INSTITUTIONAL REVIEW BOARD (IRB)

Voorhees University Policy Manual, Volume I, Pages 67-68

Revised January 2023

1.6.5.1 Institutional Review Board (IRB)

In accordance with the IRB Guidelines set forth in Volume II, the Institutional Review Board receives proposals from all students, faculty and administrative staff conducting research involving human or animal subjects regardless of the form, location, or whether or not it is funded. Students who carry out research projects involving human or animal subjects must receive prior approval from the supervising faculty member.

The IRB must have at least five members appointed by the Provost/Vice President for Academic Affairs and approved [by the] President for three-year terms.

The members must have enough experience, expertise, and diversity to make an informed decision on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place. In addition:

1. If the IRB works with studies that include vulnerable populations, the IRB should have members who are familiar with these groups. It is common for an IRB to include an advocate for prisoners when considering research that involves them.
2. The IRB should include both men and women, as long as they aren't chosen specifically for their gender. The members of the IRB must not be all of the same profession. The IRB must include at least one scientist and at least one non-scientist. These terms are not defined in the regulations.
3. The IRB must include at least one person who is not affiliated with the institution or in the immediate family of a person affiliated with the institution. These are commonly called "Community Members."
4. IRB members may not vote on their own projects.

The IRB may include consultants in its discussions to meet requirements for expertise or diversity, but only actual IRB members may vote.

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Voorhees University Policy Manual, Volume II, Pages 109-114

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2.6 Research Policies

2.6.1 Human Subjects Research

All faculty and students of the Voorhees University community contemplating research involving human subjects are responsible for familiarizing themselves with the requirements of the current IRB Guidelines of the Office for Human Research Protections (OHRP), available online at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm. In addition, the policies of Voorhees University, as provided below, must be followed.

All faculty/students contemplating research involving human subjects must request and receive approval for their research from Voorhees University. This approval is received from an **Institutional Review Board (IRB)** (see Volume I for a complete description of the board). This requirement includes any research endeavor which (a) is funded by the University or through University channels, (b) is conducted by faculty, students or employees of Voorhees University who are acting in connection with their responsibilities or relationships to the University or who intend to invoke the name of the University in any report of the activity, (c) involves the records of the University, (d) occurs on the grounds of Voorhees University or uses as subjects Voorhees University students, faculty, or staff in their respective roles, or (e) uses Voorhees University faculty, staff, students, or employees to identify and/or contact clients, patients, or students to serve as subjects, and (f) to include the use of Voorhees University equipment for the purpose of research. Research for purposes of the Institutional Review Board is defined as any process that seeks to secure information from humans or about humans that differs in any way from customary medical or other professional practice. The process need not be interactive.

2.6.1a Animal Welfare

Federal regulations require VOORHEES UNIVERSITY, when using animals as research subjects, to carefully monitor their care and use. VOORHEES UNIVERSITY is committed to observing federal regulations pertaining to animal care. VOORHEES UNIVERSITY's Institutional Review Board (IRB) shall make recommendations to the VOORHEES UNIVERSITY Administration on all matters of animal care. Forty-five (45) days prior to the submission of proposals that incorporate the use of laboratory animals, VOORHEES UNIVERSITY's "Protocol for the Use of Live Vertebrates for Research, Teaching or Demonstration" shall be completed. This protocol shall be reviewed by members of the IRB. Animal research shall be further governed as follows:

Resources

Guide for the Care & Use of Laboratory Animals, 8th Edition

Office of Laboratory Animal Welfare

Public Health Service Policy on Humane Care & Use of Laboratory Animals

2.6.1.1 Submission Procedures

The procedure for submitting proposals for review is as follows:

Step 1: Complete the appropriate Application for Human Subjects Research: Exempt, Expedited, or Full Review.

1. Exempt: To be exempt from IRB review, the only involvement of human subjects must be in one or more of the categories listed below. Research that includes both exempt and non-exempt categories is not exempt. More detailed information regarding exemptions is found on the Office for Human Research Protections website: www.hhs.gov/ohrp.

a. The research will be conducted in established or commonly accepted educational settings, involving **normal** education practices (e.g., research on instructional strategies, techniques, curricula, or classroom management methods).

b. The research will involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior where the investigator does not participate in the activity being observed, and no information is **recorded** in such a manner that human subjects can be identified directly or indirectly.
c. The research will involve collection or study of data, documents, or other records which were in existence **prior to the research proposal and to this application** and are publicly available or will be recorded in such a manner that the human subjects cannot be identified directly or indirectly.
d. The research will examine public benefit or service programs and has been approved by the appropriate department or agency head.
e. The research will involve taste and food quality evaluation or consumer acceptance studies involving wholesome foods.

2. **Expedited Review**: Certain studies may qualify for expedited review. Expedited reviews are conducted by a single IRB member rather than a majority of the IRB members. The review may be carried out by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after Standard Review. However, a single reviewer may recommend a standard review be conducted. Per the Office for Human Research Protections guidelines, the following research categories are eligible for expedited review. More detailed information and additional categories are found on the Office for Human Research Protections website: www.hhs.gov/ohrp

a. Research involving materials that have been collected, or will be collected, solely for non-research purposes.

b. Collection of data from voice, video, digital, or image recordings made for research purposes.

c. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

3. **Full Review** is conducted at a meeting of the full IRB membership that has a majority of members present and includes at least one member whose primary concerns are in nonscientific areas. Approved research shall receive the approval of a majority of those members present at the meeting.

Step 2. Return the signed application and five copies to the Chair of the Institutional Review Board.

Step 3. The Board will review the application (at which point the applicant may be asked to clarify or respond to questions).

Step 4. The Board will approve or deny the application.

It is essential that the proposal be submitted in sufficient time to allow for proper institutional review prior to initiation of research or submission of proposals to granting organizations. The Board meets on or about the 15th of each month. All applications (exempt, expedited, and full review) are due by the 1st of each month. Applicants should receive initial feedback within 5 business days after the meeting of the Board.

2.6.1.2 Faculty Research

Informed consent is required for all research projects requiring full IRB review and in most research projects which qualify for expedited review or are exempt from review. To qualify for a waiver of the informed consent requirement, a research project must meet the following guidelines: (1) the research must involve no more than minimal risk to subjects, (2) the waiver must not adversely affect the rights and welfare of the subjects, (3) the research cannot practicably be carried out without the waiver, and (4) where appropriate, the subjects must be provided with additional pertinent information after they have participated in the study.

In research with minors or other vulnerable populations, informed consent is especially necessary and must be obtained from parent(s) or legal guardian(s). An understandable explanation of the research procedures should also be given to the minors or other vulnerable participants (populations such as pregnant women, prisoners, those who lack the capacity to consent, non-English speaking individuals, etc.) for whom consent has been obtained, and they should be given the chance to volunteer to participate in the proposed activity. This is called "assent." Their wishes determine their participation. (See: Parent/Guardian Consent Form which can be found in the Student Records Office.)

2.6.1.3 Student Course-Directed Research

"Course-Directed Human Subjects Research" refers to any student Human Subjects Research that is designed to develop or contribute to hands-on learning. Students may not be familiar with

the federal government's policies that govern this type of research. For this reason, proposed student Human Subject Research must be reviewed and approved by the Institutional Review Board prior to initiation of the course work.

Students conducting Human Subjects research shall follow these parameters:

No Minors or Vulnerable Populations - The project cannot include minors or any other vulnerable populations such as pregnant women, prisoners, those who lack the capacity to consent, non-English speaking individuals, etc.

No more than "Minimal Risk - "Minimal risk" is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals. This also precludes the study of any illegal activities.

No Deception - The project cannot include any deception. Individuals must be fully informed and given the opportunity voluntarily to consent to participation.

No Publication - Data from student projects approved under this review category cannot be used for publication nor for thesis/dissertation research.

Instructor Responsibility

Course Instructors are responsible for submitting all of the Applications for Human Subjects Research. All applications, along with the class roll, should be submitted at the same time.

1. Instructors are responsible for instructing students in ethical principles for the protection of the human subjects and the relevant institutional policies and procedures.

2. Instructors are also responsible for prior review of the applications before they are sent to the Institutional Research Board.

2.6.1.4 Research Not Subject to IRB Review

Simulations of human experimentation and course-assigned data collection do not constitute human subjects research if:

1. The activities are designed for educational purposes only. However, if the information that is gathered is "Real Data," not hypothetical, it may often be Research; and

2. The data will not be generalized outside of the classroom (Reporting of data within the class is acceptable because the activities were performed solely for teaching purposes); and

3. The data will not result in an article, master's thesis, doctoral dissertation, poster session, abstract, or other publication or presentation; and

4. The student volunteers or other participants are clearly informed that the activities are an instructional exercise, not actual research.

Exceptions:
Use of experimental drugs, agents, devices, or medical procedures, even when done by students, always constitutes human subjects research and requires prior Institutional Review Board approval.

The purpose for this process is not only to protect the institution but also those individuals who are participating in this research.

2.6.1.5 Maintenance of IRB Records

In accordance with requirements set forth in the CFR (*Code of Federal Regulations*), the Chair of the IRB will prepare and maintain adequate documentation of IRB activities including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent/assent documents, questionnaires and surveys, progress reports submitted by investigators and reports of injuries to subjects.

2. Minutes of IRB meetings, which will be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and investigators.

5. A list of IRB members as required by Title 45 CFR 46.103 (b) (3).

6. Written procedures for the IRB as required by *Title 45 CFR 46.103 (b) (5*).

The records require statements of significant, new findings provided to subjects, as required by *Title 45 CFR 46.116 (b) (5).* The records required to be maintained by the IRB will be retained for at least three (3) years after completion of the research, and the records will be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services at reasonable times and in a reasonable manner as required by *Title 45 CFR 46.115 (b).*