Expedited Review – Retrospective studies: A New Path

Stephanie Gentilin, MA, CCRA
Director SCTR SUCCESS Center, eIRB Team Member

Katherine Bright
IRB, Grants Administrator

Why Change the System?

- System upgrades
- Address identified system issues or problems
- Edit language to clarify intent of question or provide help information
- Incorporate enhancements
- *When possible*
  - *Streamline processes and reduce regulatory burden*

SCTR
South Carolina Clinical & Translational Research Institute

- Education and Training Material
- Greenville Hospital System
- Medical University of South Carolina
- Palmetto Health
- Spartanburg Regional Hospital System
- University of South Carolina
- Announcements
- Code of Federal Regulation/Ethical Principles

Edit

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

Beginning at 11:00 p.m. EDT each night, system maintenance is performed on the eIRB system. It takes several hours.

Latest Changes (effective September 18, 2013): The eIRB system updates includes a change to the continuing review pathway for studies approved through the Expedited Review Category #5 retrospective review pathway implemented in August 2013. This pathway is applicable to PH, GHS, MUSC and SRHS sites. Please contact your institution's eIRB administrators with any system questions or concerns.

The update is as follows:

A new continuing review pathway has been created for studies approved as Expedited Review Category #5 Retrospective Studies (implemented in the system in August 2013). These projects will be directed through an abbreviated path to capture the relevant data, including skipping pages such as the Subject Enrollments/Demographics/Withdrawals and Research Findings SmartForms. The following new pages have been included in the path:

- Changes Required – Retrospective Review – Part 1 Study Smartform that changes question 1.0 to read 'waiver of consent'.
- Changes Required – Retrospective Review – Part 2 Smartform, created to be consistent with the naming convention of smartform Changes Required – Retrospective Review – Part 1
- Records Reviewed Smartform that replaces the Subject Enrollments and Demographics SmartForms.
- Unanticipated Problems – Retrospective Review Studies Smartform that replaces the Serious Adverse Events Smartform and that revised:
  - Questions 1.0 and 3.0 to remove references to adverse events
  - Question 2.0 to remove the question about requirements for consent form changes.
- End of the continuing review summary page that replaces 'consent changes' to 'consent waiver changes'.

Access summaries of previous system changes in the 'Announcements' folder to the left.

Manage Folders

Add | Edit

Announcements

Code of Federal Regulation/Ethical Principles

Effective August 25, 2013

- A new abbreviated application path was implemented for projects created after 8/25/2013 that involve ONLY retrospective studies for Expedited Review Category #5.
  - This is not applicable if you indicate multiple expedited review categories.
- Designed to solicit and capture relevant data

Expedited Research: An Overview

- Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes

Study Review Type

Minimal Risk means that the risks of harm anticipated in the proposed research are not greater -- considering probability and magnitude -- than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests.

1.0 * **Requested Review Type**

Select the type of IRB review you are requesting.

	Name	Description
○	Exempt	Research activities that present no risk or less than minimal risk as defined by the federal regulations 46.101 (b)
◉	Expedited	Research activities that (i) present no more than minimal risk to human subjects, and (ii) involve only procedures listed in one or more of the categories authorized by 45 CFR 46.110 and 21 CFR 56.10
○	Full IRB Review	The probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

Clear

Expedited Review Categories

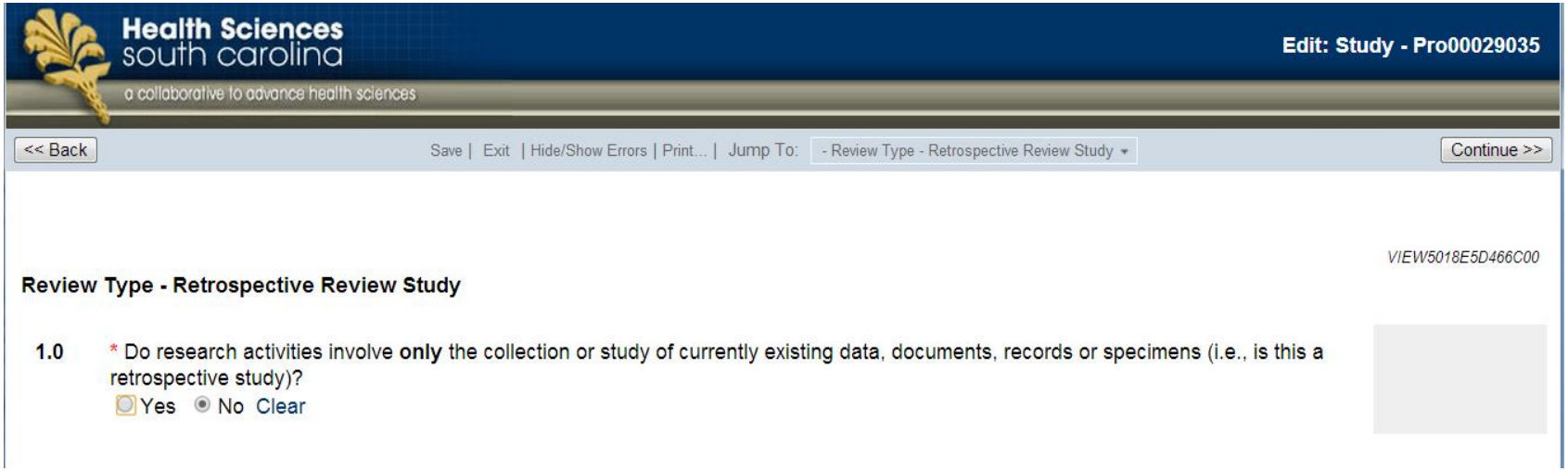
- Clinical studies of drugs and medical devices if certain conditions are met
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- Prospective collection of biological specimens for research purposes by noninvasive means
- Collection of data though noninvasive procedures routinely employed in clinical practice
- **Research involving materials (data, documents, records, or specimens) that have**

New Smartform to verify that the project involves only retrospective review

If you check this box…

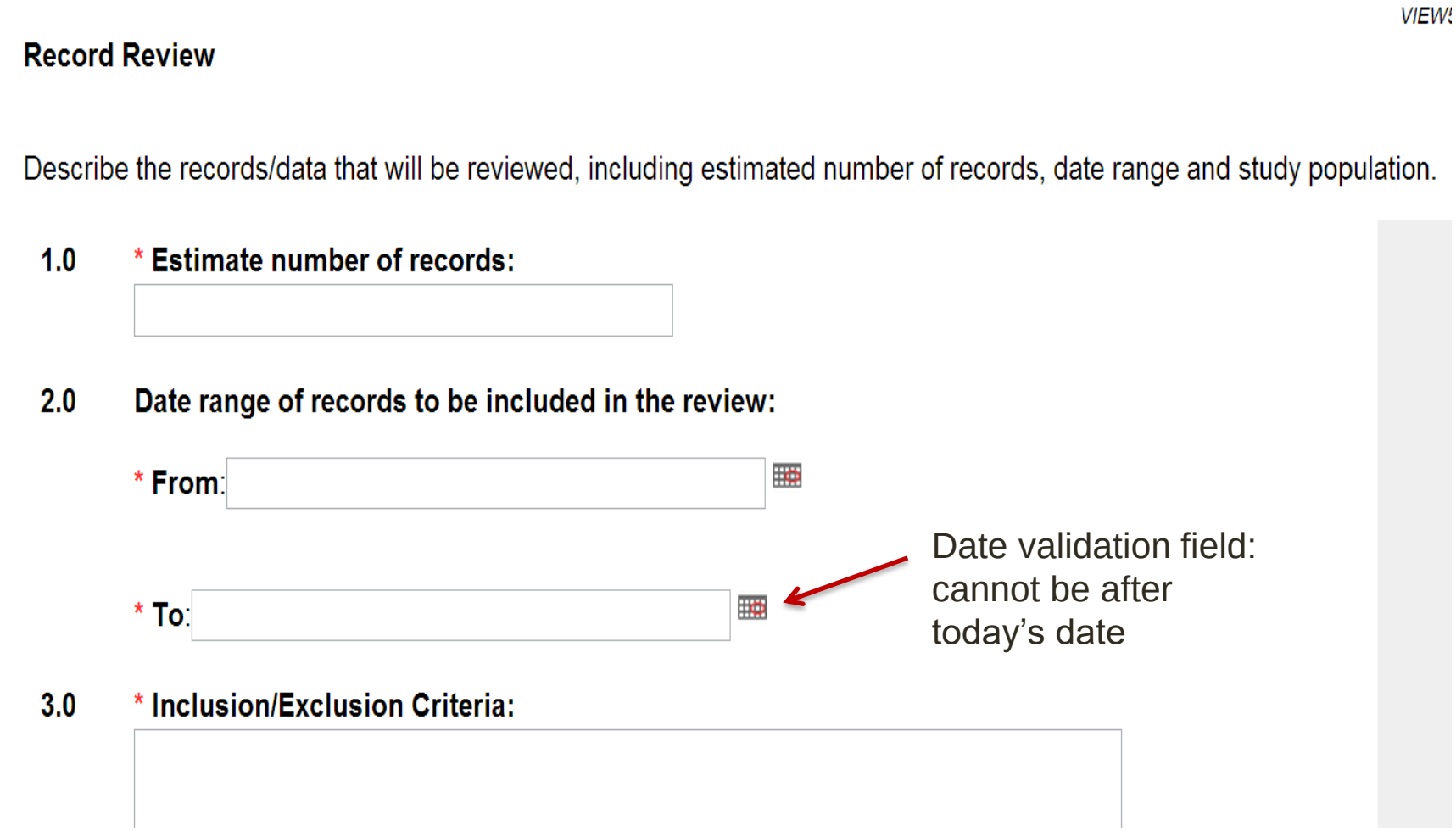
☑ **5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).**

You now get this Smartform…



New Records Review Smartform

- Requests details of the records reviewed, date range and



Application Checklist

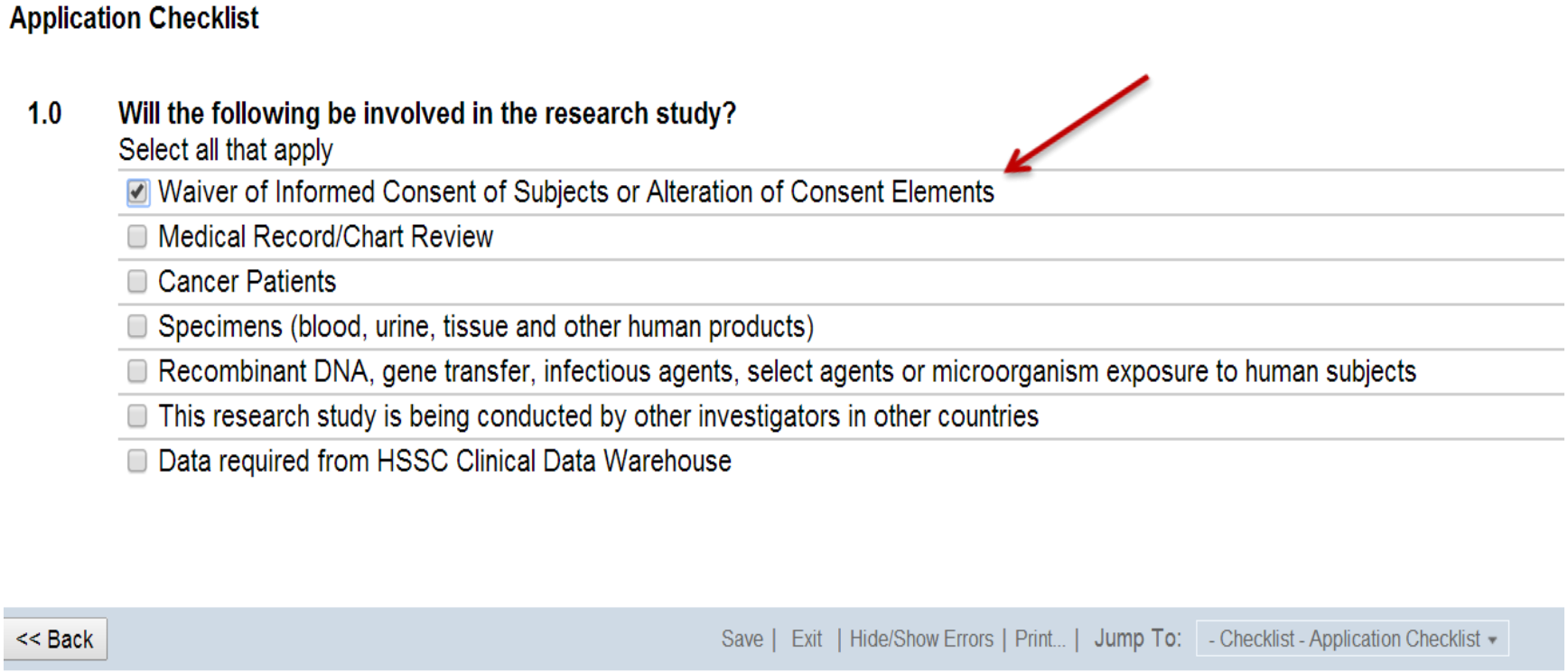
1.0 Will the following be involved in the research study?

Select all that apply

- [ ] Informed consent document(s)
- [ ] Waiver of the Requirement to Obtain Written and Signed Consent from Subjects
- [ ] Waiver of Informed Consent of Subjects or Alteration of Consent Elements
- [ ] Clinical trials
- [ ] Data Safety Monitoring Plan is used in this research study.
- [ ] Medical Record/Chart Review
- [ ] Cooperative Group/NIH Sponsored
- [ ] Vaccine Trials
- [ ] Human Genetic Research
- [ ] Human In Vitro Fertilization
- [ ] Radioactive materials, x-rays, microwave radiation, ultraviolet radiation. lasers or accelorators
- [ ] Transplantation
- [ ] Alcohol and Drug Abuse Research
- [ ] Diet/Exercise Regimen
- [ ] Post Partum
- [ ] Use of survey/questionnaire
- [ ] Interviews/Group Discussion
- [ ] Healthy, normal volunteers as research subjects
- [ ] Individuals with HIV/AIDS as research subjects
- [ ] Cancer Patients
- [ ] Individuals, other than children and those with cognitive or psychological impairment, such as unconscious or critically ill patients, who will be unable to consent for themselves as research subjects
- [ ] This research study requires the participants to be hospitalized
- [ ] Drugs will be used in this research study
- [ ] Chemicals, metabolites, nutritional substances, biological agents or other substances whether regulated or not by the Food & Drug Administration (FDA) that will be administered to subjects
- [ ] Use of Placebos
- [ ] FDA-approved drugs not part of usual care but which subjects will receive as part of the conduct of this study or that are being evaluated as part of this research study
- [ ] Investigational drugs (those not yet approved by the Food & Drug Administration (FDA))
- [ ] Investigation of medical device, instrument, machine, computer program or other device, FDA approved or non-FDA approved, including HUD
- [ ] Does your study involve the collection or special processing of tissue(s), or retrieval of glass slides, blocks or additional sections? If so, you will need to select Impacted Services, Pathology, in this application.
- [ ] Specimens (blood, urine, tissue and other human products)
- [ ] The storage of biological specimens (e.g. biological material, tissue, blood, etc.) or Data (e.g. subject level data, images, scans, recordings, etc.) for potential future, yet undesignated, research
- [ ] Blood Sample Study
- [ ] Recombinant DNA, gene transfer, infectious agents, select agents or microorganism exposure to human subjects
- [ ] Advertisements or recruiting materials
- [ ] Need GHS account number for this study for billing purposes. Note: An account number will be assigned after IRB approval
- [ ] This research study is being conducted by other investigators in other countries
- [ ] Videotaping, audiotaping, filming or photographing research subjects
- [ ] Data required from HSSC Clinical Data Warehouse

New Filtered Application Checklist

- The *Waiver of Informed Consent of Subjects or Alteration of Consent Elements* option is a defaulted selection.



Waiver of Informed Consent of Subjects or Alteration of Consent Elements

If a Waiver of Informed Consent is requested, provide the following information:

1.0 * **Explain why the research involves no more than minimal risk to the subjects.**

2.0 * **Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects.**

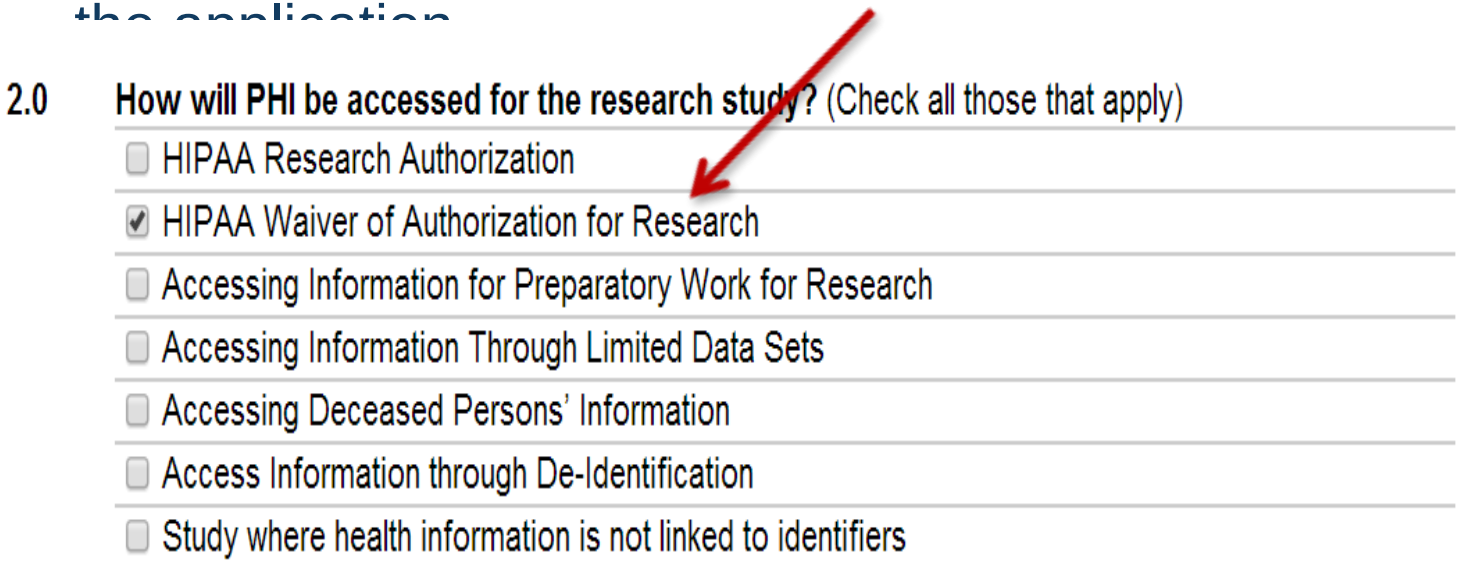
3.0 * **Explain why the research could not be practicably carried out without the waiver or alteration.**

Commonly Misunderstood question

4.0 * **Explain how, whenever appropriate, the subjects will be provided with additional pertinent information after participation in the study** (Debriefing).

The *HIPAA Waiver of Authorization* option is a defaulted selection in question #2 on the Access to PHI for Research page

- The Smartform to request a HIPAA waiver is required later in the application



Remainder of application remains the same…

Continuing Renewal– A New Path for Retrospective Chart Review Studies

CTSA Clinical & Translational® Science Awards

The Clinical and Translational Science Awards (CTSA) is a registered trademark of DHHS.

HEALTH SCIENCES SOUTH CAROLINA

A Collaborative To Advance Health Sciences

SCTR

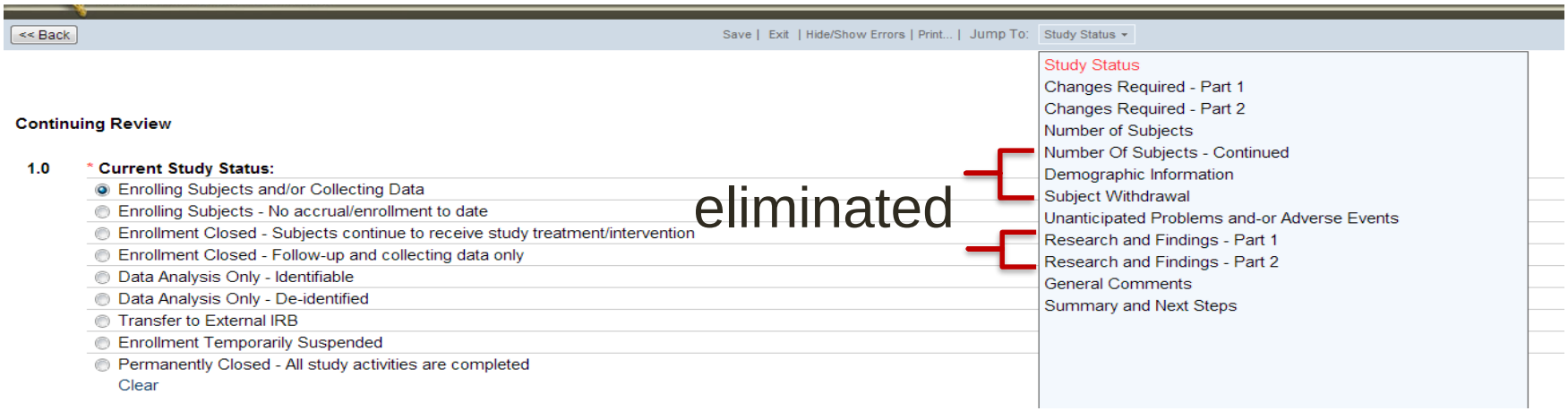
South Carolina Clinical & Translational Research Institute

Effective September 18, 2013

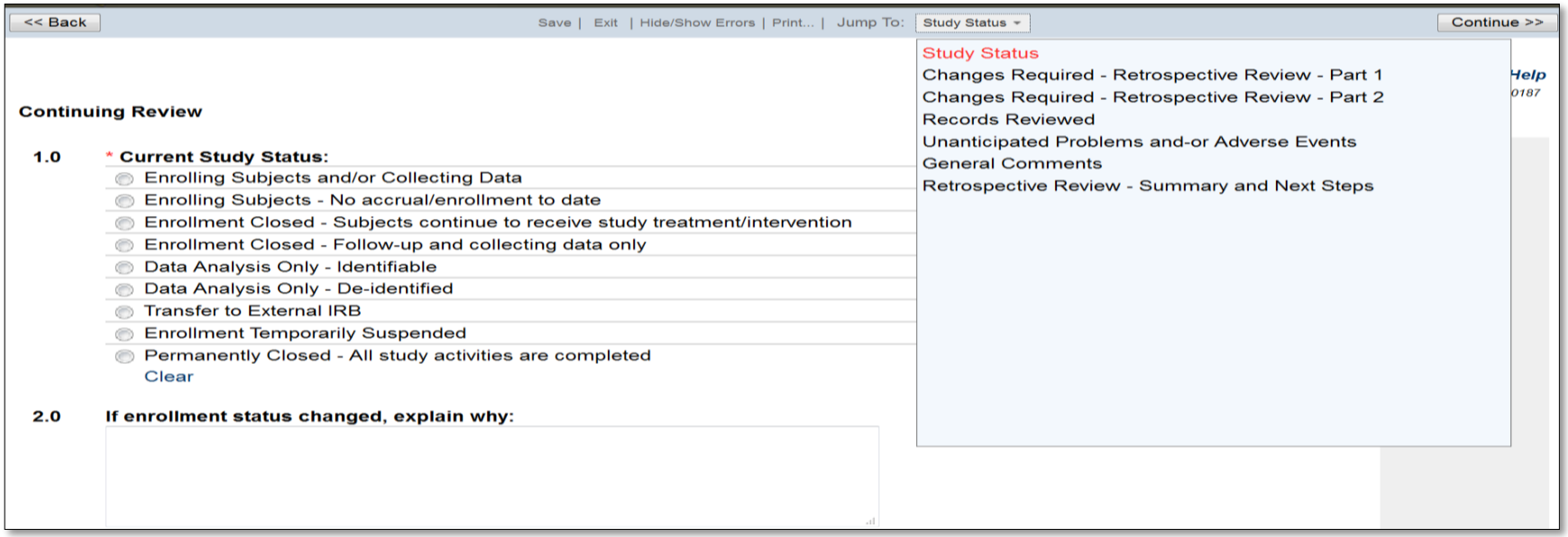
- A new continuing review pathway has been created only for studies approved as Expedited Review Category #5 Retrospective Studies
- Includes some of the most significant changes to Smartform
- Designed to capture only relevant data, as well as skip pages such as the Subject Enrollments/Demographics/Withdrawals and Research Findings Smartforms

SCTR
South Carolina Clinical & Translational Research Institute

Original Jump To Smartform Pages



New Jump To Smartform Path



Original “Changes Required” Smartform page 1

Changes Required

1.0 **Are changes required to the currently approved consent documents?**
(if not applicable, leave blank)
☐ Yes ○ No Clear

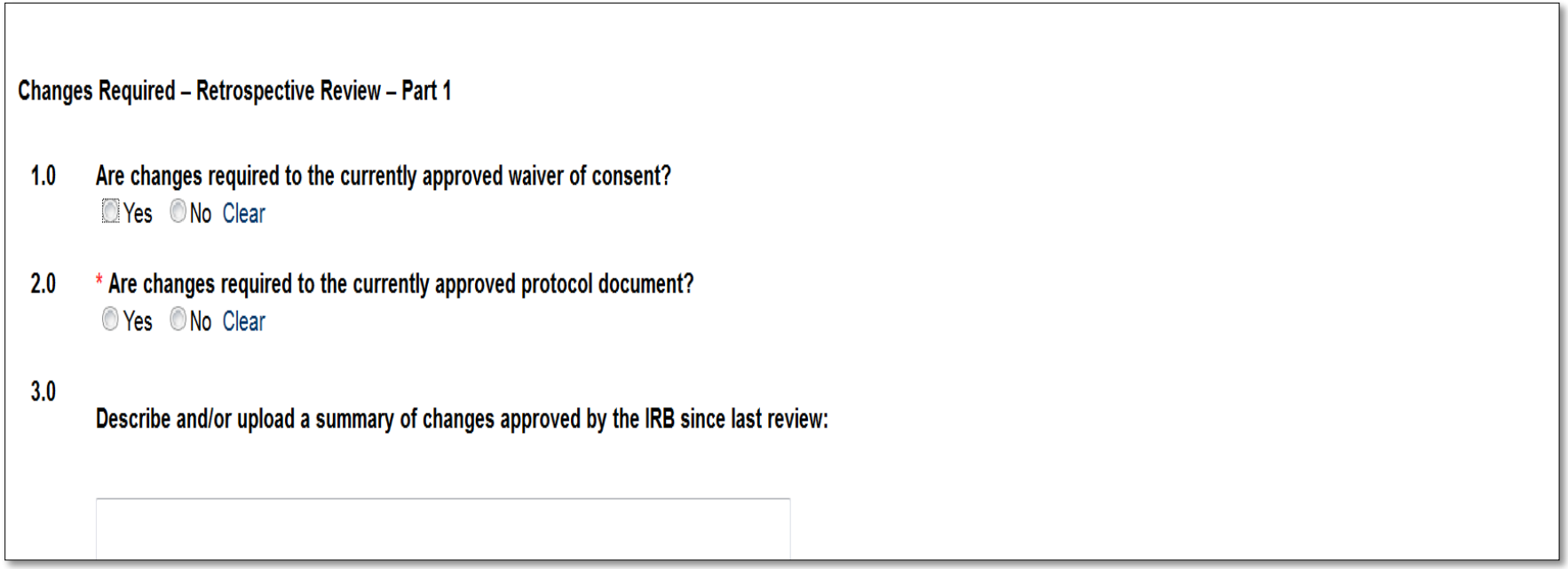
2.0 * **Are changes required to the currently approved protocol document?**
○ Yes ○ No Clear

3.0 **Describe and/or upload a summary of changes approved by the IRB since last review:**

Add

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

New “Changes Required” page – Retro Chart Review



Changes Required – Retrospective Review – Part 1

1.0 Are changes required to the currently approved waiver of consent?

Yes No Clear

2.0 * Are changes required to the currently approved protocol document?

Yes No Clear

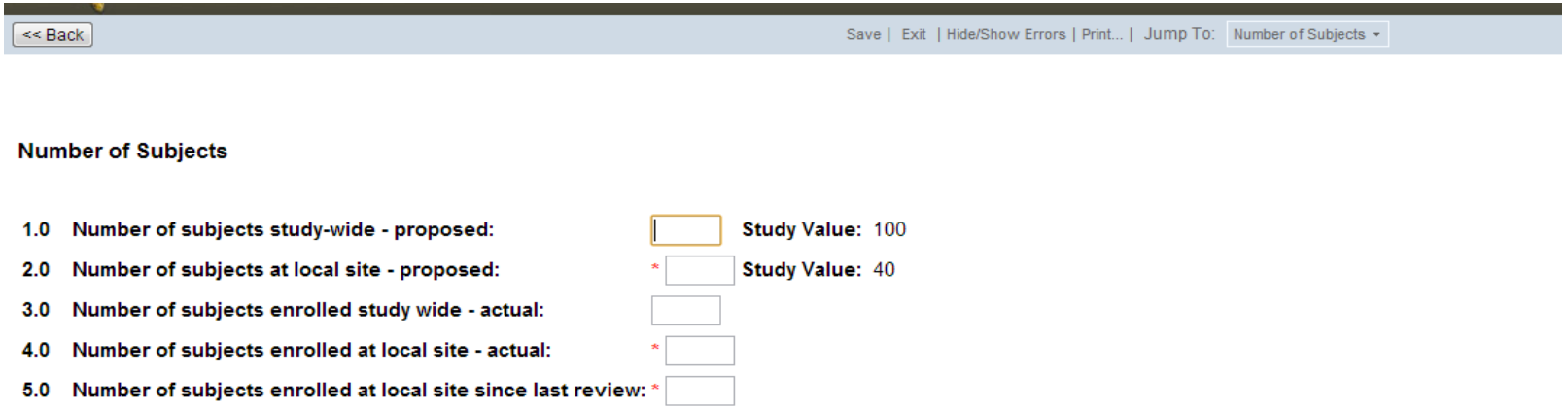
3.0

Describe and/or upload a summary of changes approved by the IRB since last review:

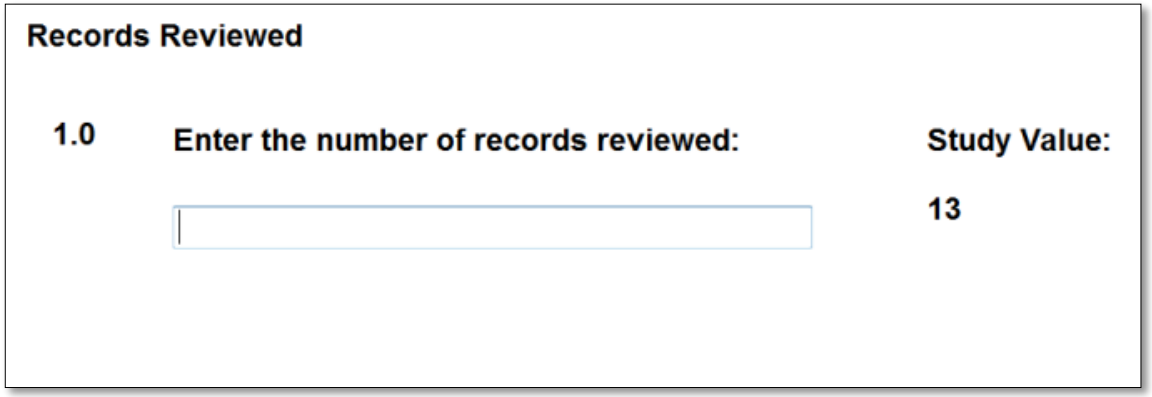
- “Changes Required” Page 2 unchanged with the exception of the title and still includes
  - Complaints
  - Interim findings
  - Relevant multi-center trial reports

Changes to “Number of Subjects” Smartform

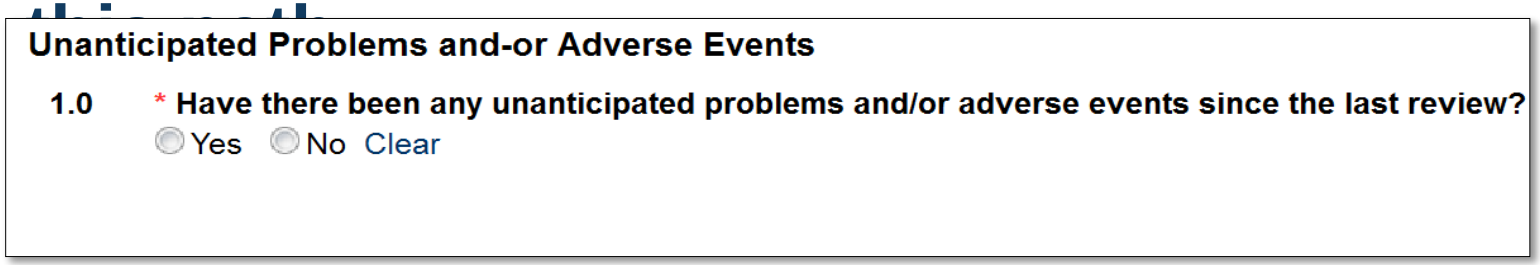
Original Smartform

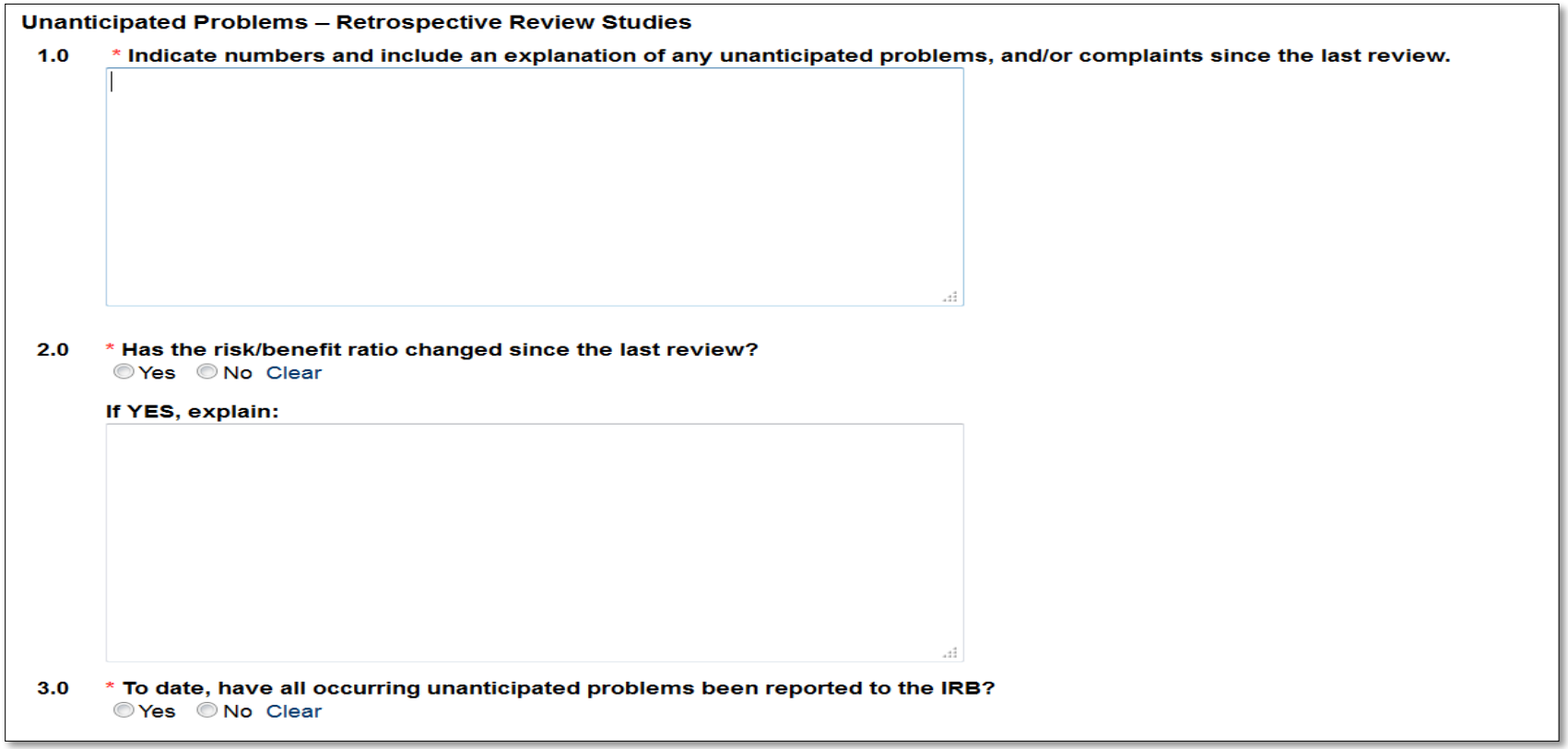


New Retro Smartform



A ‘Yes’ response to below question includes the next Smartform that’s been modified for





And Finally….

Retrospective Review - Summary and Next Steps

1.0 **Study Status:** Enrolling Subjects and/or Collecting Data

2.0 **Consent waiver requires changes:** no

3.0 **Protocol document requires changes:** no

4.0 **An Amendment is required if you answered yes to any of the above questions.**

5.0 Select the **'Finish'** button to exit this page. If you are the Principal Investigator, you may select on the **'Submit'** activity in the Continuing Review workspace to send to the IRB Office.

A New Protocol Template– A template designed specifically for retrospective studies

Expedited Retrospective Review Protocol: Key Points

- What type of data will be collected?
  - Chart data, scans, specimens, etc.
- From where will it come?
  - Internal medical records or external source
- How many subjects?
  - Give maximum
- What information will be recorded?
  - Be specific: MRN, discharge dates, lab values, test results, etc.

Key Points (cont.)

- Where will the data be stored?
  - MUSC network storage!
- How will confidentiality be protected?
  - Coding of data (data points kept separately from identifiers - name, MRN, etc. - and linked using a code), all stored on MUSC network
- Will data be maintained in accordance with IRB and OCIO data storage policy?
  - Maintain research data for 6 years

SCTR
South Carolina Clinical & Translational Research Institute

QUESTIONS?