

Procedures for Implementation of FPS #36

- I. Representation on the University's Institutional Review Board (IRB) shall include two full-time faculty members selected from Hofstra College of Liberal Arts and Sciences (one from the Department of Biology and one from the Department of Psychology), one from School of Education, Health, and Human Services, and one from School of Medicine, as prescribed in FPS #36; two University administrators, including the Associate Provost for Research and Sponsored Programs; and one "outside" (non-University) member selected by the other members of the IRB.

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.

The IRB Chair shall make every reasonable effort to arrange for the committee to meet as a whole body at least once during each academic semester. Among the tasks to be performed at this meeting 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, e.g., to conduct a review of those protocols that by Federal standards would require approval by the Full Board.

- II. The Associate Provost for Research and Sponsored Programs shall ensure the University's eligibility for a Federal-wide Assurance (FWA) from the Office of Human Research Protections. Possession of an FWA is required for the University to receive Federal grant support for research involving humans as subjects. In applying for FWA, the University will certify that:
- (1) All University research involving humans as 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.
- III. All persons conducting sponsored research involving humans as research subject shall participate in a formal education/training program before project approval may be granted. Persons conducting research without external sponsorship shall also participate in such a training program if their research requires Expedited or Full Board review. Such training shall be overseen by the IRB Chair or appropriate IRB representative. Several education/training options have been identified for investigators including:
- (1) An online tutorial developed by the National Institutes of Health (located at phrp.nihtraining.com/).

- (2) The viewing of a videotape series entitled “Protecting Human Subjects,” published by the Office of Human Research Protections, and
 - (3) The signing of a statement attesting to the fact that the investigator has read a full copy of the Belmont Report or the APA (American Psychological Association) publication, Ethics in Research with Human Participants.
 - (4) Alternative education/training programs may be developed or overseen by the IRB representatives of the different academic units for their respective disciplines (Biology, Education, Psychology, and School of Medicine) and may include professional ethics/research courses that cover professional standards in respect to research with human subjects; however, such programs are subject to the review and approval of the IRB.
- IV. Investigators shall develop a research protocol in sufficient detail to meet the IRB’s need for information.
- V. Investigators shall submit their research protocols for initial review to an appropriate IRB representative (or his/her designee) or the appropriate liaison. Investigators affiliated with the Department of Biology, School of Education, Health and Human Services, Department of Psychology, 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 initial 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.
- VI. IRB representatives and/or their designees shall make initial determinations on each protocol they receive. Options include:
- (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. IRB representative then must contact the investigator or refer the protocol to the IRB Chair for handling.
 - (5) Refer to IRB Chair for handling, for any other reason.

The IRB representatives from designated faculty disciplines shall be responsible for assuring that proposals given exemption or expedited review by him/her or his/her designee are in compliance with the guidelines and shall address issues raised regarding such proposals at IRB meetings. The membership of the IRB, including the designee in any unit assigned to make initial determinations on protocols, shall be announced each academic year.

- VII. IRB representatives will promptly communicate determinations/decisions to the IRB Administrator and provide the IRB Administrator with copy of all materials reviewed and approved, including informed consent forms.
- VIII. Upon completion of IRB review, the IRB Administrator shall prepare a formal letter of approval to be sent to the investigator and other appropriate parties, e.g., external grant providers.
- IX. 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 (copy attached) to be sent annually. At minimum, projects shall be reviewed at least annually. The actual frequency of continuous review will be determined based on level of risk. Because projects approved via Expedited Review are considered low risk, it would not be expected that such projects would be reviewed more often than annually.
- X. On a monthly basis, the IRB Administrator shall notify all IRB members of protocols 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 protocols approved via Expedited Review, this report shall also include a brief description of approved research projects.

SAMPLE

IRB ANNUAL REVIEW LETTER

Date

Name of Researcher(s)

Address 1

Address 2

City, State Zip Code

Re: Title of Protocol

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:

For your information, attached please find a copy of Faculty Research Policy Series #36 and the Implementation Procedures that supplement this policy. In addition, a listing of current University IRB members is attached to this memo.

Kindly respond by e-mail to: promgf@hofstra.edu if you have successfully completed the above-mentioned project. If your referenced work involving humans as subjects is continuing, or if you have begun new studies involving humans as subjects, please review the University Policy and Implementation Procedures to ascertain what further action may be necessary. Thank you.

Sincerely,



Sofia Kakoulidis

Associate Provost for Research and Sponsored Programs and
Administrator of the Hofstra University Human Subjects Committee (IRB)

SK/lf