

Institutional Review Board † Southwestern Assemblies of God University

Class Projects Involving Human Subjects¹

An introductory exposure to the process of conducting ethical research is an important part of students' education in many academic disciplines. The SAGU Institutional Review Board (IRB) desires to partner with course instructors to train students how to conduct ethical research. The following guidelines for teaching research will facilitate that training.

Responsibility of the Course Instructor

Research-methodology course instructors at SAGU must embrace a common framework for teaching ethical conduct during research. Therefore, all research methodology instructors and all undergraduate and graduate students enrolled in those courses should complete the online course entitled "Protection of Human Research Participants"² offered by the National Institute of Health.

Research-methodology course instructors are responsible for communicating three principles of ethical human-subjects research: respect for persons, beneficence, and justice. Specific topics that should be addressed in such courses include (1) equitable selection of research volunteers, (2) informed consent (including the risks and benefits of participation), and (3) confidentiality of research data.

Criteria for Avoiding IRB Review

Research activities that are part of a course requirement and which require the involvement of human subjects **may** not require IRB review and approval. If **all** of the following criteria apply to a class project, IRB review and approval are not necessary:

1. The activity is designed for learning purposes only.
2. The results will not be made public through presentation outside of the classroom; specifically, the results will not be published in any form or publically presented (e.g., at a state or regional meeting of discipline-specific professionals). A capstone or project paper housed only in the sponsoring department for academic purposes is not considered publically accessible.
3. The activity involves procedure with no more than minimal risk. (The phrase "minimal risk" is defined in the following section.) By definition, research of a sensitive topic or requiring the participation of those in a "vulnerable" population cannot be consider a minimal-risk study.
4. Informed consent procedures are used during the data-collection process. (Some surveys or observational activities may require disclosure of the procedures used, instead of signature-based informed consent, or no consent at all.) See appendices A, B, and C for sample informed consent templates for three distinct research methods.

¹ Adapted from <https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF8#q=Wheaton+College+Class+project+involving+human>

² See <https://phrp.nihtraining.com/users/login.php>.

5. Data obtained during a research effort will not be identifiable in print or in any subsequent discussion or presentation of the findings. Identifiable data will be completely destroyed or purged at the end of the semester. Note that photographs, video and audiotaped recordings all contain identifiable data.

Definition of Minimal Risk

Minimal-risk course-based research activities do not require IRB review. *Minimal risk* is defined in the Code of Federal Regulations thus: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”³

The course instructor must determine if the learning activity meets the definition of minimum risk. If a class research activity exceeds minimal risk for the participants, as indicated by failure to satisfy one or more of the five criteria above, the instructor should contact the IRB for assistance at irb@sagu.edu.

Examples of minimal-risk include the following:

1. An observational study of a given research variable at a public venue
2. An anonymous “on-the-street” opinion poll (with adults) about a non-sensitive topics
3. A social experiment assessing the differences in preferred interpersonal space or distance between two people engaged in a conversation

Course Projects not Meeting the Five Criteria

Class projects not meeting **ALL** criteria listed above must submit the project to the IRB for review.¹

The following steps must be takes when submitting a research activity for IRB approval.

1. Complete and submit the IRB Application form for course-based research projects. Note that the instructor is the Principal Investigator
2. Complete the Application Checklist to ensure that all required information is included.
3. Attach as appendices to the Application all essential supplemental documents, including:
 - The Protection of Human Research Participants course completion certificate (for both the instructor and the students completing the study)
 - Informed Consent document(s)
 - Copy of all surveys/questionnaires to be used (if applicable)

The IRB review process typically takes between two and four weeks. Please contact the IRB (irb@sagu.edu or Dr. Marvin Gilbert @ extension 5495) with any questions or concerns about this document or a particular instructional activity.

¹ All submission forms can be found at <http://www.sagu.edu/academicshome/institutional-review-board>.

³ 45 CFR 46.102. See <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.102>.

Appendix A

Consent for Participation in Academic Research: Individual Interview Version

I volunteer to participate in a research effort conducted by ____ [researcher's name], a student at Southwestern Assemblies of God University (SAGU). I understand that this study is designed to gather information about ____ [briefly specify topic or state dissertation/project title], under the supervision of Dr. ____ [research course instructor]. I also understand that I will be one of approximately ____ people participating in this study.

1. I understand that my participation in this project is voluntary, and I understand that I will not be paid for my participation. I may withdraw from the study at any time without penalty. If I decline to participate in or withdraw from the study, no one will be informed of this decision by the researcher, and no foreseeable negative consequences will result.
2. I understand that most informants in this study will find the interview process interesting and thought-provoking. If, however, I feel uncomfortable in any way during my interview session, I have the right to decline to answer any question or to end the interview.
3. I understand that my interview will last approximately ____ minutes. I also understand that the researcher will take hand-written or typed notes during the interview. Further, I understand that the interview will be recorded using audio- or video-tape equipment. However, if I do not wish to be recorded, I am free to withdraw from the study.
4. I understand that the researcher will not identify me by name in any reports using information obtained from my interview, and that my confidentiality as a participant in this study will remain secure. Subsequent uses of the data generated by the participants in this study will protect their anonymity.
5. I understand that no one from my ____ [institution/church/organization/employment] will be present at the interview or have access to the researcher's raw notes or subsequently prepared transcripts. This precaution will prevent my comments from having any negative repercussions.
6. I understand that this research effort has been reviewed and approved by a research-course instructor at SAGU. For research-related problems or questions regarding ethical research practices, please contact Dr. _____ at _____@sagu.edu.
7. I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study.
8. I have been given a copy of this consent form.

My Signature

_____ 20____
Date

My Printed Name

Signature of the Researcher

For further information, including a copy of the results of this study, please contact:

____ [Name of Researcher]

____ [Contact Information for Researcher]

Appendix B

Consent for Participation in Academic Research: Group Interview Version

I volunteer to participate in a research effort conducted by ____ [researcher's name], a student at Southwestern Assemblies of God University (SAGU). I understand that this study is designed to gather information about ____ [briefly specify topic or state dissertation/project title], under the supervision of Dr. ____ [research course instructor]. I also understand that I will be one of approximately ____ people participating in this study.

1. I understand that my participation in this project is voluntary, and that I will not be paid for my participation. I may withdraw from the study at any time without penalty. If I decline to participate in or withdraw from the study, no one will be informed of this decision by the researcher, and no foreseeable negative consequences will result.
2. I understand that most informants in this study will find the group discussion interesting and thought-provoking. If, however, I feel uncomfortable in any way during the group interview, I have the right to decline to answer any question or to withdraw from the group interview.
3. I understand that this group interview will last approximately ____ minutes. I also understand that the researcher may utilize an assistant who will take notes during the during the group interview. Further, I understand that the interview will be recorded using audio- or video-tape equipment. If I do not wish to be recorded, I am free to withdraw from the group interview.
4. I understand that the researcher will not identify me by name in any reports using information obtained from this interview, and that my confidentiality as a participant in this study will remain secure. Subsequent uses of the group-interview data will protect the anonymity of the individual group members.
5. I understand that no one from my ____ [institution/church/organization/employment] will have access to the researcher's raw notes or subsequently prepared transcripts. This precaution will prevent my comments from having any negative repercussions. I also promise to hold in confidence all comments by other members of the interview group.
6. I understand that this research effort has been reviewed and approved by a research-course instructor at SAGU. For research-related problems or questions regarding ethical research practices, please contact Dr. _____ at _____@sagu.edu.
7. I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study.
8. I have been given a copy of this consent form.

My Signature

Date

My Printed Name

Signature of the Researcher

For further information, including a copy of the results of this study, please contact:

____ [Name of Researcher]

____ [Contact Information for Researcher]

Appendix C

Consent for Participation in Academic Research: Questionnaire Version

You are being asked to volunteer to participate in a research effort conducted by ____ [researcher's name], a student at Southwestern Assemblies of God University (SAGU). This study is designed to gather information about ____ [briefly specify topic or state dissertation/project title], under the supervision of Dr. ____ [research supervisor]. You will be one of approximately ____ people participating in this study.

During this study:

1. Your participation in this project is voluntary; you will not be paid for your participation. You may withdraw from the study at any time without penalty or harm of any type. If you decline to participate in or withdraw from the study by not completing the questionnaire, no one will be informed of this decision by the researcher, and no foreseeable negative consequences will result.
2. Completing the questionnaire will require approximately ____ minutes. There are no known risks associated with completing the questionnaire. If, however, you feel uncomfortable in any way during this process, you may decline to answer any question, or not complete the questionnaire.
3. The researcher will not identify you by name in any reports using information obtained from your questionnaire; your confidentiality as a participant in this study will remain secure. Subsequent uses of data generated by this questionnaire will protect the anonymity of all individuals.
4. This research effort has been reviewed and approved by a research-course instructor at SAGU. For research-related problems or questions regarding ethical research practices, please contact Dr. _____ at _____@sagu.edu.

By completing and returning the questionnaire, you are indicating that you understand the four statements above, and consent to participate in this study.

This document is yours to keep for future records.¹

For further information, including a copy of the results of this study, please contact:

____ [Name of Researcher]

____ [Contact Information for Researcher]

¹ For paper questionnaires only, presented as a cover sheet. Online questionnaires may require you to click a button indicating you understand the information presented in this informed consent document.