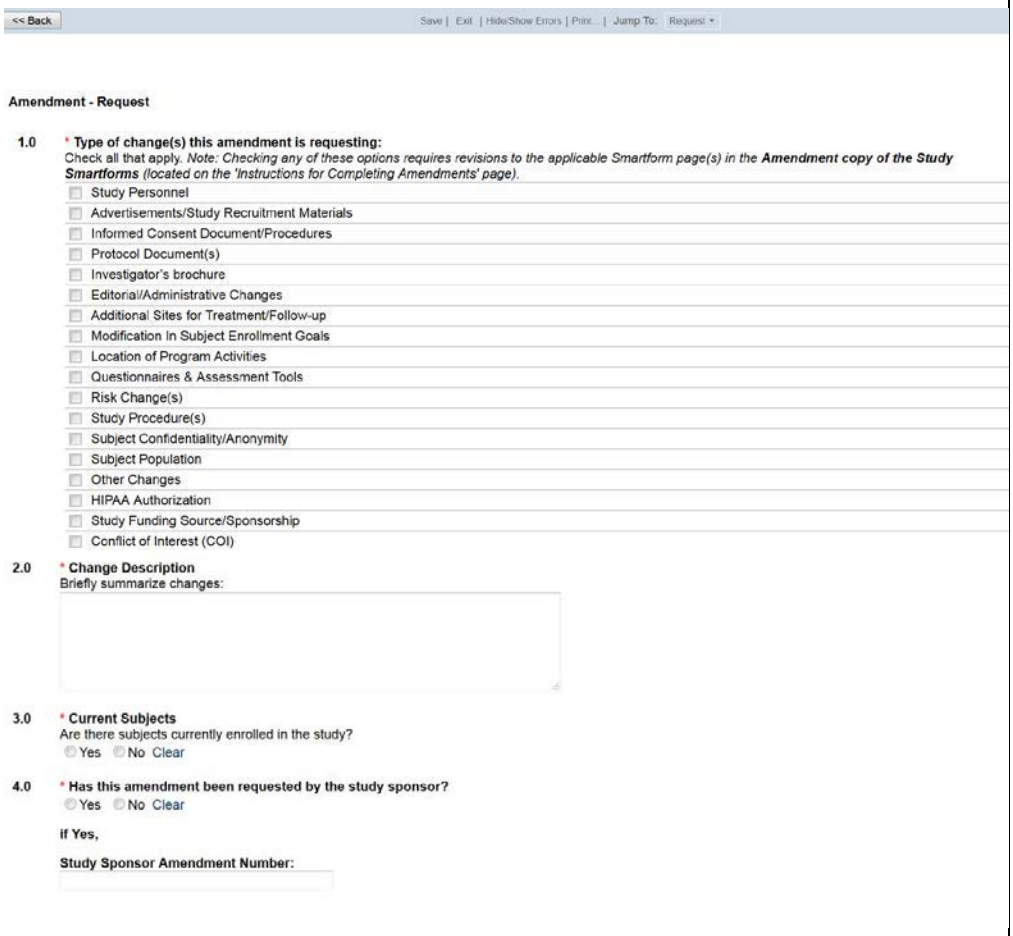
If not already completed, follow steps in the *General Completion Guidelines* section, selecting 'Editorial/Administrative Changes' as the amendment type.

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



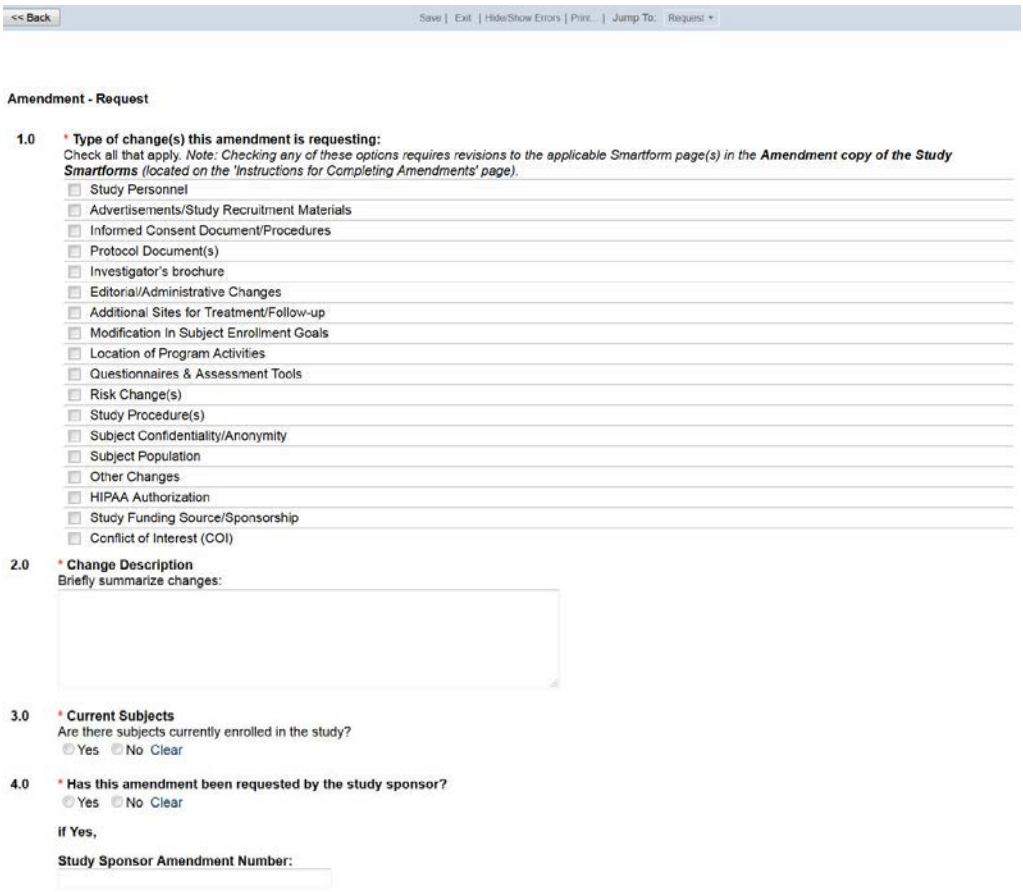
Changing sites/location of activities

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



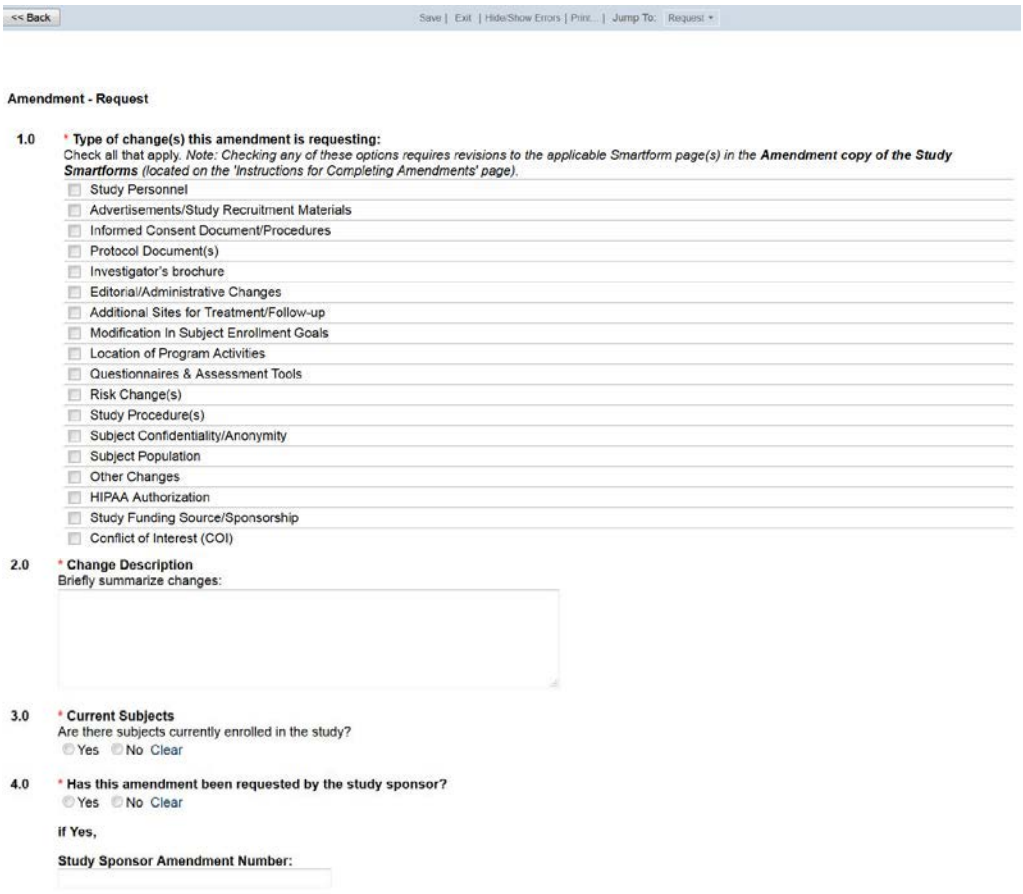
Changing subject information

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)

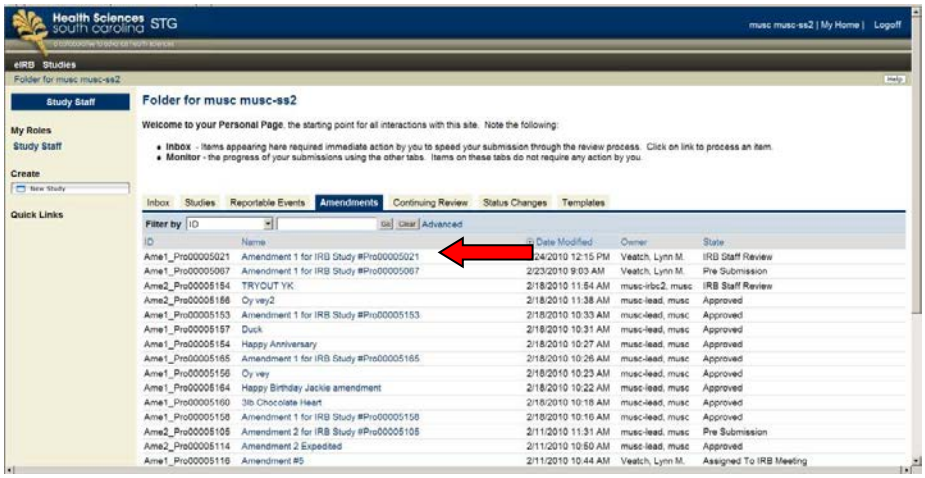
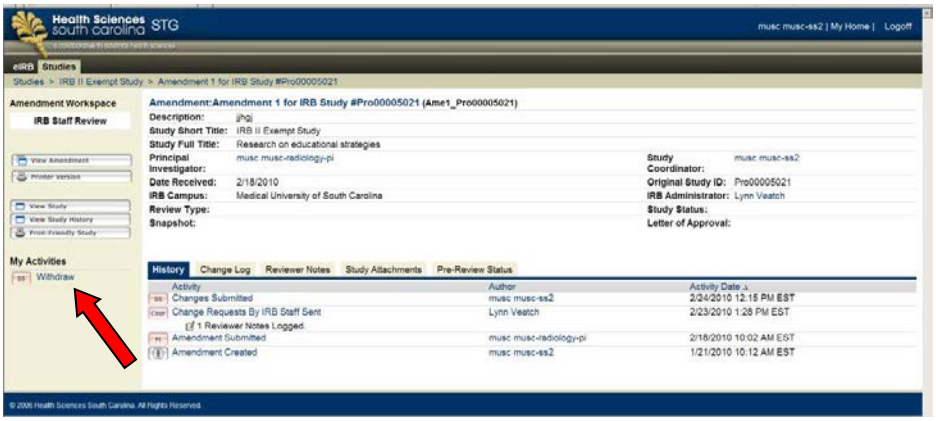
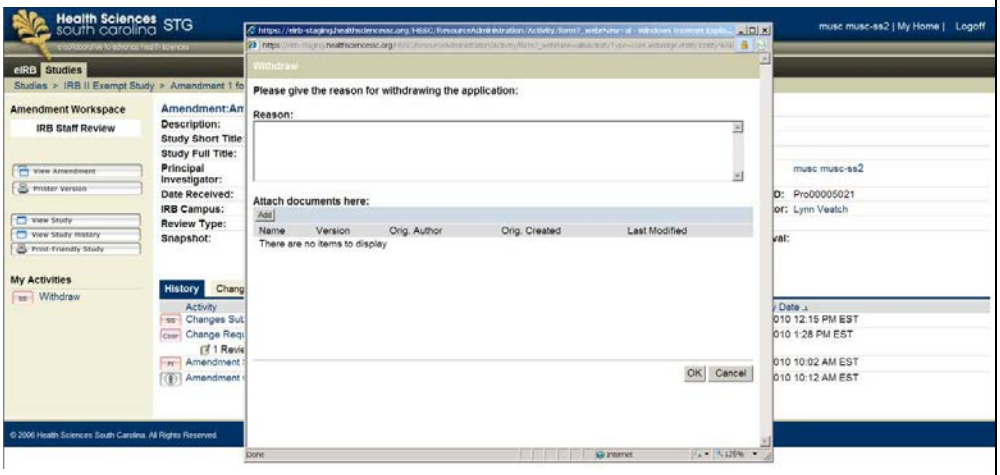
Note: after selecting a Smartform link, you will upload un-tracked (clean) copy documents directly into the current IRB application part of the amendment request, as applicable

See steps in the Finalizing the amendment section for instructions on completing the amendment request



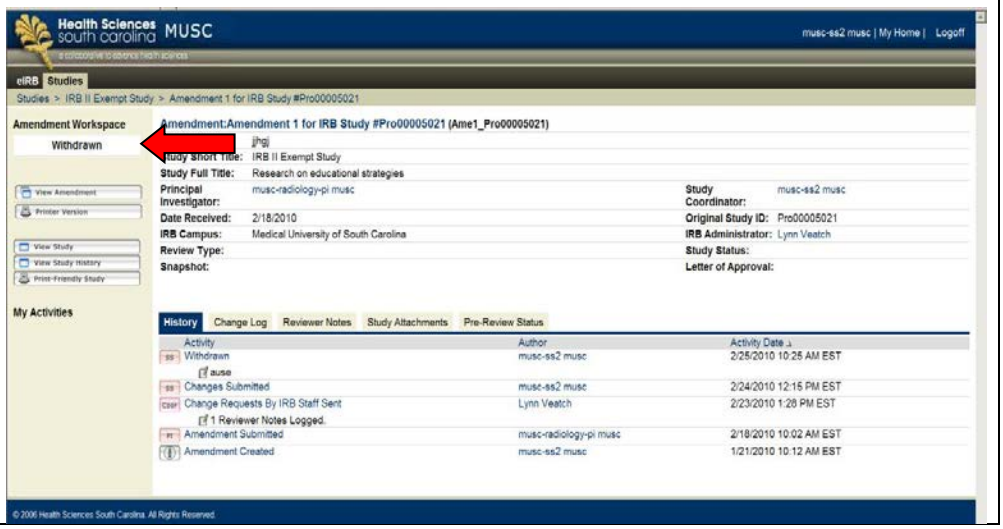
Withdrawing an Amendment

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'	

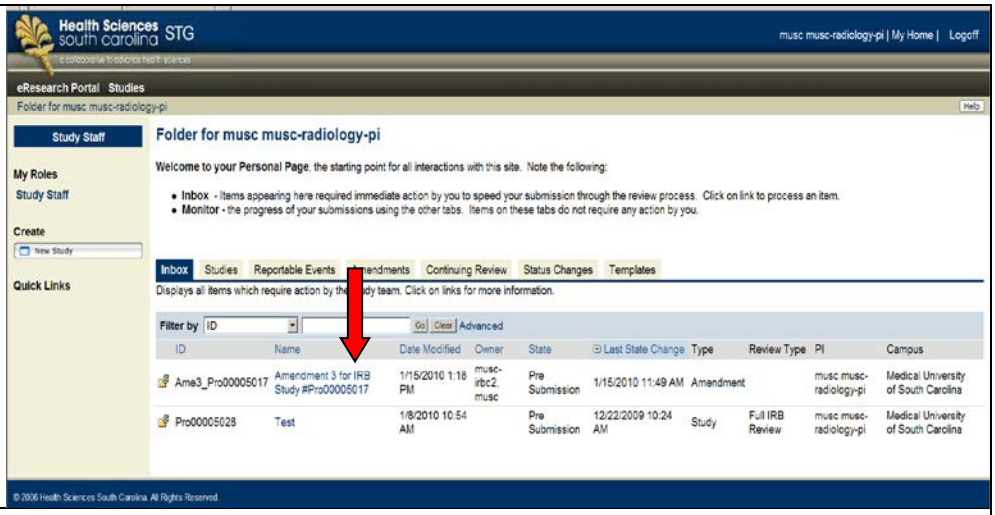
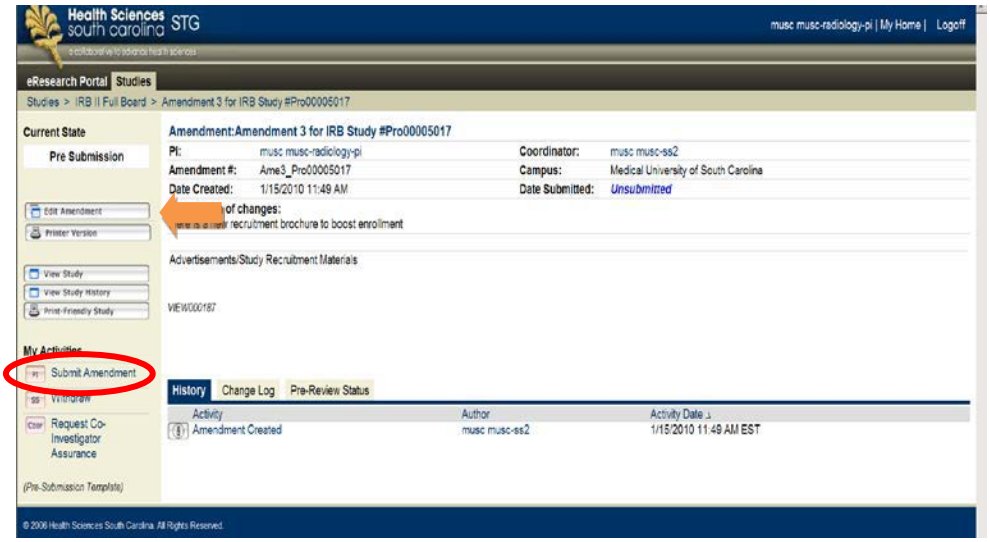
The state of the amendment is now ‘Withdrawn’.

The system has stored the study. To see a copy of the withdrawn amendment, select ‘View Amendment’.



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.	
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.	

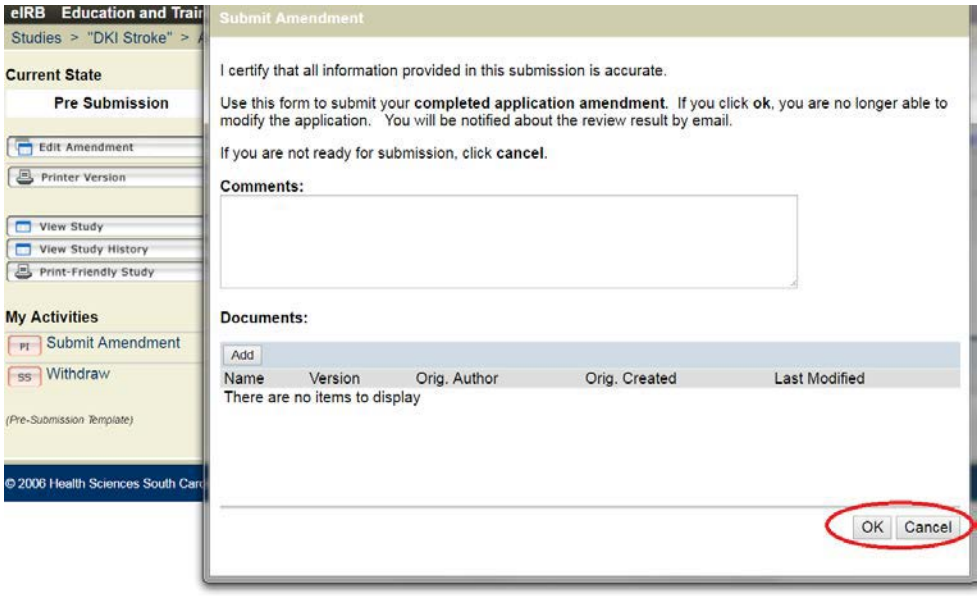
A pop up screen will appear where you can enter in any additional questions, upload any final documents and confirm that you are ready to send the amendment to IRB.

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

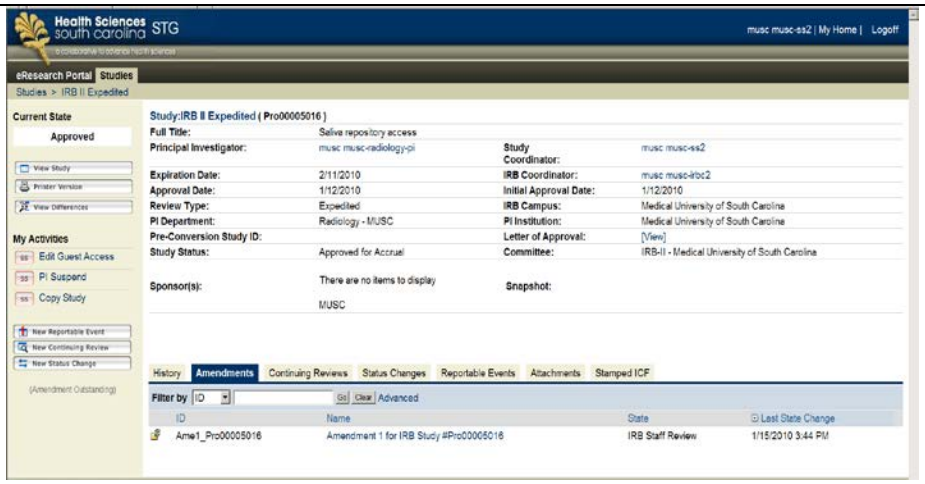
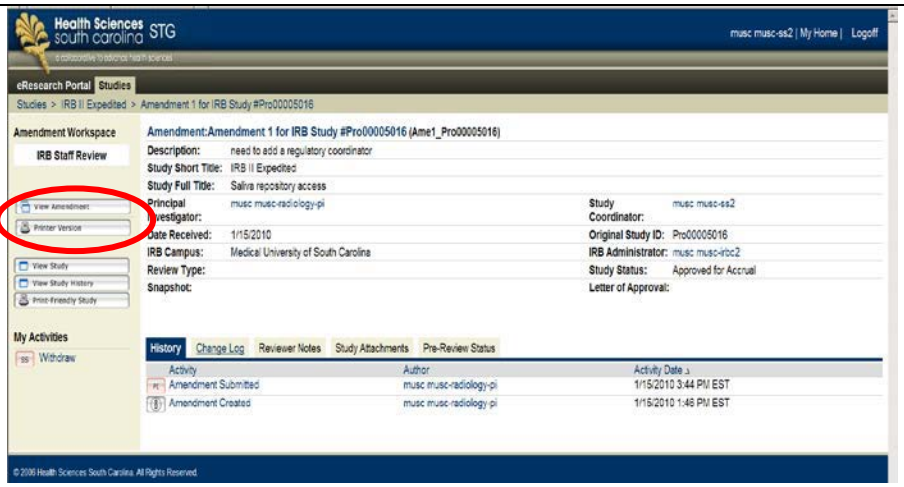
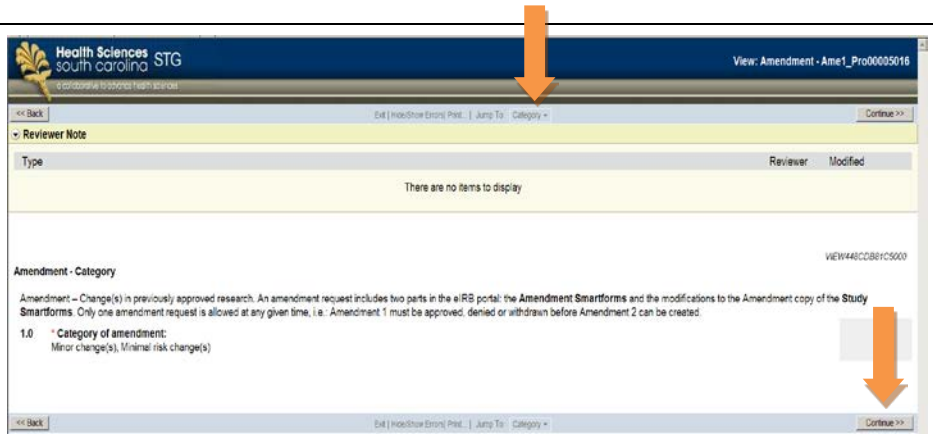
The amendment will now show up as submitted in the 'Amendment' tab on your Home Page and on the 'Amendment' tab in the study's details.



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.

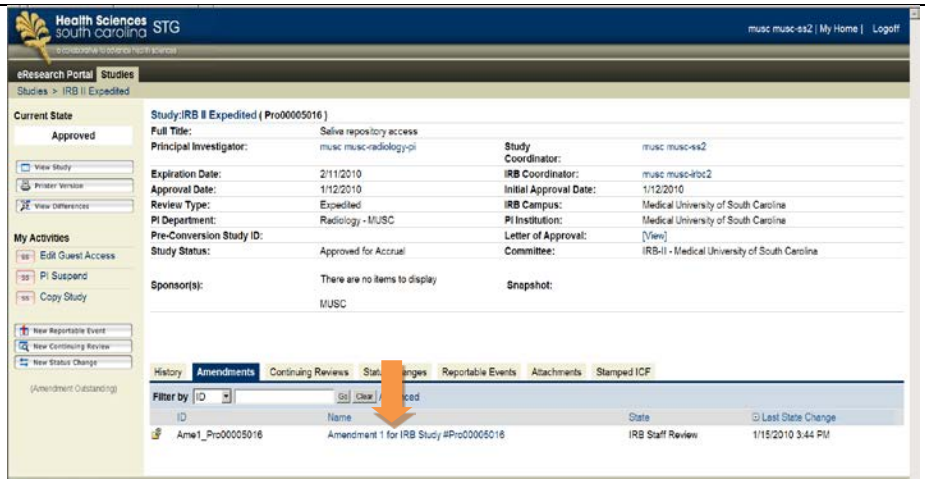
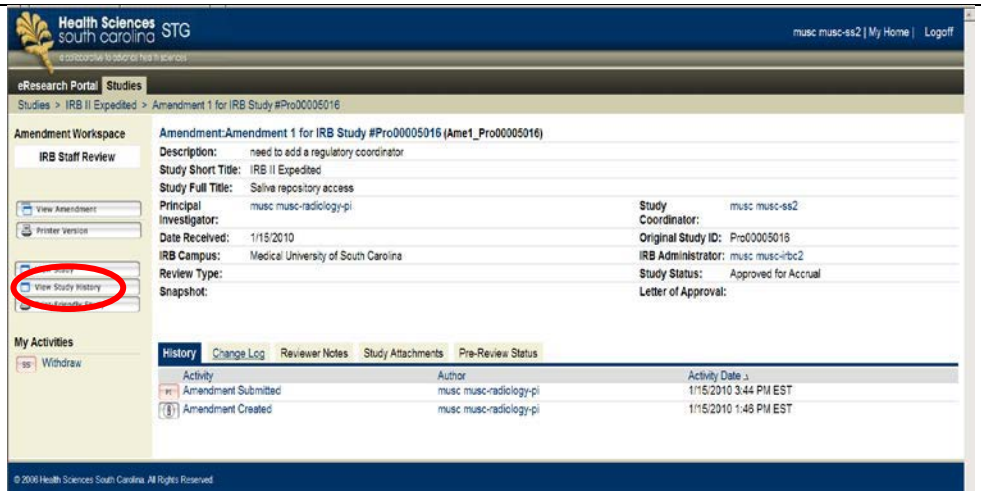
Viewing Details of Changes Submitted

Viewing a Summary of the Amendment

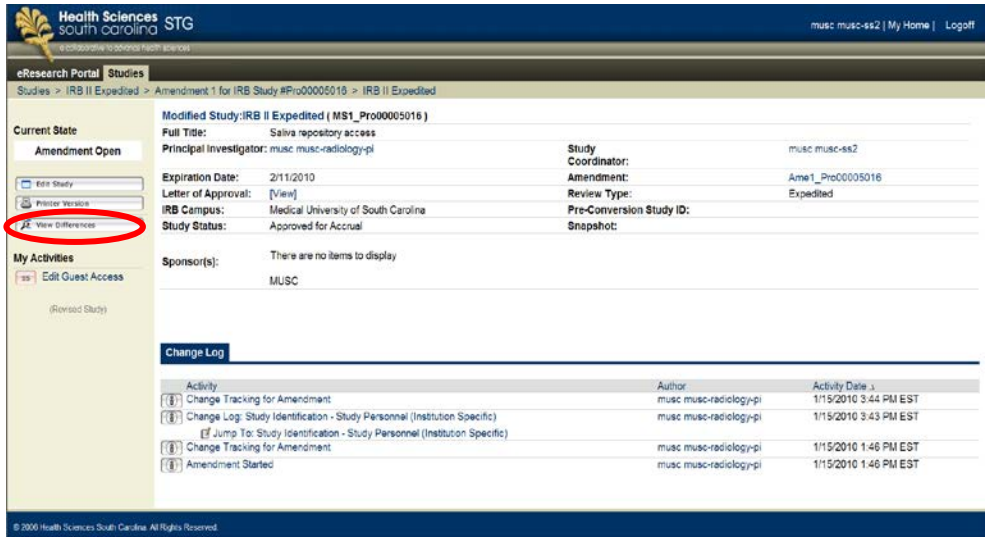
Select the Amendment tab on the study's Home page and select the amendment name.	
Select the 'View Amendment' or 'Printer version' button on the study's amendment Home page. This view will provide only a summary of the amendment changes.	
The 'View Amendment' selection requires navigation through the 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	

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.	
Click 'View Study History'	

Select 'View Differences'. This will show you the differences between the previous study details and what you submitted in this amendment.

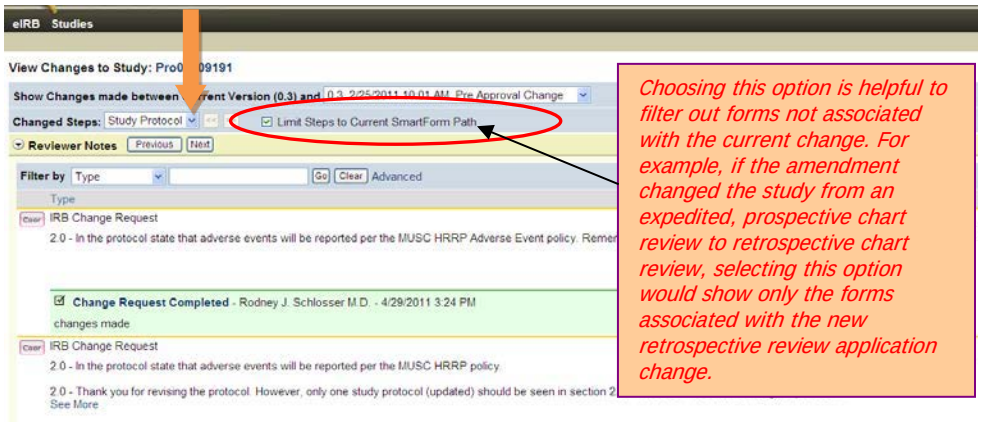


This view shows what was changed in each section of the current application as a result of this amendment.

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.

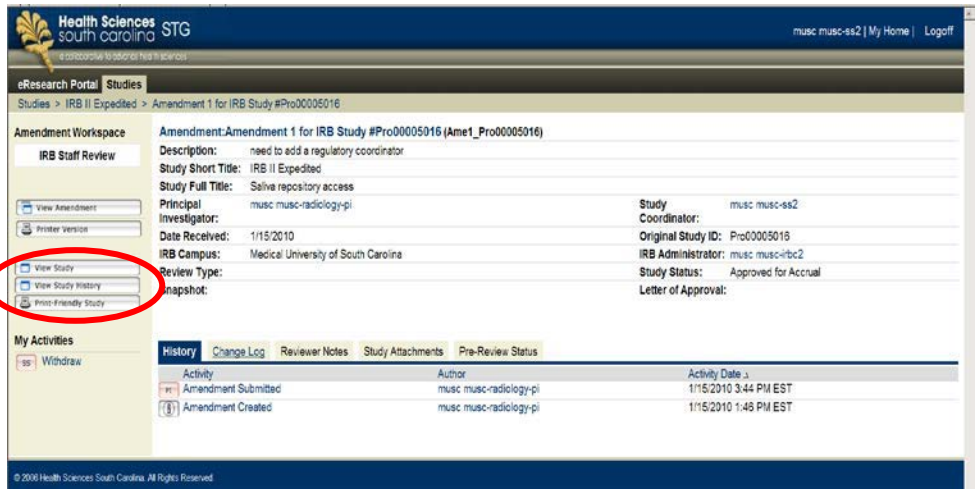


Choosing this option is helpful to filter out forms not associated with the current change. For example, if the amendment changed the study from an expedited, prospective chart review to retrospective chart review, selecting this option would show only the forms associated with the new retrospective review application change.

Viewing the Amended Study After IRB Submission

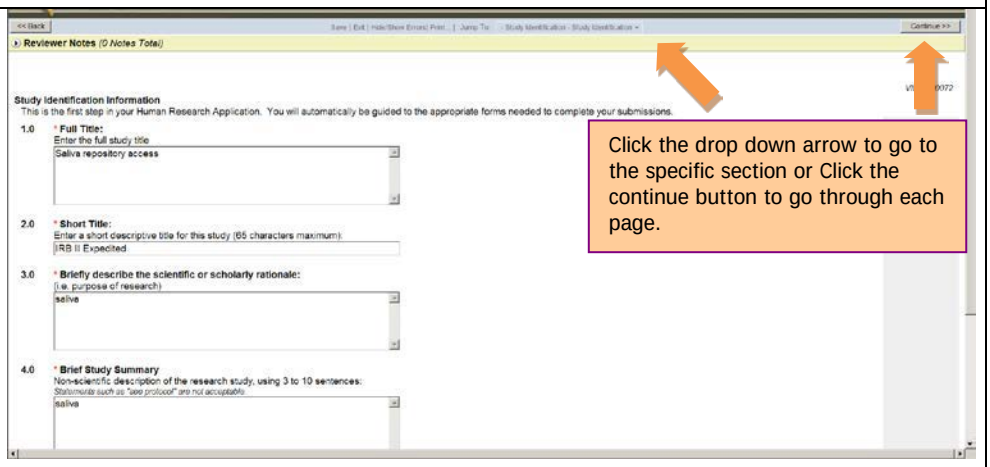
After IRB submission of the amendment, you can view the final study application with all changes incorporated during the amendment submission process. To do so, you can select one of the following from the study's amendment home page:

- 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



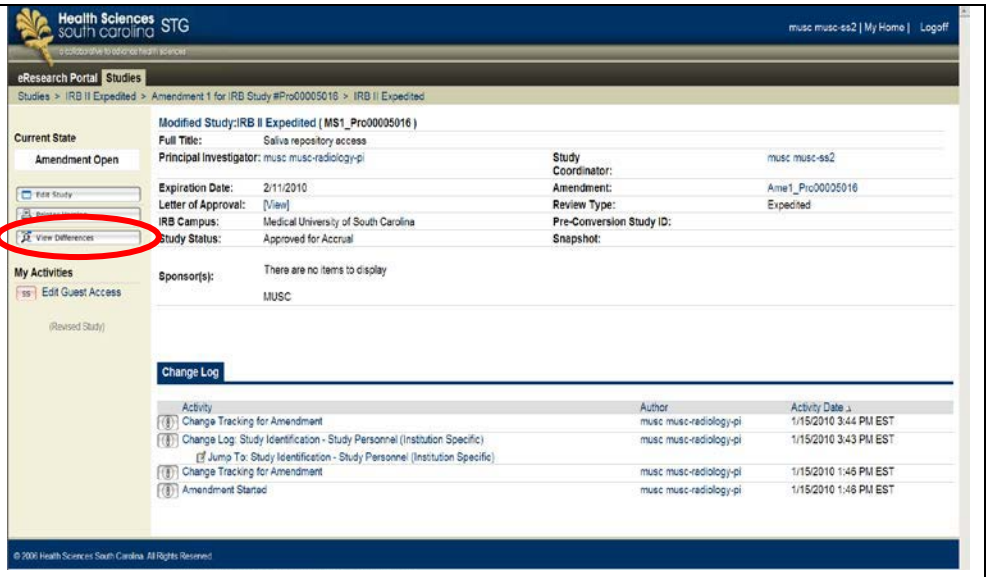
Selecting 'View Study' will allow you to navigate through the complete study application to view the incorporated changes.

Select 'Exit' to go back to the Amendment workspace main page.



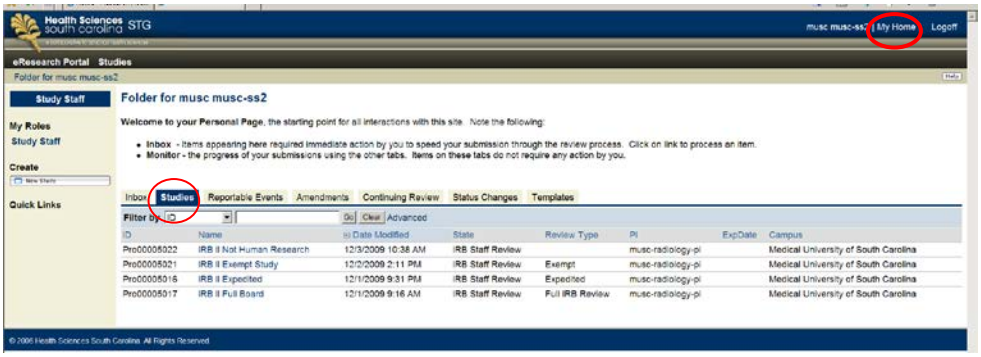
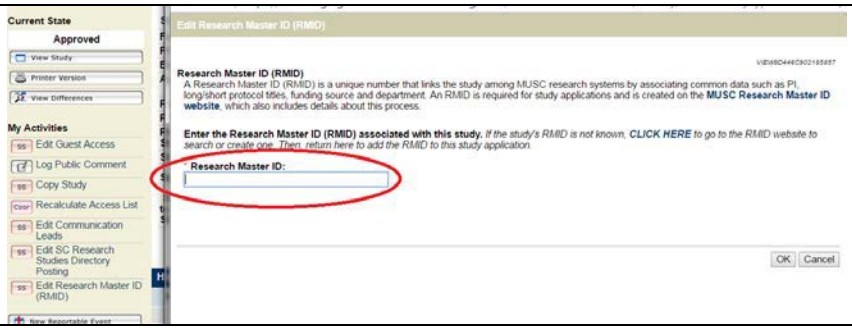
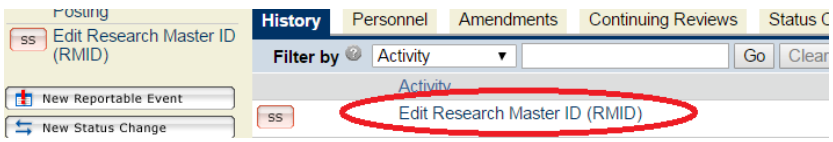
Selecting ‘View Study History’ and ‘View Differences’ the tracked changed differences between the previous study details and what you submitted in the amendment.

See section ‘Viewing Amendment Changes’ section for additional information.



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.

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 'Edit Research Master ID (RMID)' under 'My Activities'.	
A window will populate entitled 'Edit Research Master ID RMID'. Enter the correct RMID in the 'Research Master ID' field. Select 'OK'.	
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.	

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.

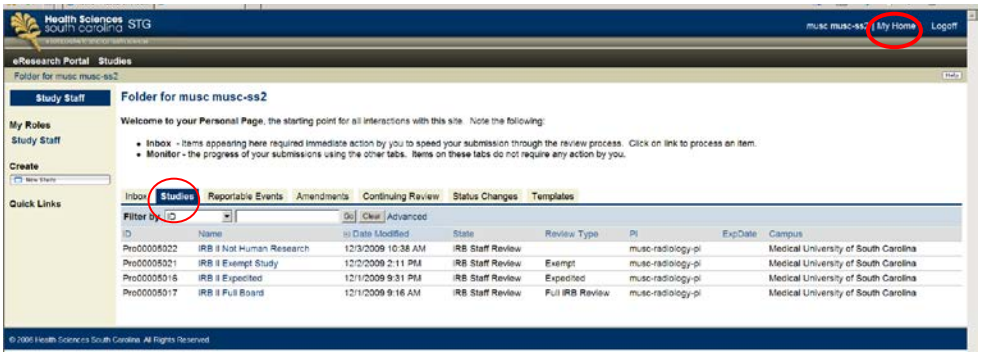
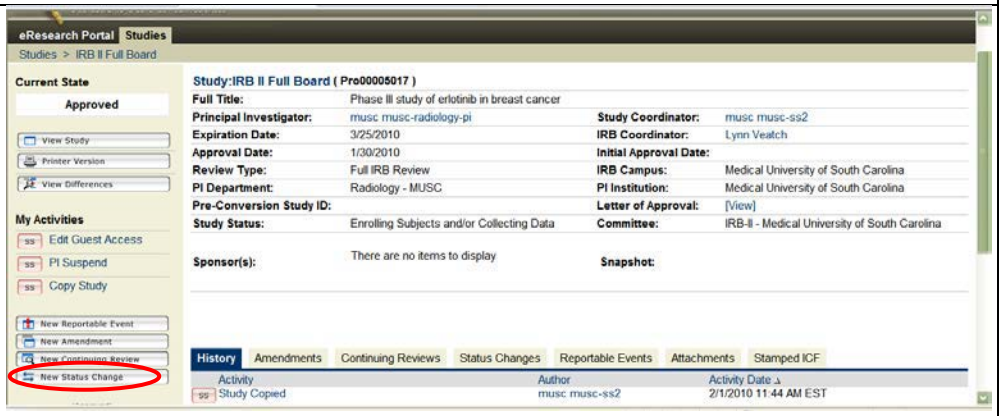
Study Status Changes

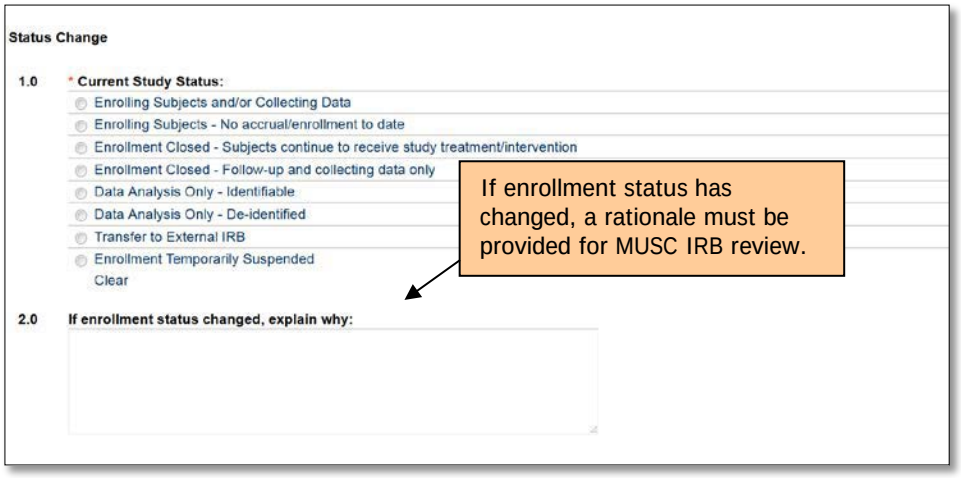
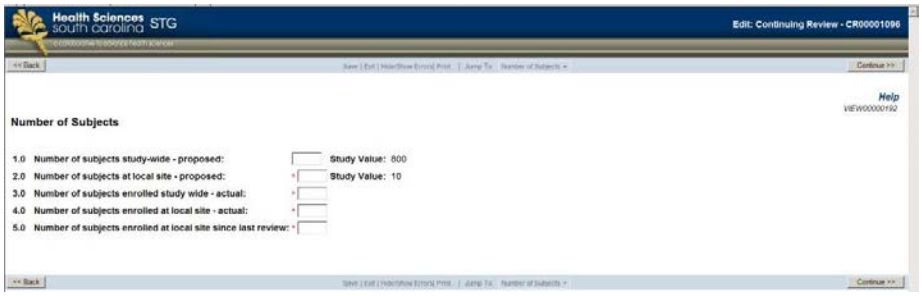
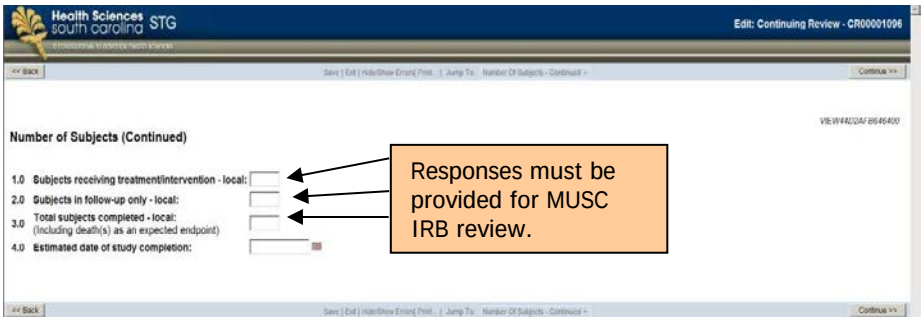
For additional assistance, view the recorded demonstration 'Creating and Submitting Study Status Changes' in the eIRB Education & Training section.

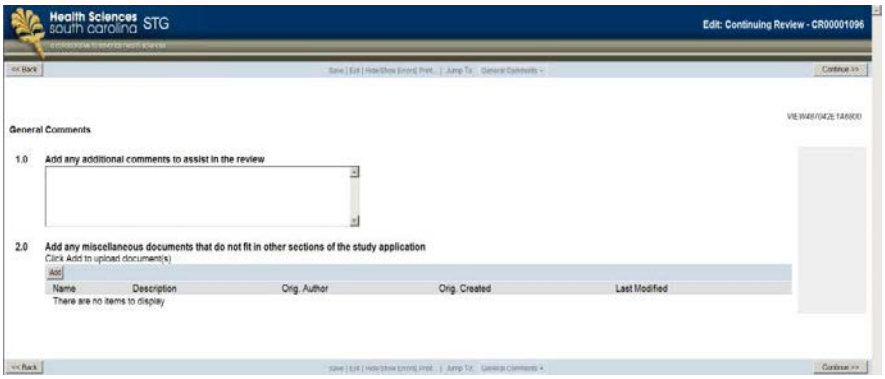
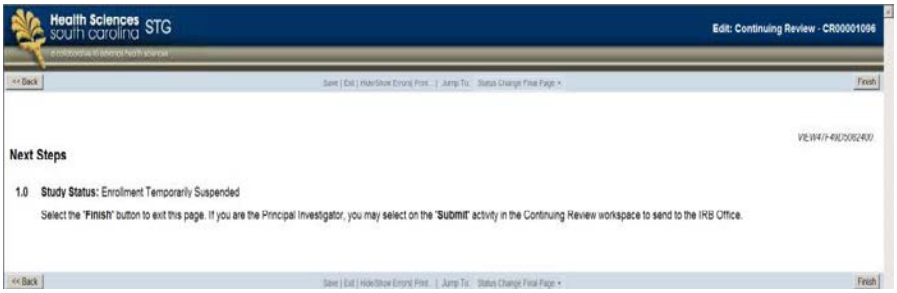
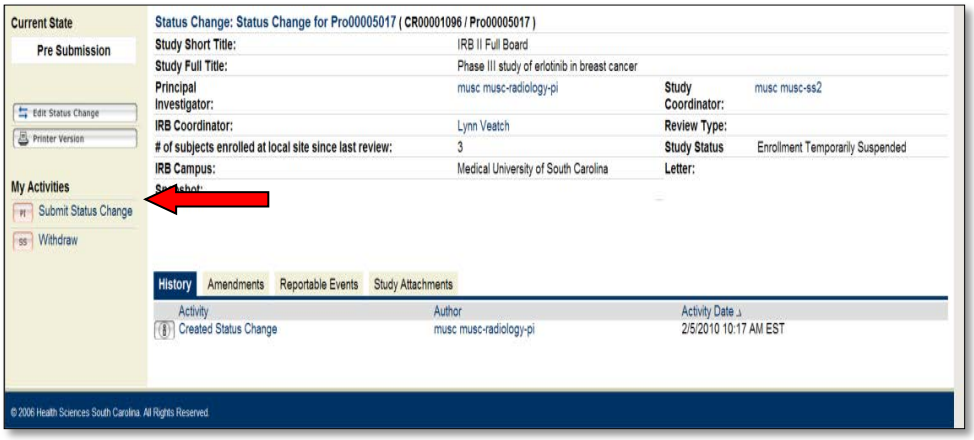
Changes in study statuses due to subject enrollment changes can be reported before continuing review time. The system will edit the current continuing review to include the status change updates indicated through this process.

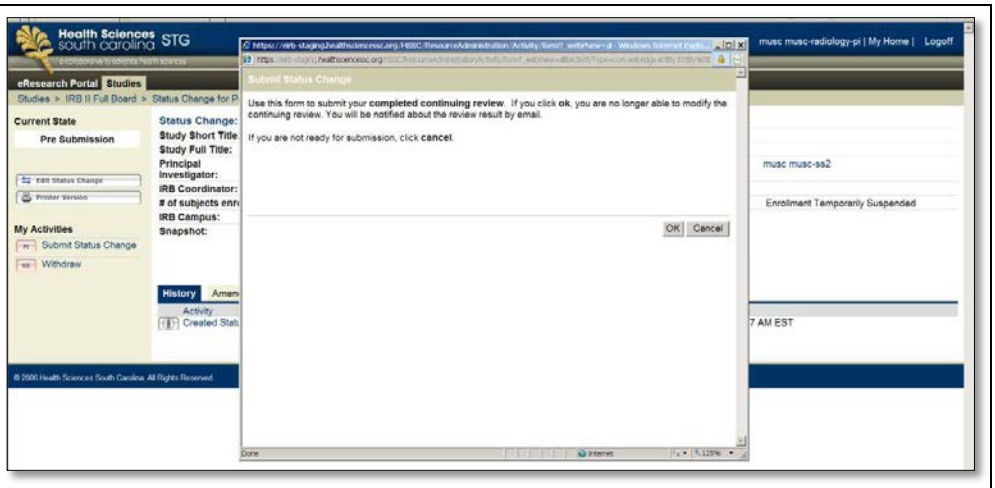
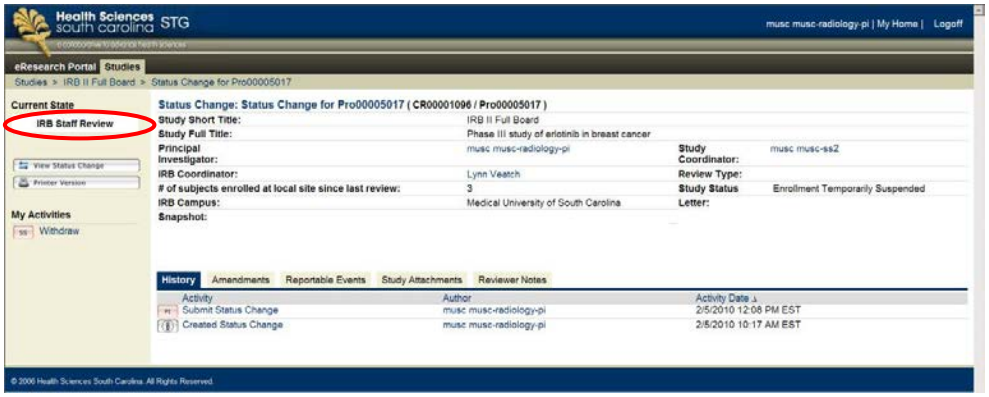
Notes:

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.*

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 Status Change' ***Note: Exempt, Not Human Subjects and External IRB Review studies cannot create new status change applications.***	

Select the updated, current status and include why the status changed (if necessary). Click Continue.	
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.***	
Indicate the statuses of subjects enrolled and estimated study completion date. Click Continue.	

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

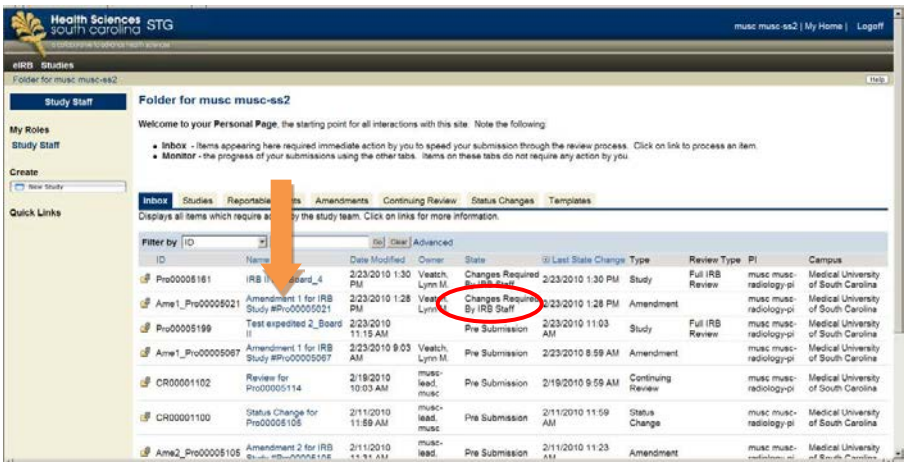
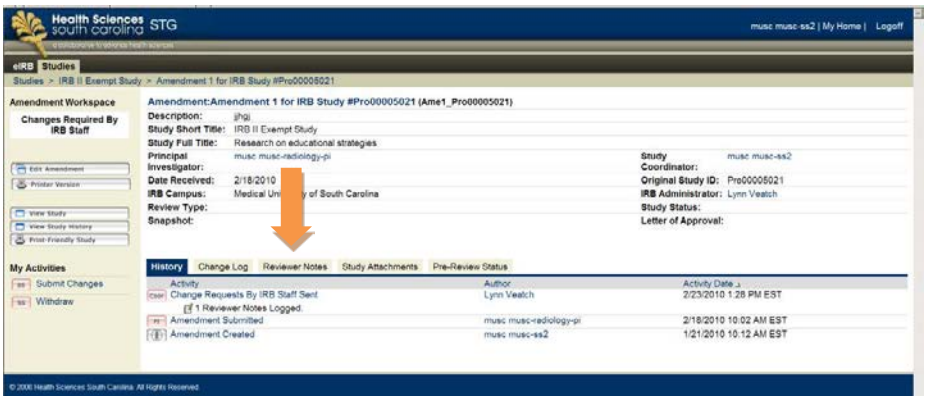
For additional assistance, view the recorded demonstration 'Responding to IRB Reviewer Comments' in the eIRB Education & Training section.

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

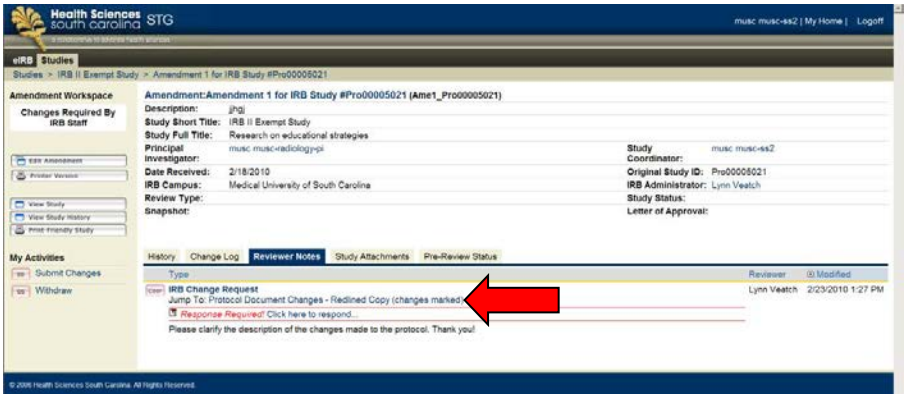
Responding to comments is a 2-step process.

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 you 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.



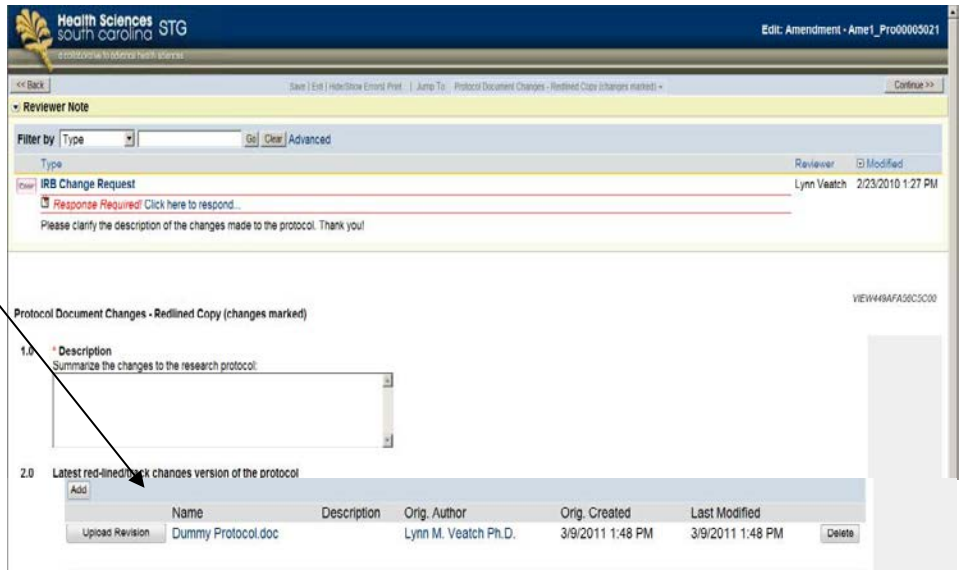
The system will take you to the question and appropriate form to review.

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.*

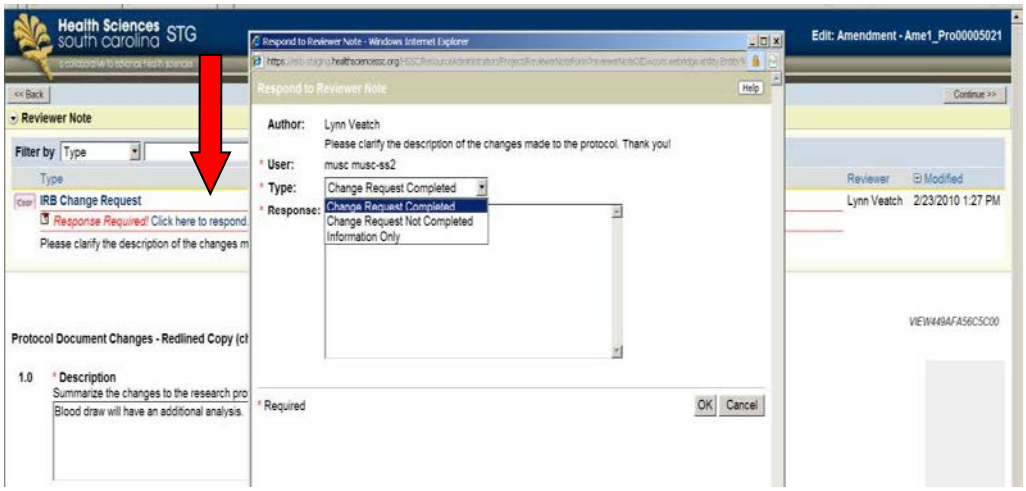
*Be sure to click 'Save' or 'Continue' to save the changes you made within the application.***



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'.

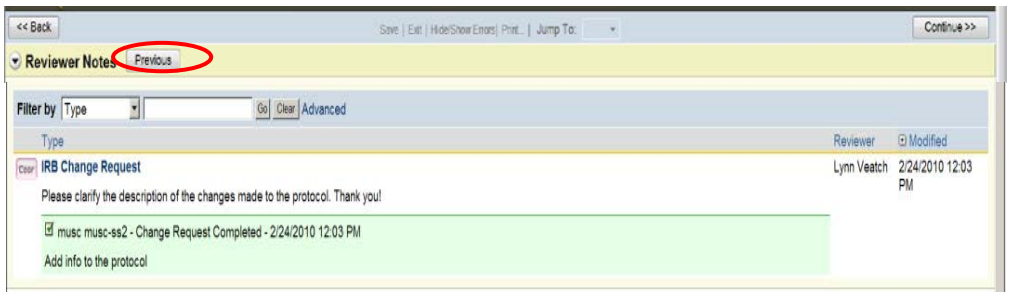
***Note: There may be multiple comments within one IRB Change Request section. The system allows you to save a response even if all comments haven't been addressed. For study management purposes, this second step should be completed only if all comments are addressed OR you have written in notes to go back and respond to remaining comments.*

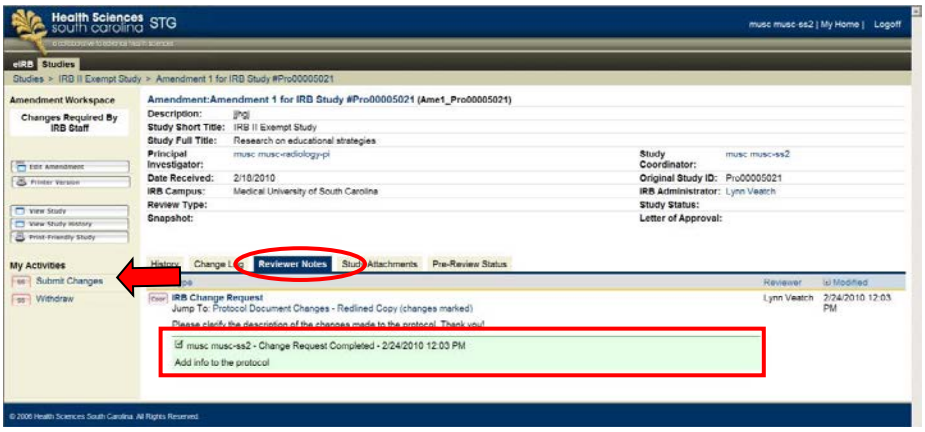
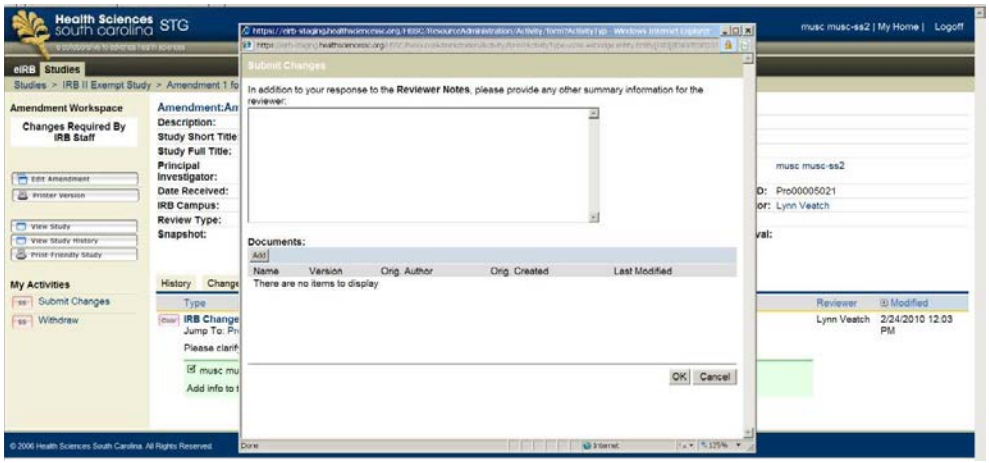
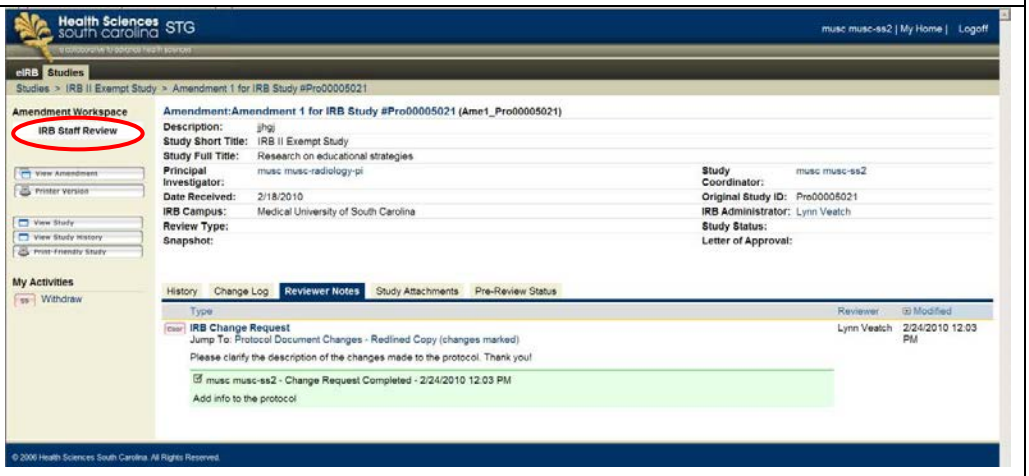


Click 'Save' when you have finished addressing the comments or to save what you have done so far.

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.

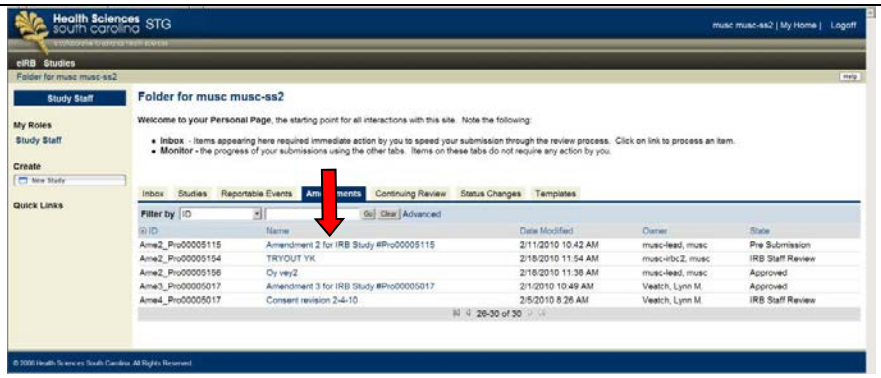
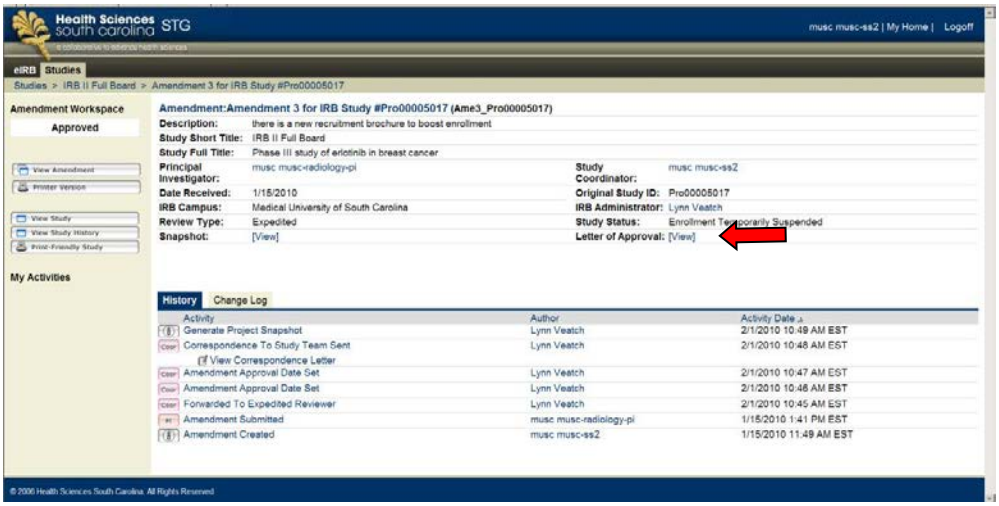


If desired, click on the 'Reviewer Notes' tab to ensure that all comments have been addressed (i.e., a green bar appears indicating you have completed the step #2 in responding to that question). When ready to send changes to IRB, click on 'Submit Changes'.	
In the pop-up window, enter in any other summaries 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.	

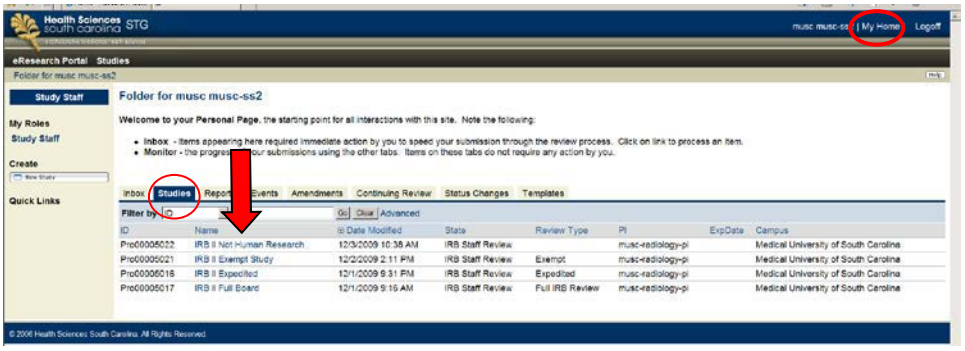
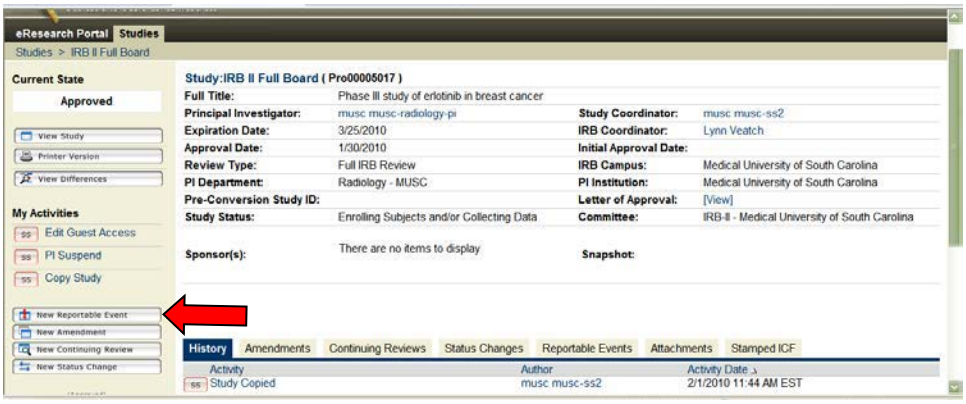
REPORTABLE EVENTS

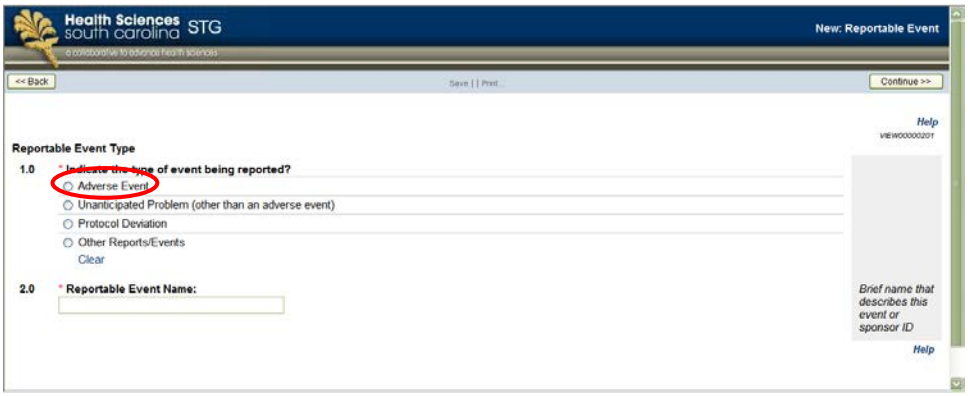
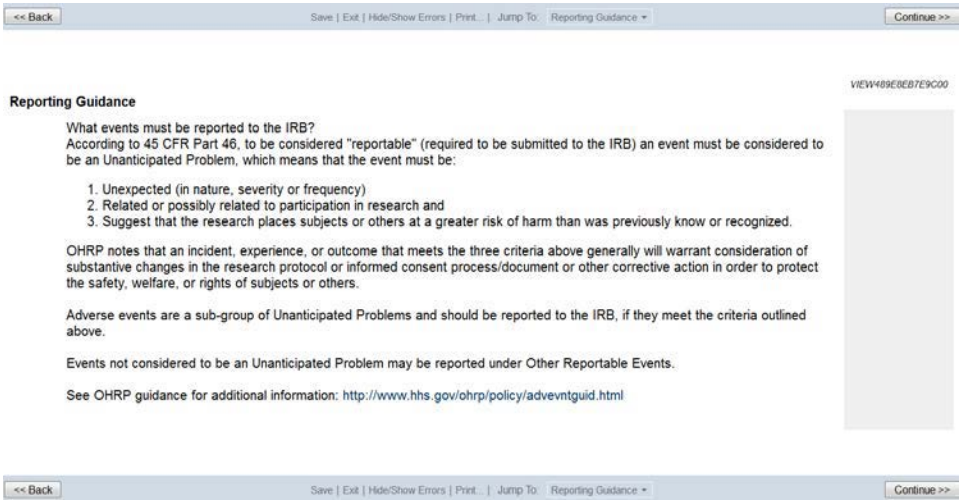
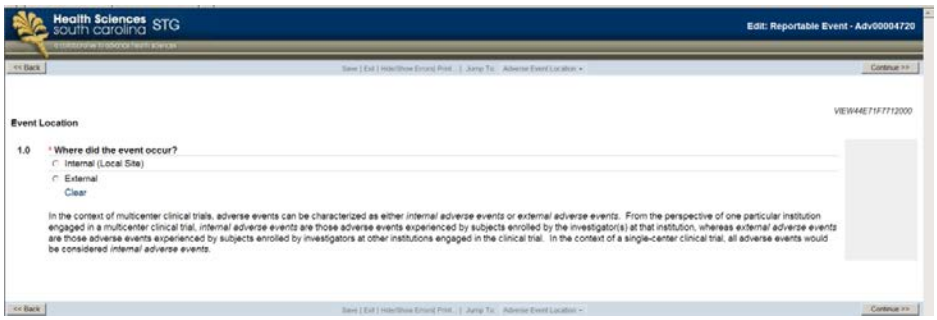
For additional assistance, view the recorded demonstration 'Creating and Submitting Reportable Events' in the eIRB Education & Training section.

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'	

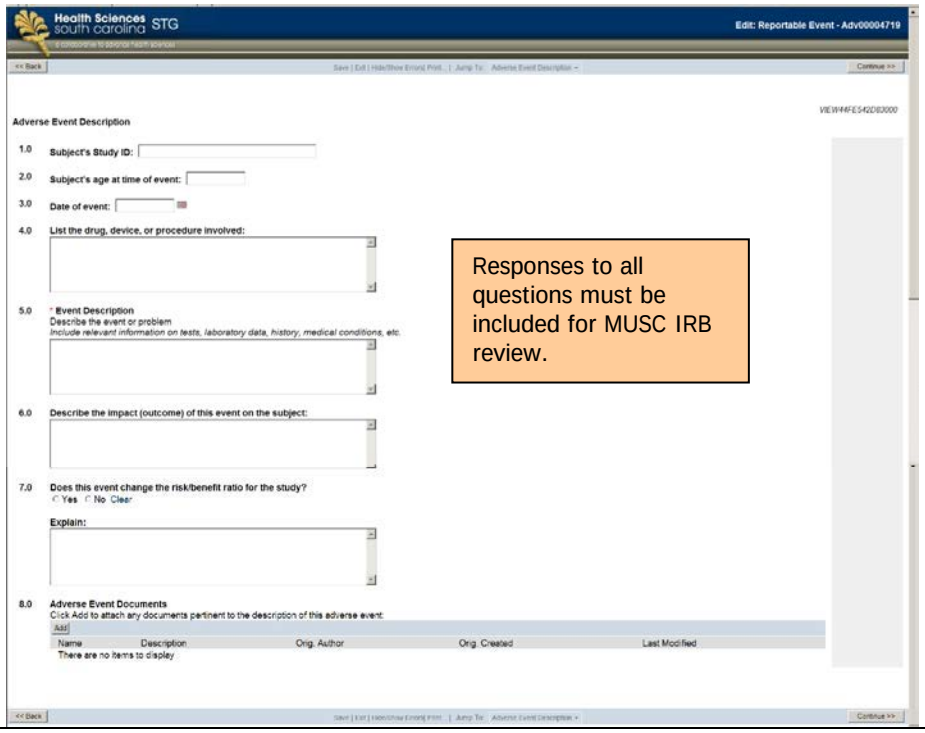
Select 'adverse event' as the reportable event and enter in an event name. Click Continue.	
The system will provide a reporting guidance to help determine if the event is reportable. Click Continue.	
Indicate the event location (internal or external source) ***Note: see on-screen definitions*** Click Continue.	

Internal Adverse Event

If not already done, complete steps in the Adverse Events section, selecting Internal (Local Site) as the event location.

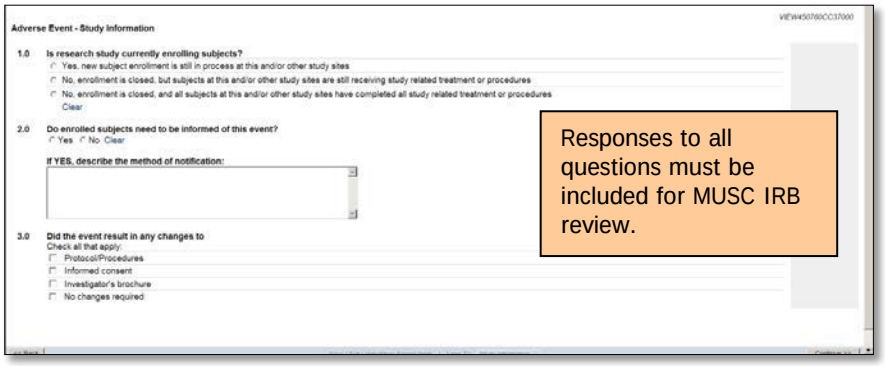
Complete information to describe the adverse event and upload any relevant documents.

Click Continue.



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.

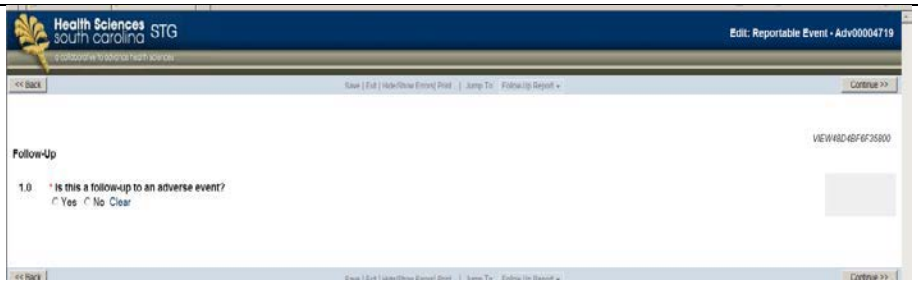
Click Continue.

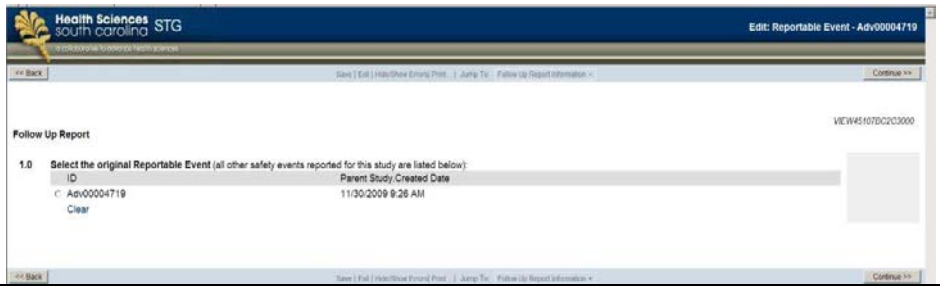


Indicate if this is a follow up event.

Click Continue.

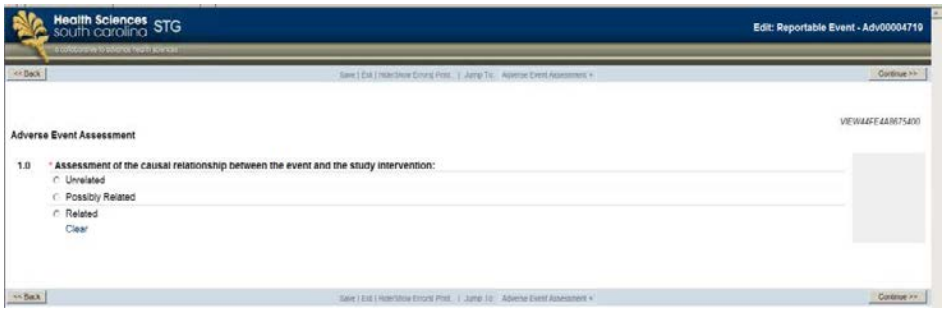
Note: if the event is a Follow-up Report, select the original event if previously reported to IRB

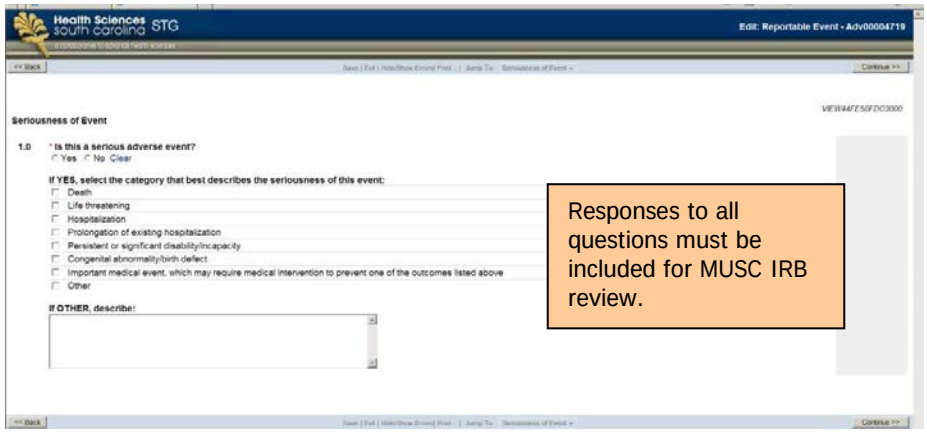




The next three screens require an assessment of the event's expectation, relationship to the study and seriousness.

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

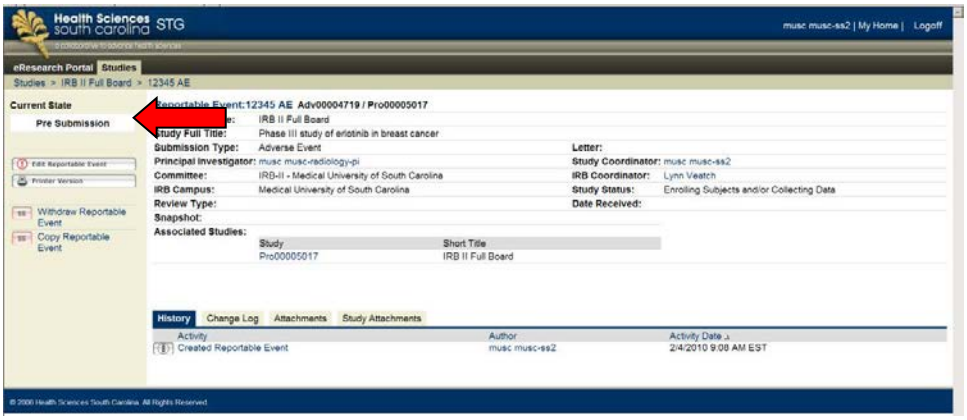
Click Finish.

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 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.

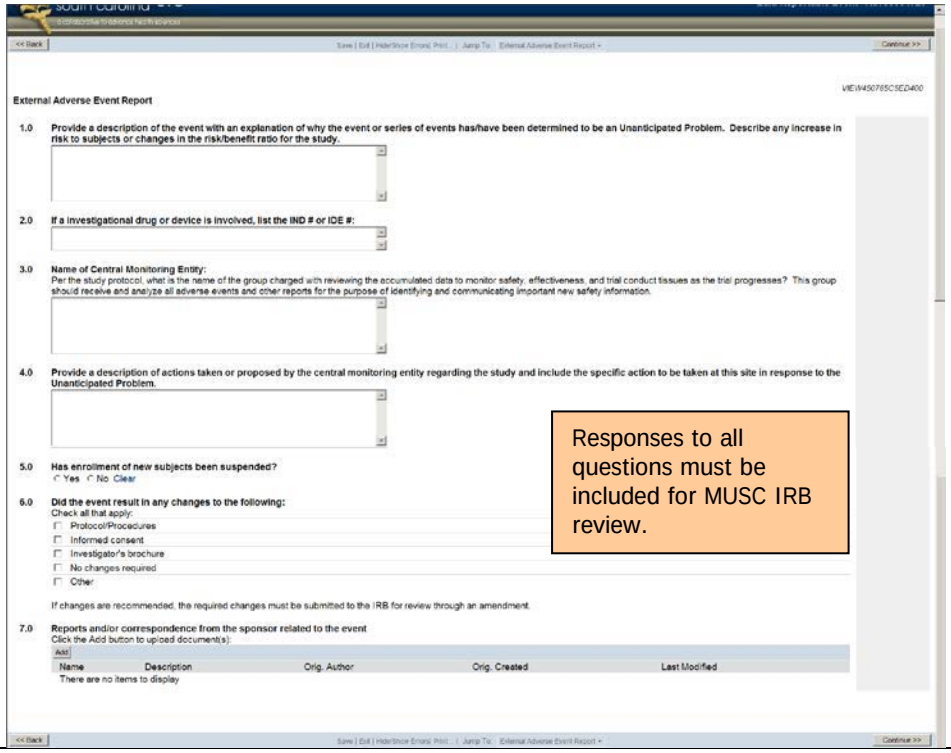


External Adverse Event

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.



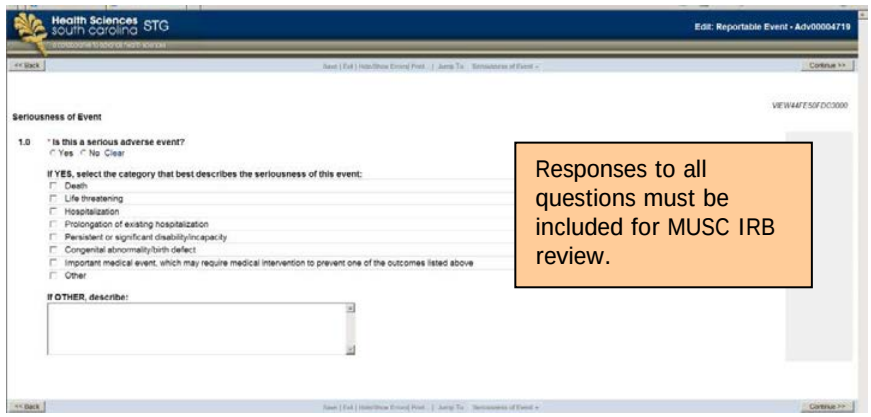
Indicate if this is a follow up event.

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.

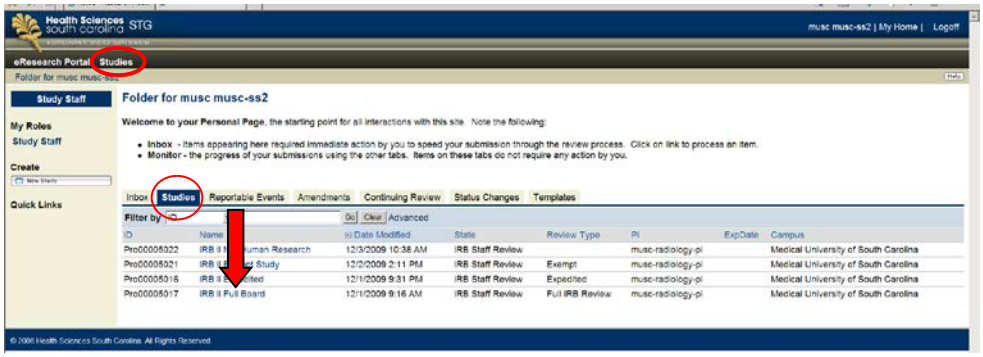
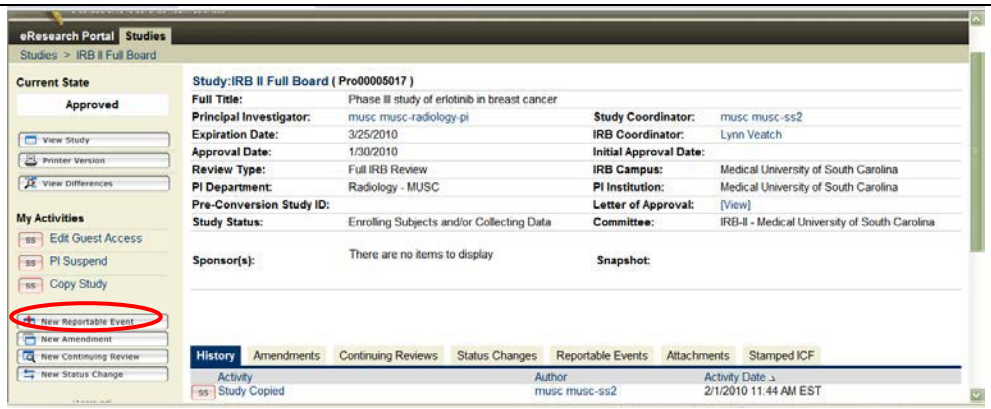
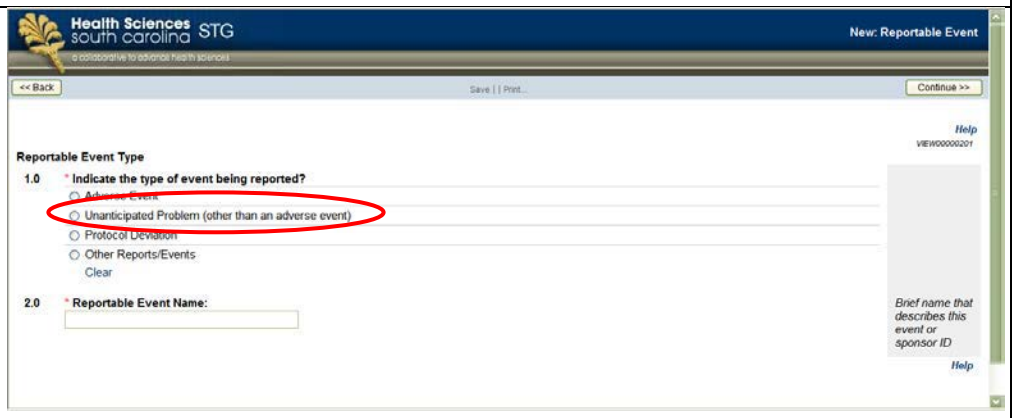
Click Continue after each screen.



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

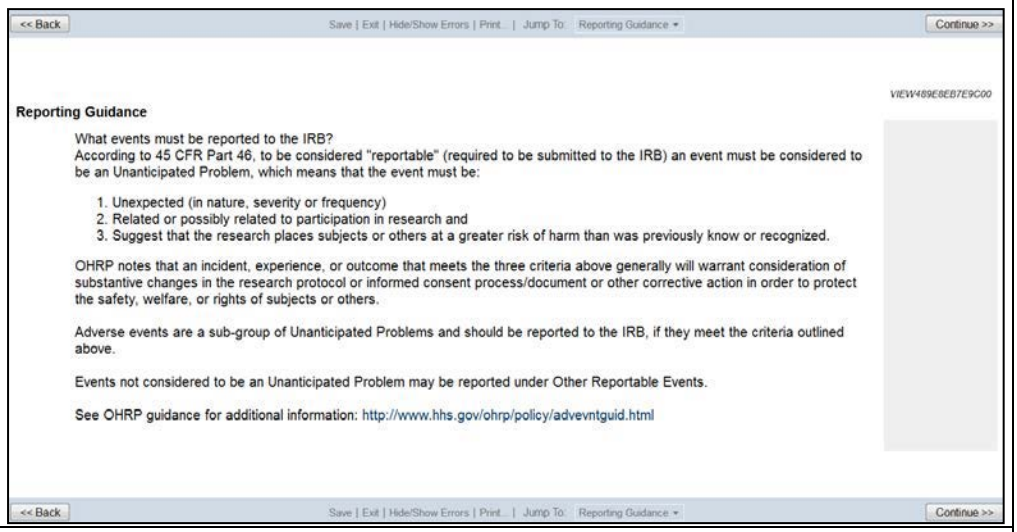
The system will provide a summary. ***Note: if the event changes the protocol, consent, drug brochure, etc. you must submit a separate amendment for IRB review*** Click Finish. ***Note: This action does not send the report to IRB. Only the PI can send the event to IRB.***	
The event is now logged in 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)

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 'unanticipated problem' as the reportable event and enter in an event name. Click Continue.	

The system will provide a reporting guidance to help you determine if the event is reportable.

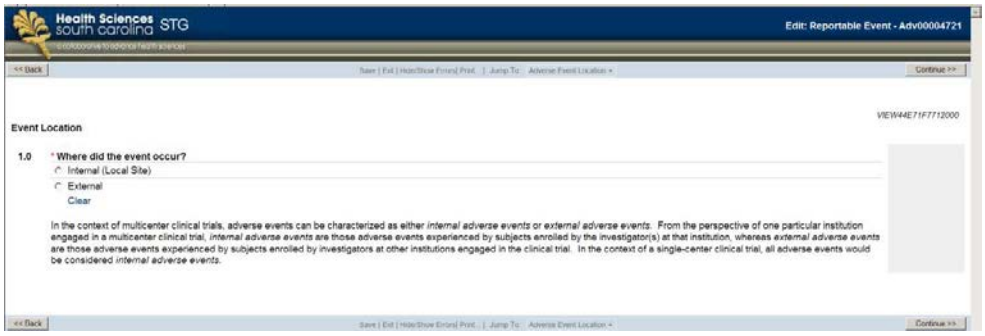
Click Continue.



Indicate the event location (internal or external source)

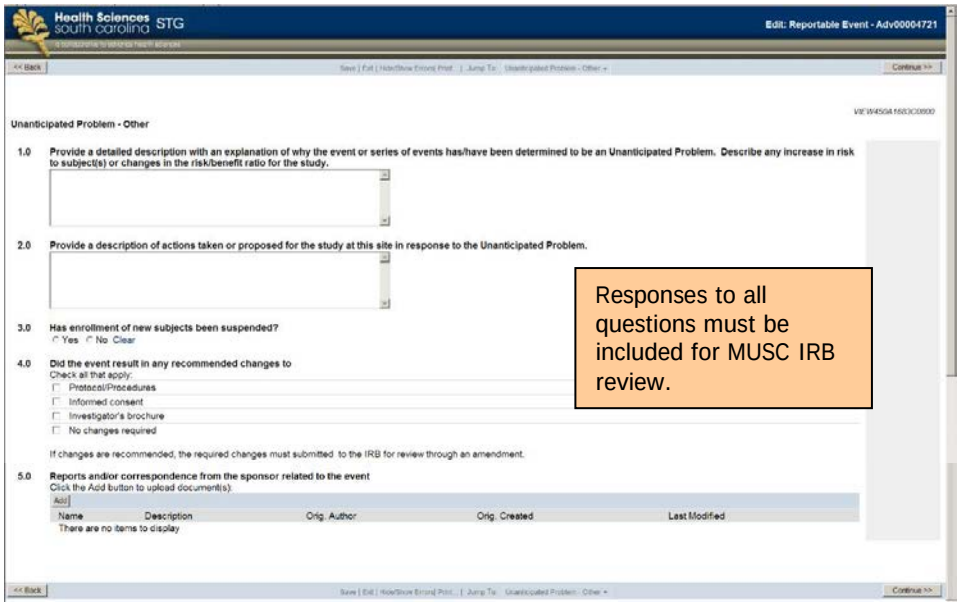
Note: see on-screen definitions

Click Continue.

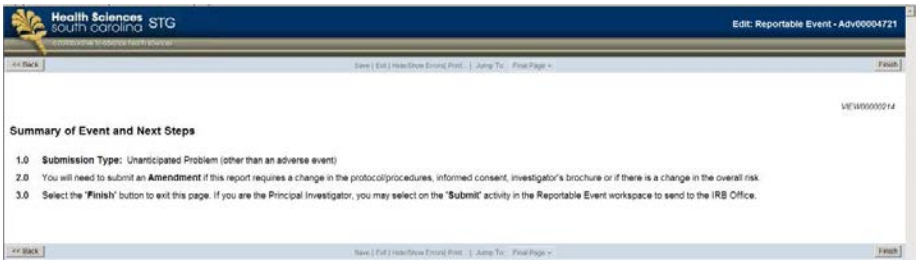
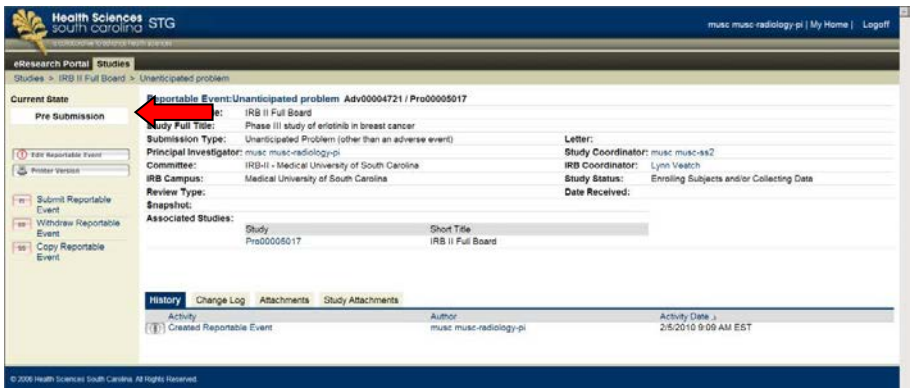


Complete information to describe the unanticipated problem and upload reports or correspondence documents.

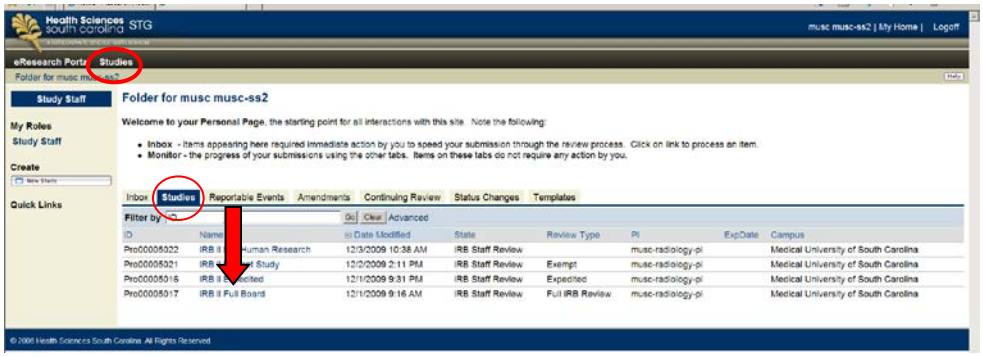
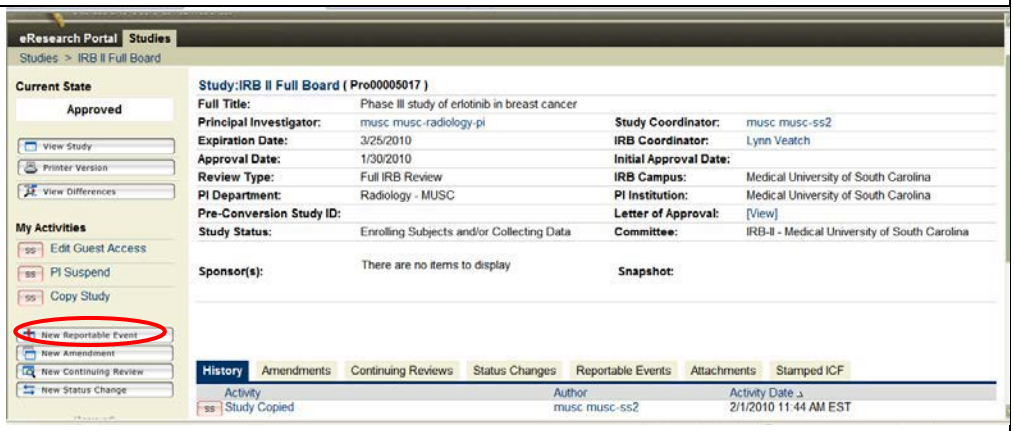
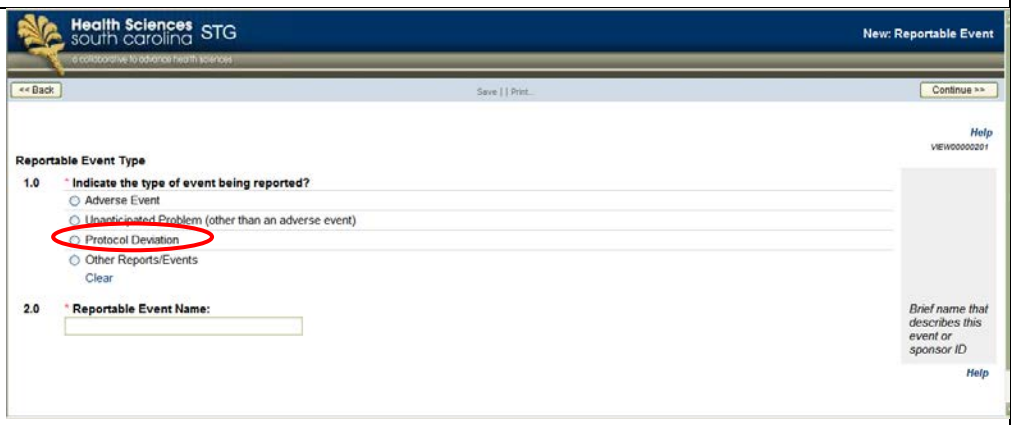
Click Continue.

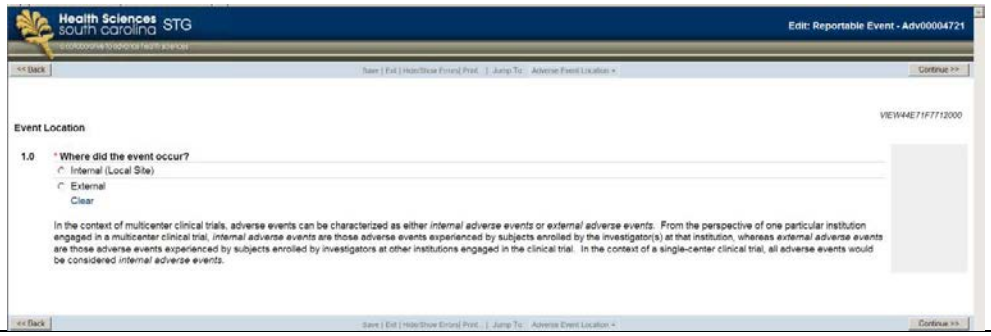


Responses to all questions must be included for MUSC IRB review.

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 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.	

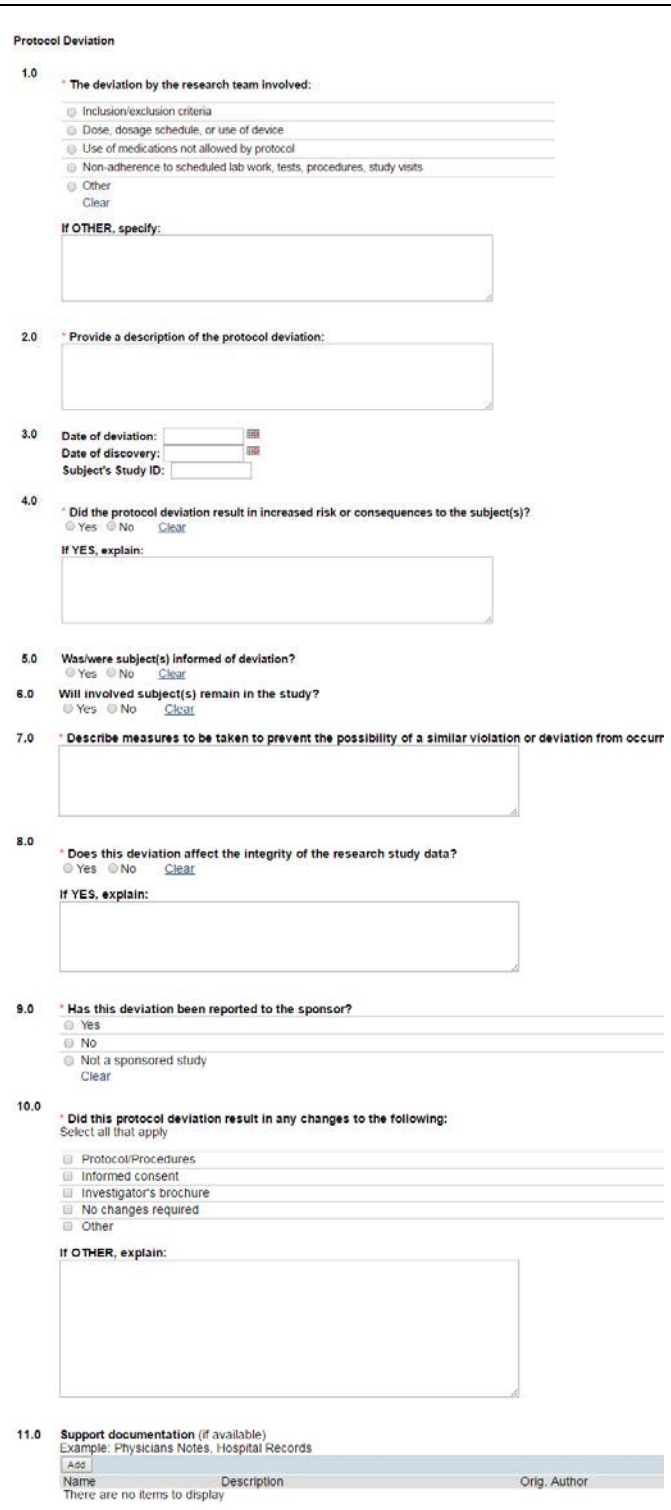
Protocol Deviation

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.	
Select 'New Reportable Event'	
Select 'protocol deviation' as the reportable event and enter in an event name. Click Continue.	

Indicate the event location (internal or external source) ***Note: see on-screen definitions*** Click 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 occurr**

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

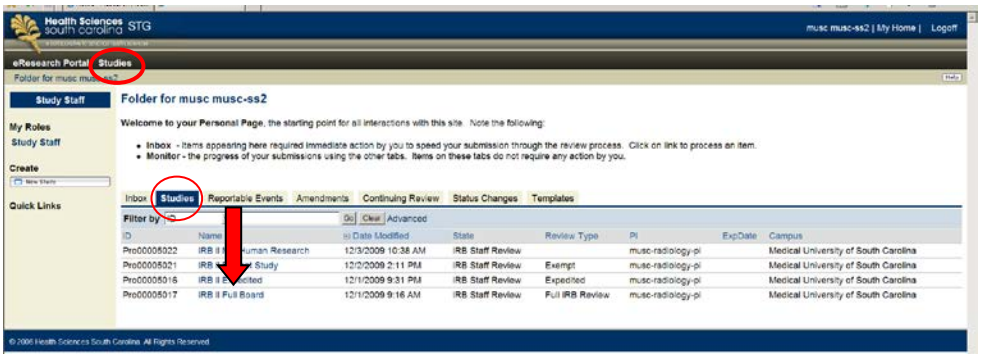
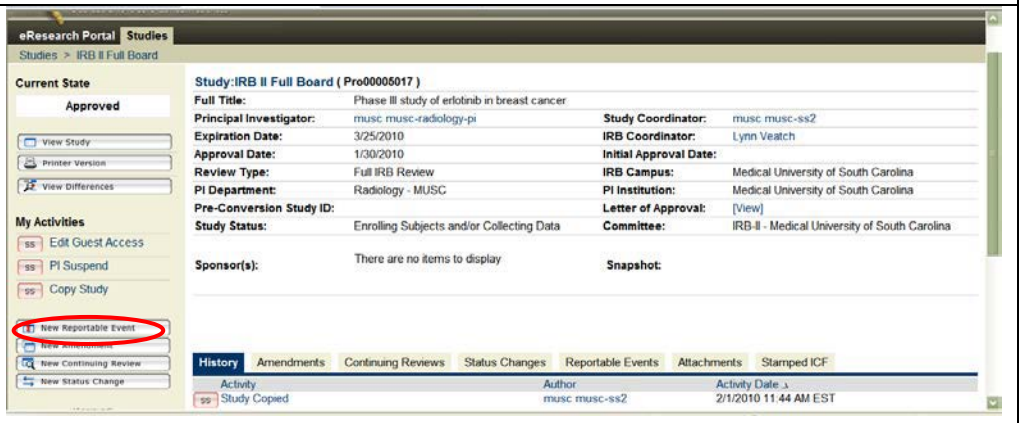
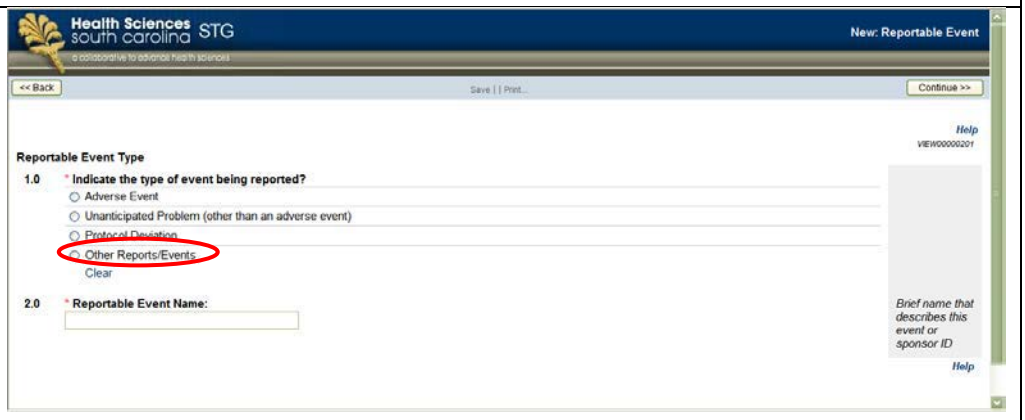
Responses to all questions, as applicable, must be included for MUSC IRB review.

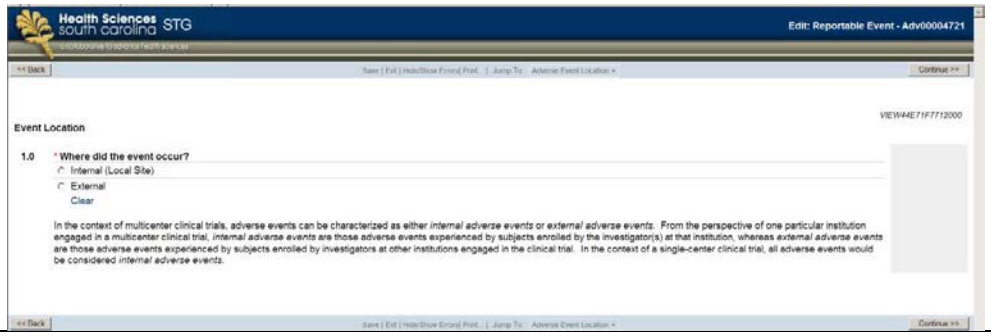
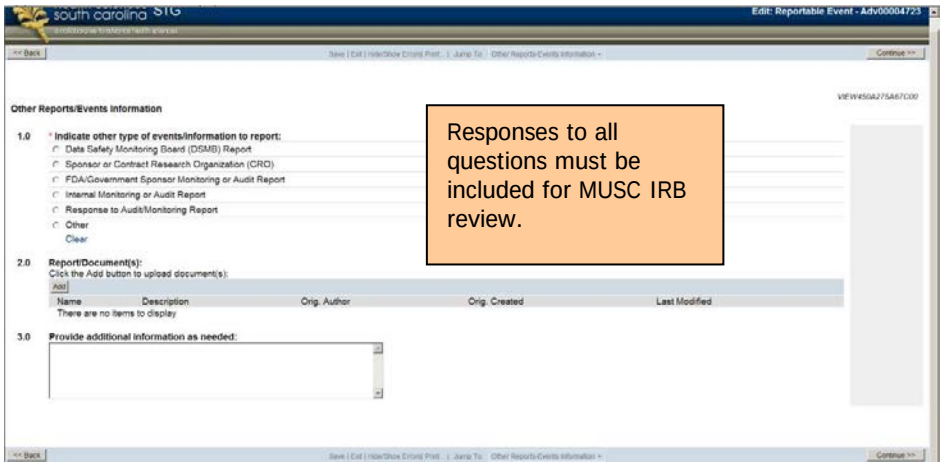
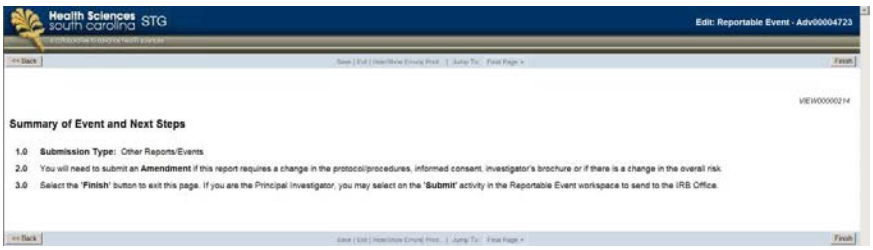
The system will provide a summary. ***Note: if the event changes the protocol, consent, drug brochure, etc. you must submit a separate amendment for IRB review*** Click Finish. ***Note: This action does not send the report to IRB. only the PI can send the event to IRB.***	
The event is now logged in 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

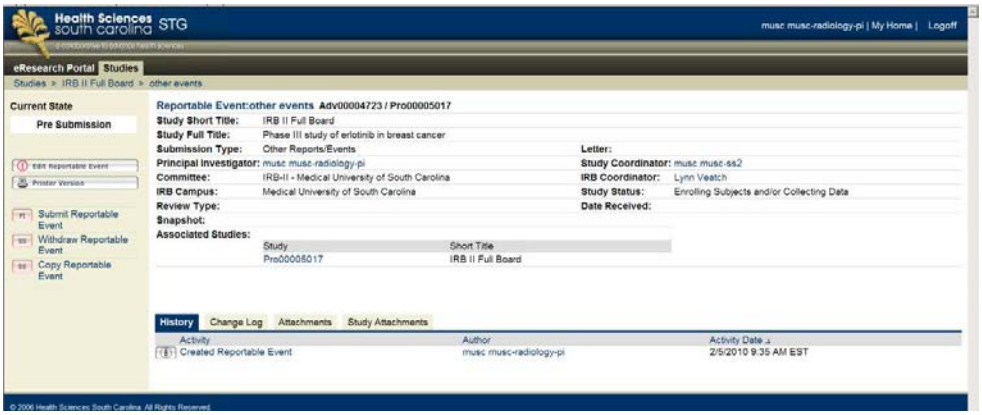
Log into eIRB. Choose the study by selecting the 'Studies' tab from 'My Home' or the 'Studies' link toward the top of the page. Click on the Name of the study.	
Select 'New Reportable Event'	
Select 'other reports/events' as the reportable event and enter in an event name. Click Continue.	

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.

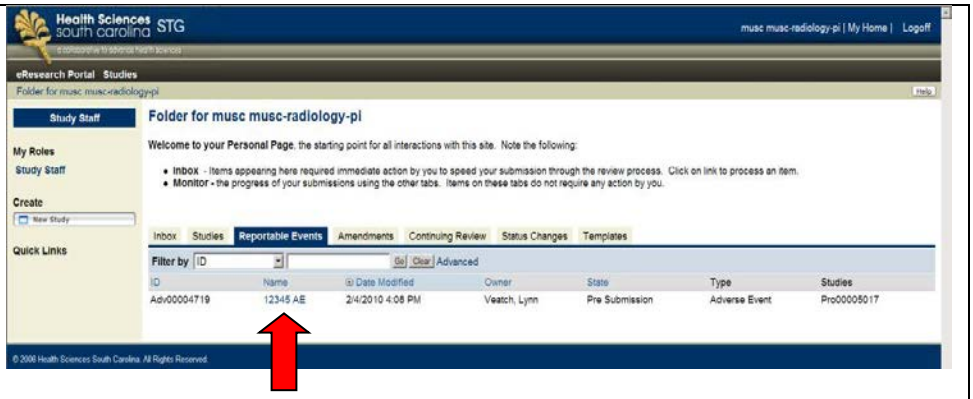
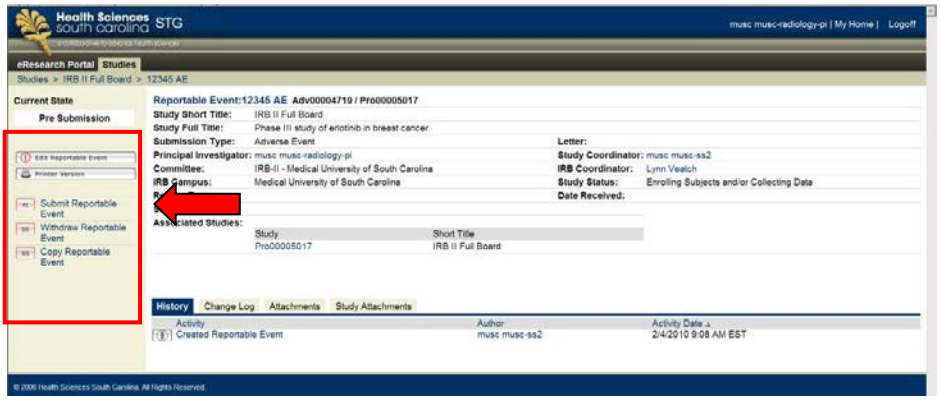
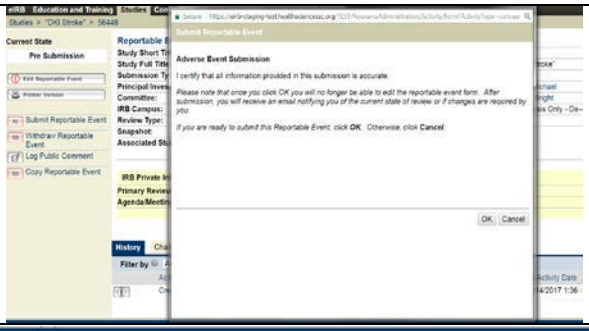
Note: e-IRB does not send automatic notification of these items. If study staff other than the PI has completed the amendment, the PI must be notified through routine communication that the amendment is pending submission.

As the PI, to send the event to IRB, follow the steps in Submission to IRB section of these instructions.



Submission to IRB

****Only the PI can submit reportable events to IRB****

Log into eIRB. Select the 'Reportable Events' tab on your home page. Choose the Name of the event.	
Options to Edit, View, Submit, Withdraw or Copy the Event are available. To View the event, select 'Printer Version'. To Edit the event, select 'Edit Reportable Event' and change the information in the applicable sections. When ready to send the event to IRB, select 'Submit Reportable Event'.	
A pop-up box will appear that includes information certifying that the event description is accurate. Click 'OK'.	
The event has now been sent to IRB. The state has changed to 'IRB Staff Review' and is no longer able to be edited. If there was an amendment completed due to the event, see instructions regarding completing and sending the Amendment to IRB.	

Responding to IRB Comments

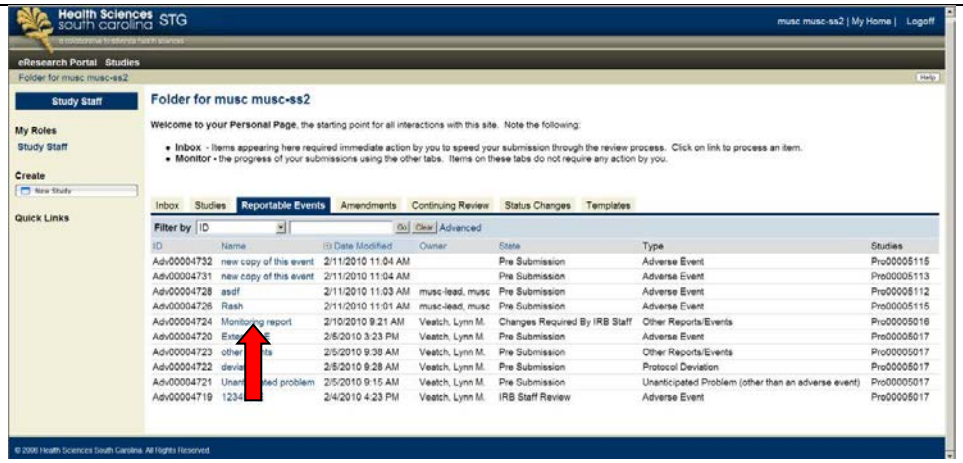
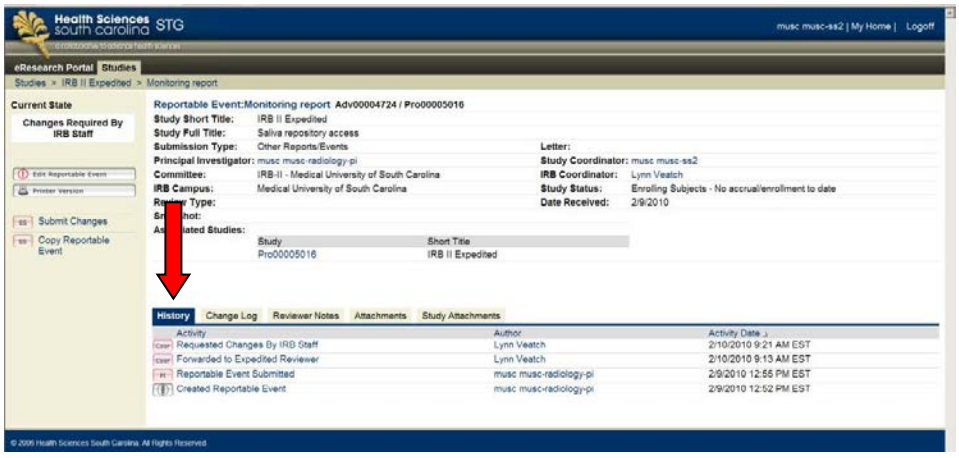
For additional assistance, view the recorded demonstrations 'Responding to IRB Reviewer Comments' in the eIRB Education & Training section.

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

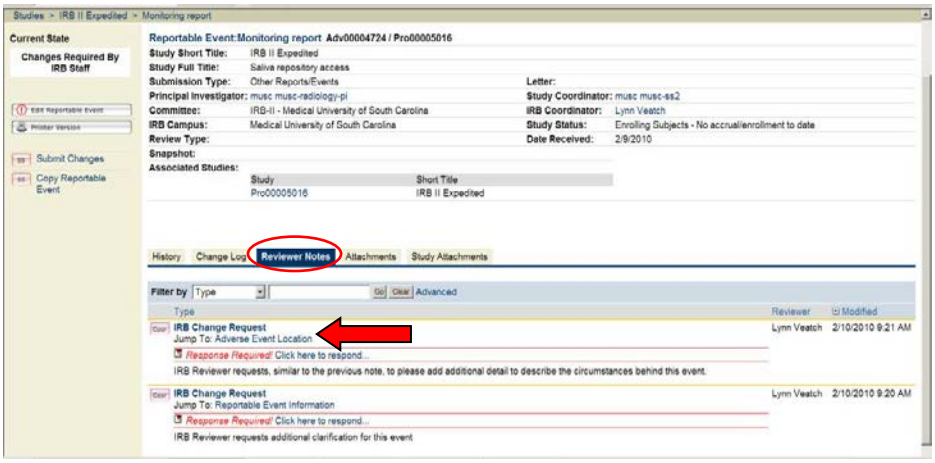
Responding to comments is a 2-step process.

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.

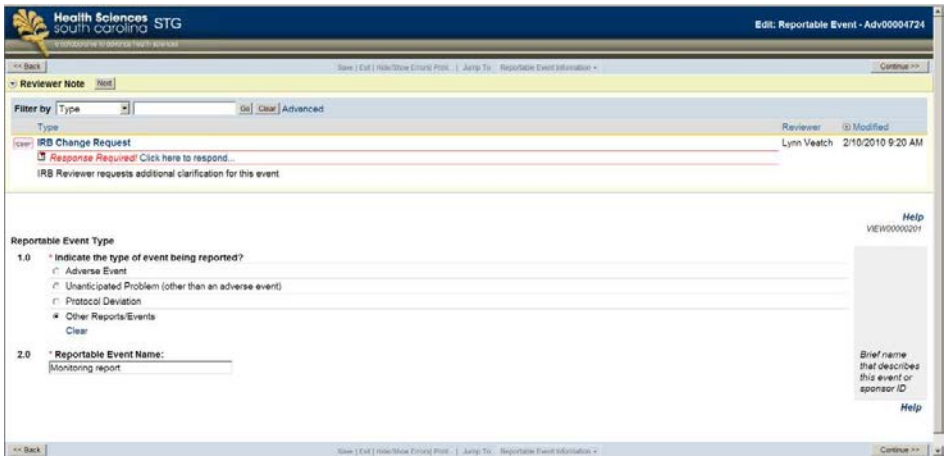
Note: do not select 'Click here to respond' at this time, as that is the second step in responding to comments

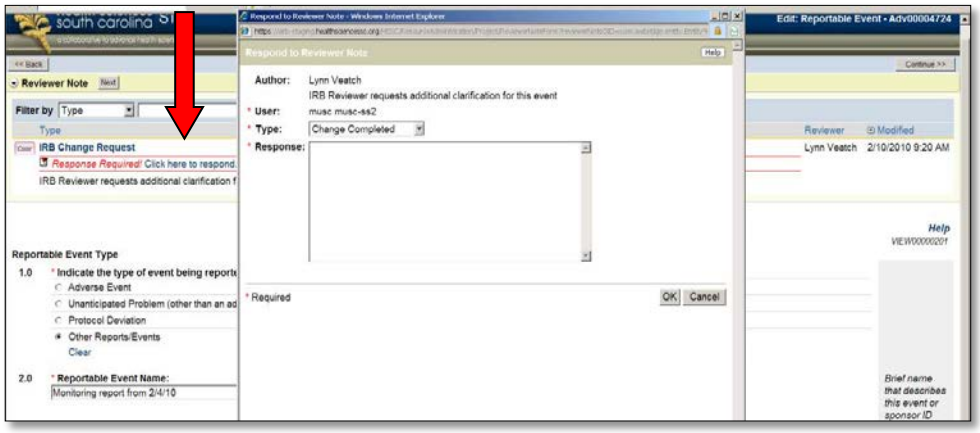
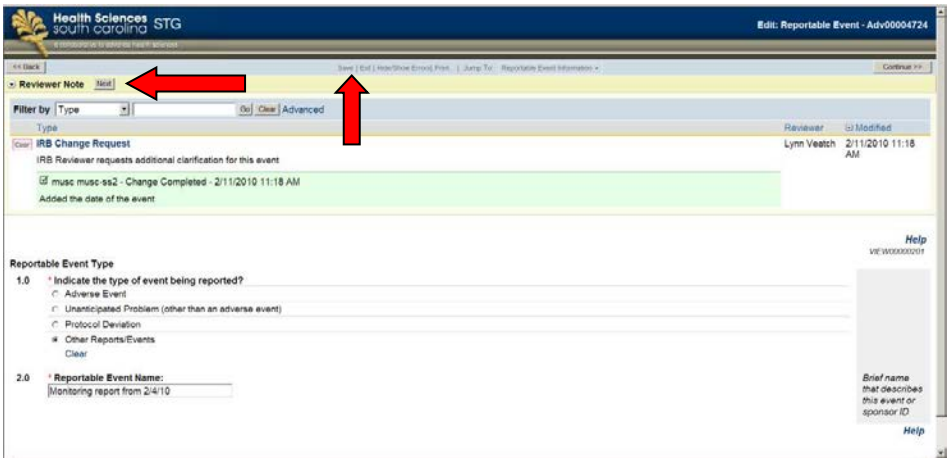


Step 1: Address the comment on the Smartform screen. Make changes directly to the information on the screen.

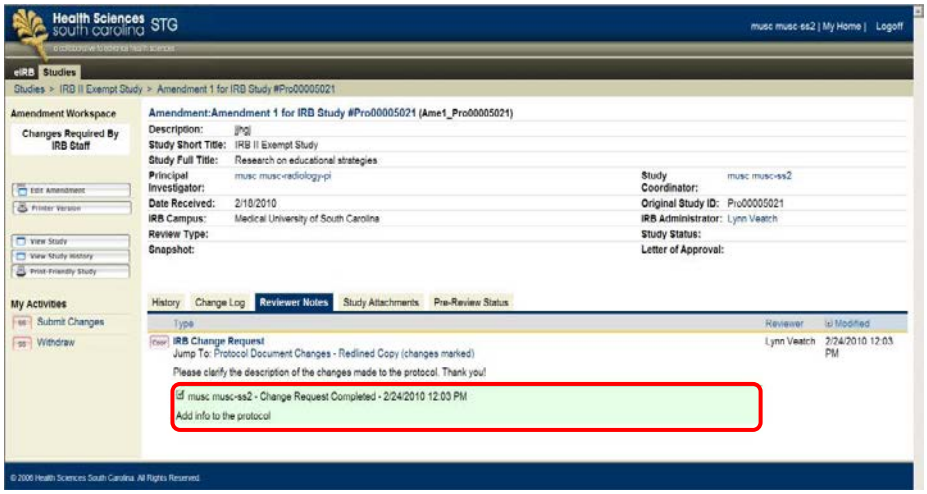
***Note: If previously submitted documents are required to be revised & uploaded, select 'Upload Revision' button next to the document's name & locate the file from your computer. DO NOT use the 'Add' or 'Delete' button unless this is the first time that document is included.*

*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.***



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).

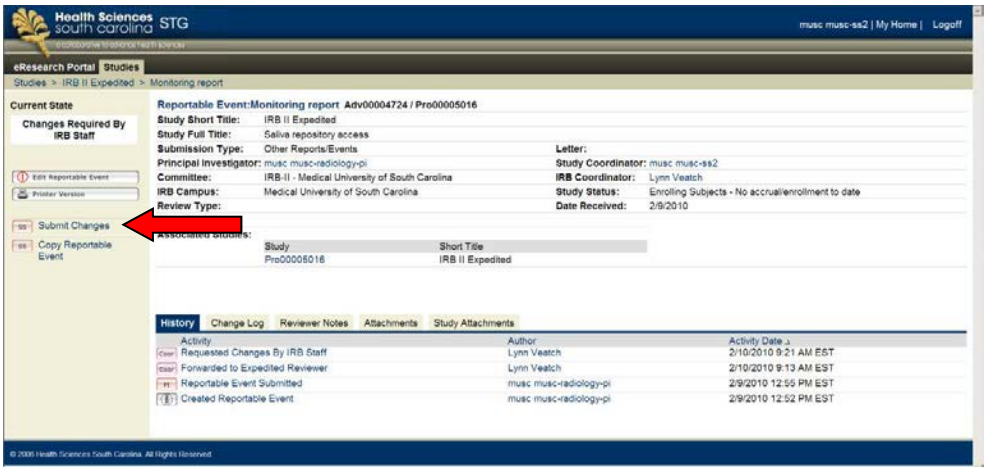


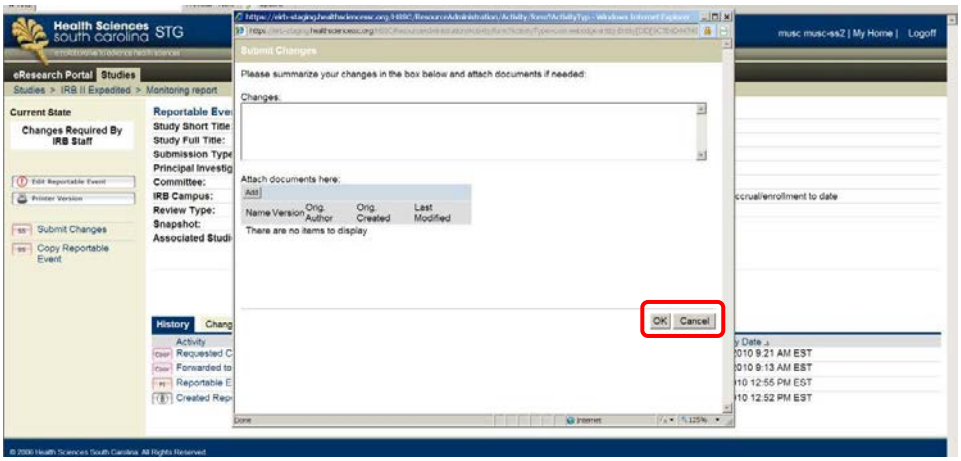
Click 'Submit Changes' to send the response to IRB.

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.

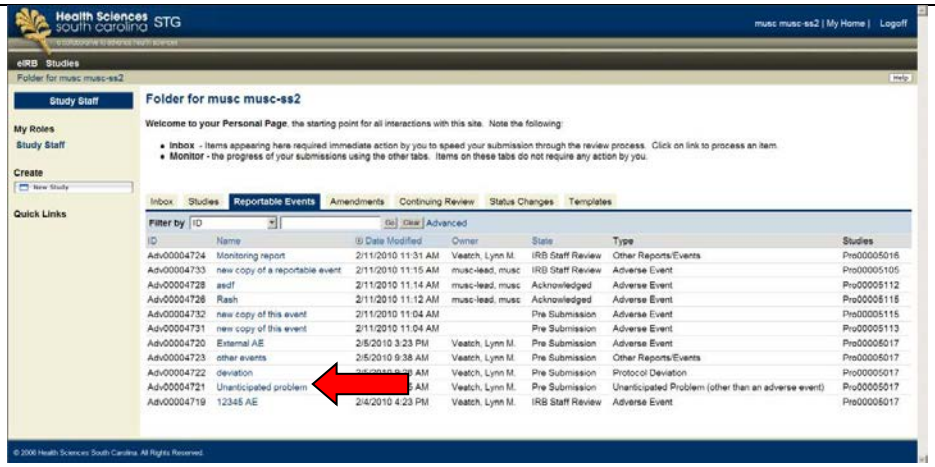
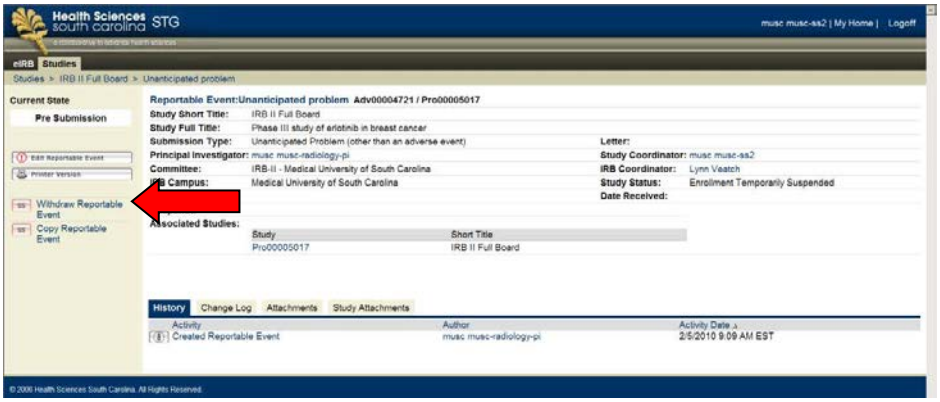
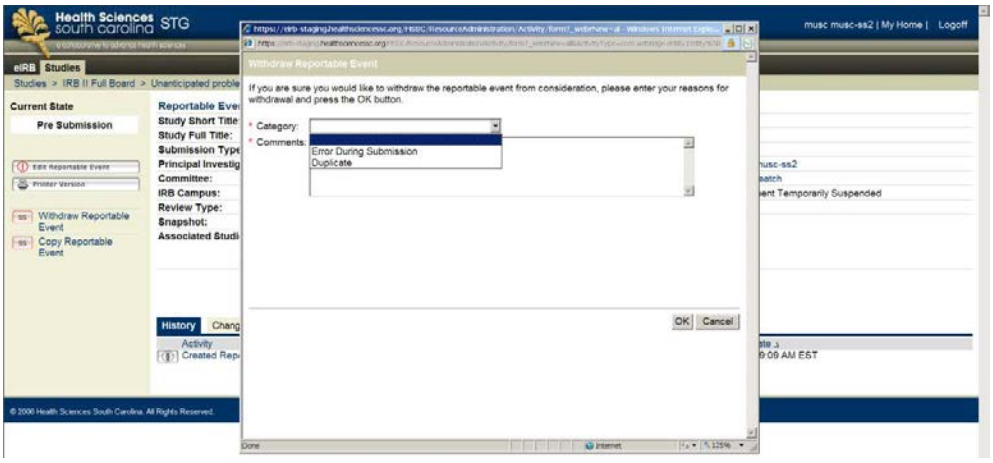




Withdrawing a Reportable Event

Reportable events can only be withdrawn before IRB submission has occurred.

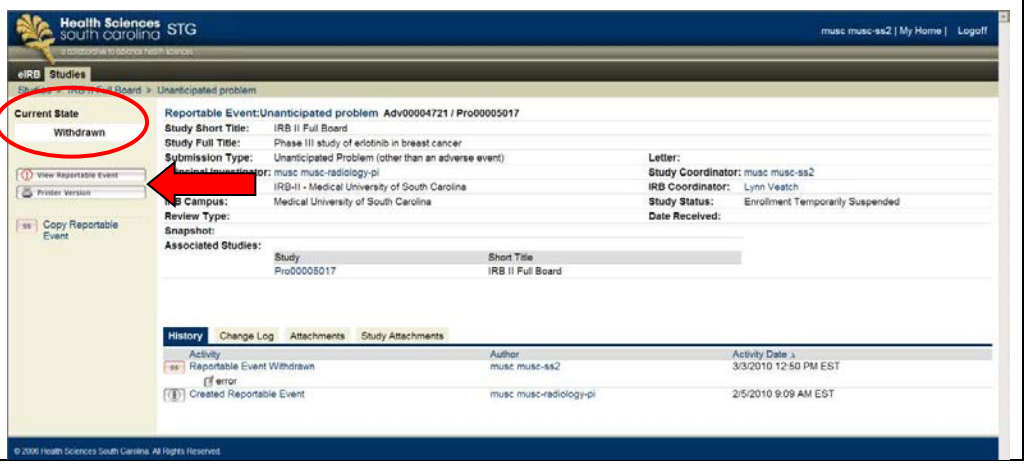
Note: events that are withdrawn CANNOT be restored to an editable state in the system

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’

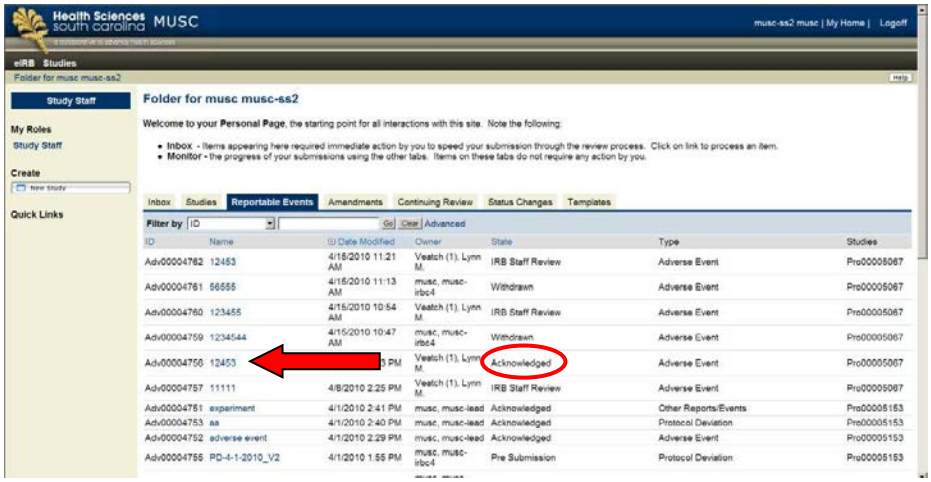
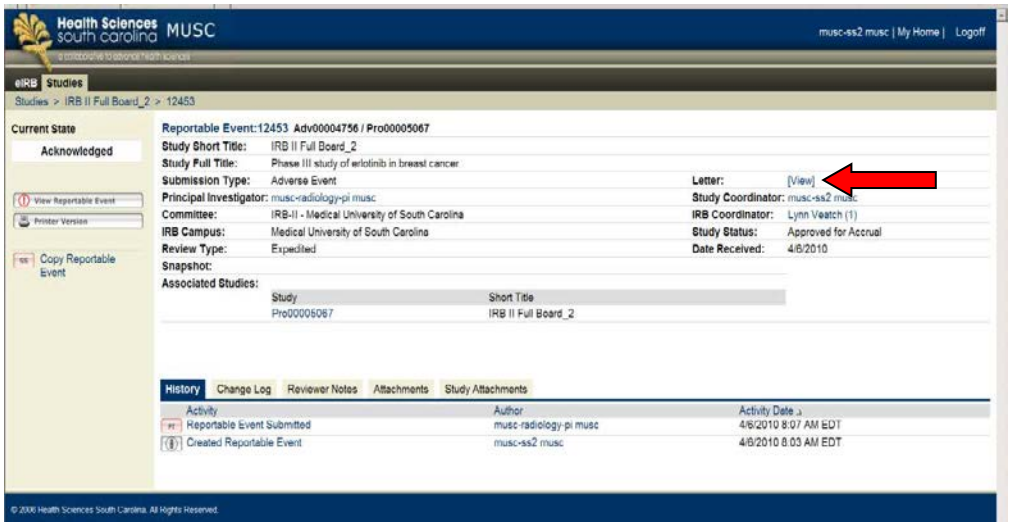
To see the event, select ‘View Reportable Event’ or ‘Printer Version’

The event cannot be restored in the system. If the event was withdrawn in error, you must copy it and create a new event.



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'***	
Click on 'View'. The option to open or save the letter as a Microsoft Word document will be available.	

CONTINUING REVIEW

For additional assistance, view the recorded demonstrations 'Creating and Submitting Continuing Review Applications' in the eIRB Education & Training section.

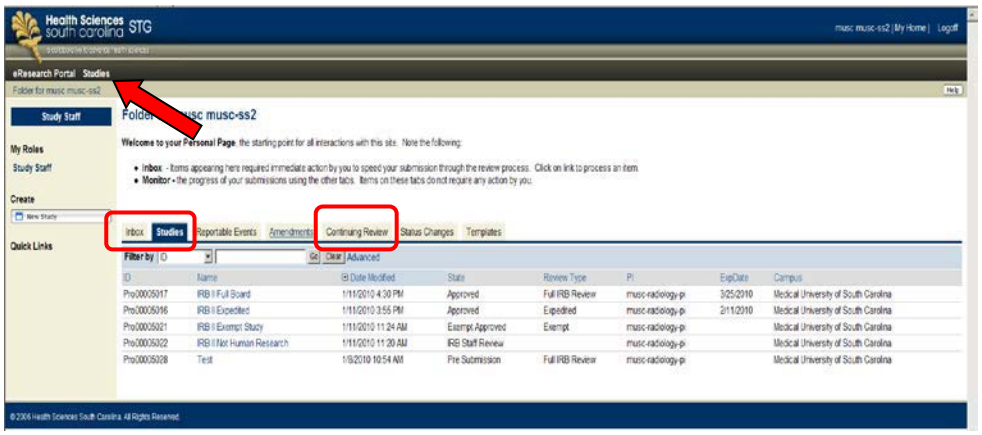
Completing the continuing review

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.

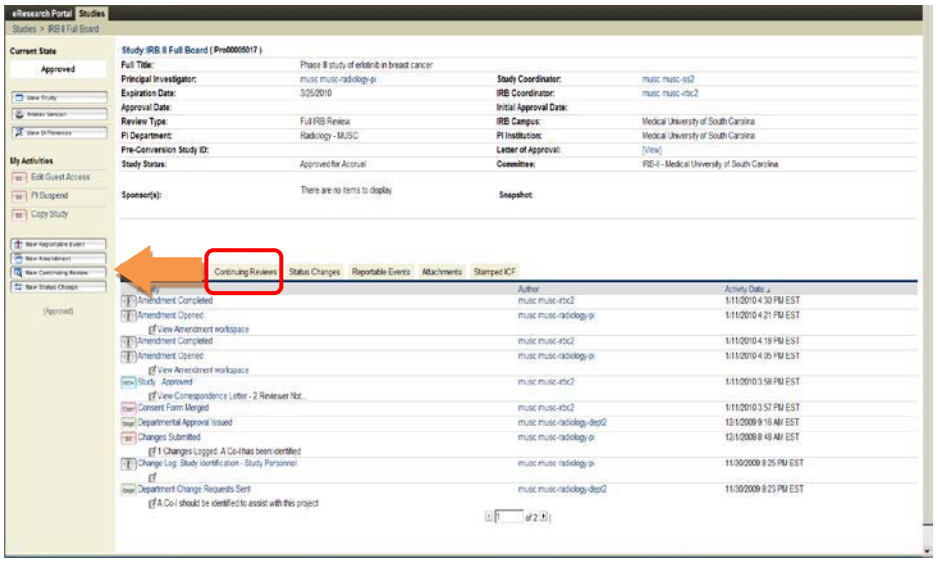


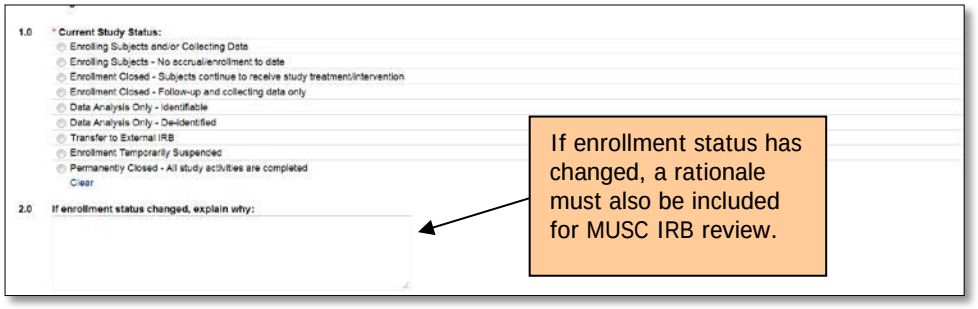
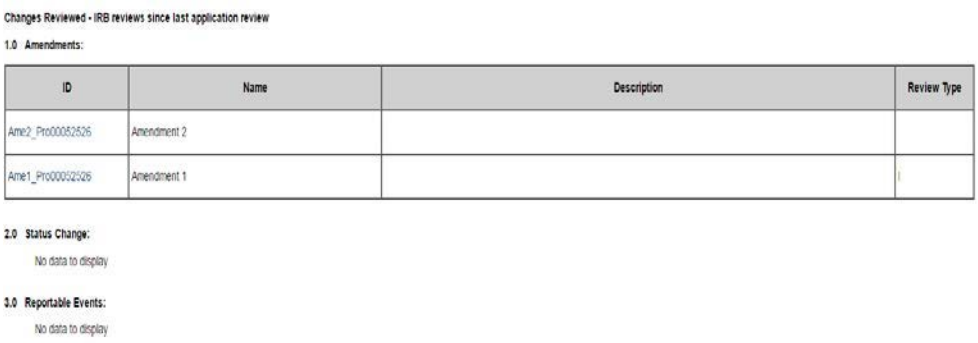
Under My Activities, select 'New Continuing Review'

***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.

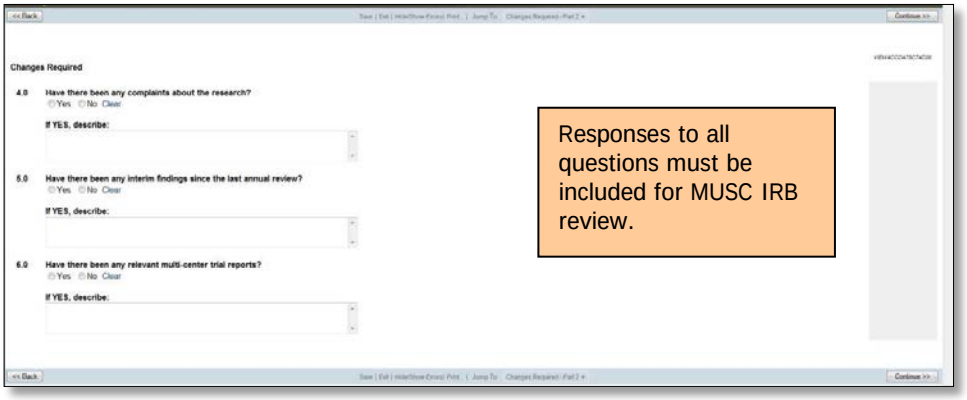
*Exempt, Not Human Subjects and External IRB Review studies cannot create new continuing review applications.***



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.***	
Any study amendments, status changes and reportable events approved/acknowledged by the IRB since the last study review will be listed here. Click Continue.	

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.

1st year continiuing 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 col

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		
4.0	Number of subjects enrolled locally, or for a chart review number of records reviewed		
5.0	Number of subjects who screen failed *("0" if no screen failures or the study has no screening procedures)*		
6.0	Number of local subjects who have completed the study *(including death(s) expected as an endpoint)*		
7.0	Number of local subjects who have withdrawn		
8.0	Number of local subjects who died unexpectedly		
9.0	Number of local subjects currently receiving treatment/intervention		
10.0	Number of local subjects currently in follow-up only		

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		0	0
4.0	Number of subjects enrolled locally, or for a chart review number of records reviewed		5	5
5.0	Number of subjects who screen failed *("0" if no screen failures or the study has no screening procedures)*		1	1
6.0	Number of local subjects who have completed the study *(including death(s) expected as an endpoint)*		0	0
7.0	Number of local subjects who have withdrawn		0	0
8.0	Number of local subjects who died unexpectedly		0	0
9.0	Number of local subjects currently receiving treatment/intervention			
10.0	Number of local subjects currently in follow-up only			

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[1]**
Hispanic/ Latino			
Not Hispanic or Latino			
Unknown/Other/Unreported			
Ethnic Category: Total of All Subjects[1]			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Unknown/Other/Unreported			
Racial Categories: Total of All Subjects[1]			

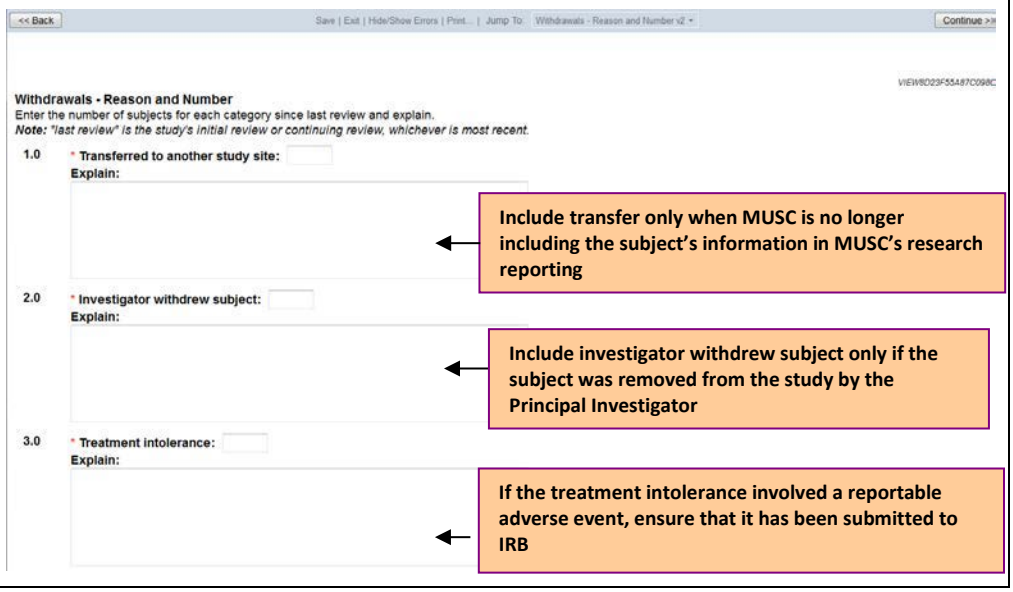
[1] Totals will be recalculated when the Save link or Continue button is selected

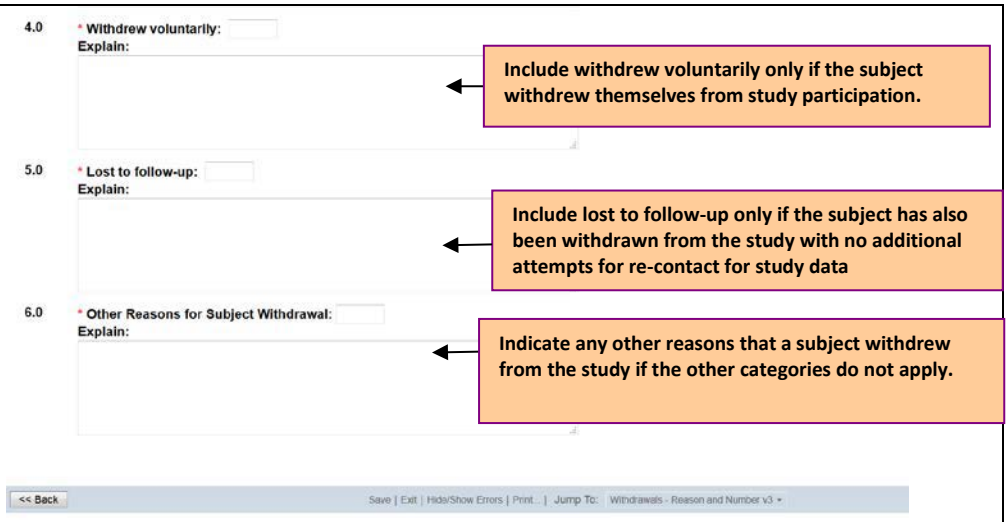
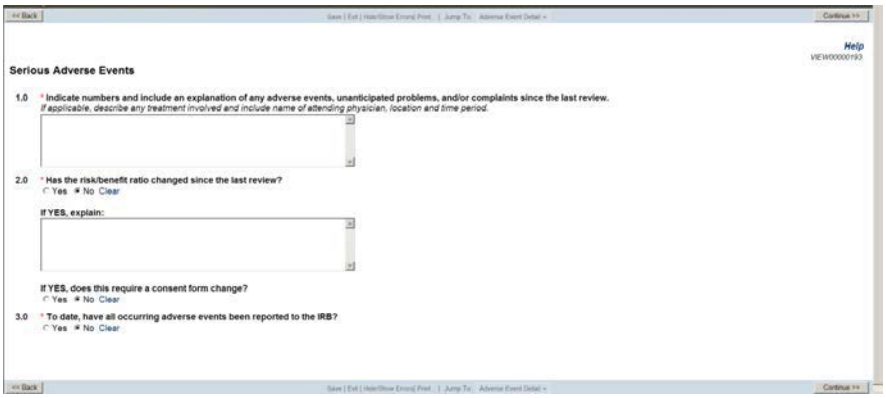
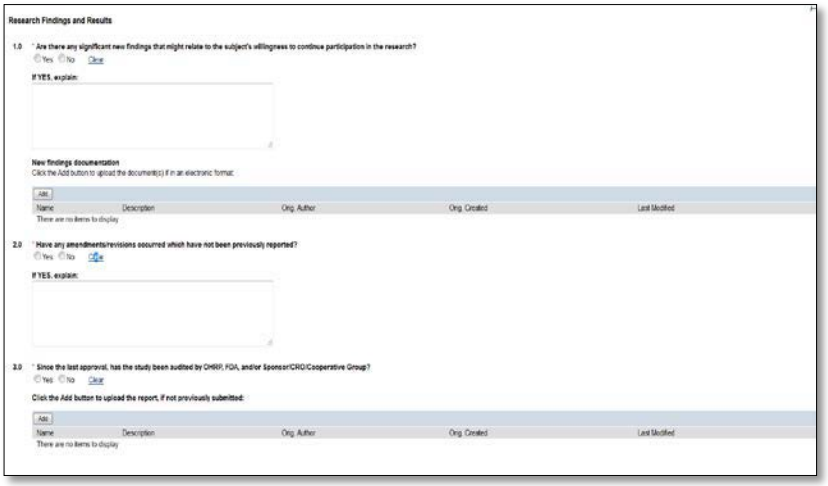
2.0 As applicable, include additional information that may explain absent or discrepant demographic data.

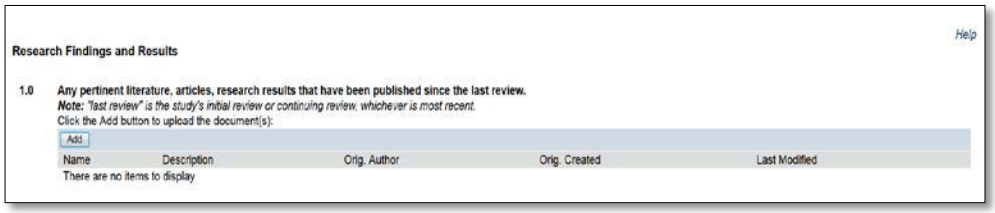
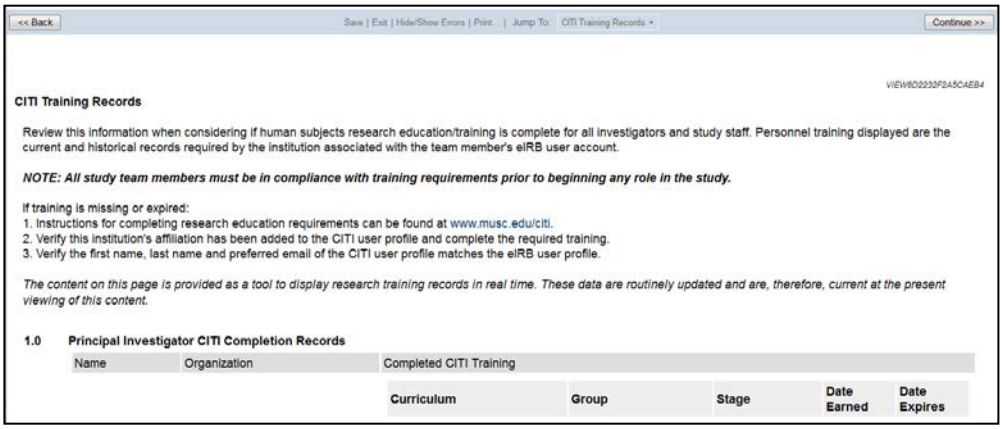
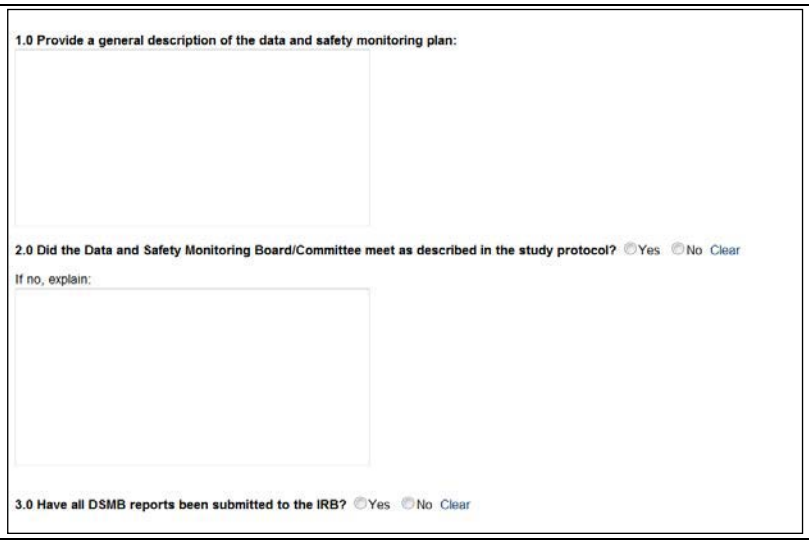
If subjects have been withdrawn, indicate the reason for withdrawal & number of subjects withdrawn for those reasons.

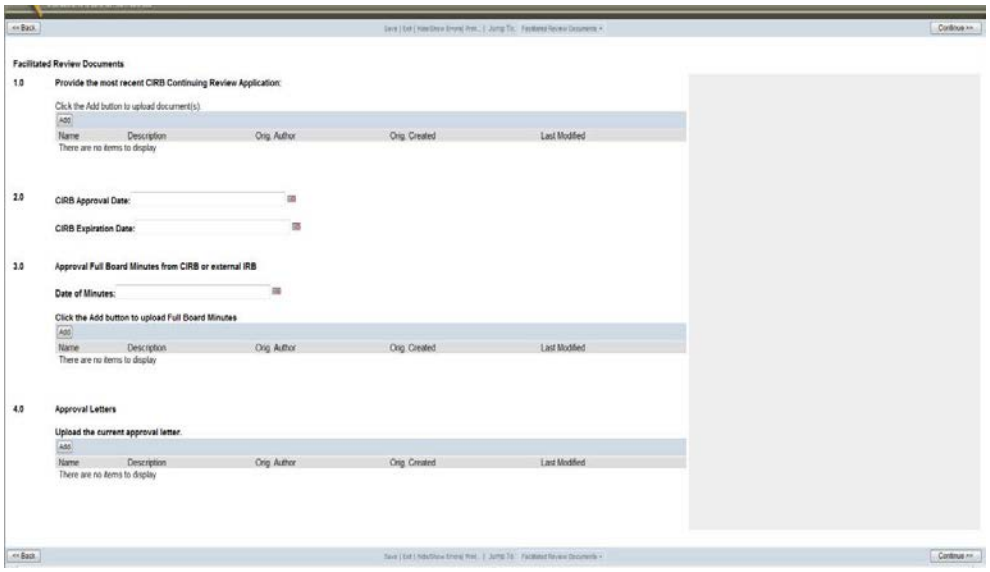
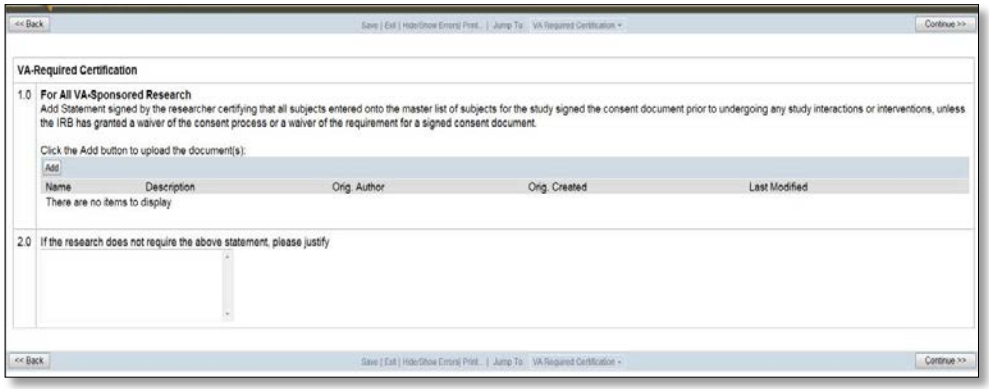
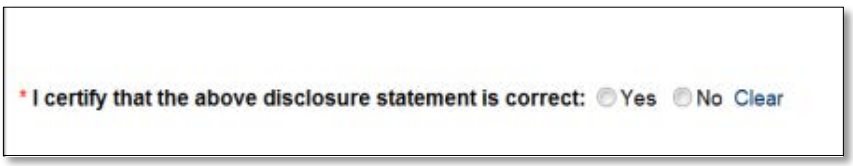
***Note: the numbers entered in on the Number of Subjects page, withdrawn section must equal the same amount entered in on this page**.*

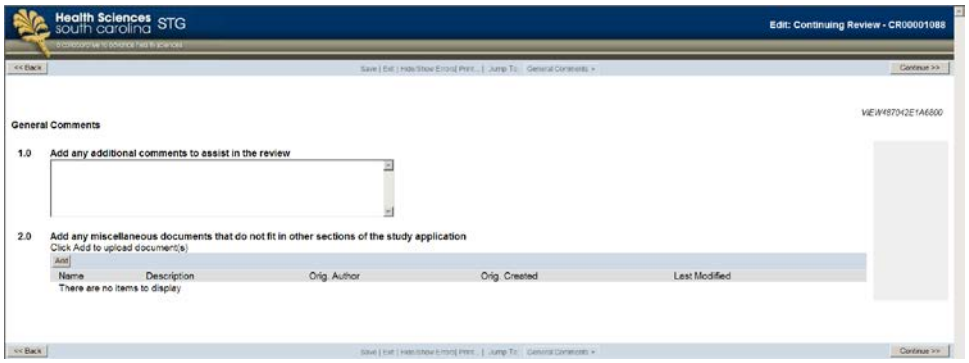
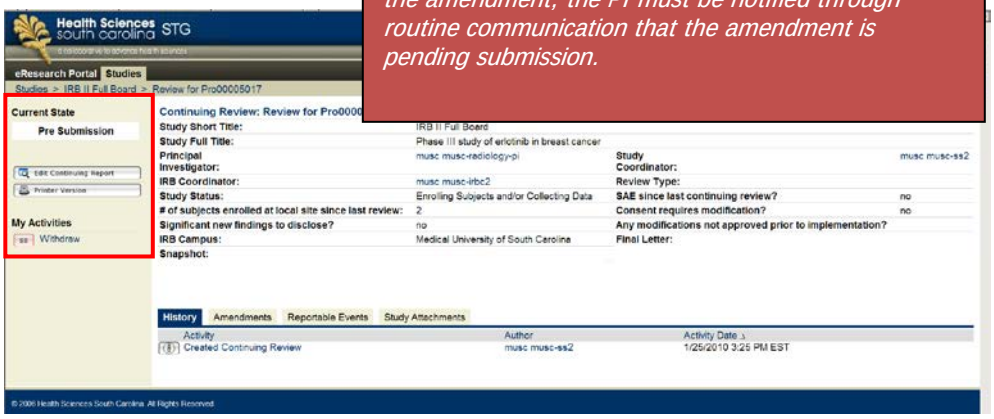
Click Continue.

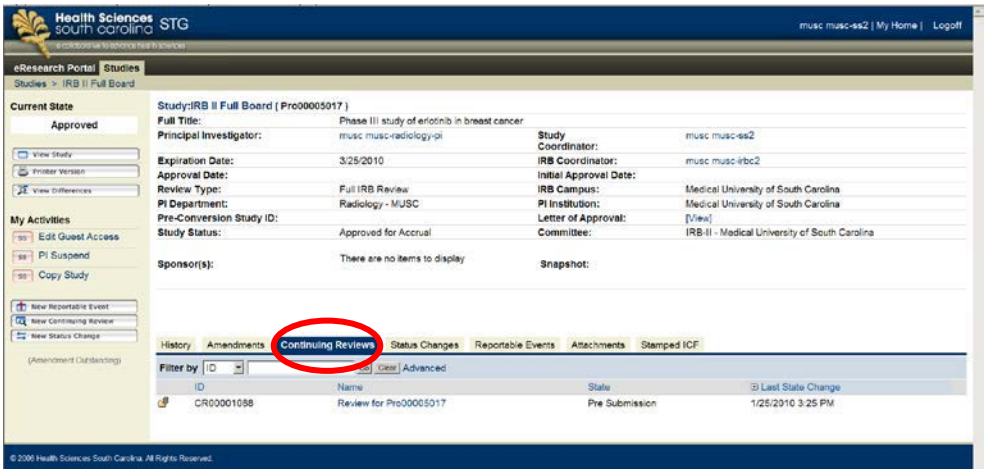


	
Indicate whether there have been any unanticipated problems or adverse events. Click Continue.	
If there have been any unanticipated problems or adverse events, include descriptions as requested. Click Continue.	
Indicate research findings results, pertinent literature, amendments, audits, and current training of research staff. Click Continue.	

Upload any new information or results published since the last review. Click Continue.	
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.	
If the study includes a Data Safety Monitoring Board (DSMB), respond to questions about DSMB meetings and reports.	

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 is 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.	*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.* 

The continuing review will also appear under the 'Continuing Review' tab on the protocol's main page.	

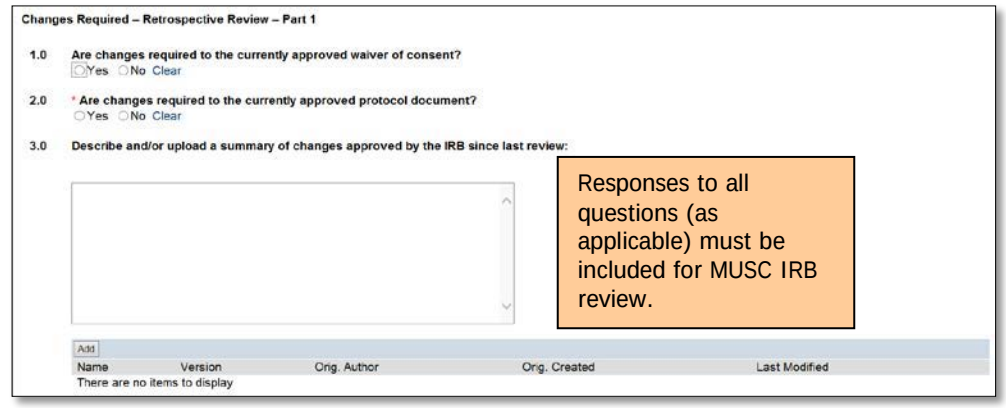
Completing the continuing review (Expedited Category 5 Retrospective Studies)

Indicate whether changes are required to consent or protocol.

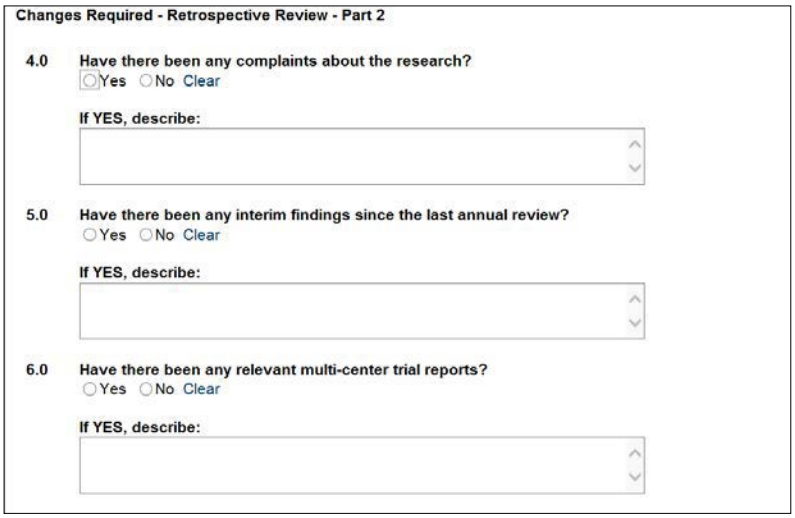
Note: If changes are required, these must be submitted to IRB via an amendment request.

If previous amendments have been IRB approved, include a summary of these changes.

Click Continue.

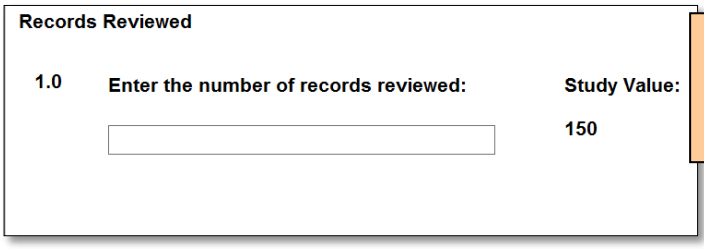


Responses to all questions (as applicable) must be included for MUSC IRB review.



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.



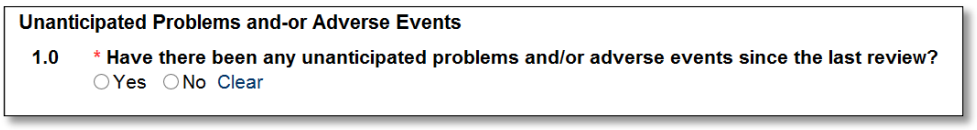
Responses to all questions must be included for MUSC IRB review.

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.

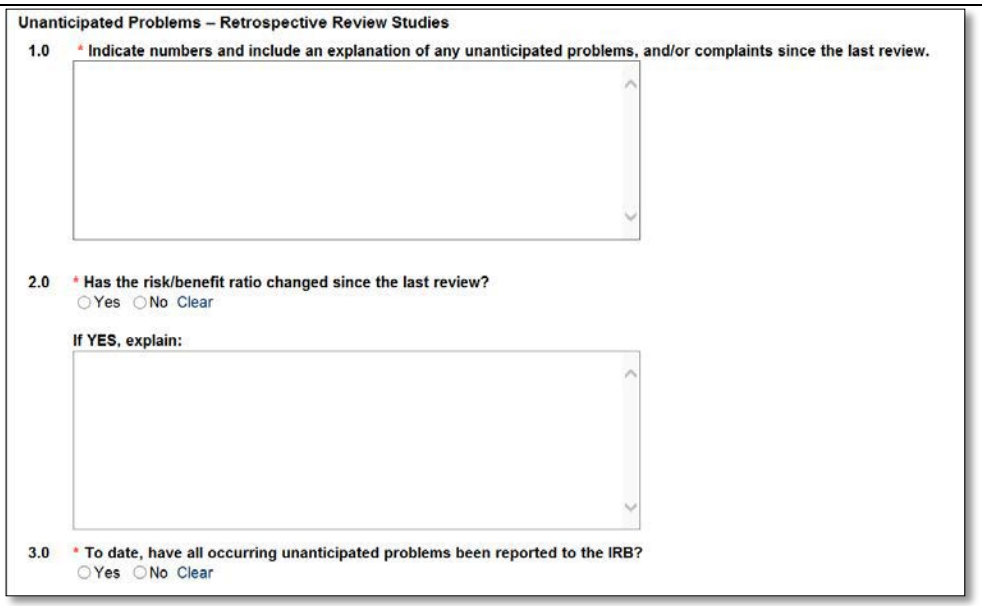
Click Continue.



Unanticipated Problems-Retrospective Review Studies

If there have been any unanticipated problems or adverse events, include descriptions as requested.

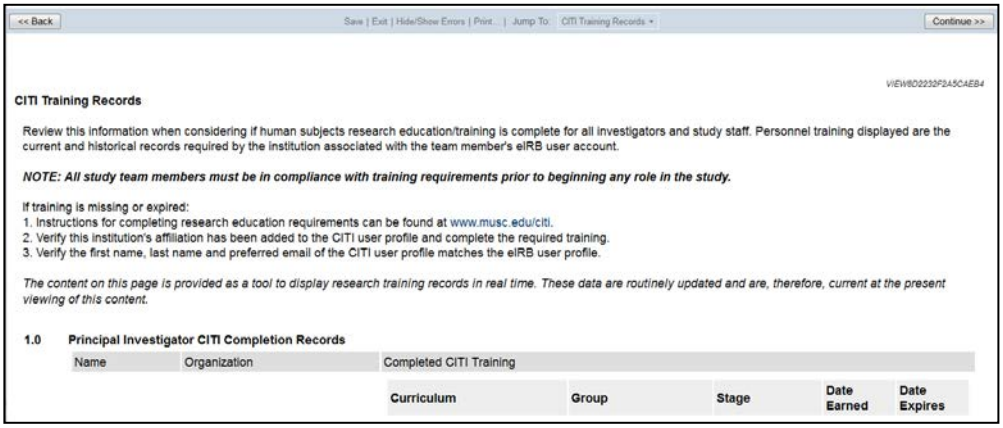
Click Continue.



CITI Training Records

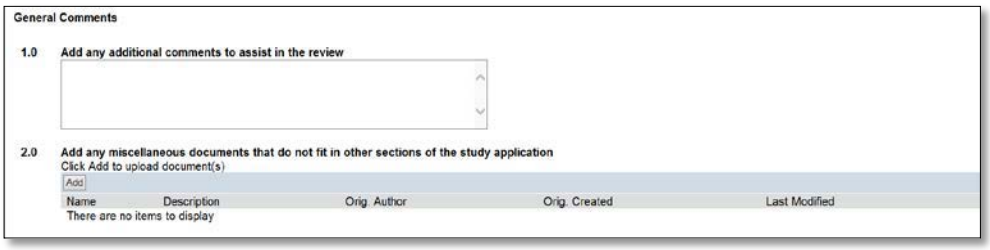
Review this information to verify that human subjects research education/training is current for all study staff.

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.



Add additional comments and upload any other relevant documents not included elsewhere.

Click Continue.

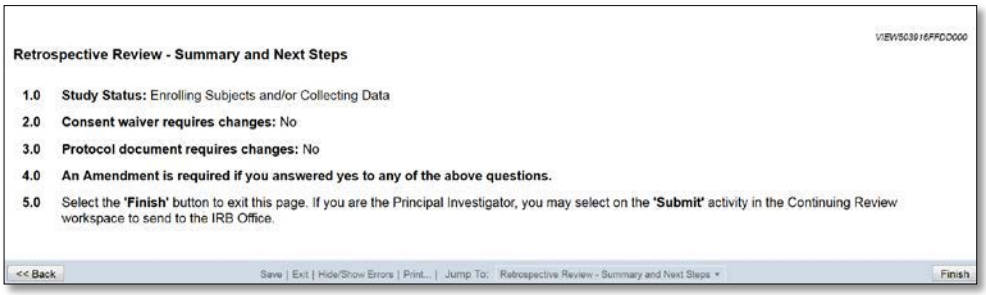


A summary of the continuing review will display.

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.

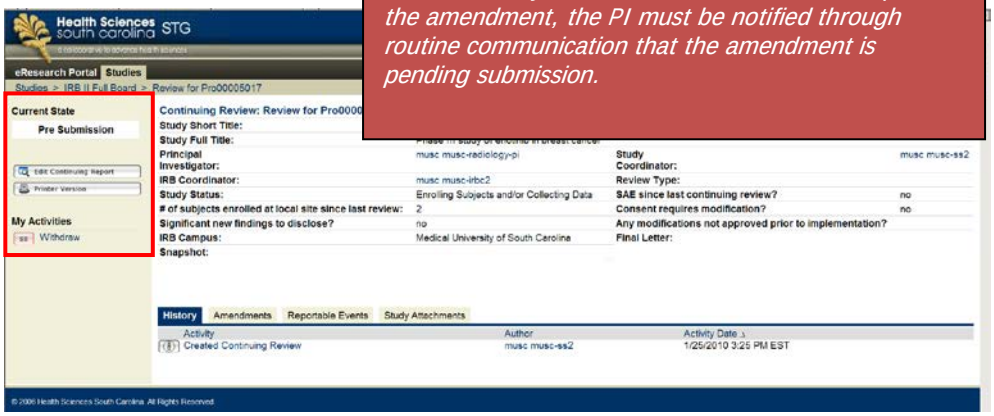


The continuing review is now is the Pre Submission state, as it has not yet been sent to IRB.

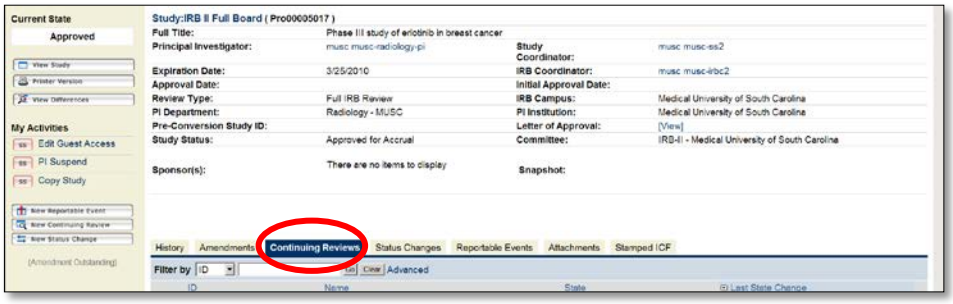
It is able to be edited, withdrawn or viewed as a printable version. The PI will also have the option to submit the continuing review.

See instructions in the Submitting a Continuing Review section of this document.

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.



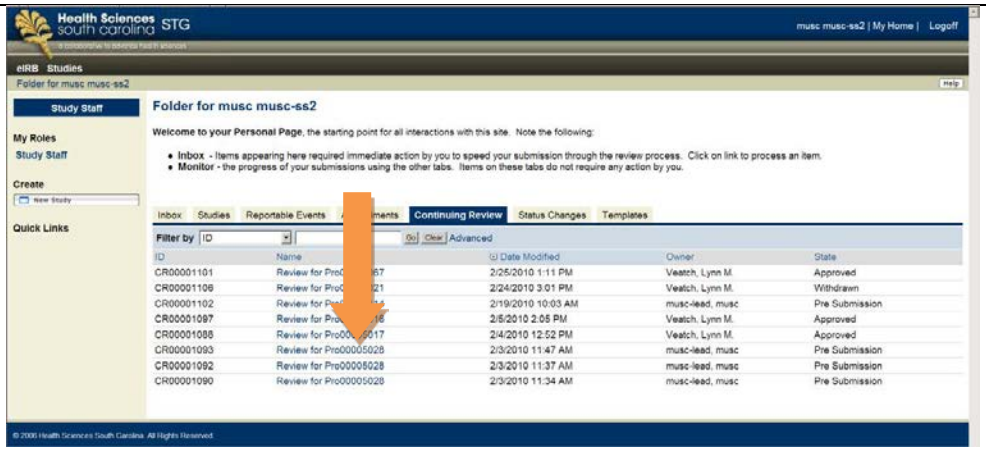
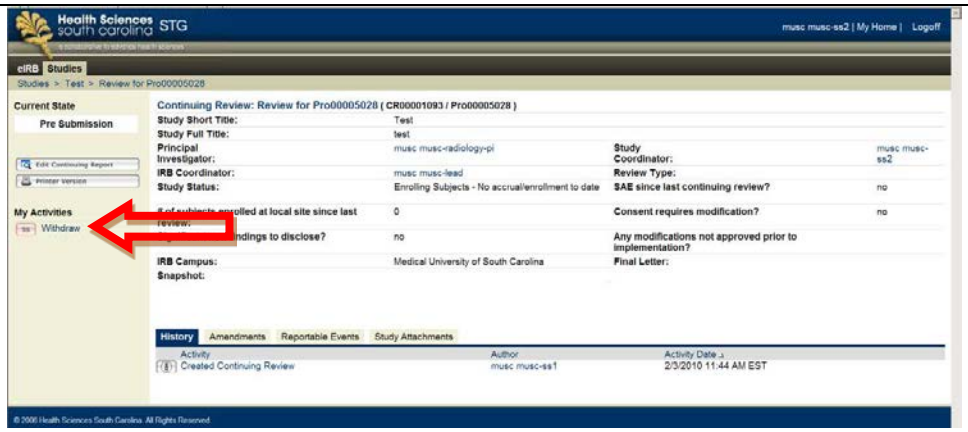
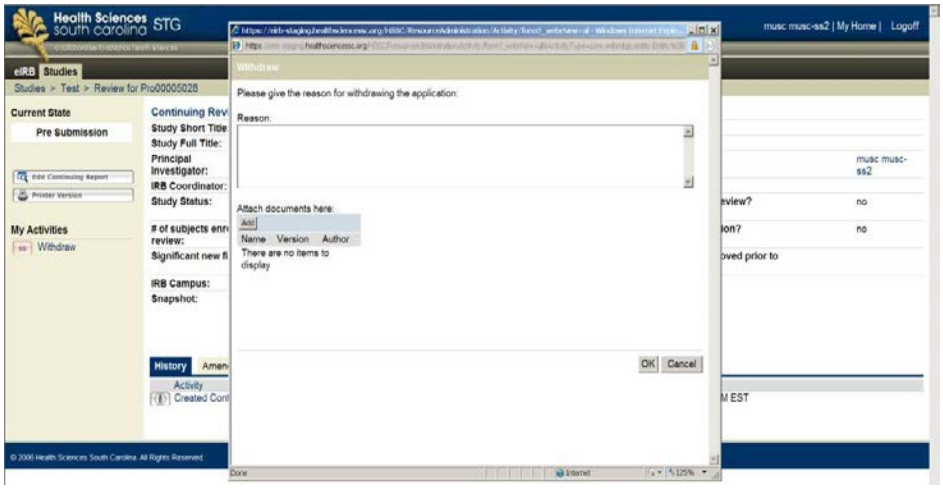
The continuing review will also appear under the 'Continuing Review' tab on the protocol's main page.

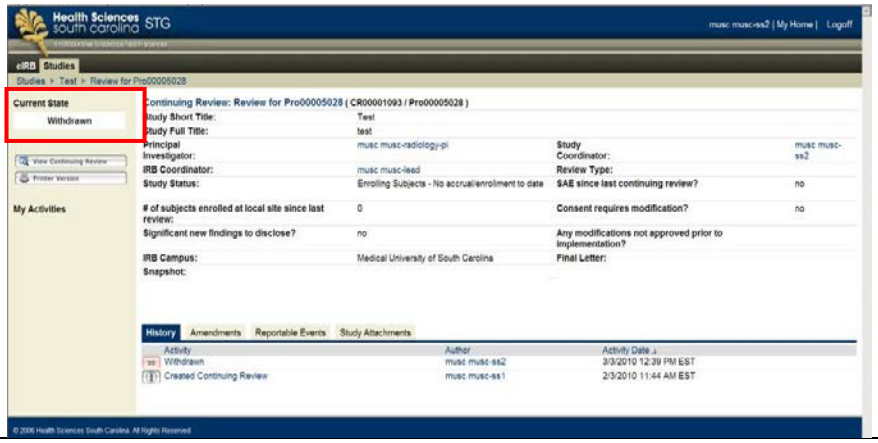


Withdrawing a Continuing Review

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'	

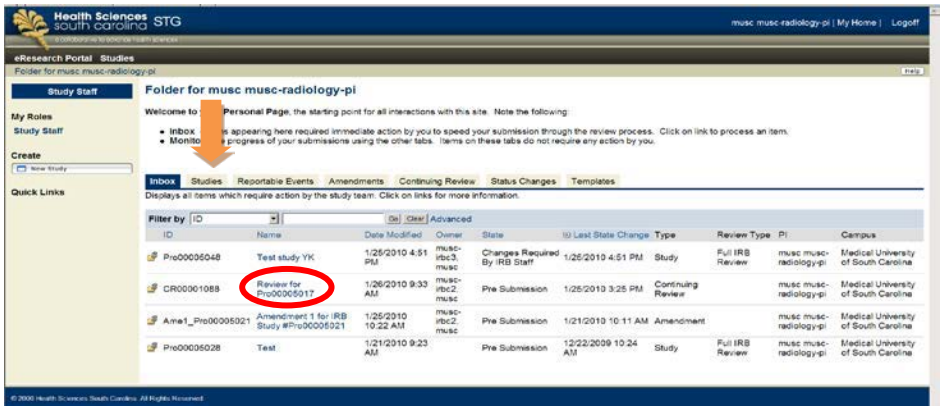
The state of the amendment is now 'Withdrawn'. The system has stored the study. To see a copy of the amendment, select 'View Continuing Review ' You will not be able to restore the status of the continuing review from withdrawn.	

Submission to IRB

Only the PI can send the continuing review to IRB

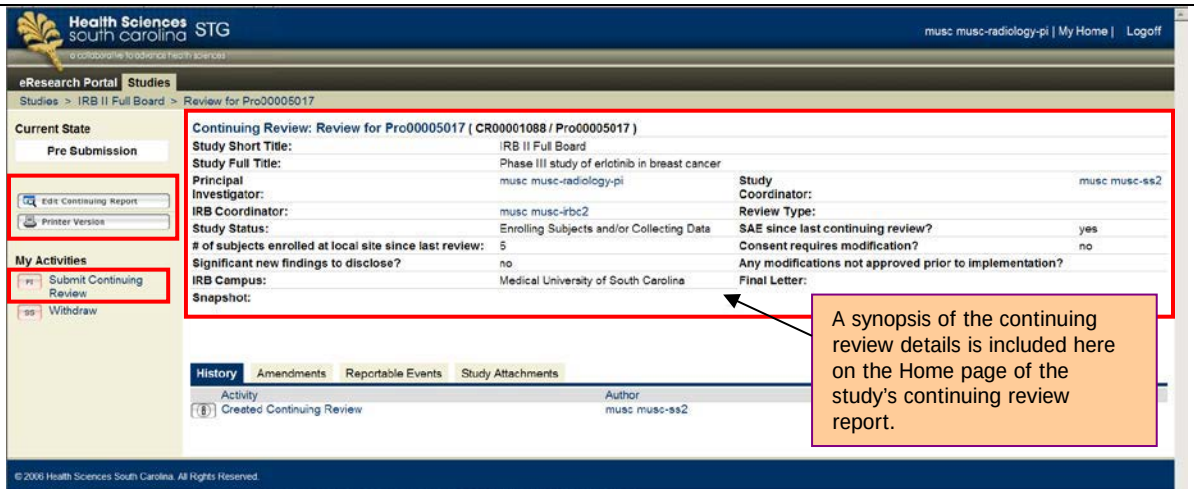
Log into eIRB (as applicable) and select the study from your eIRB Inbox on your Home page. If the continuing review has already been started, it will appear in your 'Inbox'.

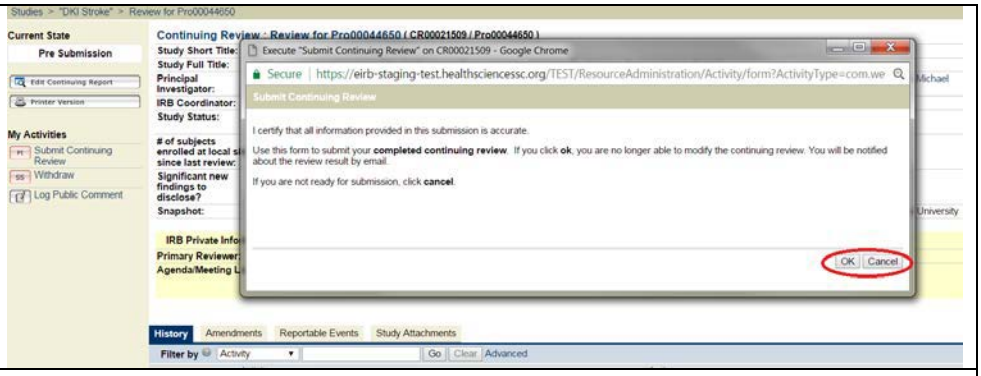
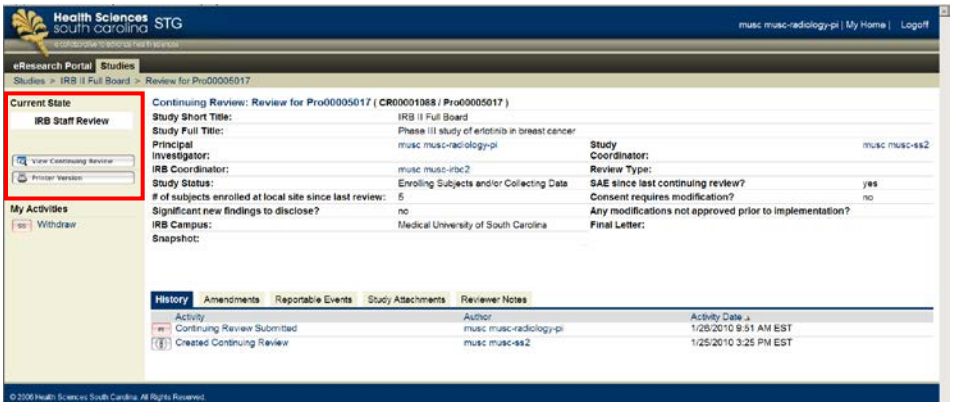
You can also select the 'Continuing Review' tab and locate the study.



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.***	

Designated personnel will receive an e-mail when the continuing review has been reviewed by IRB.

Responding to IRB Comments

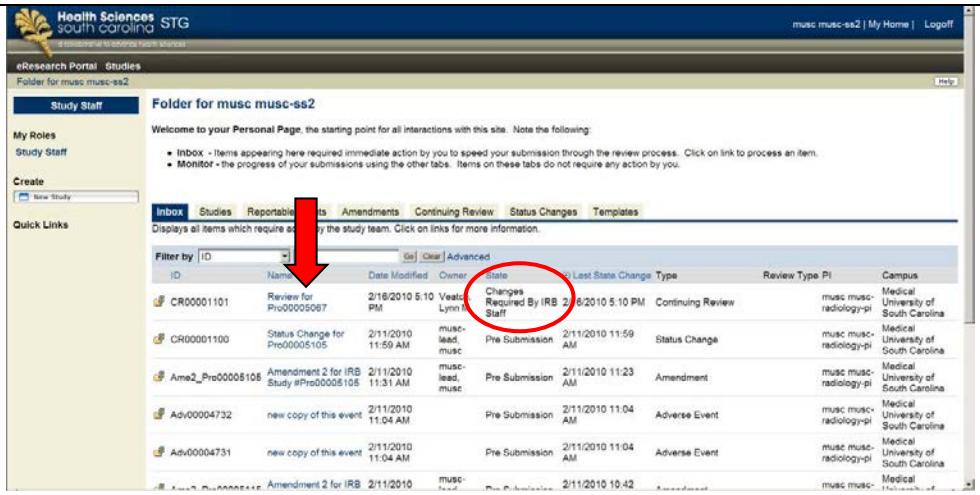
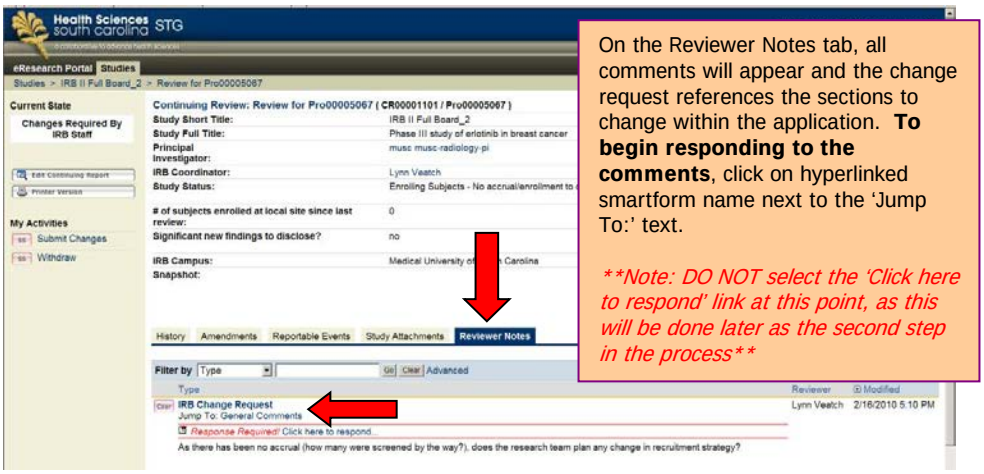
For additional assistance, view the recorded demonstration 'Responding to IRB Reviewer Comments' in the eIRB Education & Training section.

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.

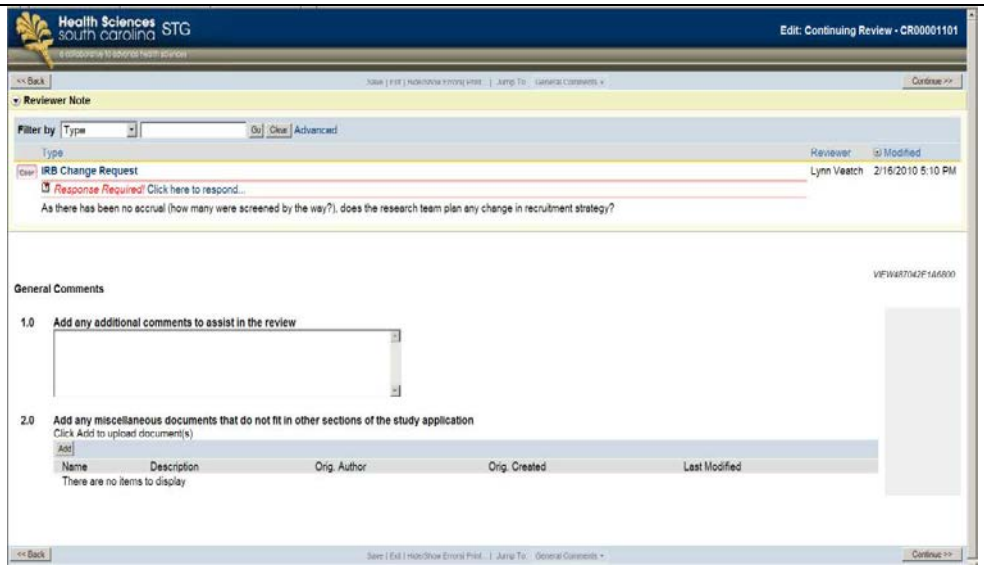
Log into the system. From you Home page, the study will appear in your eIRB 'Inbox'. Click on the study 'Name' ***Note: notice that the state of the study has changed to 'Changes Required by IRB Staff'***	
The 'History' tab logs the change request. It will also include additional notes or clarification requested by IRB. *However*, your changes will not be made from this location. Instead, click on either 'Edit Continuing Report' 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 begin responding to the comments**, click on hyperlinked smartform name next to the 'Jump To:' text. ***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***

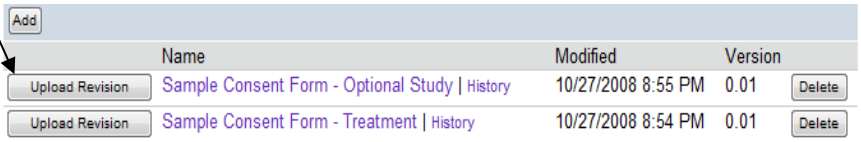
Step 1: View the comment and make changes directly to the application.

***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.*

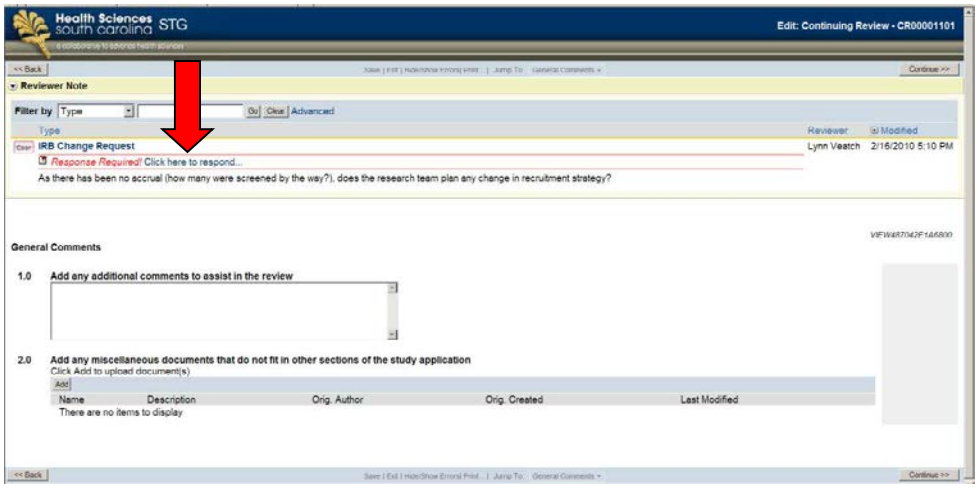
Comments may request uploading of documents when there is no upload feature on a particular smartform page. In that case, documents can be uploaded in the 'General Comments' section of the application.

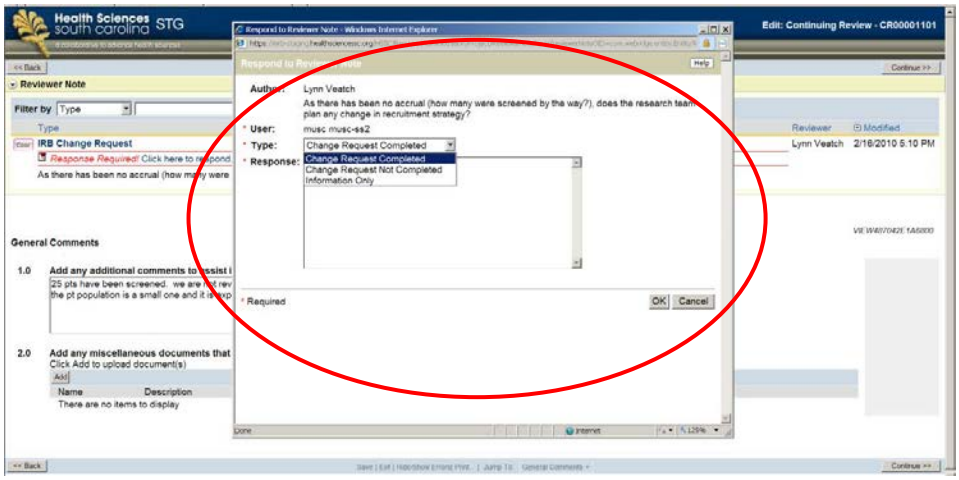
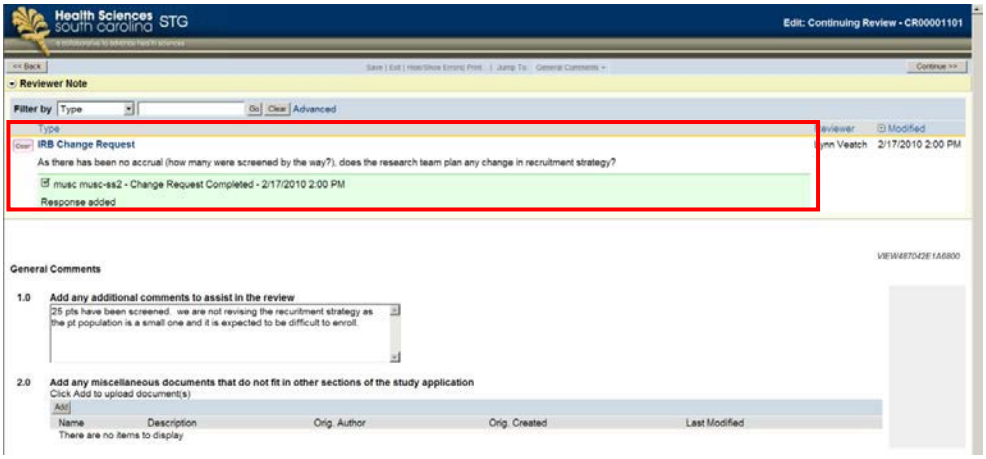
Save the information entered in on that page

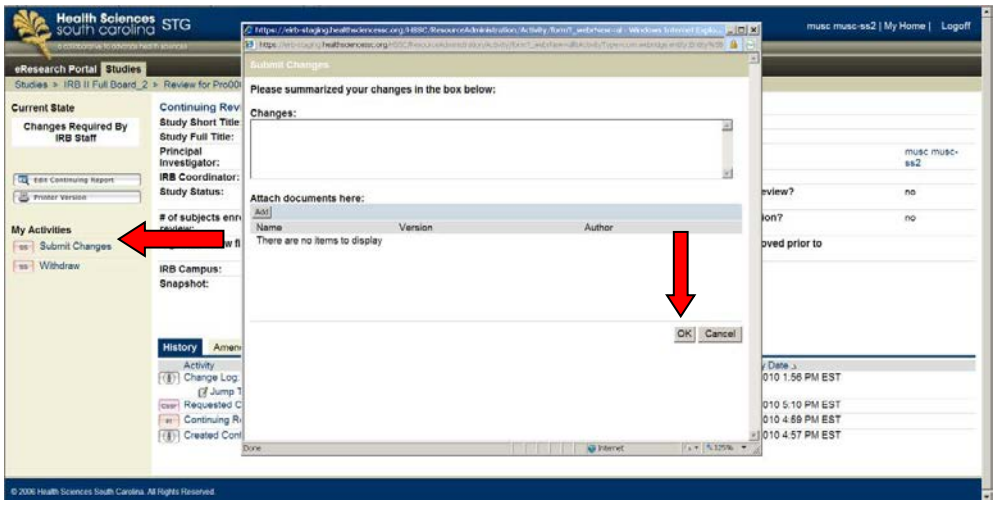




Step 2: Select 'Click here to respond' as the second step & to finalize the response for that comment only.



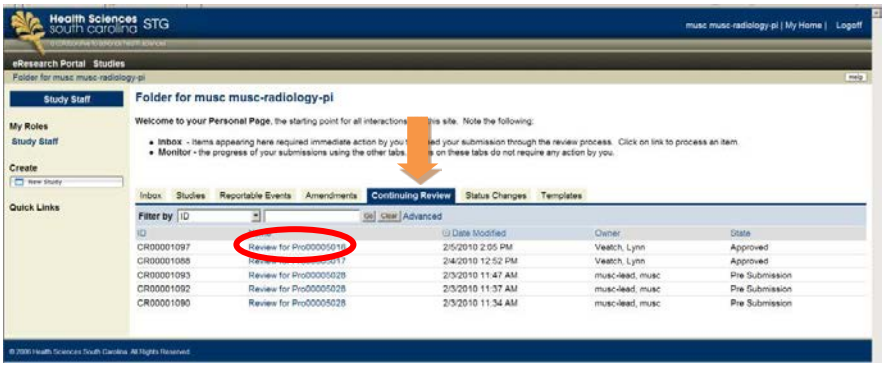
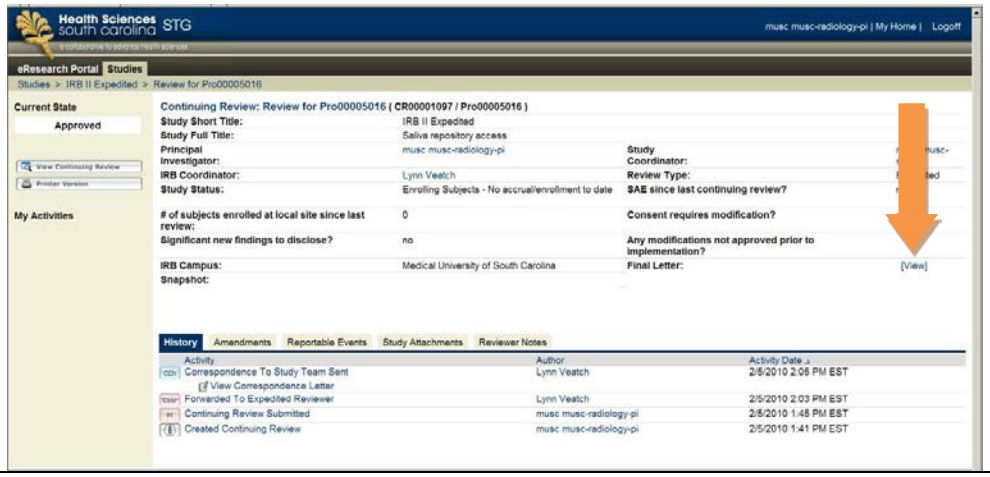
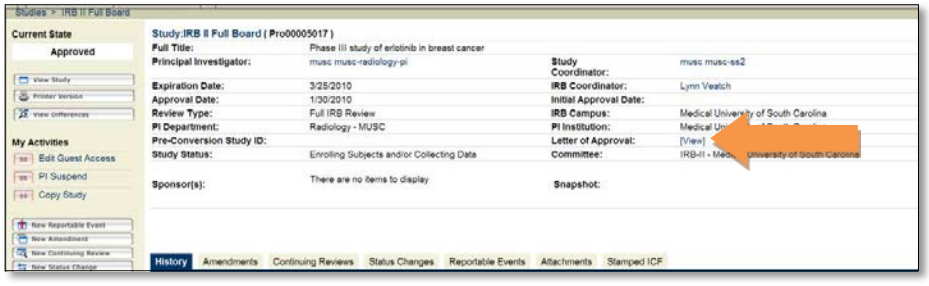
Choose the appropriate 'Type' from the drop down and enter in a response (such as 'done', attached, 'responded', etc.). Click 'Ok'. ***Note: There may be multiple comments within one IRB Change Request section. The system allows you to save a response even if all comments haven't been addressed. For 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.	

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

The S.C. Research Studies Directory (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.

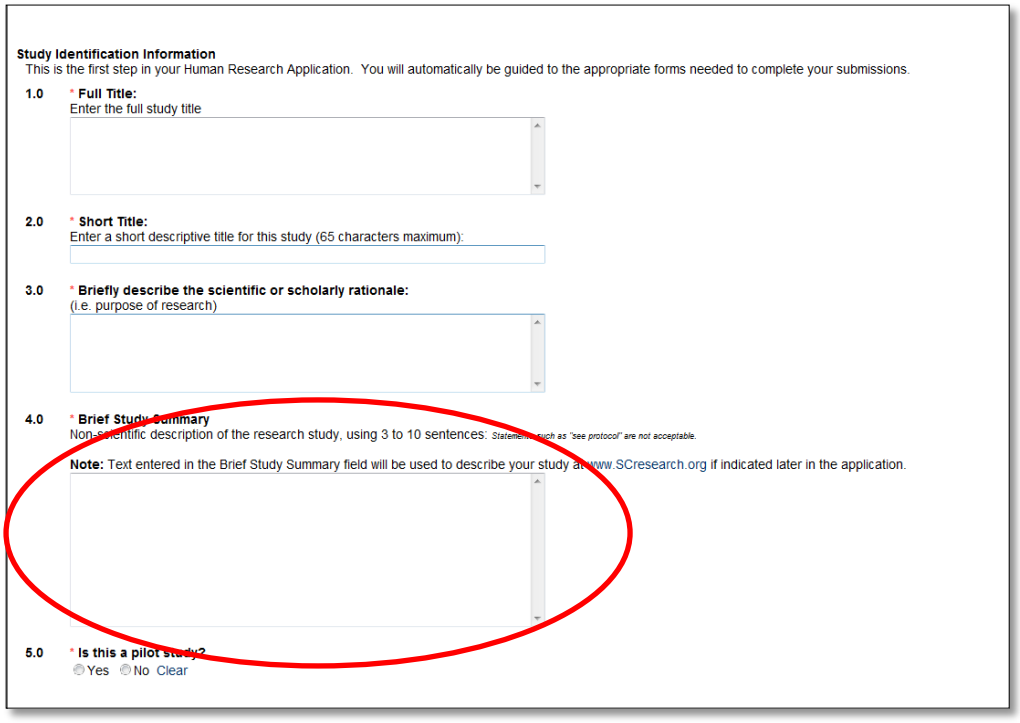
Studies that are no longer eligible for online posting (i.e., are no longer IRB approved or are closed for enrollment) are automatically removed from registry upon IRB approval of the change.

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.

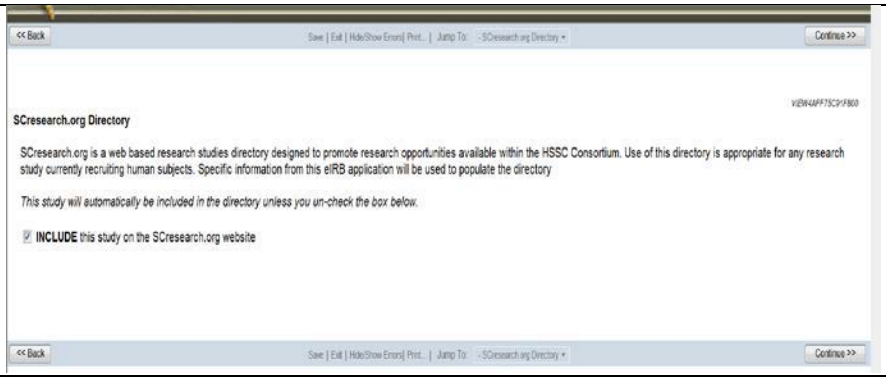
Note: Any changes to this language after it has been IRB approved can be changed via an IRB amendment.

Continue entering in study information according to review requirements.



On the S.C. Research Studies Directory smartform the option to include the study on the directory is pre-populated.

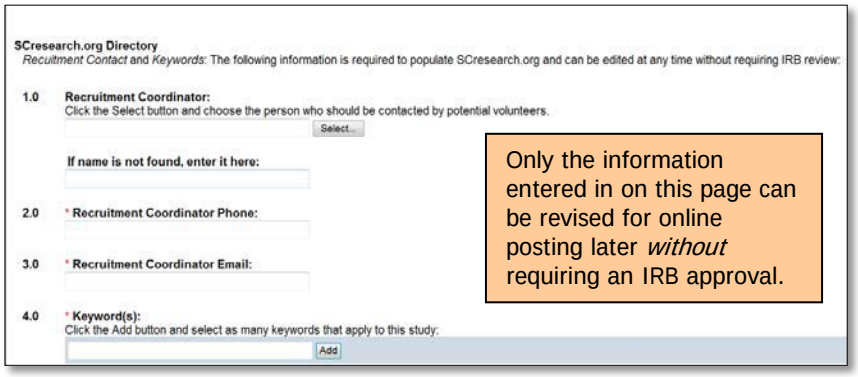
Note: if you DO NOT want your study included in this directory, you must remove the checkbox



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.

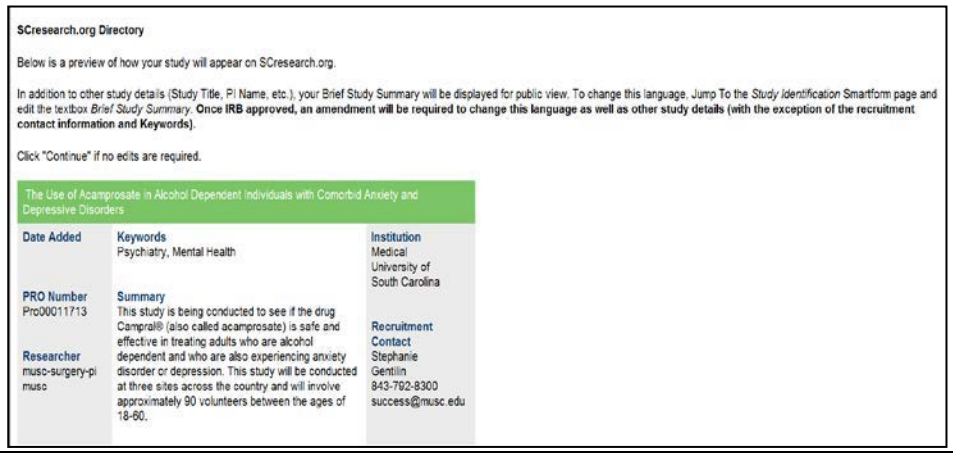
Note: the listing of other study information, such as PI and title, will be populated in the directory as entered into the applicable sections within the study application



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.

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



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.