

THE USE OF HUMAN SUBJECTS IN RESEARCH

I. Objectives

Hofstra University requires assurance that research investigations involving human subjects meet standards set by the Department of Health and Human Services (HHS). Accordingly, the following Policy is intended to insure that all such projects conducted under the auspices of Hofstra University, on campus or elsewhere, are in full compliance.

II. Coverage

All research projects conducted under the auspices of Hofstra University, which involve human subjects, are covered by this Policy.

III. Organization

A. Membership

The President shall appoint an Institutional Review Board (IRB) consisting of:

1. Two administrators, including the Associate Provost for Research and Sponsored Programs.
2. Two full-time faculty members selected from Hofstra College of Liberal Arts and Sciences (one from Psychology, and one from Biology); one from School of Education, Health, and Human Services, and one from School of Medicine.
3. One “outside” (non-University) member from medicine, dentistry, or clinical psychology. Committee members normally will serve a three-year term but may be reappointed. The President also may appoint additional ad hoc members to deal with specific issues that might arise.

B. Quorum

The “outside” member and two faculty members will constitute a quorum.

IV. Procedures

When a research project requires human subjects, the Principal Investigator (PI) will use the following procedure:

- A. Following pertinent internal (departmental) review, the research protocol will be submitted to the appropriate IRB representative (or his/her designee) or the appropriate liaison. Investigators affiliated with the Department of Psychology, Department of Biology, School of Education, Health and Human Services, and School of Medicine – those academic units with faculty representation to the IRB – will normally submit their protocol to the IRB representative or designee from their academic unit for review. Investigators from units who do not have direct IRB representation will submit their protocol to the IRB liaison assigned to his/her unit for initial review. The liaison will present the protocol to the IRB Chair for further review.
- B. The IRB will be responsible for assuring Hofstra University that the welfare and rights of individuals used in research projects will be protected. Additionally, the IRB also will review the consent forms and arrange for their proper filing.
- C. Following acceptance of a proposal (original or revised) by the IRB, the Principal Investigator will not be permitted to make changes in protocol without clearance from the IRB.
- D. The PI should refer to *Procedures for Implementation of FPS #36* for further guidance.