Protection of Human Subjects Policies and Procedures

Mission

The mission of the Human Subjects Review Committee (HSRC) is to protect the safety, privacy, and dignity of people and institutions participating in research affiliated with Wilmington University, its students, and its faculty by ensuring:

- research adheres to University policies and meets federal requirements, including the ethical principles of autonomy, beneficence, and justice;
- researchers, along with their advisors, have the qualifications and education necessary to safeguard the reputation and welfare of people, Wilmington University, and other institutions; and
- risks to participants, researchers, and the University are minimized.

The Human Subjects Review Committee is committed to serving the needs of the greater Wilmington University community by:

- providing resources and information about ethical and regulatory issues in human subjects research;
- developing and maintaining standardized protocol forms, archives, and instructional documents;
- ensuring that University students conducting thesis or dissertation research and faculty who are guiding such student research or conducting their own research have current certification;
- providing timely and effective review of all applications for HSRC approval for research;
- advising the University community about training, procedures, and regulations related to the ethical research; and
- keeping the University community informed of all changes in regulatory requirements and related changes to processes and procedures.

Introduction

Research that fits in any of the following categories must be reviewed and approved by the Human Subjects Review Committee (HSRC) of the Faculty Senate prior to collecting data:

- thesis and dissertation research projects conducted by Wilmington University students, even if the research does not involve human subjects;
- research conducted by Wilmington University faculty that involves human subjects;
- Wilmington University employees who are students at other schools and wish to collect data from the University, its students, or employees as part of thesis or dissertation requirements; or
- outside researchers who wish to collect data from the University, its students, or

employees.

Research is defined as a systematic investigation, including research plan development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity.

Federal regulations define a human subject as a living individual about whom a researcher (faculty, staff, or student) obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. All human subjects' protocols are based on the requirements set forth in 21 CFR 50 & 56 and 45 CFR 46. As previously mentioned, Wilmington University students conducting thesis or dissertation research must obtain HSRC approval even if their research does not involve human subjects as defined above.

The HSRC uses the guidelines found in 45 CFR 46.111 to guide its evaluation of research proposals.

Primary responsibility for assuring that the rights and welfare of the individuals involved are protected continues to rest with the researcher. This responsibility is shared by others engaged in the conduct of the research. Faculty who assign or supervise research conducted by students (hereafter referred to as research advisors) have an obligation to consider carefully whether the students are qualified to adequately safeguard the rights and welfare of subjects.

All researchers, research advisors, and HSRC members must complete the on-line Human Subjects Protection training track that is appropriate for their academic college or role. Copies of the certificate of completion of this training are submitted as part of the protocol packets and are archived in the HSRC SharePoint site. Certificates expire in three years.

Institutional Policy

It is the policy of Wilmington University to review all research under its auspices to protect the safety, privacy, and dignity of people and institutions. Review occurs within one of three levels:

1. Exemption,
2 Expedited review, or
3 Full HSRC review.

The Review Process

The HSRC will review a protocol packet prepared by the researcher that includes the protocol form specified by the academic program, a description of the research, procedures relating to protecting human subjects, and attachments including the

appropriate human subjects training certificate, research instrument, informed consent and/or assent forms or participant invitation for implied consent, and approval documents from other organizations (if applicable). The research advisor is responsible for reviewing the protocol packet prior to submission to an HSRC member to ensure quality and completeness.

The HSRC considers the:

- risks to the participants and institutions;
- anticipated benefits to the participants and to others;
- importance of the knowledge that may reasonably be expected to result; and
- informed consent process to be employed.

In addition, the HSRC reviews the information submitted by the researcher to determine whether subjects are adequately informed about the nature of the study, the details of their participation, and the voluntary nature of their participation, and whether the risks and benefits of the research are evenly distributed among the possible subject populations.

Implied consent may be sufficient in some exempt research. Guidelines for obtaining implied consent and sample invitation letters can be found in Human Subjects Review Materials.

Research involving some risk to the participant, nontrivial time commitment, or vulnerable parties (such as minors) requires formal informed consent and/or assent. A checklist for ensuring that key elements of informed consent are addressed can be found in Human Subjects Review Materials. The basic elements of informed consent are:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

- A description of any reasonably foreseeable risks or discomforts to the subject.

- A description of any benefits to the subject or to others which may reasonably be expected from the research.

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.

- For research involving more than minimal risk, an explanation as to whether there would be 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.

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject 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.

Assumptions

The primary responsibility for insuring ethical treatment of human subjects in a given study lies with the researcher and secondarily, if applicable, with the research advisor.

The Human Subjects Review Committee is comprised of representatives of all University academic colleges, the library, and other areas that are involved with research. As such, a broad perspective for the approval processes relating to research is attained.

Procedures

The following procedures will be employed in the review process. There are different procedures for Wilmington University students or other types of researchers.

A. Wilmington University students* conducting thesis or dissertation work:

*Wilmington University students who are also Wilmington University full-time or part-time employees should follow the student procedure as described here.

1. The researcher and research advisor will analyze the anticipated risk or potential for intellectual, physical, psychological, or social injury. They will be responsible for ensuring ethical treatment of subjects, as required by the guidelines emanating from the college, HSRC, and other participating institutions.

2. The researcher will complete the appropriate HSRC protocol packet as specified by the researcher's academic program. Completion entails attachments including the appropriate human subjects training certificate, research instrument, informed consent form or participant invitation, and approval documents from other organizations (if applicable).

3. The research advisor will submit the completed HSRC protocol packet to a college HSRC representative. (If the research advisor is a HSRC member, the advisor must submit the form to another HSRC member.)

4. The college HSRC representative decides whether the protocol packet should be processed as exempt (requiring one signature), expedited (requiring two signatures), or sent to the full committee for review. Alternately, the college

HSRC representative may request modification of the protocol packet prior to further review.

5. If the college HSRC representative decides that the petition has been adequately prepared and meets the requirements for exempt processing, the representative will sign the form and return it to the research advisor. If the college HSRC representative decides that the petition has been adequately prepared and meets the requirements for expedited processing, the representative signs the document and obtains the signature of a second committee member then returns to signed document to the research advisor. The research advisor then forwards the approved packet to the designated administrative person.

6. After informing the researcher that the protocol packet has been approved, a designated administrative person will post a PDF of the signed packet, including all attachments, in the HSRC SharePoint site. The administrative person will also keep a record about the protocol packet and its expiration date in a spreadsheet in the HSRC SharePoint site. Approvals expire after one year.

7. If the college HSRC representative decides that the petition has been adequately prepared but does not meet the requirements for being exempted or expedited, it will be necessary for the petition to be reviewed by the full committee. The committee meets on the second Thursday of each month during the academic year and may convene a special meeting in the summer if needed.

8. When a research petition is submitted from a college HSRC representative to the full HSRC committee, the committee will deliberate and make a decision. The decision will be transmitted to the researcher and the research advisor and copied to the college HSRC representative.

9. It is permitted to conduct pilot tests or to discuss survey or research design with people prior to receiving HSRC approval, provided there is no risk. **However, under no circumstances will a researcher whose research project has not been approved by the college HSRC representative, or is under review by the HSRC, be allowed to collect data until approval has been obtained.**

10. Appeals of HSRC decisions may be made by the researcher or the research advisor directly to the HSRC, and thereafter, if necessary, to the Vice President for Academic Affairs.

11. If the researcher makes changes in the research design, the researcher should submit a revised HSRC protocol packet. This document will be processed in the same way as the original submission. Expiration will occur one year after the date the revised protocol was approved.

B. Researchers who are NOT Wilmington University students,

The HSRC reviews proposals by some researchers who are not Wilmington University students. Researchers who fit into this category include:

- Wilmington University faculty who are not Wilmington University students and wish to conduct research that involves human subjects;
- Wilmington University employees who are students at other schools and wish to collect data from the University, its students, or employees as part of thesis or dissertation requirements; and
- outside researchers who wish to collect data from the University, its students, or employees.

Here are the HSRC procedural steps for researchers who are not students at the University:

1. The researcher should submit the completed HSRC protocol packet with all attachments to an appropriate University executive for signature.

2. If no executive is willing to sign the protocol packet, the request is terminated. The denied request is archived in the HSRC SharePoint site.

3. If a University executive signs the protocol packet, it should then be forwarded to an HSRC member.

4. The HSRC member then processes the HSRC protocol packet in a similar manner to those submitted by students (see above). A PDF of the signed packet is archived in the HSRC SharePoint site.

5. When a decision has been made, the decision is conveyed to the requestor, the approving authority, and the Vice President of Academic Affairs.

Exempt Human Subjects Research

Federal regulations recognize certain types of human subjects' research as being exempt from IRB oversight. Research which the researcher believes to meet the "exempt" criteria will be confirmed by the review of the proposal by a college HSRC representative. The signature of one HSRC member is required for approval of exempt research. Exempt research is either research that does not involve individuals or that fits in a category classified as being exempt in 45 CFR 46.104.

Expedited Review

The expedited review process may be used in accordance with federal regulations for projects involving no more than minimal risk. An expedited review is conducted by two HSRC members.

Security Procedures

When identifiable private information is being collected, including signed consent forms,

it is essential to establish security procedures that protect the individuals. The first security procedure is to limit the demographic information being collected, particularly if the study population is small. If it is possible to identify an individual based on the demographic information, consider making the categories for the demographics larger or ask for fewer characteristics.

Make sure that all information connected to an individual bears a code rather than the person's name and store the code list in a highly secure place.

Identifiable private information should be securely maintained for three years past completion of the research, then destroyed rendering both hard and electronic data unusable and unrecoverable.

Additional confidentiality and security information is covered in the HSRC protocol form.

Full HSCR Committee Review

"At risk" research requires a FULL REVIEW by HSRC. The research advisor will assist with the preparation of any additional required information for the FULL REVIEW.

If a potential risk exists, the researcher must take all possible and reasonable measures to minimize such risk by:

- searching for alternative procedures to avoid the risk;
- using stringent safety precautions to minimize the risk;
- screening out participants who might be particularly susceptible to the risk;
- continuous monitoring of the subject during the procedures;
- minimizing the level and duration of the risk;
- using appropriate measures to detect and correct any consequences of the risk; and/or
- consulting with colleagues regarding techniques of minimization.

The HSRC of the Faculty Senate of Wilmington University meets monthly. If a full committee review is deemed necessary by the college HSRC representative, a request will be made to one of the co-chairs of the committee for consideration at the next meeting. The co-chair of the full committee will schedule and convene the meeting. All members will vote verbally, by a show of hands or by secret ballot after full consideration of the HSRC policy and procedures. If the research advisor is a member of the HSRC, he/she should not participate in the vote. If an HSRC member has a conflict of interest, that member should be excused from the meeting prior to discussion and during the vote. In such cases, the nonvoting members do not count as part of the members necessary to constitute a vote or majority. A quorum of a majority of committee members is required for a decision.

The official minutes of the proceedings will be recorded.

Preparing a Submission for Review

Documentation, using the prescribed forms, including attachments, must be provided for all proposed research involving human subjects.

Researcher Assurance

The researcher must sign the Human Subjects Review Form assuring compliance with all federal, state, and University policies as they apply to the study.

A student may be listed as the researcher on the application forms, but a faculty member must sign the application as the research advisor. The signature of at least one HSRC college representative who is not directly involved in the research is required on the protocol. In other words, the same signature may not appear as both the research advisor and the HSRC representative.

HSRC Protocol Packet

The HSRC protocol packet must contain the following:

- protocol form
- a copy of the human subject protections training certificate;
- a copy of the Informed Consent/Assent Document(s) and/or participation invitation, if personal data is being collected;
- a copy of all data collection instruments and instrument developer approval if relevant; and
- documents indicating approval of participating organizations and, if appropriate, their IRBs.

Safeguarding Confidentiality of Information

To document the confidentiality of information, relevant procedures should be included as supporting documentation in the HSRC protocol packet. Specify how data will be collected and what procedures will be taken to ensure that individuals can not be identified. If individuals can be identified, discuss the measures that will be taken to ensure that identity codes are stored securely and separately from the responses.

State whether data will only be reported in aggregate form. Please remember that individually identifiable information should be held securely for three years following publication of research and then destroyed. Data in electronic format should be maintained in encrypted and/or password protected files. Other types of data should be kept in a locked cabinet.

Approvals from Participating Organizations

If the research will involve other organizations, it is necessary to obtain permission from

these organizations prior to collecting data. Documents providing evidence of organizational agreement to participate in the research must be attached to the HSRC protocol.

Some organizations have institutional review boards (IRBs), and it may be necessary to obtain formal approvals from these IRBs. In other cases, a document from an appropriate organizational executive would be sufficient. It is the researcher's responsibility to determine what type of approval is required and to obtain that approval.

In cases where approval from Wilmington University's HSRC is required as a precondition to obtaining approval from organizations, HSRC approval will be provisional, requiring a second step (obtaining documents from other organizations) to receive full approval.

Modifications to Proposed Research

Researchers must submit a Request for Modification of Approved Research if there are any changes to the data collection approach. The approval procedure is similar to that for the original submission.

- The form is signed and dated by the student and advisor
- The advisor submits the form along with supporting documents to an HSRC representative for review and approval
- The amendment form and supporting documents are sent to the appropriate administrative person for archiving.

It is not necessary to include the original proposal and its documents. If the human subjects training certificate is more than three years old, the student will need to retake the training and submit a new training certificate.

Vulnerable Populations (Protected Subjects)

Federal regulations involving human subjects in research include specific protections for minors, pregnant women and fetuses, cognitively impaired individuals, prisoners and others deemed vulnerable. Researchers who plan to collect data from or about vulnerable populations must complete a training module relating to that population and include that in the training certificate. Further information can be found in 45 CFR 46 Subparts B, C, and D. Please note that the special considerations for pregnant women relate only to research that has some medical risk and would not apply, for example, to survey or interview research that is unrelated to pregnancy.

Record Keeping

A PDF of the approved HSRC protocol will be posted by the appropriate administrative person to the HSRC SharePoint site. This person will also keep a record of information about that protocol in a spreadsheet in the HSRC SharePoint site. Records will be maintained for at least **three** years after studies are completed.