Bexley Seabury

# Guidelines for Research Involving Human Subjects[1]

Basic Christian ethics requires that all persons be treated at all time with full respect for their God-given human dignity.[2] This entails restraint from harm, from exploitation, from deception, from unnecessary risk, and from personal violation or abuse such as disclosure of personal information or views without consent. Further, respect for human dignity requires that persons be fully informed of the risks they may incur in undertaking any activity, and that they give full and free (i.e., uncoerced) consent.

It is particularly important that these general principles be rigorously applied in all cases of research with living participants, especially when done in the name of or for the use of the church and its ministers. The Bexley Seabury Seminary Federation presumes that *research undertaken as part of its Doctor of Ministry in Congregational Development program falls in this category*. Some research undertaken at the masters level *may* fall in this category. In that case, these policies apply to that research as well.

In conformity with Bexley Seabury's fundamental vision and mission and national standards, the Bexley Seabury Seminary Federation requires that all human subjects research formally conducted under Federation auspices be reviewed to protect participants and minimize potential risks or harm.[3] The Federation has established an Institutional Review Board (IRB) and the process outlined in this Policy in order to provide responsible, independent review of research procedures and projects that involve human subjects. The purpose of this Policy and process is to:

- Protect participants in research from inappropriate and/ or unnecessary risk;
- Minimize the potentially negative effects of research study methods;
- Assure compliance with the highest ecclesial and academic standards in research involving human participants;
- Ensure that research participants are properly informed and give consent to their participation with full awareness of the purposes of the research; and
- Assure that human-subjects research will benefit the researcher's project.

Participants in human subject research are protected under this policy whether or not the research is intended for publication or presentation at professional meetings.

**No research may be carried out unless the participants have signed a consent form. Prior to signing the form, participants must be fully informed about the research and invited to**

**participate without coercion of any kind.**

## What is Human Subjects Research? What Kinds of Research Require Review?

Examples of human subjects research that may be part of a DMin program include (but are not limited to):

- surveys and questionnaires
- interviews and focus groups
- ethnographical and other field work
- evaluations of social or educational programs

Potential risks that must be considered in a review include those of a physical, psychological, social, economic, spiritual/ religious, 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.

All research with human subjects involves some degree of risk in that such research may prompt participants to self-knowledge or knowledge of others that they may find painful or otherwise harmful. Such risk cannot be eliminated, so it is incumbent upon the researcher to make sure that subjects are protected as much as possible in every other way.

Loss of confidentiality and/or anonymity[4] is the most common type of risk encountered in DMin and other social and behavioral science research. Confidentiality and anonymity are presumed, and they *must* be maintained in all research and reports deriving from research unless the researcher obtains the express permission of the subject to do otherwise. Breach of confidentiality and/or anonymity entails at least the risks of invasion of privacy, and may carry social, economic, and legal risks as well.

Deception should be avoided in research. It may be used only if there is no other way to obtain the data reasonably, 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. Deception *must not* be used without the express permission of the Federation's IRB.

Human subjects research requiring IRB review includes but is not limited to the following:

- Research in which dual roles may be present between the researcher and the subject(s), such as using students, employees, counseling clients, or members of a congregation as research participants.
- Research in which there is a potential for more than minimal risk of harm to the participant, meaning that "the probability and magnitude of harm or discomfort 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."[5]

- Social scientific research (including practical and pastoral theology, 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.
- Research involving subjects who are not competent to evaluate the risks and benefits of participation themselves, including minors, people with cognitive disabilities, and persons who are institutionalized. All legal requirements for working with such persons, including directives by the Department of Corrections, must be followed.

*Unless DMin research is strictly historical or focused only on published or otherwise public materials, it is presumed to be research involving human subjects <u>unless</u> the Federation's IRB determines otherwise.* IRB review is not required for the required Congregational Study *unless* the study involves asking parishioners to disclose confidential, private, or potentially harmful information.

Some research undertaken at the masters level *may* require IRB review. In that case, these policies apply to that research as well. Instructors who assign such research must submit a proposal (with sample consent form) to the IRB for approval before the beginning of the term in which the course is offered.

Examples of research requiring IRB review:

- Faculty-assigned research project requiring students to have interactions (interviews, small group projects in congregations, etc.) involving participants' subjective experiences or feelings.
- DMin projects using empirical research involving direct contact with clients, patients, support groups, prisoners, 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 or other organizational life, 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.

<u>Human subjects research *not* requiring review</u> includes (but is not limited to) the following:

- Research solely for internal institutional use (e.g., course evaluations, 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.
- Research conducted by DMin students in their ministerial sites that does not reveal confidential information, does not identify individual participants, and does not carry any potential risk of harm (e.g., Congregational Study).
- Research in other settings that would not reasonably create distress or harm *and* involving only anonymous questionnaires or public observation.
- Research using existing data, documents, or records, as long as these resources are publicly available and the human subject cannot be identified.
- Research related to organizational effectiveness in settings for which there is no risk to participants' employability.

Examples of research *not* requiring IRB approval:

- Scholarly review of literature, including other published social scientific research made available to researchers.
- Archival historical research such as church records or public archives. Research must conform to the rules of the particular archive or institutional body.
- Research that engages subjects on a general level, without identification of specific persons and without reasonable potential for harm, such as evaluation responses to a program or project through instruments that maintain anonymity (e.g., responses to a new curriculum, focus groups evaluating liturgical changes in the church).

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

**Note**: If there is any question on the part of the research about whether an IRB review is needed, the student should consult the Director of DMin Programs.

## Guidelines for Researchers

**No research may be carried out prior to IRB approval of the research proposal.**

*Ethical Issues and Procedural Requirements in Human Subjects Research*

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

- Subjects must give informed consent to participate in the project.

- Subjects have the right 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 approved human subjects research, which will exclusively be for fulfilling an academic requirement.
- 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
- Researchers must guarantee that no harm will be done by participating in the research beyond what is stipulated in the approved Informed Consent Form
- The burdens and benefits of subjects' participation in the research shall be justly distributed.

*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 Proposal Form is available in the DMin Handbook.

Specifically, the protocol should address the following questions:

1. What is/are your key research questions?
2. What are the objectives and purposes of this research?
3. What research methods do you plan to use? Describe in detail.
4. 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.
5. How do you plan to begin your research?
6. Whose consent will you need to obtain? What documents will you use to explain your work? (Attach a completed Informed Consent Form)
7. What is your relationship to the people who will be part of the project?
8. What recruitment or invitation procedures do you plan to use?
9. Will subjects who participate in the project be anonymous? If not, how will you assure the privacy of the participants?

10. How do you plan to protect the data? How will you protect confidentiality of the data?
11. How and where will the research be reported?
12. Will any of the subjects be minors (under 18 years of age)? If so, how will you obtain parental consent?
13. Will any of the subjects be members of vulnerable populations (cognitively impaired, institutionalized, imprisoned, etc.)? If so, what additional protections does the research procedure provide them?
14. What are potential benefits for persons who are part of the project?
15. 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?
16. Will the project involve any deception of participants? If so, how? Why is deception necessary? What procedures will you use to debrief participants?
17. What alternative procedures are available to a subject who wishes to withdraw or who is damaged by the project?
18. Is IRB approval required by any other institution? If so, please attach your proposal (for the other institution) as an Append ix and describe the procedure and timeline for approval.

*Consent Forms*

Use the Informed Consent Form appended to this policy. Submit a completed form (i.e., all but participant names and signatures) as part of the research proposal.

## The Review Process

Some research undertaken at the masters level *may* require IRB review. In that case, these policies apply to that research as well.

An individual student proposing *any* type of research with human subjects (e.g., interviews, focus groups, educational programs, etc.) must submit her/his topic to the IRB for a preliminary determination of whether IRB review is required according to this Policy. Remember, it is presumed that all DMin thesis projects will require an IRB review unless otherwise determined by the IRB.

The 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.

Any substantive changes in project design or research instruments that are made after initial approval has been granted must be submitted for re-approval to the full IRB.

In some cases, students 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 the Federation's policy *and* that of the other institution.

Approval is made in light of the following criteria:

1. Validity of research design, methodology, and sampling is determined by weighing the value of the proposed research against any possible risk to participants.
2. 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 and its interpretation.

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 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 record electronically or otherwise 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 is normally comprised of the Director of DMin Programs and a Federation professor of theology and ethics. The President or Dean may appoint an additional faculty member if needed.

The IRB will meet as needed to review proposals. Proposals should be submitted electronically *no less than 3 months before* the student plans to begin the human subject research. The proposal must be accompanied by a sample of the Informed Consent Form(s) to be used with research subjects.

The IRB may approve any proposal as submitted, require revision and re-submission of the proposal, or reject the proposal. Approval must be in writing, and delivered in a timely fashion to the student and the student's advisor. In the case of revisions or rejections, the committee will provide a written statement detailing the reasons for rejection.

The IRB will maintain records of all its deliberations and will report these to the full faculty once a year or more often if needed.

General Notes

- Advisors, thesis directors, and readers have responsibility for reminding students of the Human Subjects Research Policy.
- The Research and Writing course and the Thesis Proposal workshop will introduce the Human Subjects Research Policy and will provide bibliography for additional reading.
- Before submitting research protocols to the IRB, advisors and thesis directors should agree that the researcher has a level of understanding of the task to do human-subjects research.
- **No research may be begun before the IRB has approved the research proposal.**
- **No research may be carried out unless the participants have signed a consent form. Prior to signing the form, participants must be fully informed about the research and invited to participate without coercion of any kind.**

## ***If Problems Should Arise***

Students are *required* to report any adverse events to the Director of DMin Programs. Adverse events include unanticipated problems involving risks to subjects or others. Unanticipated

problems may be associated with physical harm, psychological harm, spiritual harm, and/or social harm. Unanticipated problems may result from a breach of confidentiality associated with the data collected during the research.

Approved by the Bexley Hall Seabury Western Theological Seminary Federation faculty
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[1] These guidelines and the accompanying form(s) are drawn from similar guidelines and form(s) developed and used by United Theological Seminary of the Twin Cities, New Brighton, Minnesota, and Columbia Theological Seminary, Decatur Georgia. The Bexley Seabury Seminary Federation is solely responsible for the content of this material. This material is in compliance with the General Education Standards of the Association of Theological Schools, the Bexley Seabury Seminary Federation's accreditor.

[2] For example, the Baptismal Covenant in The Book of Common Prayer, p. 305.

[3] See "The Common Rule" guidelines established by the U.S. government Office of Human Research Protections, formally titled "Protection of Human Subjects," part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) and can be found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
See also ATS General Institutional Standards 3.3.5 "Ethics of Scholarship," http://www.ats.edu/uploads/accrediting/documents/general-institutional-standards.pdf.
See also American Association of University Professors, "Protecting Human Beings: Institutional Review Boards and Social Science Research," http://www.aaup.org/report/institutional-review-boards-and-social-science-research.

[4] In this context, *confidentiality* refers to maintenance of the Researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. Confidentiality protections include information obtained preliminary to research, for example, information collected from personal records to determine potential sample size or potential participants, as well as, the maintenance of the confidentiality of information after the study has ended, when identifiable information is maintained.
*Anonymity* refers to concealing the identities of all participants in any reports resulting from the research. The use of pseudonyms is not in and of itself an adequate protection of anonymity.

[5] 45 CFR 46.102.h.1, http://www.hhs.gov/ohrp/humansubjects/regbook2013.pdf.pdf.