Institutional Review Board ✦ Southwestern Assemblies of God University

The IRB Application Checklist ✦ Revised September 20, 2017

Introduction

The Institutional Review Board (IRB) application allows a researcher (hereafter, principal investigator: PI) to explain in detail how he or she will protect human subjects from harm throughout the research process in a proposed study. The application becomes a permanent file in the Southwestern Assemblies of God University (SAGU) IRB database.

A student or faculty-staff member applying for IRB approval of proposed research with human subjects must ensure that the content of the IRB application is internally congruent. This congruence includes all issues and procedures related to informed consent, access to the research venue (and the human subjects), permission to use copyrighted instruments, and other issues unique to a given application.

After a thorough review of the application and all attached documentation, the IRB will either approve or disapprove the proposed study.

An IRB application will be *approved*:

- If the application document is complete: no required fields in the application are omitted;
- If all supportive documents are attached as appendices:
  - The NIH completion certificate for the Protecting Human Research Participants course
  - All data-collection instruments, including interview guides
  - All essential permission forms signed by the appropriate authorities
  - One or more informed consent templates,[1] as may be relevant to the study
  - Confidentially agreement(s), as may be relevant to the study
- If the IRB determines that a proposed study presents minimal risk to the human subjects targeted in the study, or in the case of vulnerable populations, the PI commits to the exercise of due diligence to protect such subjects from harm.[2]

An IRB application will be *disapproved*:

- If the informed consent document(s) (1) is not appended to the application, (2) fails to provide adequate details or describe adequate safeguards, or (3) contains obvious errors;[3]
- If approvals for access to documents, institutional and archival data, and human subjects are not appended to the IRB application;

[1] An informed consent document must (1) be accurately and completely prepared, (2) document the full range of procedures anticipated in the research project, (3) explain fully the rights and prerogatives of the human subjects contributing to the proposed study, and (4) assure those human subjects of the researcher's commitment to their protection from harm.

[2] In compliance with details contained in the Code of Federal Regulations: 45 CFR 46.

[3] See the preceding footnote.

- If approval(s) for the use of copyrighted data-collection instruments is not appended to the IRB application;
- If a lack of congruence exists between the IRB application and the required appendices.
- The IRB determines that the risks of harm associated with the data-collection, data-analysis, or data-storage methodologies are excessive (i.e., the study as designed will pose significant risks of harm to human subjects);

Summary of Possible Actions by the IRB in Response to an Application

An IRB application will be either approved or disapproved, contingent upon the completion of the application form (including attachment of required documents), the accuracy of information provided therein, and the perceived risks associated with the proposed study. Note in particular that the PI must provide evidence that the organization within which the proposed research will occur has approved all aspects of the research: data-gathering processes and related organizational-access issues.

How to Prevent a Re-Submission to the IRB

1. Ensure that *all* sections of the IRB application are answered in full.
2. Ensure that *all* names and signatures match *exactly*, including academic titles (e.g., Dr, PhD, EdD), if relevant.
3. Ensure that all required supportive documents are appended (attached).
4. Ensure that the entire application package is error free.

The IRB Application Checklist[4]

Section 1: Preliminary Information (as many as 8 required elements for student researchers)	✓
Date of submission	
Title of the proposed study	
Full legal names of the PI and, when relevant, the faculty sponsor	
Sponsoring department/location (e.g., Harrison Graduate School: SAGU)	
The PI's contact details	
The faculty sponsor's contact details (when relevant)	
The PI's assurance	
The faculty sponsor's endorsement (when relevant)	
Section 2: Description of Human Subjects and the Research Design (3 required elements)	✓
Identification of all subjects who are defined as "vulnerable" by 45 CFR 46, and why their inclusion is essential	
Additional details about all human subjects needed to contribute data	
Identification of the study's primary category or classification (i.e., the research design)	
Section 3: Summary of the Research Study (9 required elements)	✓
Title of the proposed study	
Purpose of the proposed study	
Statement of the proposed start[5] and end dates, with justification for the duration of the study[6]	
Background (brief literature review)	
Methods to be used in subject selection and subject recruitment, including the exclusion of potential subjects (All recruitment resources, including flyers, must be attached as appendices.)	
Summary of all data-collection methods and instrumentation (All data-collection instruments, including interview guides, must be attached as appendices.)	
Informed consent protocol(s)	
The use of deception/misdirection (If neither deception nor misdirection is relevant to the proposed study, state this.)	
Potential risks and benefits of the proposed study	
Attachments (as many as 6 elements)	✓
NIH Certificate of course completion: Protection of Human Research Participants	
All data-collection instruments to be used in the study	
Assurance(s) of institutional access to required data sources: human subjects, data stored in current or archived database(s), essential documents, records, and test scores	
Informed consent template(s), as may be relevant to the study	
Confidentiality agreement(s)	
Recruitment flyers, letters of invitation to participate in the study, etc.	

[4] The PI (and, when relevant, the Faculty Sponsor) should use this checklist to determine when the IRB application is complete.

[5] The PI may not, *under any circumstances*, begin data collection without IRB approval. This includes pilot testing.

[6] If the planned data-collection phase extends beyond one year, the applicant must submit a re-approval request.