

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. Institutional Review Board (IRB) Organization

A. Membership

The President shall appoint, upon the recommendation of the Provost, an Institutional Review Board (IRB) consisting of:

- (1) Two administrators, including the Associate Provost for Research and Sponsored Programs.
- (2) Three full-time faculty members selected from Hofstra College of Liberal Arts and Sciences (at least one from Psychology and one from Education); and one full-time faculty member selected from each of the other Schools.
- (3) One “outside” (non-University) member from medicine, 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, including full-time faculty from any of the Schools and the Library. The membership of the IRB shall annually select from among its membership a Chair. The Associate Provost for Research and Sponsored Programs shall serve as IRB Administrator, providing assistance to the IRB and IRB Chair in maintaining appropriate IRB records and assuring prompt communication of IRB actions.

Members of the IRB are required to participate in the Collaborative Institutional Training Initiative (CITI).

B. Quorum

At least 50% of the IRB members, including the “outside” member, will constitute a quorum.

IV. Federalwide Assurance (FWA) Compliance

The Associate Provost for Research and Sponsored Program shall ensure the University's eligibility for a Federalwide Assurance (FWA) from the Office for Human Research Protections. Possession of an FWA is required for the University to receive Federal support for research involving humans as subjects. In applying for FWA, the University will certify that:

- (1) All University research involving human subjects will be guided by the principles of the Belmont Report, and
- (2) All externally-sponsored research, both Federal and non-Federal, shall be conducted in full compliance with Federal policy, which can be found at 45 CFR 46.

V. Procedures

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

- A. The [IRB application](#) will be submitted to the appropriate IRB representative. Investigators affiliated with academic units with faculty representation to the IRB will normally submit their IRB application to the IRB representative from their academic unit for review. Investigators from units who do not have direct IRB representation will consult with the IRB Administrator for guidance in submitting their IRB application.

The IRB Committee will arrange to meet at least once a month during the academic year, as required, to review IRB applications that warrant Full IRB review. Among other tasks to be performed at these meetings is the formal approval of proposals previously acted upon under the Expedited Review process. Other Full Board meetings will be called by the IRB Chair, as needed.

- 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.

All persons conducting research involving humans as research subjects shall participate in the Collaborative Institutional Training Initiative (CITI) before project approval may be granted. In addition to the required CITI Program training, alternative education/training programs may be developed or overseen by the IRB representatives of the different academic units for their respective disciplines and may include professional ethics/research courses that cover professional standards in respect to research with human subjects; however, such programs are subject to review and approval of the IRB.

Investigators shall submit an IRB application that includes sufficient detail to meet the IRB's need for information. The IRB application is available on the *Use of Humans as Research Subjects* web site.

IRB representatives shall make initial determinations on each IRB application they receive. Options include:

As outlined in the Department of Health and Human Services - Office for Human Research Protection's *Human Subject Regulations Decision Charts* (see link: <http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees/>):

- (1) Research is Exempt from Further Review; project may proceed.
- (2) Research is approved under Expedited Review; project may proceed.
- (3) Research is considered to be of greater than minimal risk and, therefore, is referred to the IRB Chair who will arrange for Full Board Review.
- (4) Additional information needed before any action may be taken (the IRB representative will contact the investigator or refer the application to the IRB Chair for handling).

IRB representatives will promptly communicate (via email) determinations/decisions to the IRB Administrator and provide the IRB Administrator with a copy of all materials reviewed and approved, including informed consent forms.

Upon completion of IRB review, the IRB Administrator shall prepare a formal letter of approval to be sent via email to the investigator and other appropriate parties, e.g., faculty advisors, external grant providers. The original letter of approval is available, upon request, from the IRB Administrator.

The IRB Chair, with the assistance of the IRB administrator, shall be responsible for assuring the continuous review of sponsored research through use of a letter to be sent annually. At minimum, projects shall be reviewed annually.

On a monthly basis, the IRB Administrator shall notify all IRB members of IRB applications received that have been deemed Exempt and actions taken via Expedited Review. Generally, this report shall contain: (1) A descriptive project title; (2) Names and academic affiliation of lead investigators; (3) The name of the IRB representative authorizing the research. In the case of IRB applications approved via Expedited Review, this report shall also include an attachment that includes the full IRB application.

- 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 IRB approval of a modification request.

SAMPLE

IRB ANNUAL REVIEW LETTER

Date

Name of Researcher(s)
Address 1
Address 2
City, State Zip Code

Re: Use of Humans as Subjects in Research: Past IRB approval

Dear Researcher(s):

We are in the process of updating the records of the Hofstra University Institutional Review Board (IRB), the committee assigned responsibility for research involving humans as subjects. Our records include the following protocol in your name:

Title of Protocol:

Approval Date:

Attached you will find the IRB Progress/Continuation Form that must be completed in connection with the above-referenced project. Please send the completed form to: annemarie.briskie@hofstra.edu.

For your information, attached please find a copy of the Faculty Policy Series #36 and a listing of current University IRB members. Thank you.

Sincerely,



Sofia Kakoulidis
Associate Provost for Research and Sponsored Programs and
Administrator of the Hofstra University Institutional Review Board (IRB) SK/ab