

Rationale and Timeline for Guidelines for Research with Human Subjects

In the summer of 2008 the external Assessment Committee evaluated DMin theses as part of the regular program assessment. In their report to the VPAAD, they recommended the DMin Committee develop procedures whereby research involving human subjects be reviewed in light of routine ethical standards. (Increasingly journals, publishers, and funding agencies require evidence of such review.) During the fall of 2008, the DMin Committee collected materials from a variety of sources: the Society of Christian Ethics, the U.S. Department of Health and Human Services, Harvard University, Hartford Seminary etc. What follows is a blending of these procedures. The DMin Committee recommends that these be published in the *Community Handbook*.

Guidelines for Research with Human Subjects Conducted by All Persons Affiliated with Saint Paul School of Theology

It is expected that all persons (faculty, administrators and students alike) who conduct research under the auspices of SPST will treat everyone involved in their research with respect and care. The following guidelines are intended to assure this effort.

SPST requires that any research that involves human subjects be approved either by the Vice President for Academic Affairs and Dean and/or a body designated by said Dean **before** any studies involving human subjects are initiated. This kind of research includes but is not limited to interviews, oral histories, focus groups, the completion of questionnaires and the like.

In every case, both the principle investigator (and their committee chair or faculty advisor, if applicable) will have completed within the last two years the tutorial on Investigator Responsibilities and Informed Consent available online at <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>. The Vice President for Academic Affairs and Dean and/or a body designated by said Dean should be provided by the principle investigator with copies of the relevant certificates of completion along with the additional information specified below prior to conducting any research.

Additionally, the principal investigator should fill out a Request for Approval of Human Subjects Research form. This form can be found at www.spst.edu under Academics/Academic Dean OR by logging in into your Saint Paul email account using Internet Explorer browser, and navigating to Public Folders/Registrar's office (for assistance, contact Saint Paul's Helpdesk). Once completed, this form should be submitted to the Vice President for Academic Affairs and Dean and/or a body designated by said Dean for approval. Only after the project has been approved should research begin; approval to continue to research is required if the investigation is not completed within the time frame specified on the approval form.

Informed Consent

The principal investigator shall explain to subjects, prior to their participation,
(A) the objectives of the research;
(B) the procedures to be followed;

- (C) the expected duration of the subject's participation;
- (D) any foreseeable risks or discomforts to the subject;
- (E) any benefits to the subject or others which may reasonably be expected from the research; and
- (F) the extent to which the confidentiality of the records identifying the subject will be maintained.

Where it is determined that the research involves no more than minimal risk to the subject (see below) and involves no procedures for which written consent is normally required outside of the research context, informed consent may be obtained *either* through a signed consent form or in an oral discussion. In the case of a written research instrument, the above information about the research should be placed in a visible place on that instrument. In the case of oral consent, the above information shall be explained at the time consent is requested. The respondent's completion of the instrument shall constitute implied consent. All investigators are advised to document the procedures by which informed consent has been gained.

Investigators shall not use individuals as subjects unless satisfied that they, or others legally responsible for their well-being, consent to participation freely and with understanding of the consequences. Subjects shall not be induced to participate by means or in circumstances that might affect their ability to decide freely. It shall be made clear to subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and without penalty of loss of benefits to which the subject is otherwise entitled.

Confidentiality

Investigators shall respect the privacy of subjects. They shall protect confidential information given them, advising subjects in advance of any limits upon their ability to insure that the information will remain confidential.

Disclosure of Affiliation

Investigators may indicate their relationship to SPST in the course of their research and the dissemination of its results, but (if indicating their affiliation) they must also disclose whether or not the research is approved by the seminary. An investigator shall disclose to a subject, upon request, the source of support for the research.

5. Suspension of Research

Research should be immediately suspended and reviewed if investigators observe any adverse consequences that may be attributable to the research.