IRB Application Checklist

The Institutional Review Board (IRB) at SC State is responsible for the review and approval of all human subject research on campus. An application to conduct human subject research on campus should be submitted to one of the following:

Mr. Elbert Malone, Co-Chair of IRB, malone@scsu.edu   Room 410 Belcher Hall, 536-8213
Dr. Donald Walter, Co-Chair of IRB, dwalter@scsu.edu   Room 130 Davis Hall, 533-3773

Deadlines September 6, 2016 – May 2, 2017:

Submission Deadline: The first Tuesday of each month beginning with September 6, 2016 and ending May 2, 2017 Note that the IRB does not hold regular meetings during the period May – August.

The IRB is entitled to 60 days to review a proposal once it is filed correctly and completely. The IRB strives to notify the PI of the status of their proposal within 30 days of the above deadlines. In some instances this may take longer but will be within the 60 day period allowed. Notification of approval will be in the form of a signed letter. Human subject activities may commence on the date indicated on the approval letter.

All of the following documents are to be **submitted in digital form through email**, including scanned copies of signed originals. Submit as a single document if possible. For security purposes, documents should be submitted in PDF, JPEG or TIFF format. **Use the most recent documents found at : http://www.scsu.edu/facultystaff/universityforms.aspx under Sponsored Programs.**

1) The SC State Application/Protocol Form must be submitted. All items need to be completed including the signatures of the Principal Investigator (PI) and the Chair, Dean or appropriate supervisor of the PI.

2) The SC State Informed Consent Form must be completed. Signatures are not required on the copy provided to the IRB.

3) Both the PI and the Co-PIs listed on the Application/Protocol Form must provide proof that they have completed NIH training in Human Subject Research. This requirement also applies to all other individuals not listed as PI or Co-PI including any student researchers who will have access to confidential information about the research subjects. Certification of completion of training must be provided as part of the application packet. **Note that a certificate is to be filed with the packet every time someone submits an application.** Previous copies of certificates are not retrieved by the IRB. Training and certification can be found at:
http://phrp.nihtraining.com

4) An **executive summary** or copy of the technical/scientific/management/implementation portion of the proposal or research project must be provided in addition to answering all of the questions on the forms above. Details regarding methodology and techniques are to be included here. A copy of the budget is not required. Please do not submit an entire thesis or proposal.

5) A letter of commitment or support must be submitted by any individual or institution that provides access, support or a service that is part of the human subject research. Examples include a letter from a principal or superintendent of a school allowing access to their campus and students; or, a letter from a clinic stating that they will be responsible for sampling and

testing the blood of participants.   Each letter must state the nature of the commitment and explicitly reference the PI and the title of the project.

6) A copy of all questions to be administered to human participants is to be included in the application package for IRB review. This applies to all questions regardless of the manner of delivery, whether administered in person (e.g. an interview) or anonymously (e.g. web survey) or by other means.

7) Students, whether graduate students or undergraduates, cannot be listed as a Principal Investigator on the forms even if the work is part of their thesis or dissertation work. A faculty member, administrator or staff member must be listed as the Principal Investigator. Students are to be listed in the appropriate field on the front page of the application form. **A faculty member can be listed as both the Principal Investigator and the Supervisor in the case where the proposed research is being conducted by a student for their thesis or dissertation.**

8) When SC State students are to be the subject of the study, the investigator must get the approval of the Vice President for Student Affairs prior to submitting the application to the IRB. The PI is to provide proof of this approval as part of the application packet submitted to the IRB. This proof should be in the form of an email message or a scanned hard copy letter of approval from the Vice President for Student Affairs. In the approval document, the Vice President must state that they "approve the participation of SC State students" in the study.   The approval document from the Vice President must also list the title of the project and include the name of the Principal Investigator in the body of the document.

9) Note that Item #11 on the Application/Protocol Form and Item #5 on the Informed Consent Form are often submitted with inadequate information provided and the IRB has to delay approval of the application until the PI has been contacted and submits the additional information. Be sure to answer all of items in both #11 and #5. The answers to these two sections should be identical.

Additional Requirements for Outside Researchers:
It should be noted that anyone who wishes to conduct human subject research on the campus of SC State and who is not a member of the SC State faculty, staff or administration, must include on their Application/Protocol form a collaborator from the campus as a PI or Co-PI. This is not to imply that the SC State collaborator must be paid or funded. They are, however, to serve as a local point of contact and responsible member of the SC State community during the period while the research is conducted.

Outside researchers must also submit a copy of the approval of the study by the IRB at their home institution.