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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 conducting 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 is 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 and 2) the appropriateness of the methods used to secure informed consent. 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

Established Criteria for IRB Reviews

As stated above, research involving human subjects that includes any activities whereby an investigator (faculty, staff, or student) obtains research data through intervention or interaction with a living individual is subject to IRB review. 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.

Data collection which takes place during the ordinary functioning of classroom activity (such as, for example, the distribution and completion of student course evaluations), and research done for purely institutional purposes do not require IRB review.

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

- The use of ethically informed research methods that minimize risks to 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 coerces his/her human subjects' participation during 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 may result in the IRB denying approval of the research.

- Informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with the law. The informed consent process must be appropriately documented. The university does not require a written consent form. However, if researchers are not using a written consent form, they instead must have a **verbal** protocol, which they use to inform a research subject of the methods, purposes and risks of the projected research.

- Adequate provisions are outlined for monitoring and archiving of 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 confidentiality of data.

Any studies previously receiving IRB approval but which are subsequently considered in noncompliance with existing federal or University requirements for research involving human subjects may be reviewed again by the IRB. If the IRB chooses to investigate a researcher for noncompliance, it will notify a researcher in writing. In cases of severe or continual noncompliance, the IRB will refer the cases to the Provost's office for further action. Researchers from other institutions wishing to conduct research at Philadelphia University and new staff and faculty members at Philadelphia University who have prior IRB authorizations from other institutions must still undergo the Philadelphia University IRB review process.

Research that is Exempt from IRB Review

Whenever research conducted by a faculty member, staff person, or student at Philadelphia University involves the use of human subjects, the researchers are encouraged to contact the IRB Chair at irb@philau.edu in order to determine whether their project is exempt from IRB review. Researcher may not request that their research be exempt from IRB review. Such a determination can only be made by the IRB.

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) any Federal statute require 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.

If a research project is not exempt from IRB review, the IRB conducts two types of reviews of research involving human subjects, which are based upon the level of intervention associated with the research: expedited review and full review. Most secondary analysis projects involving human subjects will fall under the expedited IRB review process

Types of 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 review: expedited and full.

Expedited Review

For proposals that meet the criteria for an *expedited* review, the Chair or other IRB members will review the research protocol. A researcher may not request an expedited review. Such a determination can only be made by the IRB. 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.

As stated above, 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. In the event that the reviewer finds significant ethical issues that require further consideration in the proposed research, it must, in turn, be reviewed by the full IRB . The reviewer may also decide whether 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. Any IRB member may request that a full review of any research protocol be conducted.

Research that may qualify 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 or characteristics of individuals, using survey instruments, structured interviews, naturalistic observation or similar techniques where the investigator does not manipulate the subjects' behavior and the research will not cause 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.

The IRB approves all expedited research protocols 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. Researchers will find the renewal request forms on the IRB website.

Full IRB Review

The IRB meets on an as-needed basis, at the request of the Chair, in order to evaluate proposals requiring a full review. Research protocols that propose to work with vulnerable human subject populations or that raise complicated ethical questions regarding their methodology necessitate a full 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 at the convened meeting if a two thirds quorum of IRB members are present. 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.

The IRB approves all full IRB 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. Researchers will find the renewal request forms on the IRB website.

Applying for IRB Review

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

1. The application form for IRB Review

2. All research instruments (i.e., surveys)

3. Verbal or written protocols for gaining consent of human research subjects

Requirements for Consent Forms

The following information is essential for informed consent in research and should be included on the consent form given to or verbally explained to a potential human 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 for participating human subjects
5. Provisions for outside expert intervention in case of undue stress on human subjects
6. Description of benefits of the projected research
7. Disclosure of alternatives
8. Assurance of anonymity or confidentiality of research records
9. Compensation for participation in research, if appropriate
10. Offer to answer questions
11. Non-coercive disclaimer
12. Option to withdraw from research at any time with no consequences
13. Consent to incomplete disclosure.

Appendix: Sample Written Consent Form

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)>
Email: <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 your rights as a research participant:

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 confidential. Only 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 exist, 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 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 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>