Hofstra IRB Proposal Submission Protocol

INSTRUCTIONS

Before you begin, you may find it useful to have the following information readily available:

- an abstract, overview or rationale
- description of participants
- description of methods
- measurement instruments that you've developed (surveys, interview questions, etc.)
- reference list
- your CITI basic human participants' protections training certificate* (recommended), or your NIH human participants' protections training certificate, or
- sign the affirmation of your reading of *The Belmont Report*.

You may either paste information from existing documents, or you may attach individual files to your email.

*CITI training information available at https://goo.gl/9Y5eWG > "Training in Basic Human Participants' Protection."

Overview

The US Department of Health and Human Services requires that all institutions receiving federal grants maintain an Institutional Review Board to ensure the protection of human subjects. All research conducted at Hofstra University must be approved by Hofstra's IRB.

Use this protocol to submit your proposal. The protocol has seven sections:

I. Personal Information
II. Protection of Human Subjects in Research
III. Brief Description of Research Project
IV. Research Methods
V. Attachments
VI. Reference List
VII. Submit

I. Personal Information

*required field

*Is this a new project or an amendment to a previously approved project?

- ☐ New project
- ☐ Amendment
  - If this is an amendment, attach the original proposal and use the amendment form to provide a detailed explanation of changes and highlight revisions.

*Primary Investigator: Click here to enter text.

*I Choose an item. to display my name and project title on Hofstra's IRB website's "Current Research at Hofstra."

*School or College: Click here to enter text.

*Department: Click here to enter text.

*Email: Click here to enter text.

*Preferred phone#:

Office: Click here to enter text.
Residence: Click here to enter text.
Mobile: Click here to enter text.

- If Mobile, allow text messages from IRB Representative regarding your project?

☐ Yes
☐ No

* Project Title: Click here to enter text.

* Check one:

☐ Faculty
☐ Student
☐ Staff
☐ Other: Click here to enter text.

* If you are a student researcher select:

☐ Course
☐ Master's Thesis
☐ Dissertation
☐ Undergraduate Honors Thesis
☐ Independent Study/Capstone Project

* If you are a student researcher indicate:

Course Name and Number: Click here to enter text.
Degree Program at Hofstra: Click here to enter text.
Faculty Sponsor: Click here to enter text.
Faculty Sponsor Email: Click here to enter text.

* Has this proposal has been submitted and approved by another Institutional Review Board?

☐ Yes
☐ No

- If Yes:
  Name of Institution: Click here to enter text.
  Date of Approval: Click here to enter text.
  *Attach a copy of the approval letter(s) to your email or paste it at the end of this proposal form.

II. Protection of Human Subjects in Research

Statement of compliance with Faculty Policy Series #36 THE USE OF HUMAN SUBJECTS IN RESEARCH education/training in basic human participants' protections programs

OPTIONS (select one)

☐ You have completed the *Collaborative Institutional Training Initiative* (CITI) Program.
* Attach CITI training certificate PDF to your email or paste it at the end of this proposal form.

☐ You have completed National Institutes of Health (NIH) Training *Human Participants Protection Education for Research Teams* online course.
* Attach NIH training certificate PDF to your email or paste it at the end of this proposal form.

☐ By signing below, you attest that you have read the *Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research*.

☐ By signing below, you attest that you have read the APA (American Psychological Association) publication, *Ethics in Research with Human Participants*.

☐ By signing below, you attest that you have viewed the videotape series entitled *Protection for Human Subjects*, published by the Office of Human Research Protections. (https://www.hhs.gov/ohrp/education-and-outreach/online-education/videos/index.html).

Signed: Click here to enter text.

Date Submitted: Click here to enter text.

III. Brief Description of Research Project

Your brief responses will help your IRB representative efficiently review your project.

Methods used in your project:
Check all that apply

☐ Experimental design
☐ Surveys
☐ Interviews

☐ Focus groups
☐ Case study
☐ Ethnography
☐ Other Click here to enter text.

Risks from Equipment: Will participants/subjects come into contact with mechanical or electrical equipment that may present a physical danger?

☐ Yes
☐ No
- If yes, describe the nature of contact with mechanical or electrical equipment that may present a physical danger: Click here to enter text.

Risks or Discomforts: What risks or discomforts are anticipated for participants, including physical, psychological, social or legal risks? If there are risks, what attempts to minimize these risks are harmed? Click here to enter text.

Vulnerable Populations:
Does your research include any of the following: pregnant women, human fetuses, newborns, prisoners, cognitively impaired persons, mentally ill, AIDS/HIV+, terminally ill?

☐ Yes
☐ No

Benefits: What benefits are anticipated for participants? Click here to enter text.

Deception: Does the project use deception?

☐ Yes
☐ No
- If Yes, why is deception necessary to accomplish the research goals? Click here to enter text.

Compensation: Will participants be compensated?

☐ Yes
☐ No
- If Yes, indicate how much compensation and in what form (cash, gift, etc). Click here to enter text.

Time Commitment: Is the study an experiment?

☐ Yes
☐ No
- If Yes, what is the time commitment for each participant in the experiment?

Number of visits/sessions: Click here to enter text.
Duration of each visit/session: Click here to enter text.

Timetable: When are the anticipated beginning and end dates?

☐ Begin Date:

☐ End Date:

IV. Research Methods

Please provide detailed information about your study. Some bulleted suggestions may not relate to your proposal depending on your research. You may wish to paste information from your dissertation or other similar document.

Overview

Provide a basic overview for the study.

- Include the purpose and rationale.
- Provide references where appropriate.
- The description of your research should be accessible to non-experts.

Click here to enter text.

Participants

Provide a detailed description of the participant population.

- Selection and recruitment
- Number of participants involved in the study, age, sex, and any additional information about participants
- Criteria for inclusion/exclusion if applicable. In the case of protected populations (children, prisoners, pregnant women, the mentally ill, etc.) address their special needs not need to be considered for this study.
- Only adults 18+ can provide consent. If research focuses on children, describe procedures to obtain parental consent and children's assent.

Click here to enter text.

Procedures

Provide a detailed description of the methods, materials and procedures. Include descriptions of any measures or assessment tools, questionnaires, or interview protocols.

Click here to enter text.

Informed Consent Checklist

Your Informed Consent form should include the components listed below. An explanation of Informed Consent Forms is available on Hofstra's IRB website and from the U.S. Department of Health & Human Services Office for Human Research Protections. A sample form is available here.

Check the components included your form:

☐ Contact Information for you and your research sponsor/advisor

☐ Introduction and Purpose of the Study

☐ Description of the Research
☐ Subject Participation
☐ Potential Risks and Discomforts
☐ Potential Benefits
☐ Confidentiality
☐ Compensation
☐ Voluntary Participation and Authorization
☐ Withdrawal from the Study and/or Withdrawal of Authorization without penalty
☐ Cost/Reimbursements
☐ Participant Name, Signature and Date
☐ Parental consent and children's assent if participant is under 18
*Attach your Informed Consent Form to your email or paste it at the end of this proposal form.

V. Attachments:
*Attach to email or paste all attachments at the end of this proposal form including, but not limited to:

- Measures or assessment tools
- Surveys you developed
- Questionnaires you developed
- Interview protocols you developed
- Approval letters from outside facilities (if applicable)

VI. Reference List
*List all references cited in this protocol at the end of this proposal form.

VII. Submit

Save the complete file as "IRB BriefTitle - LASTNAME mm-yyyy"
Send the proposal and any attachments to your IRB Representative or liaison:

- Alan D. Flurkey
- Sarah A. Novak
- Thomas Kwiatkowski
- Deborah Elkis-Abuhoff
- Adam Gonzalez
- Veronika Ilyuk

Paste **Informed Consent Form** here.
Click here to enter text.

Paste **Assessments, Surveys, Questionnaires and Interview Protocols** here.
Click here to enter text.

Paste **Reference List** here.
Click here to enter text.

Paste **Approval Letter(s) from Other Institution's IRB** here.
Click here to enter text.