

FASHION INSTITUTE OF TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

INITIAL APPROVAL REQUEST / APPLICATION

Please read and follow these directions carefully. Omission of required components of the application will delay review of your application pending receipt of all material.

1. Before the FIT IRB will review this application, the investigator must have completed training in the use of human subjects.
2. All information must be typed.
3. If you are currently receiving or applying for funding for this study from an external sponsor, you must include copies of your proposal to the funding agency.
4. Include copies of all instruments used in this study: *i.e.*, consent forms, surveys, questionnaires, deception debriefing scripts, *etc.*
5. Please refer to the document “Required Components of Informed Consent” when constructing a consent form.
6. **Submit the following...**
 - a. 1 copy of the funding proposal and funding review comments that pertain to the use of human subjects in your study (if applicable)
 - b. 1 copy of the Initial Approval Request form, signed and dated
 - c. 1 copy of all instruments (consent forms, surveys, questionnaires, debriefing scripts, *etc.*)

... to:
Geoffrey Rogers, Chair
FIT Institutional Review Board
Geoffrey_Rogers@fitnyc.edu
7. *Turn-around time:* Allow 4 weeks between completed submission and FIT IRB review. At the end of this time, you will be notified *via* email of the IRB’s decision.

Checklist for Initial Approval Request Form: When applicable, attach copies of:

- *Proposal/ Protocol*
- *Recruitment materials*
- *Consent/assent documents (including oral consent)*
- *Surveys/questionnaires/interview scripts*
- *Debriefing form/script*
- *Restricted/limited access dataset agreements*
- *Confirmation of review by other IRBs*
- *Foreign country collaboration documents*

INITIAL APPROVAL REQUEST

For FIT IRB Use Only

FITIRB# _____

Fashion Institute of Technology Institutional Review Board

SECTION I

Name of Investigator: _____

Email address: _____

Campus address _____

School & Department _____

Status: Faculty Ph.D. Candidate Post-doc Undergrad
 Research Associate Other Grad. Student Staff Other

Faculty member supervising project (if applicable): _____

Email address: _____

Campus address: _____

Title of Project: _____

Other Study Investigators:	Name	Affiliation	Location
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

Other Members of Research

Teams (include students):

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Have all investigators and other researchers working on this project, within the past 3 years, undergone training for research involving human subjects at <http://phrp.nihtraining.com/users/login.php>? Yes No

Start Date of Project (initial contact with subjects): _____

Estimated End Date of Project: _____

1. **Submit a detailed copy of your proposal.** It should include: protocol, hypothesis, research design, subject recruitment and protection, risks, and any other relevant procedures. Be sure to include the specific location at which any interaction with human subjects will take place.

2. Is this research funded by an external sponsor(s)? Yes No Pending approval
If Yes (or Pending), what is the name of the sponsor(s)?
If you are awaiting funding to develop instruments and/or consent forms, *etc.*, please check here:

2. Is this research being conducted for a course? Yes No
If Yes, name of course: _____

Name of instructor: _____

3. Is this research being conducted for your thesis or dissertation? Yes No

7. Outline possible benefits the proposed study may provide to an individual subject, social group, or society. If there are no direct benefits to the subjects as individuals, please state this explicitly here.

8. Please outline possible risks to subjects in your study, including special or select types of subjects. _____

9. Please describe the steps you have taken to minimize risk to subjects. _____

10. Does this study involve **secondary data analysis or restricted/limited data**? Yes No
If Yes, provide a brief description in the field below of each dataset and *indicate from which databank(s) or source(s) the data will be (has been) obtained*. For each dataset, please include the following information:
 - a. Can the names or identities of subjects in the dataset be deduced from the data fields?
 - b. Is the dataset public-use (no restrictions on use), or restricted or limited access? If restricted or limited access, attach a copy of the licensing agreement you signed with the distributor, as well as a copy of your data security plan.
 - c. Are you planning to merge geographic, company, census, community or other potentially identifying data into an individual-level dataset during the course of this project? Yes No
If Yes, attach a description of how you plan to protect the data from unauthorized use.
 - d. Will anyone other than you have access to any restricted or limited access dataset(s)? Yes No

If Yes, provide their names, and ensure that they have completed the required education in the use of human subjects. Submit copies of affidavits, non-disclosure agreements, or similar documents they were required to sign with the distributor.

If your study involves secondary data analyses only, please skip to Section II, question 18.

For all other studies, please fill out the remaining questions.

SECTION II

Please answer the remaining questions thoroughly and completely.

1. How many subjects do you plan to recruit for the entire study? _____

2. What is the expected age range of subjects? _____ to _____ years [**Note: This must match all attached documents submitted.**]

3. Will your subject sample include FIT students? Yes No
If Yes, answer (a) and (b) below:
 - a. Do you plan to recruit subjects from classes that you personally teach? Yes No
If Yes, provide a justification for the collection of data from your own students in #8 below.
 - b. Will subjects be obtained from the University Registrar? Yes No

4. Please estimate: Proportion of female subjects _____% Proportion of minority subjects (U.S. only) _____%

5. Explain how you plan to recruit your subjects. Specify the exact wording of requests, notices, or advertisements recruiting subjects. **Attach draft advertisements, flyers or letters.** (Please also indicate the specific locations where subjects will be recruited.) _____

6. Will subjects be compensated for their time? Yes No
If Yes, please describe the compensation. _____

7. Do you plan to use email or the Internet to recruit your subjects? Yes No
If Yes, be aware that email and Internet transmission are neither private nor secure. Please include a sentence in your consent document that alerts subjects that their responses could be read by a third party.

8. Check which category(ies) of subjects will be included in your study. For all categories other than the first (mentally competent adults), additional safeguards are required to protect these populations from undue influence/coercion in the recruitment process, risk during the study, *etc.* Explain the additional safeguards to be provided.

- Only mentally competent adults or secondary analyses of existing data.
- Children under 18: Active, written parental consent is a federal requirement, unless waived by PIRB after review. It is generally expected that you also obtain the *written assent* of minors 7 years of age and older. **Attach copies of parental consent form (and minor's assent form when applicable).**
- Employees of the investigating group: Please justify the use of this group, and explain how undue coercion in the recruitment process will be avoided.
- Students enrolled in your own classes: Please justify the use of this group. Federal regulations discourage the use of students enrolled in classes taught by principal investigators.
- Cognitively-impaired persons: How will you screen potentially cognitively-impaired subjects to determine when proxy consent is required? **Attach copy of proxy consent form, and subject assent form (if appropriate).**
- Pregnant or nursing women.
- Prisoners or juveniles under detention or on probation.
- People in foreign countries: Please describe how you are collaborating with the local communities, government, or other institutions (as relevant to your project), and include appropriate documentation.
- Other potentially vulnerable subjects: Who and why?

9. Check additional sources of data that will be used in your study.

- None
- Census/public records
- Discarded human materials
- Medical records
- Registries (*e.g.*, cancer registry). Name of registry: _____
- Blood, urine, or tissue samples
- Other (explain)

10. Duration of subject's participation, through each component of the study, and in total. **Please provide full information for each component of the study.** _____

11. Check any/all of the following procedures that apply to your study. For each procedure checked, 1) explain the procedure in detail, and 2) provide the ethical and scientific justification for employing the procedure.

- Deception (When and how will the subjects be debriefed? Generally, the nature of the deception and its necessity should be explained to the subjects. **Attach a copy of your debriefing form/script.**)
- Punishment:
- Use of drugs:
- Covert observation:
- Induction of mental and/or physical stress:
- Procedures that risk physical harm to the subject:
- Materials commonly regarded as socially unacceptable:
- Procedures that might be regarded as an invasion of privacy:

12. Is confidentiality promised to the subjects? Yes No If No, please explain. _____
- a. If confidentiality is promised, will access to names be under your exclusive control? Yes No
If No, who else will have access to the names, and what will be done to protect the confidentiality of the subjects?
- b. Where will the names be recorded (e.g., on test protocols, on a separate list with code numbers, in a computer file, etc)?
- c. For what purpose(s) will names be recorded?
- d. If confidentiality is promised, what additional steps are you taking to keep their data secure?
- e. Will names of subjects be included in any publication based on this study? Yes No
If Yes, for what reason(s)?
13. Will any data be gathered through photographic, video or sound-recording devices? Yes No
If yes, answer (a) - (e) below, and be sure to include all this information on your consent form(s) as well as **provide a separate signature line for the subjects to agree to be video/audio taped and/or photographed.**
- a. What types of recording devices will be used and what will be recorded? _____
- b. Please provide scientific justification for gathering data using the device(s) enumerated above. _____
- c. What will be done with the still photos, video or audio recordings after the study has concluded? (*I.e.*, used in publications, presentations, *etc.*) _____
- d. When, if ever, do you plan to destroy these records (specify when for each type)? _____
- e. How will you protect the confidentiality of the materials produced by such devices (if so promised)? (Remember that faces alone reveal identity, even if captions with names are not provided.) _____
14. Sometimes research findings are presented in a manner that permits knowledgeable readers to infer the identity of a person used as a subject, even if names are omitted. Do you expect to present findings that may possibly provide such clues? Yes No Confidentiality not promised
If Yes, explain how you will protect the identity of subjects, or alternatively how you will explain to them that their confidentiality cannot be absolutely protected. This information should also be conveyed to subjects on the study consent form. _____
15. Will information be obtained pertaining to persons other than immediate subjects (e.g., their friends)?
 Yes No
If Yes, how will the confidentiality of such persons be protected? If their confidentiality is not promised, please explain here. _____

16. Do you intend to obtain written consent? Yes No

If Yes, refer to the document "Required Components of Informed Consent", and attach a copy of the consent form. If collecting data from minors you must address both parental consent and the child's assent.

If No, please answer questions (a) - (c) below.

- a. Why do you not intend to use such forms? This must be a strong argument. _____
- b. In what manner and to what extent will you give potential subjects advance information about the study procedures? If using a contact letter, please attach it. _____
- c. In what manner will potential subjects be advised that their participation and continuation in the project is entirely voluntary? Please provide a copy of the text to be used. _____

17. If proposing to use oral consent (*e.g.*, telephone survey, illiterate subjects), provide a copy (script) of the text that you will use.

18. Has this study been reviewed (or will it be reviewed) by another institution's Institutional Review Board or another ethical review body? Yes No

If already reviewed, attach a copy of the approval/deferral notification you received from that IRB. If this study *will be* submitted to another IRB, please indicate below the institution and give the approximate date for the review.

Signature Page

This page is to be signed by the investigator(s). If the investigator is an undergraduate, graduate student, or doctoral student, the faculty supervisor must also sign in the lower box.

Investigator(s)

I certify that the information I provide in this application is correct and complete. **I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Fashion Institute of Technology Institutional Review Board.**

Signature of Investigator (1)

Date

Signature of Investigator (1)

Date

Faculty Supervisor

NOTE: A research proposal by a graduate or undergraduate student must have the following statement signed by a faculty supervisor.

“I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. I will take responsibility for informing the student of the need for the safekeeping of all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.), as well as signed consent forms, in an FIT office or computer file.”

Print Name and Title of Faculty Supervisor

Signature of Faculty Supervisor

Date

Office Phone

Please also attach a letter describing how you will provide continuing supervision over the student. ***Review of the proposal will begin after receipt of your letter.***