

OVERVIEW OF USCeRA APPLICATION PROCESS

NOTE: Under No Circumstances May Research Begin Without Specific Approval by the IRB. Additionally, final IRB approval letters will not be issued until Human Subjects Training has been completed.

We suggest that you complete the required human subjects training **prior** to completing your Human Subjects Application (HSA) so that you will have adequate knowledge of the ethical issues and legal requirements involved (see <http://orc.research.sc.edu/PDF/InvestigatorTraining.pdf> for more information). This also should speed the time required for completing the HSA and facilitate the drafting of appropriate consent/assent documents.

Please ensure that there is appropriate time for obtaining approval prior to beginning any research on human subjects. To process the HSA in a timely manner, adhere to the stated deadlines and complete and submit all of the requested documents.

Applications must be submitted through USCeRA (see <http://orc.research.sc.edu> or <http://sam.research.sc.edu>). USCeRA is the University's web-based application processing system.

Look for the acronym USCeRA (lower left of the screen). Click on it.

If you have not already registered in USCeRA, please complete your profile giving yourself a username and password (this may be different from your VIP login, or you may choose the same ID and password). You will find the registration link in the red box, upper left of the screen.

Log into USCeRA and click on "Human Subjects Application" (see red box in upper left of screen). Complete the online application form. Please note that each narrative box in the application has limited space. If you insert one character over the allotted 255 characters, an error will occur and the HSA will not be saved. If you need more space, upload a separate word document.

At the bottom of the form, there are buttons to "Save But Don't Yet Submit" and to "Upload/Manage Documents." Use the "Upload/Manage Documents" button to upload copies of the following required application documents:

- Project abstract/summary written in laymen's terms addressing the involvement of human subjects (one page maximum)
- Consent Form(s) (if applicable)
- Full description of the study (research proposal/dissertation/thesis)
- Survey Instrument(s)/ questionnaire(s)
- Cover letter (if appropriate)
- Subject Recruitment materials (e.g. flyers, advertisements)
- Letter of Support from Faculty Advisor (required for students). This may be a copy of an e-mail to you (saved and uploaded to USCeRA) or a signed memo or letter. It must verify the faculty advisor supports project, and more specifically whether they believe that: 1) the research design is appropriate to answer the study question(s), 2) the research methods and procedures are appropriate, and 3) the proposed research is of sufficient importance to justify the risks entailed (if any).
- Letter verifying permission to recruit at site (e.g., school, daycare center, physician's office, etc.)

Click on the "Save But Don't Yet Submit" button often when compiling the information for the application; otherwise the material may be lost. When you click on "Save But Don't Yet Submit", a date will be inserted at the top of the HSA form next to "Submission Date". However, this does not necessarily mean that your HSA has been submitted to the IRB (unless you clicked on the "Submit" button).

To retrieve an HSA once it has been saved but not submitted, log into USCeRA and click on the "Search HSAs" link (in the red box). The next screen will ask for Form Type, make sure it says "Human Subjects Application." **Leave all fields blank** and click on the "Search" button. This will retrieve all of the HSAs that you have saved. Project titles will appear in blue. Click on the title of the HSA that you are working on, and it will open.

Click on the "submit" button only when you have completed the HSA form and uploaded all of the required documents. Once submitted, you will be locked out of the form until it has been reviewed by the IRB. If you accidentally submit before you are ready, e-mail Arlene McWhorter at arlenem@gwm.sc.edu, and she will return the HSA to you.

Once you submit your HSA, it will be forwarded to the Office of Research Compliance. A preliminary review will be conducted to determine whether the selected review category is correct. In many instances, the reviewer will return the HSA to you requesting clarification or additional information about your application. Check your USCeRA e-mail messages frequently (it is important that your e-mail address is correct on the HSA form for this reason). The email message will say only that there is activity in your USCeRA inbox. You must log into USCeRA to read the message(s). Use the retrieval directions given above (i.e., Search HSAs) to access the returned HSA. When responding to the reviewer's request, **do not** start a new HSA or use the Protocol Change/Update link. The Protocol Changes/Update link is used only for studies that have been approved by the IRB. Respond to reviewer questions by uploading a document titled "Response to IRB Questions" to USCeRA, and to a request for revisions to the consent/assent or other supporting materials by uploading revised versions to USCeRA. Click on "Submit" when you are ready to return the HSA to the IRB.

If you still have questions, contact the Office of Research Compliance at (803) 777-7095 or arlenem@gwm.sc.edu.

Reminder: Investigators will not receive approval for human subjects' research until training is completed. Alternative training options must be approved by ORC.

Overview of IRB Review Process

EXEMPT RESEARCH *(No submission deadline)*

Human Subjects Application (HSA) for exemption may be submitted at any time; see the drop-down menu in USCeRA or <http://www.orc.research.sc.edu/PDF/ExemptResearch.pdf> for Exempt Review categories. Once submitted, the HSA routes to the Office of Research Compliance for review. If ORC determines that the project is not exempt, the investigator will be notified through USCeRA if revisions are needed.

The investigator will receive notification through USCeRA when ORC has approved the study. ORC will verify that you have satisfied training requirements, and issue a formal letter of approval via e-mail shortly thereafter. Consent documents are not required to be stamped by the IRB.

Once approval is given, no further action or oversight by the Institutional Review Board is required, as long as the study remains the same. Changes to the study may cause a reclassification in the review category; therefore, any change made to the study must be reported to the IRB. Changes are to be reported through USCeRA (see Project(Protocol) Change/Update). The IRB must review and approve the change(s) before the investigator proceeds with the project.

EXPEDITED RESEARCH *(No submission deadline)*

Research that falls into categories designated as minimal risk qualifies for Expedited review; see the drop down menu in USCeRA or <http://www.orc.research.sc.edu/PDF/ExpeditedReview.pdf>.

Prior to final approval, investigators may be required to respond to questions, provide additional information, and/or make revisions to the proposed research plan and/or consent/assent form(s). Once ORC grants preliminary approval of the HSA, it will be forwarded to the Chair of the IRB, or to his designee, for final review and approval. Once the IRB Chair approves the HSA, the investigator will receive notification through USCERA.

ORC will verify that training requirements have been satisfied, and a formal letter of approval and IRB stamped consent/assent documents will be sent via e-mail shortly thereafter. The IRB stamp will indicate when the study expires.

The IRB stamped consent/assent should to be used as a master to copy for all subject consents. Subjects may only be enrolled using informed consent/assent forms that have a valid "IRB Approval" stamp. Printed copies of PDF documents uploaded to USCeRA often do not print well, and we suggest that you arrange to bring the document(s) by the ORC office to be stamped or e-mail them to arlenem@gwm.sc.edu.

Changes to the protocol or consent/assent forms must be reported to the IRB (see Protocol Change, below). In most cases, approval for minimal risk research will remain in effect for one year. You will be required to complete a "Continuing Review" form through USCeRA when your study concludes, or to receive approval to continue conducting your study.

REVIEW AT A CONVENED MEETING

The deadline for submission of research protocols for review by the full board is ten (10) days prior to the date of the meeting. Meetings are generally scheduled on a monthly basis (check ORC website for listed dates). To obtain IRB approval for this category, submit a Human Subjects Application (HSA) through USCeRA.

The Chair will convey one of the following four decisions of the IRB in writing to the principal investigator promptly after the meeting.

Approval: If the study is approved as submitted, the investigator will receive a notice through USCeRA. Before the research can proceed, the informed consent form(s) must be stamped with the IRB approval dates.

Deferred (Expedited): The IRB determines that there are non-substantive issues related to research procedures that need clarification and/or minor revisions to the consent/assent form are needed. Comments will be sent to the investigator through USCeRA. The investigator should make changes and return the revised material through USCeRA. The IRB's Designated Reviewer will verify that all the requested modifications have been addressed appropriately. The designated reviewer may approve the HSA on behalf of the IRB, or refer it back to the Full Committee. Upon approval, the investigator will be notified via USCeRA. Before the research can proceed, the informed consent form(s) must be stamped with the IRB approval dates.

Deferred (Full Committee): The IRB determines that the research protocol and consent form(s) require major revision or there are significant questions related to subject participation. The investigator must resubmit revised materials and supporting documentation for consideration at a convened meeting. The investigator is encouraged to attend the ensuing meeting to answer questions.

Disapproved: A study is disapproved if the IRB determines that the risks to subject welfare are not justified by the potential benefits of conducting the research. The investigator may appeal the decision of the IRB. The IRB or a subcommittee of the IRB will consider (either in person or in writing) such appeals. Upon consideration of the appeal, the decision may stand (disapproved) or, if appropriate, the decision may be to approve as resubmitted, or approve after required modifications. Approval of a previously disapproved study may only be given at a convened meeting of the IRB. There is no avenue of appeal beyond the IRB and the IRB cannot be overruled.

OTHER PERTINENT REVIEWS

CONTINUING REVIEW (*pertains only to Expedited and Full Board Reviews*)

Studies reviewed by the IRB may be approved for up to one-year. In order to maintain IRB approval, the investigator must complete the Continuing Review (CR) form and submit it in sufficient time for review/approval prior to the expiration date. If changes are proposed to any of the consent/assent documents, a “red lined” or “track changes” version should be uploaded along with a clean/final copy to be stamped by the IRB.

Note: There are no provisions to cover lapsed periods between IRB approvals; therefore, there can be no study activities (e.g. enrollment, intervention, data collection) involving human subjects during the lapse in approval.

PROTOCOL CHANGES (*pertains to all review categories*)

Changes to approved projects must be reported to the IRB. The IRB must review and approve the changes before the investigator can proceed with the project. If the initial study was submitted through USCeRA the request for a protocol change also must come through USCeRA. For older studies approved prior to USCeRA, a hardcopy of the “Protocol Change/Update” form should be completed, and a PDF of it should be uploaded to a new HSA form (see <http://orc.research.sc.edu> under Forms). If changes are proposed to any of the consent/assent documents, a “red lined” or “track changes” version should be uploaded along with a clean/final copy to be stamped by the IRB.