Guidelines and Policies for Research Involving Human Subjects: Procedures for Assuring the Welfare of Human Participants in Research Associated with Philadelphia University

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Introduction

Faculty, staff and students at Philadelphia University are occasionally involved in the conduct of research involving human subjects. According to Federal Government guidelines, *human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention or interaction with the individual, or
(2) identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects

Any research conducted under the auspices of Philadelphia University must protect the rights of human subjects and requires approval from the University's Institutional Review Board (IRB). An IRB is a committee of peers that examines human subjects research proposed by Philadelphia University faculty or students for ethical concerns and determines: 1) the rights and welfare of the individual or individuals involved; 2) the appropriateness of the methods used to secure informed consent; and 3) the risks and benefits of the investigation. The IRB approves, denies or recommends changes to the proposed research to assure the protection of the rights of human subjects.

The policies and procedures associated with the review and approval of research involving human subjects at Philadelphia University are established to be consistent with current federal guidelines. For the guidelines in full, see the Department of Health and Human Services (DHHS), Protection of Human Subjects, Code of Federal Regulations, Title 45 Public Welfare, Part 46 (June 18, 1991). The following website contains this information: http://206.102.88.10/ohsrsite/guidelines/guidelines.html

IRB Membership

The IRB is comprised of five voting members. Four are full-time Philadelphia University faculty members. One member, chosen by the other four, is selected based on his/her area of academic and/or professional expertise. The fifth IRB member must come from outside of the Philadelphia University community, and is consulted on an as needed

basis. The Vice President of Academic Affairs (VPAA) or his/her designee serves as a non-voting ex-officio IRB member.

The term length of the four Philadelphia University IRB members is four years. Every two years (beginning in June 2005), two new members of the IRB are appointed by the University Advisory Board in consultation with the VPAA and two members who have fulfilled their four-year terms step down, in order to maintain a continuity of membership over time. IRB members may not serve two terms in a row.

The four Philadelphia University IRB members, once selected, designate a member to serve as Chair. The position of Chair rotates among the four Philadelphia University IRM members; as of June 1, 2005, a Chair may serve no longer than two years before being replaced by another IRB member.

In creating the IRB, consideration will be given to the following (as set forth in Title 45 CFR Part 46):

- The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of its 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 subjects.

- Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the University's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender.

- In order to maintain a balance of backgrounds and disciplines, the IRB may not consist entirely of members of one professional field or School.

- An IRB member may not participate in the initial or continuing review of any project in which that member has a conflicting interest, except to provide information requested by the IRB. If a member has a conflict of interest with regard to a specific proposal, s/he should recuse him/herself from the review in question.

- The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Established Criteria for IRB Reviews

Research involving human subjects includes any activities whereby an investigator (faculty, staff, or student) obtains research data through intervention or interaction with a living individual. Intervention includes a manipulation of the human subject's

environment or physical acquisition of data performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and the subject for research purposes.

Research projects requiring IRB approval are generally regarded to be pilot studies, primary research, replication research, and secondary analysis projects. Data collection which takes place during the ordinary functioning of classroom activity (such as, for example, the distribution and completion of Student Course Evaluations), does not require IRB review.

The IRB has the responsibility and authority to review and approve, require modification in, or disapprove any or all activities or proposed changes associated with a research project. The following requirements must be satisfied in order for the IRB to approve a research project:

- Risks to human subjects are minimized by using research procedures which are consistent with sound research design and which do not unnecessarily expose the subject to risk. Appropriate procedures already being performed on the subjects for diagnostic or treatment purposes are not altered in a way to increase risks to the human subjects.

- Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies the subjects would receive even if not participating in the research).

- The IRB shall determine if the investigator knowingly or unknowingly uses coercion for human subjects participation in research. Such coercive actions by an investigator may include using students in his/her class, assigning extra credit for participation in research or waiving other course requirements. Such actions would require the IRB to disapprove the research protocol unless there were unusual extenuating circumstances.

The IRB should also ensure that:

- Informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with law. The informed consent must be appropriately documented.

- Adequate provisions are outlined for monitoring the data collection to ensure the safety of subjects.

- Adequate provisions are outlined for the protection of the privacy of subjects and to maintain the confidentially of data.

Each of these criteria is addressed in the summary sheets provided in the appendix, and must be considered as part of any approved research project reviewed by the IRB.

Any studies previously receiving IRB approval but which are subsequently notified of possible noncompliance with existing federal or University requirements for research involving human subjects may be reviewed again by the IRB and disapproved for noncompliance. The investigator(s) will be notified in writing if the IRB chooses to investigate their research for noncompliance.

The IRB approves all complete and expedited reviews for a period of twelve months. Research extending beyond the approval period must be reviewed and approved by the IRB for a renewal period of an additional twelve months.

Types of Review

Whenever research conducted by a faculty member, staff person, or student at Philadelphia University involves the use of human subjects, the researcher is encouraged to contact the IRB Chair in order to determine whether their project is exempt from IRB review. To assure the protection of human subjects and to comply with federal law, Philadelphia University requires that all research projects involving human subjects be reviewed and approved by the IRB **prior to the initiation of the research itself**.

The IRB conducts two types of reviews of research involving human subjects, which are based upon the level of intervention associated with the research. In general, pilot studies, new research and replication research involving human subjects will require a **full** IRB review (see below). Most secondary analysis projects involving human subjects will fall under the expedited IRB review process. Secondary analysis projects involving human subjects are exempt from IRB review when the data sources are publicly available or when the data cannot be linked to the subjects.

For proposals that meet the criteria for an **expedited** review (see below), the Chair will review and decide whether to approve the proposal or send it to the full Board for a complete review. Ongoing review of multi-year projects often takes the form of a paperwork review at yearly intervals, or when the researcher anticipates major changes in research protocol or design.

Thus, the IRB only meets on an as-needed basis, at the request of the Chair, in order to assess proposals requiring a complete review. For a proposal to be approved in such cases, a minimum of three voting members of the IRB must vote for approval.

Full IRB Review

Research proposals scheduled for full review are distributed to all members of the IRB prior to the meeting. When consultants or experts are used to provide special expertise to the IRB in its review of a protocol, the research protocol is distributed to the consultants or experts prior to the meeting.

For a research proposal to be approved, it must receive the approval of a majority of those members present at the convened meeting. Where research activities were initially approved under expedited review procedures and subsequently reviewed by the full Board, the decisions reached at the convened meeting will supersede any decisions made through the expedited review.

Expedited Review

The VPAA (or his/her designee) will, in consultation with the IRB Chair, determine whether the research protocol meets the requirements for an expedited review process. Other members of the IRB are called upon as necessary to participate in the decision-making process.

The IRB also uses the expedited review process to review minor changes in previously approved research during the period for which approval is authorized. Most secondary analysis projects involving human subjects will fall under the expedited IRB review process. Secondary analysis is the analysis of a data set that has been developed in a previous study or by another investigator. It is usually conducted for the purpose of exploring specific research questions that were secondary to the primary study purpose.

Expedited review is conducted by the IRB Chair or by one or more of the appropriate IRB members designated by the Chair to conduct the review. The VPAA (or his/her designee) is also involved in the review and approval process for the expedited review. In the event that the reviewer decides to disapprove the proposed research, it must in turn be reviewed by the full committee. The reviewer may also decide the IRB should conduct a full review of any proposal submitted for an expedited review. In such instances, the IRB will request additional application materials consistent with the full review.

When the expedited review procedure is used, the IRB Chair or member(s) conducting the review informs the full committee in writing of research protocols that have been approved. Such approval is not final until 10 days after the full committee has been informed and during which time no member of the IRB requests a full review. Any IRB member may request that a full review of any research protocol be conducted. The IRB Chair will conduct a vote of the IRB committee.

Research that qualifies for expedited review includes:

- Recording of data from subjects 18 years or age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance

and do not involve input of matter or significant amount of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

- Collection of hair and nail clippings in an undisfiguring manner, deciduous teeth and permanent teeth if patient care indicated a need for extraction.

- Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to labor.

- Voice recordings made for research purposes such as investigations of speech defects [Please see Appendices for the Permission to Audiotape form].

- Moderate exercise in healthy volunteers.

- The study of existing data, documents, records, pathological specimens, or diagnostic specimens unless the data are publicly available and not linked to individuals.

- Research on individual or group behavior of characteristics of individuals, using survey instruments, structured interviews, naturalistic observation or similar techniques where the investigator does not manipulate the subject(s)'s behavior and the research will not involve stress to subjects.

- Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

The IRB reserves the right to determine whether an application submitted for expedited review requires a full review.

Research Which is Exempt From Review

Federal Guidelines specify the following exemptions to IRB review:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of U.S. Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

NOTE: Researchers who are unsure about whether their projects require IRB review (whether Full or Expedited) should informally contact the IRB Chair and/or VPAA via telephone or email to determine if their projects may be considered *Exempt*.

Applying for IRB Review

Applicants must submit a completed application at least four weeks in advance of the initiation of research involving human subjects. The IRB will notify the applicant within two weeks of receipt of the completed application of the results of its review. A completed application for IRB approval will include the following:

- the application for IRB approval;
- a signed Thesis Committee Selection Form (graduate students only);

- a complete copy of the approved Plan for Graduate Thesis (graduate students only) or complete research proposal (faculty, staff, or undergraduate students).

Requirements for Consent Forms

The following information is essential for informed consent in research and should be included on the consent form given to the potential subject. The IRB will assure that this information is clearly stated in language that the subject can understand on the consent form of all research involving human subjects:

1. Introduction of research activities
2. Statement of research purpose
3. Explanation of procedures
4. Descriptions of risks and discomforts
5. Description of benefits
6. Disclosure of alternatives
7. Assurance of anonymity or confidentiality of research records
8. Compensation for participation in research, if appropriate
9. Offer to answer questions
10. Non-coercive disclaimer
11. Option to withdraw
12. Consent to incomplete disclosure.

Appendix: IRB Application Materials and Sample Consent Form

Institutional Review Board of Philadelphia University
Application for IRB Approval

(Please submit this Application ONLY to the VPAA;
***Do not* submit the entire "Guidelines and Policies for**
Research Involving Human Subjects" Document)

Name: _____

Local Address: _____

_____

Permanent Address: _____

_____

Phone: _____

E-Mail: _____

Title of Project: _____

Degree Program (students only): _____

Thesis Advisor (students only): _____

Start Date for Research (must be at least six weeks from date application is submitted):

_____

Signature: _____

Date: _____

Please complete and attach the following summary sheet for IRB review along with a signed copy of the Thesis Committee Selection Form (graduate students only), a copy of your informed consent form, and a copy of your approved Plan for Graduate Thesis (graduate students only) or your completed research proposal.

Summary sheet for review by the Philadelphia University IRB

The following summary must accompany your proposal. Be specific about exactly what subjects will experience when they participate in your research, and about the protections that have been included to safeguard them. Careful attention to the following questions will help facilitate and expedite the review process.

1. In paragraph or abstract form, briefly describe the background and purpose of the study.

2. Briefly (one paragraph), describe, if applicable, each condition or manipulation to be included within the study.

3. What measures or observations will be taken in the study? If any questionnaires, tests, or other instruments are used, provide a brief description and include a copy of the tool.

4. Will the subjects encounter the possibility of psychological, social, physical, or legal risk? If so, please describe.

5. Will any stress to subjects be involved? If so, please describe.

6. Will the subjects be deceived or misled in any way? If so, please describe and include an outline or script of the debriefing.

7. Will there be a request for information which subjects might consider to be personal or sensitive? If so, please describe.

8. Will the subjects be presented with materials which they might consider to be offensive, threatening, or degrading? If so, please describe.

9. Approximately how much time will be required of each subject?

10. Who will be the subjects in this study? How will they be solicited or contacted? Subjects must be informed about the nature of what is involved as a participant, including particularly a description of anything they might consider to be unpleasant or a risk. Please provide an outline or script of the information which will be provided to subjects prior to their consenting to participate. Include a copy of the written solicitation and an outline of the oral solicitation.

11. What steps will be taken to insure that each subject's participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?

12. How will you insure that the subjects give their consent prior to participating? Will a written consent form be used? If so, please include the form, and if not, please indicate why not.

13. Will any aspect of the data be made part of any permanent record that can be identified with the subject?

14. Will the fact that a subject did or did not participate in a specific experiment or study be made part of any permanent record available to a supervisor, teacher, or employer?

15. What steps will be taken to insure confidentiality of the data?

16. If there are any risks involved in the study, are there any offsetting benefits that might accrue to either the subject or society?

17. Will any data from files or archival data be used? If yes, please describe the use of these data in your research.

Sample -- Informed Consent Form

INFORMED CONSENT FOR <project title>

Philadelphia University

Title of project: **<project title>**

Person in charge: **<investigator's name>**
Office: **<investigator's office address and phone>**
Residence: **<investigator's residence and phone (if necessary)>**
e-mail: **<investigator's e-mail>**

1. This section provides an explanation of the study in which you will be participating:

A. The study in which you will be participating is part of research intended to <describe goals of research project>. By conducting this study, the researcher hopes to <describe anticipated benefits of research>. The researcher is a <student/staff person/faculty member> in Philadelphia University's <list degree program or department>.

B. If you agree to take part in this research, you will be asked to <describe research procedures and data collection techniques.

C. Your participation in this research will take a total of <describe time requirements for participants>.

D. <ONLY INSERT IF APPROPRIATE> In participating in this research, you may experience <describe risks associated with participation>.

E. <ONLY INSERT IF APPROPRIATE> By participating in this research, you may experience certain benefits, including <insert description of potential benefits of research>.

F. <ONLY INSERT IF APPROPRIATE> A number of alternative treatments/interventions exist for those used in this research, including (list alternatives>.

2. This section describes <u>your rights as a research participant</u>:

A. You may ask any questions about the research procedures, and these questions will be answered. All questions should be directed to <investigator>, the person in charge of the research.

B. Your participation in this research is <u>confidential</u>. <u>Only</u> the person in charge will have access to your identity and to information that can be associated with your identity. In the event of publication of this research, no personally identifying information will be disclosed. To make sure your participation is confidential, <describe steps to be taken to preserve confidentiality>.

C. Your participation is voluntary. You are free to stop participating in the research at any time, or decline to participate further in the research without penalty.

D. <ONLY INSERT IF APPROPRIATE> This study involves minimal risk; that is, no risks to your physical or mental health beyond those encountered in the normal course of everyday life. <NOTE: only use this statement if minimal risk is involved. If potential risks exit, they should be fully described in this section>

3. This section indicates that you are giving your <u>informed consent to participate</u> in the research:

<u>Participant</u>:

I agree to participate in a scientific investigation of <project title>, as an authorized part of the education and research program of the Philadelphia University.

I understand the information given to me, and I have received answers to any questions I may have had about the research procedure. I understand and agree to the conditions of this study as described.

To the best part of my knowledge and belief, I have no physical or mental illness or difficulties that would increase the risk to me of participation in this study.

I understand that I will receive <amount of compensation/no compensation> for participating, and that I am entitled to no other compensation

I understand that my participation in this research is voluntary, and that I may withdraw from this study at any time by notifying the person in charge.

I am 18 years of age or older.

I understand that I will receive a copy of this signed consent form.

_____ _____

Signature **Date**

<u>Researcher</u>:

I certify that the informed consent procedure has been followed, and that I have answered any questions from the participant above as fully as possible.

_____ _____

Signature **Date**

Revised **<insert date>**