



APPLICATION TO INSTITUTIONAL REVIEW BOARD/PROTECTION OF HUMAN SUBJECTS COMMITTEE

Research and Investigation Involving Humans

Statement by Principal Investigator (PI) or Program Director and Approved by Department Chairman

Before completing questions in the application, refer to and review the policy and procedures for the protection of human subjects in research institutions. SWOSU Policy and Procedures may be located at <http://www.swosu.edu.osp>

This form is designed for describing proposed programs in which the investigator will be using human participants in their research. If any member of the Institutional Review Board (IRB)/Protection of Human Subjects (PHS) should require additional information, the investigator will be so notified.

Please submit the following to the Office of Sponsored Programs: an Application (one with original signatures), a specimen Statement of Informed Consent, and other documentation such as a Written or Oral Description Form, Survey, Questionnaire, Measurement Tool, etc. These documents should be submitted at least **six (6) weeks before the planned starting date.**

Title of Study: _____

Name of Principal Investigator (PI): _____

Name of Co-Researcher(s): _____

Name of Student Researcher(s): _____

Name of Faculty Sponsor (if applicable): _____

PI or Faculty Sponsor address where approval letter is to be sent: _____

PI or Faculty Sponsor email address and phone number: _____

Estimated beginning date of study: _____

Estimated duration: _____

Do you plan to publish or present in any form (i.e., workshops, journal articles, poster presentations, etc.) the information obtained from this project? : _____

Is this research being conducted for a thesis or professional paper?

Yes ☐ No ☐ For a dissertation? Yes ☐ No ☐

Is this research being conducted for a non-University sponsor? Yes ☐ No ☐

IRB FORM # HS-1 – HUMAN SUBJECTS APPLICATION

Please answer all questions:

1. Brief descriptions of the study. Describe the procedure that relates to the subjects' participation:

What is the research question you are trying to answer, or what is the hypothesis?

Provide a **brief** rationale for this project.

What will the subjects do, or what will be done to them?

How many subjects will you use, and how will they be recruited?

What, gender, age, race, and institutional affiliation will be represented in the subject pool?

2. What are the potential benefits involved in this research or investigation? "Benefits" may relate to the human subjects, area of study, society, general science knowledge, or a specific population.
3. What are the potential risks to human subjects involved in this research or investigation? "Risk" includes but is not limited to the possibility of public embarrassment, improper release of data, emotional reactions, or other issues that may be relevant to your study. Even seemingly non-significant risks should be stated.
4. Outline the steps to be taken to protect the rights and welfare of the individuals involved and all risks identified in #3 above.
5. Outline the method for obtaining **informed consent** from the subjects or from the person legally responsible for the subjects. Attach documents, i.e., a specimen informed consent form. These may be properly executed through completion of either (a) the written description form, or (b) the oral description form. A written description of what is orally told to the subjects must accompany the oral form in the application. Include elements of informed consent cited in the Policy and Procedures for the Protection of Human Subjects document.
6. If the subjects are unable to give legal consent, indicate how consent of parents, guardians, or other qualified representatives will be obtained. If this question is not applicable to your protocol, please state "not applicable".

IRB FORM # HS-1 – HUMAN SUBJECTS APPLICATION

SIGNATURES:

I have reviewed SWOSU's Policy and Procedures for the Protection of Human Subjects in Research Activities. I understand that I am responsible for the accuracy of the statements made in this protocol and for the conduct of research. I am aware that any signed consent forms are confidential and must be filed under lock and key during the research and for a period of 3 years upon termination of the research. I understand that I am to submit an annual report to the PHS Chairperson prior to the anniversary date of the approval (IRB Form # HS-3). I understand that this protocol's approval will be terminated if the annual report is not received by the anniversary date of the approval and a final report (IRB Form # HS-3) must be submitted at the completion of the protocol. If this protocol is approaching the end of the 3-year approval period, I will submit, in a timely manner, a new IRB Form # HS-1 for a new IRB review and approval in order to continue this protocol. The initial 3-year protocol's approval will be terminated if a new IRB Form # HS-1 is not received and approved by the anniversary date of the initial 3-year approval.

Signature of Approval _____ Date: _____
SWOSU Principal Investigator (PI) or SWOSU Program Director mm/dd/yyyy

I have reviewed SWOSU's Policy and Procedures for the Protection of Human Subjects in Research Activities. I understand that I am responsible for the accuracy of the statements made in this protocol and for the conduct of research. I am aware that any signed consent forms are confidential and must be filed under lock and key during the research and for a period of 3 years upon termination of the research. I understand that this protocol's approval will be terminated if the annual report is not received by the anniversary date of the approval and a final report (IRB Form # HS-3) must be submitted at the completion of the protocol. If this protocol is approaching the end of the 3-year approval period, I understand that a new IRB Form # HS-1 for a new IRB review and approval must be submitted by the PI in order to continue this protocol. I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects.

Signature of Approval _____ Date _____
(If Applicable) Co-PI or Co-Program Director mm/dd/yyyy

I have reviewed SWOSU's Policy and Procedures for the Protection of Human Subjects in Research Activities. I understand that all data and information relating to the protection of human subjects will be kept confidential and I will participate in this research according to the guidelines and policies of SWOSU.

Signature of Approval _____ Date _____
SWOSU Student(s), if applicable mm/dd/yyyy

I have reviewed SWOSU's Policy and Procedures for the Protection of Human Subjects in Research Activities. I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. I will take responsibility for informing the student of the need for safekeeping of all data and information as it relates to the protection of human subjects.

Signature of Approval _____ Date _____
SWOSU Faculty Sponsor (if not the Principal Investigator) mm/dd/yyyy

I have read the protocol described above and endorse its being conducted.

Signature of Approval _____ Date _____
SWOSU Department Chair mm/dd/yyyy

IRB FORM # HS-1 – HUMAN SUBJECTS APPLICATION

I have read the protocol described above and concur with the Department Chair's endorsement.

Signature of Approval _____ Date _____
SWOSU Dean mm/dd/yyyy

Date received by SWOSU IRB-PHS Committee Chairperson: _____

Review Status: ☐ Exempt ☐ Expedited ☐ Full Board

Action of Committee: ☐ Approved ☐ Approved with Revisions ☐ Denied

SWOSU Committee Approval Signature: _____

SWOSU Committee Approval Date: _____
mm/dd/yyyy

Date Returned: _____
mm/dd/yyyy