eIRB

Electronic Institutional Review Board

User Guide

For more information contact:
Research Administration
(803) 434-4899

Developed August 2008 by Research Development
University of South Carolina
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Introduction

Research Administration (RA) provides support and training for faculty members, researchers, students and staff in regulatory requirements for scientific research. RA is responsible for the development and implementation of university policies related to use of human subjects in research (Institutional Review Board), conflicts of interest, misconduct in science, and other regulatory compliance programs. RA also supports the Palmetto Health community in promoting the responsible conduct of research.

The eIRB is a web-based, electronic method to submit, track, and review Human Subjects Applications, including continuing reviews, adverse events, and protocol changes. The system was developed in conjunction with the partners of Health Sciences South Carolina (HSSC) and is designed to allow Palmetto Health researchers to submit applications to the IRBs at other HSSC institutions. USC requires that all human subject applications/notifications be submitted through the eIRB system found at http://eirb.healthsciencesusc.org.

What needs IRB Review and Approval?
Any research activity involving human subjects conducted by Palmetto Health faculty, staff, and students must be reviewed and approved for compliance with regulatory and ethical requirements before it may be undertaken. These activities include a wide variety of procedures such as, but not limited to, research on medical records, collection of data through surveys or observation, research using existing pathological specimens, discarded tissue or secretions, use of investigational drugs or devices and randomized trials.

Certain studies involving human subjects may be exempt from IRB review. Exempt projects fall into defined categories (see Categories for Exempt Research). Exemptions must be approved by the IRB. The project must be approved by the IRB if it meets the following criteria as defined under “Research” and “Human Subject”:

Research is defined as:
A systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to generalizable knowledge, or Activities portrayed (explicitly or implicitly) by faculty, students, or staff as “research”, or Work that is intended to fulfill requirements for a master’s thesis, doctoral dissertation, or other research requirements of Palmetto Health.

Human subject is defined as:
A living individual about whom an investigator conducting research obtains
   1) data through intervention or interaction with the individual, or
   2) identifiable private information.

Intervention includes both physical procedures by which data are gathered or manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communications or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, and information, which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.
NOTE: The FDA additionally defines a human subject as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. Because the above definition excludes non-living humans, research that uses autopsy materials or cadavers is not 'human subjects research' and therefore is exempt from review.

Non-Research Activities (IRB review not required)
Certain activities have the characteristics of research but do not meet the definition of research for IRB review. These activities do not require review by the IRB. Examples of data collection or observation activities that do not require review include:

- Data collection for internal departmental or other institutional administrative purposes (e.g. teaching evaluations, student evaluations, and “customer service” surveys), and
- Program evaluation carried out under independent contract for an external agency that is for their internal purposes only. Examples include personnel studies, human cost benefit analysis, treatment effectiveness studies, and customer satisfaction studies.

Patient care related activities (e.g., quality assurance) that involve the use of human participants but have no connection with research beyond improvement in care preclude the need for IRB review. However, efforts that lead to presentation outside of the institution and/or the publicizing of the initiative’s outcomes in any manner are considered research. Palmetto Health employees are encouraged to consult with IRB staff to determine the appropriate procedures for assuring that such projects conform to ethical guidelines.

An IRB application cannot be approved until study team members have received Human Subjects training. (Note: The application may be submitted, but final approval will not be granted until training requirements are satisfied.) For training information go to http://www.palmettohealth.org/bodyframe.cfm?id=35.
Register

To register in the eIRB system:

Go to the eIRB home page (http://eirb.healthsciencescsc.org)

Click on Registration link.

All required fields must be completed.

Students should enter a mentor’s (advisor) name. Mentors must be registered before a student application can be submitted to the IRB.

Students should list the college and/or department they are affiliated with at USC.

Click the Register button

Upon validation of the registration, an email notification will be sent containing a username and temporary password.

Email messages generated by the eIRB system will begin with “No Reply@eIRB....” If validation of registration is not received within a day, contact (803) 434-2652.
Login

Go to the eIRB home page (http://eirb.healthsciencessc.org)

Click the Login link.

Enter Username and Password and click Login.

The Personal Workspace screen or My Home will open.

Active Roles will be identified in the Navigation Column.

Roles:

- **Study Staff** – Includes the principal investigator (PI), co-principal investigator (Co-PI), study coordinator, research assistants, and other personnel designated by the investigator. The study staff role allows users to create a new study application.
- **Mentor** – This role allows the mentor to approve and monitor a student’s IRB application.
- **IRB Member** – This role allows IRB members to review submitted study applications.

Note to Mentors: Only after the student has submitted the study will it appear under the Inbox tab on the mentor’s Personal Workspace screen. The mentor will be able to return the study to the student for revisions or approve the study to be forwarded on to the IRB for review.
My Home

The eIRB “My Home” page is the investigator’s personal workspace. From this screen the investigator can access his/her approved eIRB studies and view those studies awaiting action.

Tabs on the Personal Workspace screen are:

- **Inbox** – contains all studies and other applications requiring action.
- **Studies** - to view all applications associated with the principal investigator in the eIRB system.
- **Reportable Events** - to view reported adverse and unanticipated events.
- **Amendments** - to view changes to approved studies.
- **Continuing Review** - to view applications for continuing review.
- **Templates** – to view all saved templates (see section on how to save templates).

Click **My Home** at any time to return to the Personal Workspace screen.

Click on **Study Staff** to open
Creating a New Application for Research Studies

The principal investigator or designated members of the Study Staff may complete a study application. To begin:

On the Personal Workspace screen, click **New Study**.

All fields marked with a red asterisk (*) must be completed.

Click the **Continue** button to advance to the next page, which saves the information and assigns a number to the application.

Clicking the **Finish** button at the end of the application returns the user to the **Study Workspace**; it does not submit the application.
Adding Study Personnel

The system will assign the creator of the application as the Principal Investigator (PI). This role may be reassigned by following the directions below. The following directions may also be used to assign the Study Coordinator, co-investigators and other study team members:

Click on the Select or Add button under each of five (5) questions. This opens a list of valid users.

Only one principal investigator and one study coordinator are allowed per application.

More than one person can be selected under co-investigator(s), study team members and guest.

To limit the list to only Palmetto Health personnel, use the Filter by feature. Select Organization from the drop down list and type “%ph” in the field.

Click on the Go button.

Only one name at a time can be selected. Click OK to add name to the application.
If a person’s name is not listed, either they have not registered or the chosen role was not assigned.
- To register, see the registration section in this guide.
- To have additional roles added contact Mark Spasser at mark.spasser@palmettohealth.org

To add more than one person, click Select from the pop-up screen and choose a name from the list and click OK and ADD Another.

Names will be listed on the application; however, only one name at a time will appear on the pop-up screen.

Go to [http://www.palmettohealth.org/bodyframe.cfm?id=35](http://www.palmettohealth.org/bodyframe.cfm?id=35) for additional information concerning IRB policy and procedures, examples of consent documents and review categories (e.g. Exempt, Expedited or Full Board reviews).

**Uploading Documents**

Upload only those documents requested. Other documents will be requested at appropriate points in the application.

Click the **Add** button to open a browser window.

Click the **Browse** button to locate the file.

Upon initial use of the eIRB system, a warning message may appear. Click **OK** or **GO** to both warnings. These warning messages should not appear during future applications from this workstation.

To add additional files click **OK and Add Another**.
Uploaded files will be listed in the area below the corresponding question.

- To delete an uploaded document, mark the check box and click the delete button.
- To revise a currently uploaded document, click the [Edit] button to open a browser window and upload the new file.

A one inch margin at the bottom of consent documents is required to allow for the approval stamp.
Subject Populations and Checklist

Answers to the following items determine which follow-up questions must be answered. Be sure to check all that apply to the study to ensure a complete application.

Check all subject populations involved in the study.

Check all activities/items involved in the study.

Save Application

To save but not submit an application, save as follows:

Click Save and Exit to return to the Study Workspace page without submitting the application.
Retrieve Pre-Submission Study and Edit

To edit an application in the pre-submission state:

Click on the Name of the study.

On the Study Workspace screen, click Edit Study.

Use the Back and Continue buttons to navigate through the application.
Submit Application

Applications may be completed by co-investigators, research assistants or other designated members of the Study Staff, but only the Principal Investigator can submit the initial study application.

From My Home, click on the Name of the study to open Study Workspace screen.

From the Study Workspace screen, click Submit Study.

Read the investigator assurances statement. Check the box next to the “I agree” statement and click OK.
The Study Workspace screen shows that the application has been assigned to the IRB.

The only activities available to the Study Staff at this point are also listed.

The application cannot be edited after it is submitted. Study Staff are allowed to edit study access or withdraw the submitted application.

Review Process

Full Review:
Under the full review mechanism, the IRB may take one of four actions in regard to the protocol and consent forms.

a) Approved: The investigator is sent an approval letter accompanied by an informed consent/assent document with the “IRB Approval” validation stamp.

b) Revisions and/or Additional Information Required: The investigator is sent a letter describing the revisions requested. After revision of the protocol and/or consent form, the investigator returns two (2) copies to the Research Administration office. The revisions or additions should be underlined or highlighted and reference made to the IRB number. Also, if revisions to the consent/assent form(s) are necessary, the investigator submits one clean copy of the revised consent/assent forms without highlighting or underlining. If approved, the consent/assent form(s) are returned to the investigator with a valid “IRB Approval” stamp. The revisions are forwarded to the Chairperson or a designated representative for review. If the changes are satisfactory, an approval notice is sent to the investigator along with the clean copy of the revised consent/assent form(s) with the valid “IRB Approval.” Subjects can only be enrolled using informed consent/assent forms which have a valid “IRB Approval” stamp, unless waiver from this requirement is granted by the IRB.

c) Tabled: The investigator is sent a letter which lists the reasons for tabling and includes a description of the revisions or clarifications requested. For some studies, one or more members of the IRB may be appointed to discuss the reasons with the investigator. After revising the protocol and/or consent form, the investigator submits the response to the Research Administration office. The protocol is then rescheduled for review by the IRB. For some studies, the investigator is required to attend the IRB meeting at which the revised protocol is reviewed.
d) **Disapproved:** The investigator is sent a letter describing the reasons for disapproving the protocol. One reason for disapproval of a protocol is the determination that the risk of the procedures outweighs any benefit to be gained.

**Expedited Review:**
Criteria for expedited review are delineated in the Code of Federal Regulations, Title 45, Part 46. For a copy of these regulations, contact the Research Administration office.

Under the expedited review mechanism, the review is carried out by a subcommittee which is comprised of the Chairperson and/or designated members of the IRB. The subcommittee may exercise all of the authorities of the IRB, except that it may not disapprove the research. The subcommittee’s recommendations usually fall into the three categories listed below. The subsequent procedures to be followed are identical to those described above.

a) **Approved;**

b) **Revisions and/or Additional Information Required;**

c) **Protocol Requires Full Review:** The investigator is sent a letter which indicates that full review is necessary and outlines the revisions or clarifications necessary for the submission of the protocol for review by the full board. The decision to require full review is made when the subcommittee is unable to satisfy its concerns regarding the rights and well-being of the subjects, crucial aspects of the protocol require clarification, or the protocol fails to meet the expedited review categories which are specified by the federal regulations.

**Exemption Review:**

Criteria for exempt procedures are delineated in the Code of Federal Regulations, Title 45, Part 46. For a copy of these regulations, contact the Research Administration office. The exemption certification review is conducted by the Chairperson and/or a designated representative.

The reviewer may take one of three actions.

a) **Exemption Certification Approved:** Investigator is sent a letter confirming the procedures regarding human subjects in the protocol are considered exempt under federal regulations.

b) **Additional Information Required:** The investigator is contacted by the reviewer or sent a letter describing the information required. The investigator provides the information requested. If the reviewer is satisfied that the protocol meets the exemption criteria, then a letter confirming the exemption of the study is sent to the investigator.

c) **Exemption Certification Disapproved:** The investigator is sent a letter indicating that the protocol does not fall within the exemption categories. A new application must be prepared and submitted for full review.

**Reminder:** Investigators will not receive approval for human subjects’ research until training is completed.
Check Progress

To check the progress of an application in the review process:

Go to My Home and select the Studies tab.

The state of the study can be found under State on the summary line.
Respond to Changes Required by IRB Staff

The returned application will appear under the Inbox tab and “Changes Required By IRB Staff” will appear under State on the summary bar.

Click on the Name of the study to open Study Workspace screen.

The history line will show there are changes requested by the IRB Staff.

Requested changes may be included in summary form as a general comment and/or under reviewer notes.

Click Reviewer Notes tab to access reviewer’s comments.

The Jump To feature allows the user to answer question on each screen. Clicking on the page name after “Jump To” will allow the user to go directly to that page of the application.
Click on the arrow next to **Reviewer Notes** to view the reviewer’s request.

If the reviewer comments text exceeds the space on the screen, click on **IRB Change Request** to open the comments box.

To respond, use the **click here to respond** link.

Select the **Type** of response (e.g. change request completed, change request not completed, or information only) and use the Response box to reply.

After locating the first request for changes, use the **continue** button to jump to the next request.

When finished, click **Exit** to return to the Study Workspace screen.
Click **Submit Changes**.

Use the pop-up window to add final comments.

Click **OK** button to submit.

Once changes are submitted the study returns to **IRB Staff Review**.
Submit an Amendment

Amendments can be submitted only for approved active studies, and only one amendment can be processed at a time. To submit an amendment, go to the Study Workspace for the approved active study:

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<tr>
<th>Click the <strong>New Amendment</strong>.</th>
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<tr>
<td><img src="image1" alt="New Amendment" /></td>
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<tr>
<th>Click the <strong>continue</strong> button to navigate through the required screens. (See editing documents and making changes to the study in this Guide.)</th>
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<td><img src="image2" alt="Continue Button" /></td>
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<tr>
<th>After you have completed all the fields, click <strong>Finish</strong> then click <strong>Submit Amendment</strong>.</th>
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<td><img src="image3" alt="Finish Button" /></td>
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Report of Adverse or Unanticipated Events

To report an adverse event:

Open study in Study Workspace and click the **New Adverse Event** button.

Click **Continue** to navigate to the next screen.
Submit a Continuing Review

Open study in Study Workspace and click **New Continuing Review**.

Use the **Continue** button to navigate through the form.

Clicking **Finish** returns user to the Study Workspace, it does not submit the application.

Click the **Submit Continuing Review** button.

Only IRB Staff requested changes can be made at the time of the Continuing Review. If the protocol and/or informed consent document(s) require changes at the time of continuing review the request must be made through the amendment process.
Print Application

The print version of the study includes only the required application sections. To print the application, go to the Study Workspace:

Click **Printer Version**.

Click the **print** button.

Click the **print** button.
Copy Study

To copy an existing study to use as a template for future studies:

Click **Copy Study**.

Complete the fields on the screen and click **OK**.

All attachments will be copied.

A copied study retains the **principal investigator** and will be placed in the **inbox**.
**Edit Study Access**

To allow additional personnel access to a study application:

1. Click on the *Name* of the study.

2. Click the *Edit Study Access* link on the Study Workspace screen.

3. Click the *select* button then click *OK*. See previous instructions for adding personnel.
Profile

Update Profile Information

To update your profile in the eIRB system:

On the Personal Workspace screen click Username.

Update profile information then click Apply.
Change Your Password

On the Personal Workspace screen, click **Username** in the upper right corner of the screen.

Click on the **Account** tab.

Enter **Current Password** and **New Password** then click **Apply**.

Changes are effective immediately.