Additional Frequently Asked Questions

About the Application Process

What training is required before I submit my research for review by the SAGU IRB?

The SAGU IRB requires all principal investigators to complete a free online training course hosted by the National Institutes of Health Office of Extramural Research before submitting your IRB Application. This self-paced course is titled, "Protecting Human Research Participants." You may access the course at http://phrp.nihtraining.com/users/login.php.

This course can be completed in approximately two hours. Upon successful completion of the course, you should print at least two copies of the "completion certificate" from the NIH/NCI website (the certificates are time and date stamped). A paper copy of the certificate must be submitted as an appendix to the completed IRB application. Another copy may be needed if external funding is acquired. Training certificates are valid for three years from the completion date or upon major changes to Federal Regulations.

What aspects of my proposed research project will be reviewed by the IRB?

The IRB's review of human-subjects research is limited to procedures impacting the ethical treatment of human subjects. The review process focuses on such issues as minimizing risks to subjects, ensuring voluntary participation, verifying that selection of subjects is equitable, ensuring informed consent, and protecting privacy and confidentiality. The complete list of IRB review criteria is set forth at 45 CFR 46.111. The IRB does not review proposals for research merit, although the IRB co-chairs welcome opportunities to assist investigators with strategies to improve their research design and data collection efforts.

What happens if I do not comply with SAGU and Federal regulations regarding human-subjects research?

If non-compliance is alleged by anyone included in, or associated with your research, one of the IRB co-chairs will initiate an investigation. You will be informed of the allegations and given ample time to respond to them. One of the IRB co-chairs will then review the relevant information with the IRB membership and recommend actions to the Vice President for Academics, the designated Institutional Official. Possible corrective actions to be taken include, but are not limited, to:

- destruction of all data collected improperly;
- requiring additional training for the person involved in the non-compliance;
- temporary suspension of an investigator's eligibility to conduct human subjects research;
- notifications to subjects about the non-compliance;
- a letter of reprimand to the person involved in the non-compliance.

Non-compliance can have serious consequences for both you and SAGU. If you conduct human-subjects research without IRB approval or deviate from your IRB-approved protocol, you are personally liable for all risks and damages incurred, which may include legal charges (criminal and civil). Approval for the project may be terminated, and SAGU could be at risk of losing all federal or other funding related to research activities. If the Institutional Official determines the non-compliance to be either serious or continuing, it must be reported to the Office for Human Research Protections (OHRP) and, if the project is sponsored, to the sponsoring agency or entity.

Many social, behavioral, and educational journals require prospective authors to submit proof that all human-subjects research data discussed in the article was approved in advance by an IRB. Failure to obtain prior IRB approval may prevent a scholar from publishing the results of research in a journal or at an academic conference.

IRB approval of my research will expire before I finish your project. What do I do to maintain IRB approval?

You are responsible to submit a renewal request to the IRB at least 30 days prior to the expiration date of the IRB approval. If approval for the research study is not extended prior to the expiration date, all data collection must cease as of the original expiration date, and a new IRB proposal must be submitted for review to obtain IRB approval. Data collection may not resume until a new approval letter has been issued.

If you want to change your research methodology, do you need to resubmit everything to the IRB?

All substantive changes in the project that deviate from the original submission must be approved by the IRB prior to their implementation, except when changes are necessary to eliminate immediate risks to the subjects. You must obtain approval of such a modification by submitting a request to the IRB describing in detail all the proposed change(s) and attaching a copy of any revised informed consent forms, survey instruments, etc. The relevant IRB co-chair will determine whether review by the full board is needed.

Minor changes such as adding a new research assistant or deleting one of the data collection instruments can be approved by the IRB Chair. If the requested changes are approved, you will receive a letter from the IRB Chair approving the modification. Please note that no changes can be implemented before this approval letter is issued.

If someone participating in my study has an unexpected or negative reaction, what do I do?

Any unanticipated problems, termed adverse events, involving risks to subjects must be reported immediately to the SAGU IRB. The relevant IRB co-chair will report in writing any report of significant adverse events to the SAGU Institutional Official. The Official will, in turn, report as needed to (1) the relevant Department or Agency Head (sponsor), (2) any applicable regulatory body, and (3) the Office for Human Research Protections, as mandated in the Federal Regulations.

My funding agency requires proof of IRB approval before it will release funds, but the money is needed to develop the instruments and procedures for the study. What should I do?

Many times funding is needed to develop and finalize the instruments and procedures that will be used in a study. This presents a dilemma regarding the IRB's responsibility to thoroughly review human subject research submissions prior to awarding of funding. In accordance with 45 CFR 46.118, the following procedure will be used: When an investigator plans to involve human subjects in a research project but has not yet developed the instruments and/or procedures that will be used in the research, an IRB proposal should be submitted that includes all relevant information known at that time. The investigator should indicate that approval is being sought for the purpose of "concept approval" only. The submission will then be reviewed by the IRB co-chairs and, (if applicable), the full board; the project may be approved for the purposes of development only, with the condition that no human subjects may be involved in the proposed project until all instruments and procedures for the study have been reviewed and approved by the IRB.