

FASHION INSTITUTE OF TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

REQUIRED COMPONENTS OF INFORMED CONSENT

Informed consent is not a single event or just a form to be signed; it is an educational process that takes place between the investigator and the prospective subject. The basic elements of the consent process include:

- Full disclosure of the nature of the research and the subject's participation,
- Adequate comprehension on the part of the potential subject, and
- The subject's voluntary choice to participate.

The consent form documents that the informed consent process took place. It must contain all the required components of informed consent, as defined in 45 CFR 46.116, and listed below. The consent form must be written in language that assures the potential subject's comprehension: avoid technical terms and complex sentences, even for the educated layperson. When the subject population is not homogeneous, different consent documents may be required for different populations. Guidelines for constructing a consent form include:

- Replace technical terms with ordinary language.
- Write in the second person "You". Example: "You are invited to participate in a research project..." "You will be asked to..."
- Do not, however, make coercive statements such as "you understand that ..." "you have been told that..."
- Use active tense rather than passive tense verbs. ("We did" rather than "It was done".)
- Write in short sentences.
- Use headings for paragraphs. These are helpful and make the form easier to read.
- Use adequate white space so that the form is easy to read. Avoid find print.

INFORMED CONSENT FORM

1. Provide a clear, concise explanation of the purposes of the research including the name of the study (FIT-IRB can waive this if the study is found to require deception).
2. Explain what will be happening to the subject during the study, and indicate subject's time commitment for each component.
3. Describe the frequent and/or important risks, side effects or discomforts of the study procedures. See the Sample Consent Form below for examples of proper wording or risk statements, etc.

4. Describe any benefit from participating. Learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research subject is NOT a benefit. Gifts and extra credit are considered compensation.
5. State that the subject's participation is voluntary, the subject may refuse to participate before the study begins, discontinue at any time, or skip any questions that may make him/her feel uncomfortable, with no affect or penalty to him/her, the compensation earned before withdrawing, or academic standing or record.
6. State that the subject is allowed to ask questions concerning the study, both before agreeing to be involved and during the course of the study. See required contact information in #11 below.
7. Describe how subject's confidentiality will be protected.
8. Describe what will be done with the data once the study is completed.
9. Indicate that recording devices, audio or visual, are being used (when applicable).

- i. Describe what will be done with any video or audio tapes upon the completion of the study (destroyed, erased, archived, etc.), and when (after transcription, 3 years, 5 years, etc.).
- ii. Provide a separate signature line on the consent form for the subject to agree to be video/audio taped or photographed. For example:

Please sign below if you are willing to have this interview recorded on tape (specify audio or video). You may still participate in this study if you are not willing to have the interview recorded.

I am willing to have this interview recorded on tape:

Signed: _____

Date: _____

10. Indicate that the subject shall receive a copy of the signed and dated consent form.
11. Provide the name(s) of the investigator(s) and contact information.
12. Indicate that the subject may contact the Fashion Institute of Technology Institutional Review Board (FIT-IRB) with any concerns or complaints.
13. Include the following statement at the bottom of the form: "This consent form will be kept by the researcher for at least three years beyond the end of the study and was approved by the FIT-IRB on [date]."

REMEMBER: if the subject is under the age of 18, parental consent is required. This includes college and university students under the age of 18. If the subject is 7-17 years old, child assent is also required.

[Title of Study] Consent Form

You are invited to participate in a research study of [insert general statement about study]. You were selected as a possible participant because [explain how subject was identified]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Background Information: The purpose of this study is [explain research questions and purpose in lay language].

Procedures: If you agree to be in this study, we will ask you to do the following: [explain tasks and procedures; subjects should be told about length of time for participation, frequency of procedure, etc.]

Risks and Benefits of Being in the Study: There is the risk of [risks must be explained, including the likelihood of the risk].

or

We do not anticipate any risks for you participating in this study, other than those encountered in day-to-day life.

The direct benefits to participating are [if no direct benefit to the subject, state that fact here].

and/or

Indirect benefits to participation are [explain how subjects might benefit; e.g. contribution to knowledge, etc.]

[Learning about how experiments are conducted, or having the “opportunity to interact with investigators” is NOT a benefit of participating in a study.]

Compensation: [If the subject will receive a cash or other incentive or extra credit in a class for participating, that should be listed here --NOT under Benefits.]

Voluntary Nature of Participation: Your decision whether or not to participate will not affect your current or future relations with the Fashion Institute of Technology [or with other cooperating entities]. [If questionnaire or survey, explain that subject may skip any questions they don't feel comfortable answering.] If you decide to participate, you are free to withdraw at any time without affecting those relationships. [Explain if monetary benefits will be adjusted due to early withdrawal.]

Confidentiality: The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Research records will be kept in a locked file; only the researchers will have access

to the records. [If tape recordings or videotapes are made, explain who will have access, how they will be kept secure, if they will be used for educational purposes like publications and/or presentations, and when they will be destroyed. If they are to be kept in perpetuity, explain that here as well.]

Contacts and Questions: The researcher(s) conducting this study are _____ and _____. Please ask any questions you have now. If you have questions later, you may contact them at [phone, mailing address, email address]. [If the researcher is a student, include advisor's name and telephone number.] If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Fashion Institute of Technology Institutional Review Board (FIT-IRB) at 212-217-3037, Geoffrey Rogers, Chairperson.

You will be given a copy of this form to keep for your records.

Statement of Consent: I have read the above information, and have received answers to any questions I asked. I consent to participate in the study.

Signature _____ Date _____

This consent form will be kept by the researcher for at least three years beyond the end of the study and was approved by the FIT-IRB on [date].