Research and Institutional Review at Wilmington College

Any research involving human subjects (this includes any and all surveys) is subject to review by the Wilmington College Institutional Review Board (IRB). Applications should be filed in the Office of Academic Affairs. The Vice President of Academic Affairs serves as the clerk of the IRB. There may be times during the year when surveying is limited to Institutional Assessment surveying.

The Public Health Service Act (Title IV, Part G, Section 491 a) required the Department of Health and Human Services (DHHS) to issue regulations for the protection of subjects of research and to implement a program of instruction and guidance in ethical issues associated with such research. The regulations are codified as Title 45 Part 46 of the Code of Federal Regulations, Protection of Human Subjects (45 CFR 46), issued on June 18, 1991.

To address these regulations most colleges and universities have formed Institutional Review Boards (IRB's) or Human Subjects Review Boards (HSRB's) to review prospective research. Wilmington College needs to establish such a Board to comply with federal regulations.

Memberships

An IRB should have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB members need to be sufficiently qualified through experience and expertise to promote respect for their advice and counsel in protecting the rights and welfare of human subjects. Consideration should be given to balance in terms of race, gender, cultural backgrounds, and sensitivity to community attitudes. Someone needs to be familiar with (or able to become familiar with) institutional commitments and applicable law. If campus research regularly involves children, prisoners, handicapped persons, pregnant women or mentally disabled persons, then a member of the IRB should be knowledgeable about and experienced in working with these groups.

The full committee is not used for exempted and expedited reviews (described later). In other cases, a majority of the membership must be present for a review and at least one person whose concerns are not primarily scientific should be present.

Exempted Review

Most research projects conducted at Wilmington College will be eligible for exempted review (which means they do not need review). Research that meets all the following criteria is exempt from review. If your project is exempt, a short description of the project should be filed with the committee. The description should clearly state that all criteria for exemption are met by the project. Class projects (even if there are individual variations by student or group) may be filed as a single project by the professor if all meet the criteria.

The description will be reviewed by the Clerk of the IRB or his/her designee within 2 working days. If all conditions are met, the research will be approved. Appendix A of this document is a copy of the "Request for Exempted Review" form.

Criteria for Exemption

1. Research is conducted in an established or commonly accepted educational setting and involves normal educational practices. Examples include research on regular and special educational strategies or research on the effectiveness or the comparison among institutional techniques, curricula, or classroom management methods.
2. Research involves use of educational tests, survey procedures, interview procedures or observation of public behavior and subjects cannot be identified individually, directly or through identifiers linked to the subjects. Disclosure of the human subject's responses outside of the research cannot reasonably place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, or reputation.
3. Research involves the use of educational tests, survey procedures, interview procedures or observation of public behavior does not exempt under b. It is still exempt if the human subjects are elected or appointed officials or candidates for public office or if federal statutes require that confidentiality be maintained throughout the research and thereafter.
4. Research involves collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens as long as subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research or demonstration projects which are conducted by or subject to approval of Department or Agency heads and which are designed to study, evaluate, or otherwise examine: a) public benefit or service programs, b) procedures for obtaining benefits or services under those programs, c) possible changes in or alternatives to those programs or procedures, or d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies: a) if wholesome foods without additives are consumed, or b) if a food is consumed that contains an 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 U.S. Department of Agriculture.
7. The College has the right to further restrict research. Further restrictions will require committee approval and must be reexamined if questioned by a member of the College community.

Expedited Review

Types of research that present only minimal risk to participants are eligible for expedited review. Criteria are given below. A list of materials that should be submitted for research in this category is also given below. The materials need to be reviewed by at least two members of the IRB. Approval of projects for expedited review should not require more than one week. Appendix B of this document is a copy of the "Request for Expedited Review" form.

Criteria for Expedited Review

1. Research involves collections of hair, nail clippings, dental plaque and/or calculus, or teeth in a non-disfiguring manner, or bodily secretions.
2. Research can involve collection of small (less than 450 ml. over an eight-week period and less than 2 samples per week) amounts of blood by venipuncture from subjects 18 years of age or older who are in good health and not pregnant.
3. Research involves speech recordings made for research purposes such as the investigation of speech defects.

4. Research involves moderate exercise by healthy volunteers.
5. Study may involve use of existing data, documents, records, pathological specimens, or diagnostic specimens with possible identification of participant.
6. Research may involve looking at individual or group behavior where the investigator does not manipulate subject's behavior and the research will not involve stress to subjects.
7. Research may involve work with drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
8. Research must meet all the criteria.

Full Review

A full review requires a majority of committee members, one of which must be a committee member whose concerns are not primarily scientific. Because of the need to call a meeting with up to three members present, this type of review may take several weeks. If your research does not fit all the criteria for either exempted or expedited review, you must request full review. An application for this type of review is in Appendix C of this document and needs to be submitted to the IRB.

Other Points to Consider

If any part of your research takes place at another facility, you will need to make sure that you have complied with that facility's IRB regulations as well as with the IRB regulations at Wilmington College. In some cases, alternate facilities will accept Wilmington College's approval if written documentation is provided. Wilmington College will approve projects approved by other organizations.

The Department of Health and Human Services has additional regulations for research involving children as subjects. If your research will involve children, please check the regulations (http://www.hhs.gov/ohrp/policy/faq/children-research/)to ensure that you are in compliance. The Clerk of the IRB should be able to assist you in interpretation of the regulations.