University of South Carolina
Overview of the IRB Application Process

NOTE: Under No Circumstances May Research Begin Without Specific Approval by the IRB.

We suggest that you complete the required human subjects training prior to completing your IRB Application, so that you will have adequate knowledge of the ethical issues and legal requirements involved. This also should speed the time required for completing the application and facilitate the drafting of appropriate consent/assent documents. Final IRB approval letters will not be issued until Human Subjects Training has been completed.

Applications must be submitted through the eIRB Research Portal. eIRB is a web-based system that allows USC researchers and others who are affiliated with a Health Sciences South Carolina (HSSC) member organization to manage the IRB review process.

For additional IRB information go to http://orc.research.sc.edu click on “Human Subjects Research” then click “Institutional Review Board.”

IRB Review Categories

The level of IRB review primarily depends on the potential risks to the subjects involved in the research. As the potential risks to subjects increases, so too does the level of review required by the IRB. The three levels of review and procedures for approval for each are as follows:

EXEMPT RESEARCH (No submission deadline)
Exempt research categories are defined in the Federal regulations governing research involving human subjects. These categories include the following:

- Study of normal educational practices in commonly accepted educational settings
- Survey/interview/educational testing of adult subjects (anonymous data collection or about non-sensitive topic areas)
- Survey/interview/educational testing of public officials
- Public observation of adults and children (if researchers do not interact with the children)
- Use of existing data or specimens if researchers do not record identifiable information
- Taste and food quality evaluation and consumer acceptance studies

Research involving prisoners does not qualify for exemption, and research involving other vulnerable subject populations, including children, may not qualify for exemption. For more details, see: (Categories for Exempt Research).

An IRB application for exemption may be submitted through eIRB at any time. If you are a student, the application will route to your faculty advisor/mentor for approval before it is reviewed by the Office of Research Compliance (ORC). ORC will determine if the study qualifies for exemption. The investigator is notified through eIRB if there are questions or issues that need to be addressed prior to approval, and when final approval is granted. ORC will verify that training requirements have been, and issue a formal letter of approval. The
formal approval letter will be uploaded to eIRB. Exempt studies do not require a stamped and dated consent document.

Once the exemption is granted, no further action or oversight by the Institutional Review Board is required, as long as the study remains the same. Substantive changes to the study may cause a reclassification in the review category; therefore, such changes made to the study must be reported to the IRB. Changes are to be reported through eIRB, by completing an Amendment application. The IRB must review and approve the change(s) before they are implemented.

**EXPEDITED RESEARCH (No submission deadline)**
Research that falls into categories designated as minimal risk qualifies for Expedited review. The Expedited Categories include the following:

- Collection of blood samples by finger stick, heel stick, ear stick or venipuncture.
- Collection of data through noninvasive procedures (e.g., weighing, moderate exercise, muscular strength testing, body composition assessment) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

For additional categories and more details, please see: (Categories for Expedited Review). An IRB application for expedited review may be submitted through eIRB at any time. If you are a student, the application will route to your faculty advisor/mentor for approval before it is reviewed by the Office of Research Compliance (ORC).

Prior to final approval, you 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 application, the application is forwarded to the Chair of the IRB, or to his designee, for final review and approval. Upon approval by the IRB Chair or designee, the investigator will receive notification through eIRB.

ORC will verify that training requirements have been satisfied, and a formal letter of approval and IRB stamped consent/assent documents will be uploaded to eIRB. The IRB stamp on the consent/assent documents indicates the IRB approval dates. The IRB stamped and dated consent/assent should be used as a master to copy, and subjects may only be enrolled using informed consent/assent forms that have a valid “IRB Approval” stamp.

In most cases, approval for minimal risk research will remain in effect for one year. Upon expiration of approval, a “Continuing Review” application must be submitted in order to renew the IRB approval. Changes to the protocol or consent/assent forms must be submitted to the IRB for review and approval, using the Amendment application in eIRB.

**REVIEW AT A CONVENED COMMITTEE MEETING (Full Board Review)**
If your study does not qualify for exempt or expedited review, review at convened meeting of the IRB is required. The deadlines for submission of research protocols for review by
the full board are on the IRB website. Meetings are generally scheduled on a monthly basis (check the IRB website for listed dates). The application is submitted through eIRB to the Office of Research Compliance (ORC), where a preliminary review is conducted. ORC may return the application and request clarification or revision in preparation for review by the IRB.

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

**Approved:** If the study is approved as submitted, the investigator will receive a notice through eIRB. The formal approval letter and stamped consent/assent documents (if applicable) will be uploaded to eIRB.

**Approved with Contingencies:** The IRB determines that the study may be approved once non-substantive issues related to research procedures are clarified and/or specified revisions to the consent/assent forms are made. Comments will be sent to the investigator through eIRB. Upon receiving the investigator’s response, the IRB’s Designated Reviewer will verify that all requested modifications have been addressed appropriately. The designated reviewer may approve the application on behalf of the IRB, or refer it back to the full committee. Upon approval, the investigator will be notified via eIRB, and the IRB approval letter and stamped consent/assent documents (if applicable) will be uploaded to eIRB. The IRB stamped and dated consent/assent should be used as a master to copy, and subjects may only be enrolled using informed consent/assent forms that have a valid “IRB Approval” stamp.

**Tabled:** 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 Principal Investigator must complete the Continuing Review application in eIRB and submit it in sufficient time for review/approval prior to the expiration date. It is strongly encouraged that Continuing Review applications be submitted at least one month prior to the study’s expiration date. The Principal Investigator, Co-Investigator, and Study Coordinator (if applicable) will receive email notifications at 90, 60, and 30 days prior to the IRB expiration date as a reminder that the study is due for Continuing Review. If changes are proposed to
the study protocol or to any of the consent/assent documents, the investigator must complete a separate Amendment application prior to completing the Continuing Review application.

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 any lapse in IRB approval.

Protocol Changes/Amendments (pertains to all review categories)

Changes to approved projects must be submitted to the IRB. The IRB must review and approve the changes before the investigator can proceed with the protocol. Protocol changes are requested by completion of an Amendment application in eIRB. If changes are proposed to any of the consent/assent documents, a “red lined” or “track changes” version must be uploaded.

Reportable Events and Adverse Events
According to 46 CFR Part 46, to be considered "reportable" (required to be submitted to the IRB) an event must be considered to be an Unanticipated Problem, which means that the event must be:

1. Unexpected (in nature, severity or frequency)
2. Related or possibly related to participation in research and
3. Suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.

Adverse events must be reported to the IRB using eIRB if they meet the criteria outlined above. See the IRB website and OHRP guidance for additional information on Adverse Events.

Other Reportable Events include such things as DSMB reports, FDA/Government Sponsor Monitoring or Audit Reports, Follow up reports for previously submitted Reportable Events, and Internal Monitoring/Audit Reports. These reports must be submitted using eIRB.

Protocol Deviations

A Protocol Deviation is any departure from the procedures and treatment plans as outlined in the protocol as submitted and approved by the USC IRB. Protocol deviations are unplanned and unintentional events. Anticipated changes to a protocol should always be submitted to the IRB as a study amendment before the changes are initiated. Protocol deviations have the potential to place participants at risk and can also undermine the scientific integrity of the study thus jeopardizing the justification for the research. The Principal Investigator must complete and submit a Reportable Event application in eIRB for all protocol deviations that occur during the course of a study immediately upon discovering them and no later than 10 working days following the discovery.

The Principal Investigator also reports all protocol deviations to the sponsor, if applicable, following the sponsor's requirements.