

**HUMAN SUBJECTS SOCIO-RELIGIOUS RESEARCH POLICY**  
**COLUMBIA THEOLOGICAL SEMINARY**  
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The extension of human knowledge and wisdom and the demands of justice to protect the vulnerable are both commitments grounded in the Christian scriptures and tradition. Exceptional care is required when these two commitments interact. The communal nature of Christian faith demands our mutual accountability to each other. In all of the expressions of our life together, including our work and research, these commitments should find full expression.

Students, faculty, and staff of the seminary frequently conduct research that involves humans as the primary subjects. In conformity with "The Common Rule" guidelines established by the U.S. government Office of Human Research Protections and general practice in academic research, Columbia Theological Seminary requires that all human subjects research formally conducted under Seminary auspices be reviewed to protect participants and minimize potential risks or harm.<sup>1</sup> The faculty has established an Institutional Review Board (IRB) and the review process outlined in this Policy in order to provide a venue for responsible, independent review of research procedures and projects that involve human subjects and to

- protect the subjects of research from inappropriate risk,
- minimize potentially negative effects of socio-religious research study methods,
- assure compliance with the highest academic standards in research involving human subjects,
- ensure that human subjects are properly informed and consent to their participation with full awareness of the purposes of the research, and
- assure that human-subjects research will benefit the student's project.

Such review also helps to limit risks of liability on the part of the seminary, the researcher, and agencies funding that research. Participants in human subjects research are afforded protection under this policy whether or not the research is intended for publication or presentation at professional meetings. The guidelines set forth in this Policy are meant to be sufficiently flexible to allow for appropriation depending on the degree program in which the student is participating (e.g., the Th.D. degree program has requirements compatible with the standards of their professional organizations).

**What is Human Subjects Research and What Kinds of Research Require Review?**

Examples of human subjects socio-religious research and data collection include, but are not limited to, surveys and questionnaires, interviews and focus groups, field work (e.g., ethnography), inter-cultural and inter-religious field comparative work, evaluations of social or educational programs, and cognitive and perceptual experiments. Potential risks that must be considered in a review include those of a physical, psychological, social, economic, or legal nature. Risk/Benefit assessment should include weighing of potential harm, use of deception if any, and steps to be taken to minimize risk and to care for subjects.

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<sup>1</sup> The Common Rule, formally titled "Protection of Human Subjects" is part 46 of Title 45 of the Code of Federal Regulations ("45 CFR 46"). See also American Association of University Professors, "Protecting Human Beings: Institutional Review Boards and Social Science Research," <http://www.aaup.org/statements/Redbook/repirb.htm>.

Loss of confidentiality is the most common type of risk encountered in social and behavioral science research. Confidentiality is presumed and must be maintained in all research unless the investigator obtains the express permission of the subject to do otherwise. Risks from breach of confidentiality include invasion of privacy, as well as social, economic and legal risks.

Deception is generally to be avoided in research and may only be used if there is no other way to reasonably obtain the data, the risk of harm is minimal, the knowledge sought is important enough to justify deception, and an appropriate procedure is proposed for debriefing of subjects after the conclusion of the research.

Human Subjects Research requiring review includes the following:

- Research in which there is a potential for more than minimal risk of harm to the subject. As defined in the Common Rule, minimal risk "means that 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.*"<sup>2</sup> It is up to the review board to determine whether risks involved exceed this definition, and if so, whether sufficient procedures are in place concerning informed consent and referrals in case of harm.
- Research that falls within the content and methods of the social sciences (including pastoral care, psychology, sociology, anthropology), and research investigating subjective experiences or feelings about issues normally considered private or confidential, such as sexuality, addiction, boundary violations, conflict, or violence requires review.
- Research involving subjects who are not competent to evaluate the risks and benefits of participation themselves, including minors or people with cognitive disabilities, must be reviewed. All legal requirements for working with such persons, including directives by the Department of Corrections, must be followed.
- Research in which dual roles may be present between the researcher and the subject(s), such as using students, employees, or counseling clients as research participants.

Examples of research requiring review include:

- Faculty assigning a research project to students that requires the students to have interactions (interviews, small group projects in congregations, etc.) involving human subjects' subjective experiences or feelings, as described above.
- ThD dissertations or DMin/DEdMin. projects using empirical research involving direct contact with clients, patients, support groups, or any vulnerable population.
- Any research involving direct contact with minors or persons with cognitive disabilities.
- Research employing small group discussion formats in a congregational context that entail disclosure of private information of a sensitive nature, where the subjects could easily or readily be identified
- Research on specific issues of recent conflict in congregational life or in other organizations, when the actors are readily identified or identifiable
- Research that has the potential for causing harm or inciting further conflict in congregations or in the wider community.

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<sup>2</sup> 45 CFR 46.102.h.i, cited in AAUP.

Research **not** requiring review includes the following:

- Research solely for internal institutional use (e.g., course evaluations or institutional self-study)
- Research for a classroom project that does not involve outside participants and is not disseminated publicly or part of a permanent data base
- Archival or historical research, as long as the subjects are no longer living, are not identifiable, and/or no living heirs of the subjects would be caused any harm by dissemination of the research.
- Research in education settings on instructional techniques, curricula, or classroom-management methods, or research involving established and commonly accepted educational practices and instructional strategies, such as case studies and simulations
- Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, **unless** the subject can be identified and disclosure of the subjects' responses could put the individual at risk of criminal or civil liability or could damage the subject's financial standing, employability, or reputation
- Research conducted by DMin or DEdMin. students in their ministerial sites that does not reveal confidential information, does not identify individual subjects or participants, and does not carry any potential risk of harm
- Research in other settings that would not reasonably create distress or harm and involving only anonymous questionnaires or public observations
- Research involving elected or appointed officials or candidates for public office
- Research using existing data, documents, or records, as long as these resources are publicly available or the human subject cannot be identified
- Research of public benefit or service programs
- Research that does not place participants in a criminal or civil liability or damage their financial standing, employability, or reputation
- Research related to organizational effectiveness in settings for which there is no risk to participants' employability.

Examples of research where review is **not** required include:

- Scholarly review of literature, including other published social scientific research and social scientific data that is made available to researchers
- Archival historical research such as church records or public archives. Most archives restrict access to certain materials, and many require permission to cite or use material from persons who have died within the last 50 years. Research must conform to the rules of the particular archive or institutional body.
- Research that is part of a DMin or DEdMin project that engages subjects on a general level, without identification of specific persons and without reasonable potential for harm, such as evaluating responses to a program or project through instruments that maintain anonymity, assessing responses to a new curriculum, or holding a focus-group to evaluate liturgical changes in the church.

NB: Research not requiring an IRB does not require an informed consent form to be obtained from participants.

NB: If there is any doubt on the part of the researcher whether an IRB review is needed, s/he should consult the Chair of the IRB and may choose to submit a proposal to determine its necessity.

## The Review Process

1. An **individual student** should apply for review after having sought and received approval for his or her research proposal with the faculty advisor involved in overseeing the project, and before actually beginning the research project. Normally a ThD, DMin or DEdMin student would receive approval for the dissertation/project proposal from the student's advisory committee prior to submitting the proposal for IRB review. The advisory committee's approval is made "pending IRB approval." DMin, DEdMin, and ThD students must receive approval as part of the overall proposal approval process, prior to beginning their projects or any pilot testing.
2. A **faculty or staff member** should submit a research proposal for review before submitting a proposal to a potential funding source, outside agency, or publisher and prior to beginning their projects or any pilot testing.
3. A **faculty member** should submit a proposal on behalf of her or his students in the case of a class assignment or project before distributing the syllabus if the assignment is identical for each student. In the case of such class assignments, the faculty person monitors and maintains responsibility for the potential risks to research subjects. Approval applies to subsequent years of the course assignment, as long as no significant changes were made.
4. Any substantive changes in project design or research instruments that are made after initial approval has been granted must be submitted for re-approval.
5. In some cases, students and faculty may be conducting research in contexts where other institutions also have Human Subjects Research policies in place. Researchers must be certain to comply *both* with Columbia's policy *and* that of the other institution.

Approval is made in light of the following criteria:

1. The value of the research project for the overall advancement of knowledge. Validity of research design, methodology, and sampling is determined by weighing the value of the proposed research against any possible risk to participants.
2. Credentials of the investigator and supervisor, and plan for student supervision
3. Selection of subjects and competency to consent
4. Voluntary informed consent/assent and confidentiality
5. Plans for dissemination of the data

Advisors, students, or faculty wishing to consult with the committee prior to submitting the required forms are encouraged to do so. The Human Subjects Research Review form may be submitted to the chair of the IRB at any time, but the researcher should understand that processing and approval of the proposal will take some time, especially if it is submitted at a time other than during the fall or spring semester.

The faculty or student conducting the research will be responsible for maintaining all supporting documentation related to the research, including:

- Documented approval of the research proposal
- Signed consent forms
- Any further documentation related to the research of human subjects, including field notes or other reports.

- Researchers are expected to maintain supporting documentation for seven years following completion of their research projects.

In cases where oral interviews are included as a component of research, consent forms must be used. Where possible the researcher is to electronically or otherwise record the conversations and transcribe the interview, and to submit a copy of the transcription to the human subject who was interviewed for her or his signed approval.

In the case of small group discussions or other situations where approval of actual conversations is not possible to obtain following the fact, the researcher is to take notes and sign and date them, and to make them available to their faculty advisor or members of the review board for inspection if requested.

### The Institutional Review Board (IRB)

The IRB will be constituted annually by the faculty as one of its regular standing committees, appointed by the Dean of Faculty, with members of the committee being permitted to serve continuously. The committee will have a minimum of 5 members, which will normally include representatives from the tenured and non-tenured faculty, administration, and student body. At least two shall have documented training and/or expertise in research methods involving human subjects.

The IRB will meet monthly or as needed to review proposals. Proposals may be submitted in writing or by email in a timely fashion to allow adequate consideration by the board. In the case of DMin or DEdMin proposals that require review, candidates may submit the proposal research components and receive tentative approval prior to completion of the final proposal, but the IRB must review the final proposal with the research components included.

The IRB may approve any proposal as submitted, require revision and re-submission of the proposal, or reject the proposal. Member(s) of the IRB who are serving as Advisor or Reader to the student whose proposal is under review shall have voice but not vote regarding that student's proposal. Approval must be in writing, and delivered in a timely fashion to the individual proposing to undertake the research. In the case of revisions or rejections, the committee will provide a written statement to the faculty member or student detailing the reasons for rejection. The IRB will maintain records of all its deliberations and will report these to the full faculty at its regular meetings. In the case of ThD proposals, results of the IRB deliberations will be reported to the ThD student's advisor, who will in turn report to the ATA ThD Committee.

1. Advisors, first readers, and dissertation committee members have responsibility for reminding students of the Human Subjects Socio-Religious Research Policy.
2. Every research methods course will introduce the Human Subjects Socio-Religious Research Policy and will provide bibliography for additional reading;
3. Before submitting research protocols to the IRB, advisors, first readers, and dissertation committee members should corroborate that the researcher has a level of understanding of the task to do human-subjects research;
4. The Advanced Degrees Committee will provide Faculty members advising human-subjects research with brief training in this policy and reminders of pertinent procedural requirements

and ethical issues, including the following: a) levels of confidentiality, b) levels of intervention and risk, and c) most importantly, the rights of subjects.

## Guidelines for Researchers

### A. Ethical Issues and Procedural Requirements in Human Subjects Research

Requirements intended to protect the rights of human subjects in research projects include:

- The informed consent of the subject to participate in the project
- The right of the subject to withdraw from participation at any time, including the final stage of the project
- There will be no financial gain based on the use of the human subjects research, which will exclusively be for fulfilling an academic requirement. If any financial gain (potential publication with royalties, or lectures) is anticipated, the researcher needs to communicate this to the subjects
- Respect for the research subject: in order to allow the human subject to express self-determination, the researcher must give accurate information about the project and its results and ultimate purposes
- Guarantee that no harm will be done by participating in the research
- Justice for the human subjects by way of adequate distribution of burden and benefits (explaining the responsibilities and contributions of the human subject in the research).

### B. Preparing a Protocol for Human Subjects Research:

The written protocol that researchers submit to the Institutional Review Board should include a statement of clearly defined objectives that demonstrate reliable research theory and methods, an explanation of intended methodology, and clear indications of adequate attention given to the protection of human subjects who will participate in the study. A blank Human Subjects Research (IRB) Proposal Form is available on the Seminary website. Specifically, the protocol should address the following questions:

1. What is/are your key research question(s)?
2. What are the objectives and purposes of this research?
3. What research methods do you plan to use?
4. How do you plan to begin your research?
5. Whose consent will you need to obtain? What documents will you use to explain your work? (See below, "Consent Forms")
6. What is your relationship to the people who will be part of the project?
7. What recruitment procedures do you plan to use?
8. Will subjects who participate in the project be anonymous? If not, how will you assure the privacy of the participants?
9. Will any of the subjects be minors (under 18 years of age)? If so, how will you obtain parental consent?
10. What questions do you plan to ask? If you are using a questionnaire or structured interview, please include a copy of it as an Appendix to your proposal.
11. What are potential benefits for persons who are part of the project?

12. What are potential risks for persons who are part of the project, including physical, mental, or social discomfort, harm, or danger? How will you respond if any participant has adverse effects as a result of your research?
13. Will the project involve any deception of participants? If so, how? What procedures will you use to debrief participants?
14. What alternative procedures are available to a subject who wishes to withdraw or who is damaged by the project?
15. How do you plan to protect the data? How will you protect confidentiality of the data?
16. How and where will the research be reported/disseminated?
17. Is IRB approval required by any other institution? If so, please attach your proposal as an Appendix, and describe the procedure and timeline for approval.

NB: A current IRB Proposal Form shall be posted on the seminary website.

### C. Consent Forms

Consent Forms should include:

1. The purpose of the project.
2. A description of the types of issues and questions to be asked from the human subject.
3. A clear statement of potential risks and benefits of participation for the human subject.
4. Research procedures to be used (e.g., anonymous questionnaire, structured interview, case study, open-ended interview, focus group, etc.); permission to record and transcribe any oral interview/focus group, and permission to photograph (if relevant); permission to contact them with any follow-up questions following a survey/interview.
5. An assurance of the right of the human subject not to answer any question, or that any answer is acceptable; and the right to stop participation at any time, and to withdraw any or all of these consents up to the final publication of the project results by contacting the project director in writing at the email or street address listed on the consent form; if the participant has any questions, s/he may write, email or phone the project director, supervisor, or chairperson of the CTS Institutional review Board at any time.
6. A clear statement about how confidentiality will be maintained (anonymity or using names by written permission? secure storage of materials).
7. A brief statement of projected outcomes (whom the project is intended to benefit) and how and to whom the research may be published or disseminated; and an offer of what the researcher is willing to give them (a final report; a summary of the final report; interview transcript, a draft of the research for participants' review prior to publication, etc.).
8. A statement re: costs and payments. (Normally this will read "There are no costs for participation in this study. Participation is completely voluntary and no payments will be provided.)
9. Parental permission for human subjects under the age of 18.

NB: A current Informed Consent Form shall be posted on the seminary website.

### If Problems Should Arise

Faculty and students who are conducting human-subject research are to report any adverse events to Associate Dean of Advanced Professional Studies, and in the case of ThD students, to the ATA ThD faculty via the student's advisor. Adverse events include unanticipated problems involving risks to subjects or others. Unanticipated problems may be associated with physical harm, psychological harm, and/or social harm. Unanticipated problems may result from a breach of confidentiality associated with the data collected during the research.

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