

Southern Adventist University Institutional Review Board Process Directions

Begin by identifying which IRB form(s) you need to submit.

IRB Approval is not required for a literature review or academic exercises which will not be published or presented off of the SAU campus.

Exempt Review – Form A

Studies qualifying for an Exempt Review are those with no risk to the participants. These studies usually include research that is conducted in established or commonly accepted educational settings and involves normal education practices, such as the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Other studies that may fall under an Exempt Review are research that involves the use of educational tests, survey procedures, interview procedures, or observation of public behavior, as well as research that involve the collection or study of existing data, documents, records, pathological specimens, or diagnosis specimens. Confidentiality of all personally identifiable information must be managed throughout the research and thereafter. The information collected must be recorded in such a manner that the human subjects cannot be identified directly or indirectly. If any disclosure of information outside the research could reasonably place the subject at risk of criminal liability or civil liability or be damaging to the subject's financial standing, employability or reputation then it no longer qualifies for an Exempt Review.

Expedited Review (non exempt) – Form A

Studies qualifying for an Expedited are those with minimal risk to the participants. Minimal risk is defined by research that does not exceed the average probability and degree of psychological or physical harm normally encountered in the everyday life of a human being. It also must not exceed the risk or harm experienced during a routine clinical intervention.

Full Review – Form A

Studies that involve more than minimal risk to the subjects and require review of the full IRB committee membership. Please note that the types of research conducted at SAU rarely require the full Board hearings so investigators are encouraged to contact IRB Chair prior to submitting a Full Board application. In most cases, expedited review is possible.

Other: Animals/Plants Review – Form A

University policy and federal law require review and approval for proposed activities related to the humane care and use of animals; and the use of plants.

Changes to the Study, Annual Review, Termination of Study – Form B

Use this form if you need to make substantial changes, would like to extend your study, or have completed your study.

Student Class Based Research – Forms C, D, & E

If you are a research professor that has completed the CITI training and are qualified to approve student research, please complete all three of these forms within the semester they are applicable. The purpose of these forms is to keep track of student research from the IRB application and approval phases to the completion phase for both the professor and the IRB.

All IRB forms should be signed, scanned and emailed to IRB@southern.edu

Please Review Your Application before Submitting IRB Forms

SOUTHERN ADVENTIST UNIVERSITY — INSTITUTIONAL REVIEW BOARD

All sections of the application must be completed. The application itself will include specific details on what information needs to be included. Please read each section carefully to ensure that you have provided all of the required information.

Researchers – Please list the name of the Principal Investigator and Other Investigators on the project. Contact information for all researchers should be included in the application. If the project is a student research project, the student (s) will be listed as investigator(s) and a Faculty Advisor must be listed. Please note that if this is student research, the application will have to be submitted electronically by the Faculty Sponsor directly to the IRB on behalf of the student or the student can obtain the signature of the Faculty Advisor, scan the form, and then submit themselves to the IRB.

Research Start Date – The anticipated start date entered on the application must be a date in the future (not a calendar date that has already passed by the time the application is submitted).

Research Purpose – The purpose of the research must be adequately explained. Give precise details on why you are conducting the research including information on your hypotheses and/or research questions. Describe the objectives of your research. This should be written so that the reviewers will have a clear understanding of exactly what you plan to do.

Background/Rationale – Clearly define the reason why you are conducting the research and explain your rationale for doing so. You must also include citations/references from previous research that has been done on the same or similar research topic.

Methods – Clearly describe the research methodology that will be used including information on the data collection procedures and how the procedures will allow you to address the hypotheses/research questions for your project.

Sample Population - Describe the sample population and the number of participants that you anticipate recruiting for the study. Describe the recruitment methods that will be used. If the research involves those considered as vulnerable populations, please be sure to check the appropriate box on the application form.

Informed Consent – Full details about the consent process should be included in the application. You will need to disclose the type of consent that will be used. Informed consent can be in an oral or written format, and in rare circumstances a waiver to consent can be requested. A waiver of consent can be requested when the consent itself would be the only identifiable information about the participant. When oral consent will be used, the same elements that would be included in a written consent should be verbally communicated to the subject before he or she agrees to participate. If the research involves children it may require both a parental consent form and an assent form (which the child signs). As a general rule, children age 7 and up can understand the basic information of the study if it is provided to them at their level.

Risks/Benefits- Describe in detail any risks (if any) associated with participation in the research project. Risks can range from physical dangers/side effects to psychological dangers/side effects. Inconvenience, travel, or boredom may also be considered risks of participation. Include information in the application about what precautions will be taken to minimize risks and/or what resources will be available to assist participants should some unforeseen instance occur. Describe the anticipated benefits to the participants or benefits that could contribute to generalizable knowledge.

Privacy/Confidentiality – Research cannot be both anonymous and confidential. Anonymous research is research that does not contain any identifiable information about the participants. Confidential research is research that does include some identifiers but the research data will be maintained in a confidential manner (only the researchers will know the identity of the participants). Within the application please clearly define if the research is anonymous or confidential. If the research is confidential please define how the records will be coded, how the data will be stored, how long the data will be maintained, and what will be done with the data once the information will no longer be maintained. If video or video tapes will be used you will need to include about how these instruments will be secured/stored and how/when they will be disposed of. If video or videotapes are used please add a sentence in the consent form stating that the participant can request that the videoing be stopped at any time.

Questionnaires/Other Instruments

Any questionnaires, tests, survey instruments or data collections sheets which are not standard and well known must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.