

Procedures for Implementation of FPS # 36

- I. Representation on the University's Institutional Review Board (IRB) shall include three full-time faculty members selected one each from the Department of Biology, the School of Education and Allied Human Services, and the Department of Psychology, 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 an 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 subjects 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 <http://cme.nci.nih.gov/>);
 - (2) the viewing of a videotape 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 and Psychology) 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. Investigators affiliated with the Department of Biology, School of Education, and Department of Psychology – those academic units with permanent faculty appointments to the IRB – will normally submit their protocol to the IRB Representative or designee from their academic unit for initial review. All other investigators should submit their protocol for initial review to the IRB Chair.
 - 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/herself 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 an IRB Progress Report/Continuation Form (copy attached). At minimum, projects shall be reviewed at least annually. The actual frequency of submission of such reports 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.

Attachment:
IRB Progress Report/Continuation Form

Hofstra University
IRB PROGRESS REPORT/CONTINUATION FORM

Investigator's Name: _____

Investigator's Address: _____

Investigator's Telephone: _____ Investigator's Email Address: _____

Project Title: _____

(1) Is all the above information current? yes, no. If no, please provide correct information below:

(2) Is this research expected to extend beyond _____? yes, no. If yes, please advise how long the research is currently expected to proceed.

(3) Over the past year, have any negative, harmful or adverse events resulted from this research? yes, no. If yes, please describe below or on additional pages as needed.

(4) Do you propose to make any changes to your previously approved protocol? yes, no. If yes, please describe below or on additional pages as needed.

Investigator's signature: _____ Date: _____

PLEASE RETURN THIS COMPLETED FORM TO THE IRB
ADMINISTRATOR, WEST LIBRARY WING, RM 218, BY NO LATER THAN _____.