FASHION INSTITUTE OF TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

APPLICATION PROCESS / PROCEDURE

The Fashion Institute of Technology Institutional Review Board (FIT-IRB) is a committee that reviews research involving human subjects to insure that the rights and welfare of the human subjects are protected. The ethical principles underlying the acceptable conduct of research involving human subjects is set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. *The Belmont Report* elucidates on three principles:

- Respect for persons – the need to obtain informed consent
- Beneficence – the need to minimize risks
- Justice – subjects must be fairly treated

Any researcher affiliated with FIT doing research involving human subjects, or any such research taking place at FIT, must first apply to the FIT-IRB for approval of their research protocol. The application involves submitting a completed INITIAL APPROVAL REQUEST / APPLICATION form (item E below), submitting a written protocol, and training in the ethical use of human subjects in research.

Upon review, the FIT-IRB may approve the proposed research, require modification (to secure approval), or disapprove. The FIT-IRB will notify investigators in writing of its decision to approve or disapprove, or of the modifications required to secure approval. If the FIT-IRB decides to disapprove the proposed research, it will include in its written notification a statement for the reasons for its decision and give the investigator an opportunity to respond in person or in writing. In addition, the FIT-IRB will conduct continuing review of research at intervals of not less than once per year. The procedures and activities of the FIT-IRB are consistent with federal regulations 45 CFR 46 and are overseen by the Office of Human Research Protections (OHRP) of the United States Department of Health and Human Services.

The principle investigator will be provided all of the FIT-IRB procedures, as well as an application form. In addition, all researchers involved in the project must complete an online training session on the protection of human subjects by logging onto http://phrp.nihtraining.com/users/login.php, registering an account, and following the instructions.

The FIT-IRB procedures are outlined in the following documents:

A) APPLICATION PROCESS / PROCEDURE is this document. It provides an overview of the role of the FIT-IRB and the application process.
B) INITIAL REVIEW OF RESEARCH provides the procedures used by the FIT-IRB in its initial review of the proposed project.

C) CRITERIA FOR APPROVAL OF RESEARCH provides the criteria by which the FIT-IRB determines whether the proposed protocol adequately protects human subjects.
D) REQUIRED COMPONENTS OF INFORMED CONSENT provides the rationale and procedures of informed consent. It also offers an informed consent form template.
E) INITIAL APPROVAL REQUEST / APPLICATION is the application form to be submitted by the researcher along with the protocol.
F) CONTINUING REVIEW / MODIFICATIONS AFTER INITIAL PROTOCOL APPROVAL provides the procedures used by the FIT-IRB in continuing review of the project, and outlines the responsibilities of the researcher in keeping the FIT-IRB informed of any changes that may occur in the protocol once the project is underway.
G) RECORD KEEPING outlines the responsibilities of the FIT-IRB in maintaining written records of its activities and decision making processes.
H) Also provided to the researcher is a copy of the *Belmont Report*, the document in which the ethical guidelines for research involving human subjects was first explicated.