

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

Students, faculty, and staff of the seminary frequently conduct research that involves human 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 all research that is formally conducted under Seminary auspices be reviewed to protect human subjects and minimize potential risks or harm.¹ In order to do so the faculty has established an Institutional Review Board (IRB) and review process. Responsible independent review of research procedures and projects that involve human subjects is intended to

- protect the subjects of research from inappropriate risk
- minimize any 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
- 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. These guidelines are flexible, and may vary 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.

¹ 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.

Research requiring review includes the following:

- Research involving human subjects 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.*"² 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 human subjects' 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, especially when it entails feeding back or incorporating the information gathered into papers, presentations or class discussion.
- ThD dissertations 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.
- Holding small group discussion formats for learning 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

² 45 CFR 46.102.h.i, cited in AAUP.

- Research that has the potential for causing harm or inciting further conflict in congregations or in the wider community

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 Doctor of Ministry 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 Doctor of Ministry 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.

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. D.Min., D.Ed.Min., and Th.D. 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.
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 or 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 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 documented 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 Doctor of Ministry 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 of 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-subject research;
4. The Advanced Degrees Committee will provide Faculty members advising human-subject 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 subject 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 Human Subjects Research Review Committee should include a statement of clearly defined objectives that demonstrate reliable research, an explanation of intended methodology, and clear indications of adequate attention given to the protection of human subjects who will participate in the study. More specifically, the protocol should address the following questions:

1. What are your key research questions?
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. What questions do you plan to ask? If you are using a questionnaire, please include a copy of it.
9. What are potential benefits for persons who are part of the project?
10. What are potential risks for persons who are part of the project? How will you respond if any participant has adverse effects as a result of your research?
11. What alternative procedures are available to a subject who wishes to withdraw or who is damaged by the project?
12. How do you plan to protect the data? How will you protect confidentiality of the data?
13. How and where will the research be reported?

C. Consent Forms

Consent Forms should include:

1. A clear statement of potential risks and benefits of participation for the human subject;
2. A description of type of questions and issues to be asked from the human subject;
3. An assurance of the right of the human subject not to answer any question, or that any answer is acceptable;
4. Parental permission for human subjects under the age of 18;
5. A certificate of confidentiality as applicable;

When a signed consent form is not required, given minimal risks in the project, a research information risk sheet will be provided when possible.

D. If Problems Should Arise

Faculty and students who are conducting human-subject research are to report any adverse events to Director of Advanced 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.