

XIII. Protection of Human Subjects Policies and Procedures

Introduction

Wilmington College has a functioning committee and procedures to review and approve all research involving human subjects. All human subjects research conducted by the College is reviewed under the auspices of the Human Subjects Review Committee (HSRC) of the Faculty Senate. Wilmington College is primarily a teaching institution rather than a research institution, therefore, the HSRC procedures emphasize its teaching mission.

Research is defined as a systematic investigation, including research 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 an investigator (faculty, staff, or student) conducting research 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 regardless of sponsorship.

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

All faculty advisers, HSRC committee members, and principal investigators must complete an on-line tutorial concerning Human Subjects Protection at the NIH website:
<http://cme.nci.nih.gov/> .

Institutional Policy

It is the policy of Wilmington College to review all research under its auspices to determine the protection of human subjects. This occurs within three elements or levels:

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

The Review Process

The fundamental responsibility of the HSRC is to assure that all ethical issues have been fully addressed in the protection of human subjects who volunteer to participate in research studies. The HSRC considers the following:

- 1) The risks to the participants,
- 2) The anticipated benefits to the participants and to others,
- 3) The importance of the knowledge that may reasonably be expected to result; and
- 4) The informed consent process to be employed.

In addition, the HSRC reviews the information submitted by the Principal Investigator* to determine whether subjects are 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.

The basic elements of informed consent are as follows:

1. 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;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether 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;
7. 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; and
8. 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 Principal Investigator* and his or her research committee.

* *The Principal Investigator will most often be a student, but may be a faculty or staff member.* Wilmington College is a private institution that focuses on students' development and success. It maintains a core full-time faculty that typically serve as the primary mentors and advisers of student research projects. Academic project decisions, including research endeavors, should be made as close to the student-instructor/adviser level as possible. This level of decision making helps to protect the values of the College mission, the individual nurturing of students, faculty freedom, and institutional integrity.

The Human Subjects Review Committee is comprised of representatives of all College academic divisions that sponsor student research; therefore, members of HSRC have a direct link to all research projects in the College.

The HSRC members have a collective understanding and possession of written information on the policies and guidelines associated with the requirements for research involving human subjects, and have accepted the responsibility of insuring that each research project conducted by a student in their respective division is appropriately reviewed in accordance with these requirements. Therefore, the decision for an exemption qualification will be made by the HSRC representative. Studies that are not exempted at the research adviser or division/HSRC representative level, because they are considered questionable regarding subjects protection, should be reviewed via an expedited or full committee process.

Procedures

The following procedures will be employed in the review process:

1. The student and his or her research committee adviser will determine the anticipated risk or potential for intellectual, physical, psychological, or social injury that is associated with a student's research project. They will be responsible for insuring ethical treatment of subjects, as required by the guidelines emanating from a division, HSRC, and participating institutions.
2. The student's research committee adviser will provide its division representative on the HSRC information that will clearly indicate:
 - a) The title and concept of the study, and steps taken to insure protection of human subjects, including informed consent, and
 - b) An exemption from further protection of human subjects review, or requirements for a HSRC review.

The division representative on the HSRC will assess the information received from the

student's adviser, and will:

1. Sign off on the submitted study concept indicating that the research project is exempt from further review and the study may proceed, or
 2. Request a meeting with the adviser and/or student to discuss the situation, or
 3. Submit the concept to the HSRC for an expedited or full committee review.
4. When research concepts are submitted from division HSRC members to the HSRC committee, the committee or its designee(s) will deliberate and make a decision. The decision will be transmitted to the student and the research adviser and copied to the divisional HSRC representative.
5. Under no circumstances will a student whose research project has not been reviewed by the divisional HSRC representative, or is under review by the HSRC, be allowed to conduct his or her study until a decision has been rendered.
6. Appeals of HSRC decisions may be made by the student or his/her adviser directly to the HSRC, and thereafter, if necessary, to the Vice President for Academic Affairs.

Exempt Human Subjects Research

Federal regulations recognize certain types of human subjects research as being exempt from IRB oversight. **Wilmington College requires that all human subjects research proposals be reviewed under the auspices of the HSRC.** However, research meeting the "exempt" criteria will be confirmed by the review of the proposal by the division representative of the HSRC and there will be no requirement for continuing review.

If an investigator believes that the research meets the criteria for exempt human subjects research, he/she may indicate that on the application form. The investigator's adviser has the responsibility of reviewing the proposed study to determine its exempt status. The approval of exempt status rests with the HSRC division representative.

Exempt research is limited to research involving no more than minimal risk and the only involvement of human subjects is in one or more of the following categories:

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

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if: (a) information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; or (b) if subjects could be identified directly or through linked identifiers, disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or by

damaging to the subjects' financial standing, employability, or reputation.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior not otherwise exempt under the above category, if: (a) the human subjects are elected or appointed public officials or candidates for public office; (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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 subjects.

Research to evaluate or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payments for benefits or services under those programs.

Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed; or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the US Department of Agriculture.

The HSRC, at its discretion, retains the right to require continuing review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

Expedited Review

The expedited review process may be used in accordance with federal regulations for applications that qualify for expedited or exempt from continuing review. Only those projects involving no more than minimal risk will be considered for expedited review. This review is conducted by at least two HSRC members. If the review confirms the judgment that the proposal is of "minimal risk" and written notice to this effect is indicated, then the principal investigator may consider the professional obligations regarding human subjects to have been satisfied.

Expedited review of a project may be requested by the principal investigator at the time of submission of the application by so noting on the Human Subjects Review Form with criteria under which expedited review is possible. The faculty adviser will take this under consideration, but will have the responsibility for making the decision whether to request, through the division HSRC representative, an expedited process or referral to the full board.

The committee chair, assistant chair or his/her designee, may approve projects as submitted by the division HSRC representative or require modifications prior to approval. They are not empowered to disapprove projects reviewed through the expedited process; in such cases, the

application will be submitted for full board review along with the comments and recommendations for the committee chair, assistant chair or his/her designee. In cases where the full board concurs with the recommendation to disapprove a research project, the investigator may appeal the decision to the Vice President for Academic Affairs.

Criteria for Expedited Review

The expedited review process may be used for projects involving no more than minimal risk and the only involvement of human subjects is in one or more of the following categories:

- .1 Collection of blood samples by finger stick, heel stick, or venipuncture as follows:
 - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, amounts drawn may not exceed 550 ml in an 8-week period and no more than 2 times per week; or
 - b. From other adults and children, considering age, weight, and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and no more than 2 times per week.
2. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
3. Collection of data from voice, video, digital or image recordings made for research purposes.
4. Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
5. Continuing review of research previously approved by the convened HSRC where:
 - a. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects;
 - b. Where no subjects have been enrolled and no additional risks have been identified; or;
 - c. Where the remaining research activities are limited to data analysis.

The expedited review procedure will not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Full HSCR Committee Review

“At risk” research requires a FULL REVIEW by HSRC. The investigator’s adviser will assist with the preparation of any additional required information for the FULL REVIEW.

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

1. Searching for alternative procedures to avoid the risk;
2. Using stringent safety precautions to minimize the risk;
3. Screening out participants who might be particularly susceptible to the risk;

4. Continuous monitoring of the subject during the procedures;
5. Minimizing the level and duration of the risk;
6. Using appropriate measures to detect and correct any consequences of the risk; and/or,
7. Consulting with colleagues regarding techniques of minimization.

The HSRC of the Faculty Senate of Wilmington College meets monthly. If a full committee review is deemed necessary by the division HSRC representative, a request will be made to the chair of the committee for consideration at the next meeting. The chair or assistant chair of the full committee will schedule and convene the meeting. All members will vote by a written ballot or a show of hands after full consideration of the Wilmington College HSRC policy and procedures. The official minutes of the proceedings will be recorded.

Preparing a Submission for Review

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

Investigator Assurance

The principal investigator, in whose name the approval certification is issued, must sign the Human Subjects Review Form assuring compliance with all federal, state, and college policies as they apply to the study.

A student researcher may be listed as the principal investigator on the application forms, but a faculty or staff member must sign the application as the faculty adviser. The signature of the HSRC division representative is required on the protocol. In other words, the same signature may not appear as both the faculty adviser and the HSRC representative.

Supporting Documentation

The Human Subjects Review Form must be accompanied by:

1. One copy of the appropriate Human Subjects Research Protocol, including confidentiality safeguards,
2. A copy of the Informed Consent Document(s),
3. A copy of all data collection instruments, and
4. A sample of advertising or other materials used to recruit participants.

Safeguarding Confidentiality of Information

To document the confidentiality of information, the following information should be included as supporting documentation in the Human Subjects Research Record.

All participation will be on a voluntary basis. There are no perceived risks to human subjects. All data collected through the use of [**Specify - surveys, interviews, focus groups, tests, archived data, etc.**] will remain confidential and will be reported in the aggregate [**if this is true**]. All identifying information will be deleted and anonymity preserved.

Modifications to Proposed Research

Investigators must report planned changes that affect protections of human subjects in the conduct of a study and receive approval from their faculty adviser. The faculty adviser will determine the need for continued review and the appropriate documentation. If continued review is considered necessary or desirable by the faculty adviser, the adviser should notify the Division HSRC representative in writing, and include appropriate

documentation. The HSRC division representative will review the adviser's request and make a determination concerning the necessity of an expedited or full HSRC committee review.

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 by the IRB.

Minors

The OPRR has determined that minors between the ages of eight and seventeen must be given the opportunity to assent to participation in research. Documents should be written in language that is easily understandable. Assent by minors does not replace the requirements of parental/guardian consent.

Research involving minors generally falls into one of three categories:

1. Research that does not involve greater than minimal risk may be approved if adequate provisions are made for soliciting the assent of the minors and the permission of their parents or guardians.
2. Research involving greater than minimal risk, but presenting the prospect of direct benefits to an individual subject, or a monitoring procedure that is likely to contribute to the subject's well-being may be approved if:
 - a. The risk is justified by the anticipated benefit to the subject,
 - b. The relationship of risk to benefit is at least as favorable as any available alternate approach, and
 - c. Adequate provisions are made for soliciting the assent of the minor and permission of their parents or guardians.
3. Research involving greater than minimal risk with little or no prospect of direct benefit to individual subjects may be approved if the HSRC finds that:
 - a. The risk represents a minor increase over minimal risk;
 - b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in standard treatment or practice;
 - c. The intervention or procedure is likely to yield some general knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition; and
 - d. Adequate provisions are made for soliciting assent of the minors

and permission of their parents or guardians.

Pregnant Women and Fetuses

When the social science/education research is directed toward pregnant women as subjects, the investigator must explain that the purpose of the activity is to obtain information about the educational and/or social needs of the mother. Moreover, the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary.

Cognitively Impaired

Individuals in a wide variety of situations may have impaired decision making capacity. For example, impairment may occur at times of great stress. Impaired capacity is not limited to individuals with neurologic, psychiatric, or substance abuse problems; conversely, individuals with neurologic, psychiatric, or substance abuse problems should not be presumed to be decisionally impaired. Individual's capacities, impairments, and needs must be taken into account in order to develop practical and ethical approaches to enable them to participate in research. A clear understanding of the implications of various cognitive impairments, along with a careful consideration of proposed clinical research methodology, is required.

Prisoners

Only limited categories of research involving prisoners are permitted under federal regulations. These include:

1. Studies of the possible causes, effects, and processes of incarceration and of criminal behavior, provided there is no more than minimal risk to the subjects;
2. Minimal risk studies of prisons as institutional structures or of prisoners as incarcerated persons;
3. Research on conditions particularly affecting prisons as a class; and
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

Record Keeping

A copy of the records of all actions taken by the HSRC division representatives concerning research exemptions will be kept by the division representative. Proceedings of the HSRC committee concerning expedited or full committee reviews, and related records, will be kept by the committee chair. Records will be maintained for at least three years after studies are completed.