HUMAN SUBJECTS RESEARCH REVIEW POLICIES AND PROCEDURES

Class projects or Research Assignments

Garrett-Evangelical Theological Seminary

1. **Rationale:** 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.

   Any student conducting research with human subjects must give attention to the potential risks for those subjects. The researcher must identify threats to the rights or well being of persons or groups of persons who participate in any studies conducted under the auspices of the institution. In general, classroom research projects will not need to be reviewed by the Human Subjects Research Review Committee if they present low risks to the human subjects. Examples of projects which would ordinarily involve low risk would include:

   a) Recording of data from subjects 18 or older using non-invasive procedures

   b) Anonymous voice recordings for research purposes

   c) participation observation in a public venue such as worship services or other community gathering places

   d) Study of existing data, documents, or records

   Other research which would involve greater risks to the human subject(s) must be undertaken with the utmost care and attention to protecting confidentiality and to keeping risks at a minimum and must be reviewed by the Human Subjects Research Review Committee.

2. Any person conducting research with human subjects must give attention to:

   a) **Respect for persons:** The subjects must be respected. They must be informed about the nature of the research, how their confidentiality will be protected, and what form the reporting will take. Any notes or recordings must be kept under the control of the researcher and should be destroyed when the project is completed.

   b) **Risk/benefit ratio:** Any research subject must be informed about the potential risks and benefits of participating in the research project. The research subjects should be informed about the risk of loss of confidentiality. Research may uncover personal material that is painful or wounding. Some information uncovered during the conduct of classroom research may be subject to legal or ethical demands for reporting. Students who have questions about risk in their project should consult with the instructor of the class.

   c) **Confidentiality:** The research investigator will be expected to remove identifying names, locations, and dates from the report shared in class unless permission to share has been explicitly given by the human subject and all others who would be identified in the research report. In most cases, the instructor of the course will be denied access to the identity of the human subjects of the research. Research investigators are responsible for retention of research files and for destroying them when the project is complete.

3. Human Subjects Review Types

a) Categories of Human Subjects Review

i) *General Review:* All research involving human subjects should be reviewed by the HSRC.

ii) *Expedited Review:* There are certain categories of minimal risk human subjects research designated as qualifying for expedited committee review. The expedited review application must be completed, as well as the rest of the form.

iii) *Periodic Review:* All human subjects research must be reviewed and approved at least once every two years. Notification of the need to submit the human subjects review form for periodic review will be sent to the investigator a month prior to the month in which annual review is to be accomplished.

iv) *Revised Projects:* Revisions of protocols and/or consent forms must be reviewed and approved by the HSRC prior to implementation.

b) Further information and guidelines are available through the Northwestern University Institutional Research Board at: http://nuinfo.northwestern.edu/research/OPRS/irb/.

c) Elements of a Research Protocol

i) A research protocol should include the following:

ii) Protocol title and date, name and address of principal investigator, site(s) where study will be performed

iii) Background, rationale, or literature review -- basis for doing the clinical research study

iv) Key questions/hypothesis

v) Research objectives and purpose

vi) Research methods

vii) Protection of subject confidentiality

viii) Anticipated results and potential pitfalls

ix) How and where the research will be reported

4. Responsibilities of Investigators Conducting Human Subject Research

a) In designing a study, investigators should consider the three underlying ethical principles for conducting research with human subjects: respect for persons (informed consent); beneficence (risk/benefit ratio); and justice (equitable selection of subjects).

b) Research investigators acknowledge and accept their responsibility for complying with all requirements of the Garrett-Evangelical HSRC.

c) Investigators are responsible for ensuring that all research involving human subjects is submitted to the HSRC prior to initiation of research.

d) Investigators are responsible for obtaining and documenting informed consent in accordance with federal regulations. Consent forms may only be used for one year from the date of the last protocol approval.

e) Research investigators will promptly report proposed changes in previously approved human subject research activities to the HSRC. The proposed changes will not be initiated without HSRC review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

f) Research investigators are responsible for retention of research files and informed consent documents for at least three years after completion of the research activity.

g) When other hospitals or institutions are participating in research protocols for which a Garrett-Evangelical investigator has primary responsibility, those institutions must possess an applicable assurance prior to involvement of human subjects in those research protocols.

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