



Permission to Use Human Subjects in Research

The Southern Baptist Theological Seminary

Risk Assessment Process for Research Involving Human Subjects

The following procedures cover all academic or professional research conducted by faculty, staff, or students involving human subjects, and research conducted by external scholars involving any member of the Southern Seminary community.

The researcher must complete all of the steps outlined below before conducting data gathering involving human subjects. Failure to comply with and abide by these processes can result in disciplinary action as outlined in the Student Handbook and/or Faculty Staff Manual.

Students writing a thesis, project, or dissertation that does not include the use of human subjects, must still complete the Approvals for Using Human Subjects in Research form and the Assessment of Risk to Human Subjects in Research form and file them with the Research Ethics Committee before engaging in the collection of data.

Permission to conduct research by the Research Ethics Committee does not constitute permission to conduct the research in a specific institution or organization. The researcher is responsible for securing institutional approval to conduct research in a specific institution or organization as required by those bodies.

An application to conduct research is not necessary under the following conditions:

1. The research is being conducted by the seminary internally and/or externally for the purposes of institutional assessment and/or institutional development and not for degree research, such as instructional assessments, services assessments, etc.
2. Consultation with an author of published material is for the sole purpose of clarification of the meaning of the published material. However, interviewing an author or multiple authors for peer perspectives requires the filing of a *Research Profile* and the permission of the Research Ethics Committee.

Step One: Create a *Research Profile* to Request Permission to Conduct Research

Prepare a brief, clear, concise, and precise *Research Profile* describing the proposed research with human subjects. If your research does not include human subjects, complete items 1, 2, 3, and 6 only.

1. The *Approvals for Using Human Subjects in Research* form with the top portion completed. This form serves as the cover page.
2. A completed *Assessment of Risk to Human Subjects in Research* form.

3. A copy of the *Title Page* from your study.
4. A copy of the following statements and sections from your study pasted into a single-spaced document:
 - The precise *Research Purpose* stated in the introduction of your study (not the longer introduction or rationale for the study. Usually this precise research purpose statement is reflected in the title of your study. Include a copy of stated *Delimitations of the Study*, if any.
 - The *Research Questions, Hypotheses, or Goals* from the introduction of your study.
 - The *Research Methods* or *Design Overview* from the introduction or methodology section of your study as appropriate.
 - The *Population* and *Sample* statements from the methodology section of your study. Include a copy of stated *Delimitations of the Sample* and *Limitations of Generalization*, if any. If your study does not include any or all of these items, skip this section in the *Research Profile*.
5. A copy of *Instrumentation* (surveys, inventories, tests, interview instructions, etc.) and/or a description of proposed instrumentation to be used in conducting the research. Instrumentation **MUST** demonstrate *informed consent* according to the highest level of risk identified by the *Assessment of Risk to Human Subjects in Research* form (see the *Risk Accommodation Guide*). Instrumentation completed later in the research process **MUST** be approved by the research supervisor prior to use with human subjects. If no instrumentation is involved in the study, skip this section in the *Research Profile*.
6. A copy of your *Vitae* from your study or similar short statement of your credentials.

Step Two: Submit the *Research Profile* for Approval

Submit the completed *Research Profile* to the Research Supervisor (the appropriate course instructor, Project Methodology Supervisor, Thesis Supervisor, Dissertation Supervisor, faculty colleague, Department Chair, Associate Dean, or School Dean directly overseeing the researcher of the study). The *Research Profile* must then undergo three (3) levels of approval *prior to conducting the research with human subjects*.

1. *Approval Level 1: Research Supervisor*—the research supervisor *immediately* evaluates the *Research Profile* upon receipt from the researcher and either:
 - A. Signs the approval form and forwards the *Research Profile* to the Research Ethics Committee for evaluation at Approval Level 2; or
 - B. Returns the *Research Profile* to the researcher for modifications to informed consents, the assessment of the levels of risk to human subjects in the study, and/or further accommodations of the levels of risk.

2. *Approval Level 2: Research Ethics Committee*—the Research Ethics Committee *immediately* evaluates the *Research Profile* approved by the research supervisor upon receipt and either:
 - A. Signs the approval form and finalizes processing of *Research Profile*, if risk level at or below low risk; or
 - B. Signs the approval form and forwards the *Research Profile* to the Senior Vice President for Academic Administration with or without minor modifications to informed consents, the assessment of the levels of risk to human subjects in the study, and/or further accommodations of the levels of risk; or
 - C. Returns the *Research Profile* to the research supervisor to forward to the researcher for significant modifications to informed consents, the assessment of the levels of risk to human subjects in the study, and/or further accommodations of the levels of risk.

The evaluation of the *Research Profile* at Approval Level 2 is conducted by a member of the Research Ethics Committee, or a faculty member or administrator of the seminary as appointed by the committee. This evaluation consists of an assessment of the risk to human subjects in the study and the accommodation of risk only—*any other assessment of the study is beyond the purview of the evaluator*. For example, the evaluator is not empowered to critique the research title, the research topic, the level of research, the choice of research design (text based), etc. The only evaluation conducted is that of an assessment of the level of risk to human subjects in the study and the subsequent accommodation of that risk.

The research supervisor of Approval Level 1 cannot also serve as the evaluator of the *Research Profile* at Approval Level 2 and/or Approval Level 3.

The Research Ethics Committee will meet to accept, modify, or reject the *Research Profile* based on the concurrence of the assessment of informed consents, the assessment of the levels of risk to human subjects in the study, and/or further accommodations of the levels of risk at Approval Levels 1 and 2. If research risk is deemed above low risk (Level 2), the profile will proceed on to Level 3 approval to the Senior Vice President for Academic Administration. Otherwise the Ethics committee will finalize processing.

3. *Approval Level 3: Senior Vice President for Academic Administration*—the Senior Vice President for Academic Administration *immediately* evaluates the *Research Profile* approved by the research supervisor and Research Ethics Committee upon receipt and either:
 - A. Signs the approval form and forwards the *Research Profile* to the Research Ethics Committee for final processing; or
 - B. Returns the *Research Profile* to the Research Ethics Committee to forward to the research supervisor and researcher for modification to informed consents, the assessment of the levels of risk to human subjects in the study, and/or further accommodations of the levels of risk.

Step Three: Await Notification of Approval Before Conducting Research

The researcher is free to conduct data gathering with human subjects *only upon receipt of the Approvals for Using Human Subjects in Research* form signed as approved at the three levels. One of two decisions will be noted on the form:

1. *Approved*—the researcher is free to conduct his or her research in accordance with the documentation submitted in the application process, and with required modifications, if any, as noted on the *Approvals for Using Human Subjects in Research* form; or
2. *Not Approved*—the researcher must redesign the research and resubmit the application in full with appropriate modifications.

The following stipulations apply to conducting research with human subjects upon approval at all three levels:

1. Any instrumentation (surveys, interview questions, etc.), informed consents, debriefings, and/or institutional permissions to conduct research developed or obtained after the approval to conduct the research is received must be submitted to the Research Supervisor for approval prior to gathering data with the instrumentation.
2. Raw data and processed data must be kept for seven years and treated with the level of confidentiality indicated to the subject at the time of data gathering.

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