Institutional Review Board

Policy RC002
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Responsible Office: Academic Affairs
Responsible Administrator: Vice President for Academic Affairs
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Policy Statement

The Fashion Institute of Technology's Institutional Review Board (FIT-IRB) reviews research that will be conducted by FIT faculty, students, staff, auxiliaries, and affiliates with the goal of safeguarding the health, safety, dignity, and general welfare of human participants in that research. The FIT-IRB is responsible for upholding the norms of acceptable research practice set forth by applicable state and federal laws and regulations.

Reason for the Policy

In order to protect the rights of persons who are participants in all FIT-sponsored or FIT-affiliated research projects, the college adheres to the ethical principles underlying the acceptable conduct of research involving human participants, as set forth in institutional standard, best-practices document, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, which outlines the basic ethical principles in research involving human subjects.

The FIT-IRB is in compliance with the Federal Policy for the Protection of Human Subjects, or the "Common Rule," which outlines the basic provisions for Institutional Review Boards, informed consent, and Assurances of Compliance.

Who is Responsible for this Policy

- Vice President for Academic Affairs
- Chairperson of the FIT-IRB
- Serving members of the FIT-IRB

Who is Affected by this Policy

- All members of the FIT community (i.e., faculty, staff, students, and affiliates) who plan to conduct or participate in research involving human subjects.

Definitions

- **Human Subject** is defined as "a living individual about whom an investigator conducting research obtains either a) data through intervention or interaction with the individual or b) identifiable private information."

- **Informed Consent** is one of the central protections of human subjects. Potential research subjects must be provided with information about the research project that is understandable and that permits them to make an informed and voluntary decision about whether to participate. The amount of information and the manner of presentation will vary depending on the complexity and risk involved in the research study. Informed consent is an ongoing educational interaction between the Principal Investigator and the research participant that continues throughout the study. Study subjects have the right to decide to participate or to withdraw from participation at any time without adversely affecting the relationship between the subject, the investigators, and the college.

- **Intervention** includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment performed for research purposes.

- **Interaction** includes communication or interpersonal contact between investigator and subject.

- **Principal Investigator** is the faculty member or other employee with primary responsibility for a research project. The Principal Investigator is responsible for complying with all financial and administrative policies and regulations associated with the research. Although Principal Investigators may have researchers or administrative staff to assist with the management of the project, the ultimate responsibility for the management and administration of the project rests with the Principal Investigator.

- **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Research activities that involve the study, and/or collection, of information that reveals, or could be used to determine, the identity of any research subject constitute private information. Private information includes any such potentially identifiable data or observations that are collected as part of any research, or in any circumstance wherein an individual could reasonably expect that no observation or recording is taking place, or is provided by the individual for a specific purpose with the reasonable expectation that such information or data will not be made public (e.g. a medical record.) Such private information is protected and must be maintained as confidential and should only be shared in accordance with data sharing procedures agreed to by the PI in consultation with the FIT-IRB. The PI is responsible for ensuring that all private information is shared only to the extent necessary, as well as ensuring subjects have been fully informed and consented to such sharing. As part of the FIT-IRB review and approval process, the PI may be required to outline their data management and security procedures and protocols to ensure the privacy and protection of private information.

- **Research** is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The vast majority of scholarly work in academia is intended to be shared, published, presented to colleagues, and is intended to have an impact on others within a discipline. Activities that are disseminated with the intent to influence behavior, practice, theory, or future research designs are contributing to generalizable knowledge. Research is subject to the FITIRB, regardless of funding, when it includes activities that involve human subjects as defined by regulations.

- **Researcher** is any faculty, staff, or student involved in administration of the research project and who is not also the Principle Investigator.

Principles

- Principles for Ethical Research Involving Human Subjects
  The principles for ethical research involving human subjects include:
    - **Respect for persons** – outlines the moral requirement to acknowledge autonomy and the requirement to protect vulnerable populations, such as pregnant women, children, prisoners, the mentally ill, the physically ill, the developmentally disabled, and the physically disabled; and that all private information is shared only to the extent necessary; as well as ensuring that subjects have consented to sharing of such information;

    - **Beneficence** – the obligation to do no harm and to maximize possible benefits and minimize possible risks that could result in harm;

    - **Justice** – outlines the obligation to consider research with respect to who ought to receive the benefits and who ought to bear the burdens;

    - **Informed consent** – information about the research procedure, the purpose of the research, risks and anticipated benefits, alternative procedures, and statement offering the participant the opportunity to ask questions and to withdraw at any time from the research;

    - **Assessment of risks and benefits** – risks should be reduced to those necessary to achieve the research objective and risks must be thoroughly described in documents and procedures used in the informed consent process;

    - **Selection of subjects** – fair procedures and outcomes in the selection of research subjects. Recruitment and selection of participants must be equitable within the confines of the study. Researchers may not exclude participants on the basis o actual or perceived protected characteristics, including age, citizenship status (except as required to comply with law), color, creed, disability, ethnic background, familial status, gender, gender identity, genetic information, marital status, military service or veteran status, national origin, pregnancy (including childbirth and breastfeeding), race, sex, sexual orientation, transgendered status, unemployment status, an individual's relationship or association with a member of a protected category, a caregiver, or any other criterion prohibited by application federal, state, or local laws, except to the extent required by legitimate research requirements approved by the FIT-IRB. Any such limitations shall be explicitly disclosed and outlined by the Principal Investigator in the process of FIT-IRB review and approval. The benefits and burdens of research must be fairly distributed.

- **FIT Institutional Review Board (FIT-IRB)**
    - The FIT-IRB has the exclusive authority to:

- Approve, require modifications in (to secure approval), or disapprove of all research activities involving human subjects conducted at FIT.
- Suspend or rescind approval of research involving human subjects not conducted in accordance with the FIT-IRB's requirements or that has been associated with unexpected serious harm to subjects.
- The FIT-IRB consists of five members serving three-year terms. Candidates for the FIT-IRB are nominated by the Vice President for Academic Affairs and are appointed by the President. Members should have varying backgrounds to promote complete and adequate review of research activities commonly conducted at FIT. The FIT-IRB shall be sufficiently qualified through the experience and expertise of the members, and through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- The FIT-IRB's responsibilities include maintaining written records of its activities and decision-making processes. Record Keeping outlines these responsibilities.

- **Categories of IRB Review**
  The Chairperson of the FIT-IRB determines the level of review necessary for a project. Proposals will fall into one of three categories: Full Review, Expedited Review, or Exempt.
  - **Full Review** – Projects that involve human participants and that pose more than minimal foreseeable risk, are funded by federal grants, involve deception, involve participants from a group awarded special protections (e.g., prisoners, children) require full review and will be voted on by a quorum of the full FIT-IRB.

  - **Expedited Review** – Projects that involve human participants and that pose minimal foreseeable risk to the health, dignity, or welfare of the research participants can be expedited by the FIT-IRB Chairperson. Projects eligible for expedited review will be voted upon by three members of the FIT-IRB selected by the Chairperson.

  - **Exempt** – Projects that are not deemed "research" per the federal definition, that do not involve human participants, or that do involve human participants but pose very little or no foreseeable risk to the health, safety, dignity, or welfare of the participants. Proposals deemed exempt by the FIT-IRB Chairperson will be reported to the full FIT-IRB.

- **Complaints**
  Any person who has a complaint about a human research project shall submit in writing to the Chairperson of the FIT-IRB a statement of complaint and a brief description of the events that document the complaint. The Chairperson shall refer the complaint to the FIT-IRB to determine if there has been a violation of protocol. If the FIT-IRB determines that this policy has been violated or that the project was conducted in violation of protocol, it shall recommend to the Vice President for Academic Affairs the course of action the college should take, including the possibility of a sanction to be imposed against the Principal Investigator.

Responsibilities

- **Responsibilities of the Principal Investigator**
  The Principal Investigator(s) is responsible for all aspects of a research project. The Principal Investigator will be provided all the FIT-IRB procedures, as well as an application form. In addition, the Principal Investigator will ensure that all researchers involved in the project complete an online training session on the protection of human research participants by logging onto PHRP Training, registering an account, and following the instructions. A completion certificate is required for the Principal Investigator and all researchers prior to receiving approval from the FIT-IRB. The Principal Investigator is also responsible for keeping the FIT-IRB informed of any changes that may occur in the research once the project is underway.

- **Responsibilities of Researchers**
  The primary responsibility of Researchers is to support the research project goals as defined by the Principal Investigator and to work to ensure that the ethical aspects of such research, as outlined in the Belmont Report and the Common Rule, are adhered to at all times.

Procedures

- **Application for FIT-IRB Approval**
  Any Principal Investigator or research group affiliated with FIT doing research involving human subjects must first apply to the FIT-IRB for approval of their research protocol. The application includes:
    - Required Components of Informed Consent, which describes the rationale and procedures of informed consent. A modifiable informed consent template is provided.
    - Initial Approval Request/Application is the application form to be completed and submitted by the researcher along with the written research protocol.

- **FIT-IRB Application Review and Decisions**
  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. Initial Approval Request/Application lists the procedures used by the FIT-IRB in its initial review of the proposed project. Criteria for Approval of Research provides the criteria by which the FIT-IRB determines whether the proposed protocol adequately protects research participants.

  If the FIT-IRB decides to disapprove the proposed research, it will include in its written notification a statement explaining the reasons for its decision and will provide the investigator an opportunity to respond in person or in writing.

- **FIT-IRB Continuing Review**
  The FIT-IRB will conduct continuing review of research at intervals of not less than once per year. Continuing Review/Modifications after Initial Protocol Approval provides the procedures used by the FIT-IRB in continuing-review research projects and outlines the responsibilities of the Principal Investigator in keeping the FIT-IRB informed of any changes that may occur in the protocol once the project is underway.

Violations

If it is alleged that any violation of this policy has or will occur, or that a researcher has engaged in human subjects research without proper approval, or such approval was granted under false, misleading or incomplete information, the allegation will be brought before the FIT-IRB. The FIT-IRB will review the reported violation and determine if additional information or further investigation is required. Affected supervising administrator(s) will be copied on all correspondence between the FIT-IRB and the involved parties. If it is determined that a violation of this policy has occurred, the FIT-IRB will require that the activity in question be halted until corrective action is taken. In situations where participant or researcher health or safety is compromised, or where the alleged policy violation is egregious and reasonably apparent, the Chairperson of the FITIRB will require the immediate suspension of the research or activity, prior to full review by the FIT-IRB. Where the FIT-IRB determines that the violation involves possible scholarly or scientific misconduct, the Vice President for Academic Affairs will be notified.

In situations where participant safety is compromised, and/or the violations are apparent, the Chairperson of the FIT-IRB, in consultation with other members and administrators, as appropriate, will require immediate suspension of the activity prior to review by the full FIT-IRB membership. If the FIT-IRB determines that the violation involves possible scholarly or scientific misconduct, the Vice President for Academic Affairs will be notified. While the FIT-IRB can and will assist in the investigation, the review board will adhere to the decisions made by the Vice President, which must consider all appropriate actions considering established college policies and procedures.

Sanctions for violations of this policy will be handled in accordance with the following:

- **Employees:**
  Employees covered by the Collective Bargaining Unit will be disciplined according to the Collective Bargaining Agreement, as well as relevant law and college policy. For non-bargaining employees, the Vice President for Human Resource Management and Labor Relations, or their designee(s), will review the violation and make a recommendation for appropriate disciplinary action based upon relevant law and college policy.

- **Students:**
  The Dean of Students will review the violation and implement appropriate counseling and/or disciplinary action in accordance with the Code of Student Conduct.

- **Third Party or Contractor**
  Violations of FIT policies by third parties will be addressed by FIT senior leadership at its sole discretion and in accordance with the relevant policy, laws, and circumstances.

Related Policies

- Employee Code of Ethical Conduct
- Code of Student Conduct
- Intellectual Property
- Public Access to Records
- Records Retention and Disposition

Related Documents

- FIT-IRB Record Keeping
- Office for Human Research Protections, Department of Health and Human Services
  The Belmont Report

Contacts

- **Office of the Vice President for Academic Affairs**
  (212) 217-4040

- **Chairperson of the FIT-IRB**
  (212) 217-4922

- **Office for Human Research Protections**
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