Policy for the Protection of Human Subjects: Friends University Institutional Review Board

Friends University commits itself to the pursuit of excellence in research while seeking to protect the welfare, rights and privacy of all persons who are involved in research projects. The university is guided by the common federal policy of the protection of human subjects (Title 45 Code of Federal Regulations Part 46 “Protection of Human Subjects,” July 14, 2009) and the amendments in the federal register, and the Belmont Report delineating respect for persons, beneficence and justice as the ethical principles guiding research using humans as participants. Questions concerning these procedures should be directed to the sitting Chair of the institutional review board (IRB) at irb@friends.edu.

Regulations of the U.S. Department of Health and Human Services (HHS) require that all universities that receive federal funding in support of research with human participants establish an IRB. The IRB is mandated to: 1) examine all proposals for research that involve human subjects before the research is conducted to determine that the research protocol has adequately considered the ethical dimensions of the project and 2) to provide assurance as required to the university, to funding agencies and to the Office of Human Research Protection (OHRP) that all research with human subjects is in compliance with federal regulations.

The IRB has the authority to approve, require modifications in order to secure approval, or reject all research activities covered by the HHS regulations, including proposed changes in ongoing and previously approved human research. It has the authority to suspend or terminate the approval of ongoing, previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected, serious harm to participants. For externally funded research that involves the use of human participants, IRB approval needs to be acquired prior to proposal approval by the Office of Institutional Research and Assessment

In addition to relying on the sections of the Common Code cited by number throughout this document, sections of the Friends IRB policy are modeled after comparable and more research oriented institutions adhering to the same federal guidelines, including Moravian College of Bethlehem, The University of South Florida, Pennsylvania State, Kansas State, The University of Tampa, Clemson University, and Rollins College.

Domain of IRB Authority

The participation of humans in research can raise fundamental ethical and civil rights questions. Therefore, all faculty, staff, and students who involve human beings as participants in any research, whether funded or not, that is: 1) in any way sponsored by the university, 2) conducted by or under the direction of any Friends faculty, staff, or student, 3) uses Friends facilities or property for the collection or analysis of data or 4) involves the use of Friends nonpublic information to contact or identify participants or prospective participants must obtain IRB approval before beginning their research. This policy also applies to research conducted at other institutions by Friends faculty, staff, and students, even if the other institution has its own review process. The University does not accept responsibility for research that is conducted in violation of this policy or without required IRB approval.

The IRB policy described in this document applies to research using human participants. As per federal guidelines (46.102d), research is defined as “systematic investigation designed to develop or contribute to generalizable knowledge.” Any activity conducted at Friends University that meets this definition of research is subject to the conditions set forth in the common code and explained in this document. A human participant (sometimes referred to as a subject) is defined as “a living individual about whom an investigator conducting research obtains data through communication or interpersonal contact or identifiable private information (46.102f)

IRB Expertise

IRBs should:

1. be familiar with Federal regulations, applicable state law, and institutional policies and procedures for the protection of human participants.

2. have effective knowledge of participant populations and other factors that can foreseeably contribute to a determination of risks and benefits to participants and their informed consent.

3. be able to judge the adequacy and accuracy of information in the informed consent document, advertising, and any other materials to be presented to participants.

4. regularly review research that involves a vulnerable population such as children, prisoners, pregnant women, or handicapped or disabled persons, include in its membership one or more individuals who are knowledgeable about and experienced in working with these subjects.

5. have the professional competence necessary to review the research proposals presented for approval.

IRB Composition

The Vice President of Academic Affairs (VPAA), who will consult with the Faculty Senate before making appointments, will appoint members of the IRB. The composition of the IRB shall be composed of at least five members, not all from the same discipline. One member must be from a science and one must be from a non-science discipline. One member needs to be unaffiliated with the university nor have a family member affiliated with the university (46.107). The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

The committee members shall elect the Chair of the IRB. In certain cases, the IRB may consult with non-voting ad hoc members or authorities whose expertise and/or experience is relevant to a particular submission or in conditions when the committee members lack expertise to make an adequate review of a protocol. Members of the IRB shall not vote on protocols on which they are an investigator or have other conflicts of interest, although they may provide information to IRB members regarding the submission.

Responsibilities of IRB Chair

1. Inform investigators in writing of: 1) questions/issues arising from a submission and 2) IRB decisions.

2. Maintain copies of correspondence between the IRB and investigators for three years after the completion of the research. Records may include copies of submitted proposals, signed informed consent documents, reports of any injuries to subjects, continuing projects, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, and all other correspondence concerning the use of human participants.

3. Insure compliance with federal regulations regarding committee composition, quorum, record keeping, and the Office for Human Research Protection (OHRP) annual report.

4. Report information as appropriate to the OHRP, the IRB, principal investigators and other university personnel on issues dealing with changes in regulations, new requirements and ongoing IRB issues

5. Notify appropriate personnel of cases of injury, unanticipated problems, serious or continuing noncompliance with IRB requirements and suspension or termination of IRB approval should such cases arise

6. Keep appropriate minutes of IRB meetings, a list of current IRB members and written procedures for the IRB.

Responsibilities of Investigators

Investigators have the primary responsibility to:

1. Protect the rights and welfare of human research subjects and comply with all applicable provisions of the Friends IRB policy.

2. Be knowledgeable about the requirements of the HHS regulations, applicable state law, and institutional policies and procedures for the protection of human participants.

3. Conduct their research according to IRB-approved protocol.

4. Obtain and document the informed consent of each participant or each participant's legally authorized representative and provide a copy of the IRB-approved informed consent document to each participant or the participant's legally authorized representative at the time of consent, unless the IRB has specifically waived either of these requirements.

5. Ensure that each potential participant understands the nature of the research and participation.

6. Promptly report proposed changes in previously approved human research activities to the IRB. The proposed changes cannot be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.

7. Promptly report to the IRB any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with the HHS regulations or determination of the IRB.

IRB Decisions

The IRB may take the following actions with respect to submitted research proposals (46.109d):

1. Approval: for a period of not greater than (and possibly less than) one year. After receiving written notification of approval, no further action is required from the investigator before beginning the study. If the study lasts longer than12 months, the investigator should inform the IRB chair of the status of the project, any changes in protocol, and if any adverse events have occurred.

2. Revise and resubmit: The IRB may request written clarification and/or modification of one or more aspects of the proposal from the investigator. After receiving written notification of a revise and resubmit decision, the investigator should submit a revised application that clarifies the issues involved and/or answers the IRB's questions, provides the requested documentation or agrees to make requested modifications. The revised and resubmitted proposal will either be approved or asked for further modification/clarification.

3. Rejection: because of the level of risk involved, the proposed research cannot be justified. Written notification of rejection must include reasons for the decision and offer the investigator an opportunity to respond in person or in writing. If rejected, investigators are encouraged to review and resubmit their proposal in accordance with the criteria for acceptance.

IRB Application

All investigators must complete the Friends IRB application. Investigators will indicate which of three levels of review they believe to be appropriate to their proposal: exempt research, expedited review, or full review (described in detail below). In general, exempt research is that which involves no risk to subjects, expedited review involves only "minimal risk," and full review involves risks greater than "minimal risk." The IRB has the authority to move a proposal to a higher level of review if necessary.

Submitted proposals will be reviewed as they are received on a case-by-case basis. Written notification will generally be given within three days of submission for exempt proposals, within one week for expedited proposals, and within one month for proposals that require full review. However, careful consideration of submitted proposals will take precedence over speed of review.

Levels of Review

1. *Exempt research*: Exempt studies must be submitted to the IRB for review and granted exemption status by the IRB chair before data collection begins. Exemption refers to relief from the requirement of continuing IRB oversight but not from the requirement that the investigator inform potential subject of proposed procedures and their rights as subjects in accordance with the standards established in that investigators' discipline. The conditions for exemption are:

Part A (all items must apply)

a. The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as participants.

b. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the individual's financial standing, employability or reputation.

c. The research does not involve the collection of information regarding sensitive topics or personal aspects of the subject's behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

d. The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1,3,4 and/or 5 in Part B).

e. The research does not involve deception.

f. The research does not require a waiver from informed consent procedures.

g. The procedures of the research are generally free of foreseeable risk to the participant. Risk can be mental, physical, psychological or social. In Minimal risk, harm or discomfort anticipated in the proposed research is no greater than an individual would normally encounter in his/her everyday life or during the performance of routine physical or psychological examinations or tests.

Part B (at least one should apply):

The DHHS recognizes the following categories of exempt review (46.101b):

a. Educational research in an educational setting using normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula or classroom management methods)

Note: In order for a project conducted in classrooms outside of Friends University, to be reviewed under the exempt category, the investigator must supply a letter from the appropriate school district official certifying that the project will: a) not differ in significant ways from the normal range of activities of the class, school or district; b) involve only customary and noncontroversial instructional goals; c) not deny any students educational benefits they

would otherwise receive; d) promise direct benefits to the classroom, school or district; e) incorporate adequate safeguards to protect the privacy (anonymity or confidentiality) of all individuals who might be subjects of the research; or f) involve only existing data on students which are non-identity specific.

b. Research using survey procedures, interview procedures, observing public behavior or using educational tests where the information is recorded anonymously (i.e. so that the subject cannot be identified directly or indirectly through identifiers linked to the subject). All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as participants is exempt, whether or not data collection is anonymous.

c. Research involving collection or study of existing data, documents, records or diagnostic specimens. These sources must be publicly available or the information must recorded by the investigator anonymously (in such a manner that the participants cannot be identified, directly or through identifiers linked to the participant).

d. Research (and demonstration projects) conducted by or subject to the approval of department or agency heads and designed to study evaluate or otherwise examine a) public benefit or service programs, b) procedures for obtaining benefits or services under those programs, c) possible changes in or alternatives to those programs or procedures, or d) possible changes in methods or levels of services under those programs.

e. Research involving taste and food quality evaluations or consumer acceptance studies, if wholesome foods without additives are consumed or foods which contains additives at or below that level and for a use found to be safe by the FDA, or approved by the EPA or the food safety and inspection service of the U.S. Department of Agriculture.

2. *Expedited review*: Expedited proposals are reviewed by the Chair and two members of the IRB appointed by the Chair, and approved unless one or both of the reviewers recommends rejection or more information, in which case the proposal is sent for full review. All members of the IRB will be advised of proposals accepted as expedited. Conditions for expedited review are (46.110):

<u>Part A (all items must apply):</u>

a. The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as participants.

b. The research does not involve the collection or recording of behavior that, if known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the individual’s financial standing employability or reputation.

c. The research does not involve the collection of information regarding sensitive or personal aspects of the subject's behavior (i.e. drug or alcohol use, illegal conduct, sexual behavior).

d. The procedures of the research present no more than minimal risk to the participant. Risk can be mental, physical, psychological or social. In minimal risk, harm or discomfort

anticipated in the proposed research is no greater than an individual would normally encounter in his/her everyday life or during the performance of routine physical or psychological examinations or tests.

Part B (at least one item should apply)

a. Research that involves existing non-public identifiable data, documents, records or specimens that have been collected or will be collected in their entirety prior to the research or for a purpose other than the proposed research (such as medical research or diagnosis). Although confidentiality will be strictly maintained, information will not be recorded anonymously (use will be made of audio or video records, names will be recorded even if not directly associated with the data).

b. Research on individual or group characteristics or behavior (including but not limited to study of perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) and/or research employing surveys, interview focus group program evaluation, human factors evaluation or quality assurance methodologies that involve adults where: 1) the research does not involve stress to the participants and identification of the participants and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the participant's financial standing employability or reputation; 2) involve children where the research involves neither stress to participants nor sensitive information about themselves or their family; no alteration or waiver of regulatory requirements for parental permission has been proposed; and identification of the participants and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of the participants or their family members.

c. Collection of data from voice, video, digital or image recordings made for research purposes where identification of the participants and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability or reputation.

d. Collection of data through use of the following procedures: 1) noninvasive procedures (not involving general anesthesia) routinely employed in clinical practice, but not involving x-rays or microwaves; 2) physical sensors applied either to the surface of the body or at a distance and that do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; 3) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging, diagnostic infrared imaging, Doppler blood flow and echocardiography; 4) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects.

e. Prospective collection by noninvasive means of biological specimens for research purposes (ex. Hair clippings, saliva, buccal scraping); research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.

f. Research that involves deception. Deception must be scientifically justified and debriefing procedures must be outlined in detail.

g. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or observation of public behavior where although confidentiality will be strictly maintained, information will not be recorded anonymously (use will be made of audio or video records, names will be recorded even if not directly associated with the data)**.**

h. Research previously approved by the IRB 1) where a) the research is permanently closed to the enrollment of new subjects b) all subjects have completed all research related interventions and c) the research remains active only for long term follow-up of subjects, 2) where the remaining research activities are limited to data analysis or 3) where no new subjects have been enrolled and no additional risks have been identified.

3. *Full review*: Any research that does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status. Convened meetings are necessary when a proposal goes through full review. In order for action on a proposal, a majority of the members of the IRB must be present, including at least one member whose primary concerns are in non-scientific areas. A proposal must receive the approval of a majority of those members present at the meeting. Meetings may be conducted by conference call or by email, provided that each participating IRB member has received all pertinent material prior to the meeting and can actively and equally participate in the discussion of all protocols. Minutes of meetings must be taken and should document: a list of attendees at the meeting, if appropriate, documentation that the criteria for participation via conference call or email were met; actions taken by the IRB; the number of members abstaining, voting for, and voting against each proposal; the basis for requiring changes in or disapproving research; and a written summary of the discussion of debated issues and their resolution. Conditions for full review are:

<u>If any of these apply:</u>

a. Any research involving the use of vulnerable participants (participants who may not be able to make fully informed consent). Vulnerable populations include children under the age of 18 (unless as described previously), prisoners, fetuses, pregnant women, seriously ill, mentally or cognitively compromised adults, persons under treatment for an illness relevant to the project and individuals who may risk retribution by a person with authority over them as a consequence of participation or non participation in the study. Additional protections as delineated in subparts B (pregnant women and fetuses) and C (prisoners) will be used in studies involving these vulnerable populations.

b. The research involves the collection of information regarding or recording of behavior which if known outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability or reputation

c. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g. drug or alcohol use, illegal conduct, sexual behavior)

d. The procedures of the research involve more than minimal risk. Risk can be mental, physical, psychological or social. Minimal risk defined as harm or discomfort anticipated in the proposed research is no greater than an individual would normally encounter in his/her everyday life or during the performance of routine physical or psychological examinations or tests.

4. *Continuing review*: IRB review is an ongoing process and does not end with the initial project approval. All approved projects must be resubmitted annually (46.109e). Continuing review occurs as follows:

a. Continuation of ongoing research: projects whose IRB approval has expired will be granted renewal of approval by the Chair of the IRB if no changes have been made to the project.

b. Minor revisions in protocol: minor revisions in protocol that do not significantly change the methodology and do not introduce risk are reviewed in an expedited manner.

c. Major revisions in protocol: major revisions in protocol, such as including a new subject population, using different methodology, or changes in level of risk require the submission of a new application.

d. Reports of unforeseen events: All unforeseen negative events that arise in the conduct of research shall be reported immediately to the IRB by the investigator or by subjects. The IRB shall suspend approval of the research until the events are reviewed and a determination made regarding any necessary changes in protocol.

Informed Consent

Unless specifically authorized by the IRB as stated below, no investigator may involve a human being as a participant in research covered by the HHS regulations unless the investigator has obtained the legally effective informed consent of the subject or the participant's legally authorized representative (46.116). Investigators are responsible for making sure that informed consent is documented by using a written consent form approved by the IRB.

1. *Criteria for Informed Consent*

Informed consent refers to the voluntary choice of an individual to participate in research based on an accurate and complete understanding of, among other things, its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate. Legally effective informed consent shall (46.116):

a. Be obtained from the participant or the participant’s legally authorized representative.

b. Be in language understandable to the participant or representative and written at a level appropriate to the understanding of the participants to be enrolled; technical language and "first person" statements that ask participants to make statements that they are not in a position to verify should be avoided.

c. Be obtained under circumstances that offer the participant or the representative sufficient opportunity to consider whether the participant should participate.

d. Not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

At a minimum, informed consent shall provide the following information (46.116a). A sample form is provided in the Appendix:

a. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation, and a description of the procedures to be followed

b. any reasonably foreseeable risks or discomforts to the participant

c. any benefits to the participant or to others which may be reasonably expected from the research

d. a disclosure of appropriate alternate procedures of courses of treatment, if any, that might be beneficial to the participant

e. the means by which confidentiality of records identifying the participant will be maintained

f. a statement explaining how and with whom the results of the study will be shared

g. for research involving more than minimal risk, an explanation of any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so what they consist of, or where further information may be obtained

h. contact information for the investigator and for the IRB chair should participants have questions regarding their rights as participants, and contact information in the event of a research related injury

i. a statement explaining that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Certain projects, if requested to do so by the IRB, can and may require additional statements of informed consent (46.116b), including:

a. a statement that the treatment or procedure may involve risk to the participant (or to an embryo or fetus, if the subject is or may become pregnant) which is currently unforeseeable

b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

c. any additional costs to the subject that may result from participation in the research

d. the consequences of a subject's decision to withdraw from the research and procedures for termination of participation

e. a statement that new findings obtained during the research may relate to the subject's willingness to continue participation and

f. the number of participants involved in the study

Documentation of informed consent may be either (46.117b):

a. Written: a written consent document that contains all elements of informed consent as described above. This form may be read by or to the participant or the participant's legally authorized representative, and the investigator should give either the subject or the representative adequate opportunity to read it before it is signed, OR

b. Oral Short form: a short form document, acknowledging that the elements of informed consent as described above were presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the IRB-approved oral presentation of the informed consent (need form for oral summary of informed consent), who will sign both the short form, which will be signed by the participant or the representative, and a copy of the oral presentation. A copy of the oral presentation and a copy of the short form shall be given to the participant or representative.

2. *Waivers of Informed Consent*

The IRB may waive or alter the requirement for a signed consent form for some or all participants if it finds either (46.117c):

a. the consent document is the only record linking the participant with the research and the principal risk would be potential harm resulting from a breach of confidentiality (e.g. studies on potentially sensitive topics such as illegal drug use, other illegal conduct or sexual behavior). In this case, each participant will be asked if they want documentation to remain with them or with the research records, and the participant's wishes will govern OR

b. the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research setting

The IRB may approve a consent procedure that does not include or alters some or all of the elements above, or waive or alter the requirement for the investigator to obtain informed consent if (46.116c)

a. the research or demonstration project is to be conducted by, or is participant to the approval of state or local government officials and is designed to study, evaluate or otherwise examine 1) public benefit or service programs, 2) procedures for obtaining benefits or services under those programs, 3) possible changes in or alternatives to those programs or

procedures, or 4) possible changes in methods or levels of services under those programs AND

b. The research could not practicably be carried out without the waiver

OR (46.116d; all four conditions must be met)

a. the research involves no more than minimal risk

b. the waiver or alteration will not adversely affect the rights and welfare of the participants

c. the research could not practicably be carried out without the waiver or alteration AND

d. whenever appropriate, the subjects will be provided with additional pertinent information after participation

Research with Children

Federal regulations require that all research conducted with children and/or adolescents must be reviewed (cannot be exempt). The exceptions to this rule are:

1. observations of children's public behavior with no interaction with the children

2. research conducted in educational settings of normal educational practices (e.g., on instructional strategies or curricula)

3. research using existing records or data, if these sources are publicly available or if the information is recorded in such a way that the child cannot be identified.

Another requirement is that assent must be obtained from the child. Children (those under 18) should be given an explanation at a level appropriate to his/her age, maturity, experience and condition, of the general purpose of the research, procedures to be used, anticipated discomfort and inconvenience. Children should be asked if they wish to participate in the research or not, and failure to object should not, in the absence of affirmative agreement, be construed as assent.

The IRB proposal should include:

1. how assent will be obtained from the child and whether or not the child's parent and/or guardian will be present,

2. how assent will be documented. Children may either sign an assent form or verbally indicate a willingness to participate. A copy of either the assent form or a script of the explanation given to the child must be submitted with the proposal.

Research conducted off campus or outside the United States of America:

If some or all of the research is conducted at another institution, that institution must provide evidence of review and agreement from the host institution. If the host institution does not have an IRB, a letter on institutional letterhead signed by an official of the host institution agreeing to permit access to the study population will be required. If the research is conducted outside the United States of America, research must also conform to ethical and legal standards for research involving human subjects of the host country.