

Hartwick College Institutional Review Board Policy

1. Rationale

The United States Department of Health and Human Services (DHHS) requires peer review approval of all research involving human subjects conducted by investigators at institutions that receive funding from federal agencies. Hartwick College further requires that the DHHS regulations apply to all apposite investigations involving human subjects, discarded human tissue, or the collection of data from the same, regardless of location of the activities or sources of funding. Research protocols describing such activities are to be approved by the Institutional Review Board (IRB) prior to their initiation and are to be reviewed again either annually or more frequently if necessary. The IRB is charged with protecting the rights and welfare of human subjects recruited to participate in selected research activities conducted under the auspices of investigators affiliated with Hartwick College, including student investigators.

2. Membership

- a. General guidelines for membership
 1. The IRB will be comprised of at least five voting members.
 2. Appointed members to the IRB will be sufficiently qualified in their experiences and expertise and sensitive to community attitudes so as to be respected for their advice and counsel in safeguarding the rights and welfare of human subjects.
 3. An IRB member shall not participate in the review of any project in which the said member is involved as a researcher or subject, thus avoiding even the appearance of a conflict of interest.
 4. All attempts will be made to ensure diversity among board members, including gender, ethnicity, and primary discipline.
 5. The IRB Chair may be a member of the faculty or an officer from the Office of Academic Affairs. The Chair will be appointed by the Chief Academic Officer.
 6. All IRB members (other than *ex officio* members) will be appointed by the Chief Academic Officer in consultation with the IRB Chair, to three-year staggered terms.
- b. Membership will include
 1. Chair
 2. At least three members of the faculty, including:
 - a. One tenured faculty member from the physical & life sciences
 - b. One tenured faculty member from the social and behavioral sciences
 3. One external reviewer (a person who is not otherwise affiliated with the College or an immediate family member of a person who is affiliated with the College)
 4. Director of Corporate, Foundation and Government Relations [*ex officio, non-voting member*]
 5. When research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children under 18), the IRB will include at least one ad hoc voting member who has as a primary concern for the welfare of these subjects.

3. Responsibilities

The IRB operates under the rules set forth in the *Code of Federal Regulations 45 CFR 46* and *The Belmont Report*, both publications of DHHS. The primary duties of the IRB are as follows:

- a. To approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by federal, state, and local regulations and College institutional policies. [The Chief Academic Officer has the authority to overrule an IRB approval of a research protocol based on institutional considerations. The Chief Academic Officer does not have the authority to overrule an IRB rejection.]
- b. To protect human subjects from undue risk and deprivation of human rights and dignity, including exclusion from studies of no scientific merit.
- c. To ensure that participation by subjects is both confidential and voluntary, as indicated by a well-articulated informed consent process.
- d. To maintain an equitable balance between potential benefits of the research to the subjects and/or society and the risks assumed by the subject.
- e. To determine that the research design and study methods of a protocol are appropriate to the objectives of the research and the field of study.
- f. To ensure compliance of research protocols with the regulations of DHHS and other funding agencies when appropriate.