Hofstra IRB Proposal Submission Protocol

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 work conducted at Hofstra University that meets the definition of human subjects research must be reviewed and approved by Hofstra's IRB.

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

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

Key Dates

IRB representatives review proposals on a rolling basis. Proposals that qualify as **"exempt"** or **"expedited"** based on specific categories can be approved quickly, usually within 2 weeks. Proposals that require **"full board review"** because they exceed minimal risk or involve interactions with children will be discussed at the next monthly IRB meeting. Please submit proposals focusing on children or with elevated risk at least 10 days before the IRB meeting to ensure that it can be reviewed without delay.

The Spring 2020 IRB meetings will be on February 12 (submit by 2/3), March 11 (submit by 3/1), April 10 (submit by 3/31), and May 8 (submit by 4/29).

Instructions

1. Always download the most recent version of this form from the IRB webpage.
2. You may find it useful to have the following information readily available to paste into this document:
   - an abstract, overview or rationale
   - description of participants
   - description of methods
   - informed consent documents
   - measurement instruments that you're using (surveys, interview questions, etc.)
   - reference list
   - your CITI basic human participants' protections training certificate (CITI training information available at Training in Basic Human Participants' Protection)
3. The form fields on the following pages can expand when necessary and there are additional blank pages at the end of the form if you need them.

I. Personal Information

Is this form the most recent version posted on the IRB webpage?

- ◯ Yes
- ◯ No

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

- ◯ New project
- ◯ Amendment
  - If this is an amendment, you do not need to complete this form. Instead, attach the original proposal and use the amendment form to provide a detailed explanation of changes and highlight revisions.

Primary Investigator:

Co-Investigators:

Note: all investigators must submit certificates or affirmations of training in protection of human subjects in research at the end of this application.

School or College:

Department:

Email:

Preferred phone# for contact (if necessary):

Office: Residence:

Mobile:

- If Mobile, allow text messages from IRB Representative regarding your project?
  - ◯ Yes
  - ◯ No

Project Title:

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

- ◯ Yes
- ◯ No
  - If Yes:

    Name of Institution:

    Date of Approval:

    *Paste a copy of the approval letter(s) at the end of this proposal form.

Primary Investigator's status at Hofstra:

☐ Faculty (including adjunct faculty)
☐ Graduate Student
☐ Undergraduate Student
☐ Staff
☐ Other:

If you are a student researcher, is your proposal describing a:

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

If you are a student researcher, please indicate:

Course Name and Number:
Degree Program at Hofstra:
Faculty Sponsor:
Faculty Sponsor Email:

II. Protection of Human Subjects in Research

Faculty Policy Series #36 requires researchers to complete the *Collaborative Institutional Training Initiative* (CITI) Program. Registration directions can be found on Hofstra's IRB website at Training in Basic Human Participants' Protection.

☐ CITI training certificate is pasted at the end of this proposal form.

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

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 proposed?

Vulnerable Populations: Does your research involve people from vulnerable groups (for example, but not limited to pregnant people, human fetuses, newborns, prisoners, people with cognitive impairments, people with a mental health condition, people with a physical illness, people who are terminally ill?

- ◯ Yes
- ◯ No
  - If yes, describe the vulnerable population and how your research methods are affected:

Deception: Does the project use deception?

- ◯ Yes
- ◯ No
  - If Yes, how so, and why is deception necessary to accomplish the research goals?

Benefits: What benefits are anticipated for participants?

Compensation: Will participants be compensated?

- ◯ Yes
- ◯ No
  - If Yes, indicate how much compensation and in what form (cash, gift, etc).

Time Commitment: What is the time commitment for each participant in this study?

Number of visits/sessions:

Duration of each visit/session:

Timetable: When are the anticipated beginning and end dates of the data collection phase of the study?

Begin Date:

End Date:

Risks from Equipment:

Does the research involve the use of any mechanical or electrical equipment?

- ◯ Yes
- ◯ No
  - If yes, describe the mechanical or electrical equipment:

Will the participant come into contact with any equipment?

- ◯ Yes
- ◯ No
  - If yes, please describe:

Are there any potential hazards associated with the use of the equipment?

- ◯ Yes
- ◯ No
  - If yes, provide any product information for the equipment that will be used:

Will there be any chemicals used in the research?

- ◯ Yes
- ◯ No
  - If yes, state how the chemical/product will be used in the research and attach copies of the Safety Data Sheets for each chemical to this proposal:

Will the research involve the collection of blood or any Other Potential Infectious Materials (OPIM) (e.g. urine)?

- ◯ Yes
- ◯ No
    - If yes, all research staff must complete Bloodborne Pathogen training specific to the research activities being conducted. Attach Bloodborne Pathogen training certificates for each researcher to this proposal.

Will any type of Personal Protective Equipment be required for use by either the PI/Researcher or Participant?

- ◯ Yes
- ◯ No
    - If yes, describe the Personal Protective Equipment that will be used:

Are there any unusual or unique processes for which a Standard Operating Procedure (SOP) should be developed?

- ◯ Yes
- ◯ No
    - If yes, describe the SOP and attach a copy to this proposal:

IV. Research Proposal Details

Purpose or Rationale

What is the purpose or rationale for the study? Please describe in terms a general audience can understand.

Participants

Describe your proposed participants, including (if relevant):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 to participate. If research focuses on children, describe procedures to obtain parental consent and children's assent.

Procedures

Provide a detailed description of the method and materials. Space is provided at the end of this protocol to paste **assessments, surveys, questionnaires, or interview protocols**.

Informed Consent Checklist

Your Informed Consent form should include components listed below. Not all components may be relevant to your study. 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
☐ Concerns/Complaints
☐ 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:
*Create one document by pasting all attachments to the end of this proposal form including, but not limited to:

- CITI Completion Report
- Informed consent form
- Measures or assessment tools
- Surveys
- Interview protocols you developed
- Approval letters from outside facilities (if applicable)

VI. Submit

Paste all documents into this proposal form using the following pages

Save the complete file as a single PDF using filename format:
"IRB Proposal [BriefTitle] - LASTNAME mm-yyyy"

Submit your IRB Proposal Form by uploading a single PDF here:
www.hofstra.edu/IRBsubmit

General questions or problems with our forms or uploading tool? IRB.help@hofstra.edu
You can also contact your IRB Representative:

Dr. Sarah A. Novak
Projects originating in the Department of Psychology

Dr. Amy J. Catalano
Projects originating in the School of Education and other HCLAS units besides Psychology

Dr. Adam Gonzalez
Projects originating in the School of Health Professions and Human Services

Dr. Veronika Ilyuk-Morace
Frank G. Zarb School of Business

Dr. Thomas Kwiatkowski
Projects originating in the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

Dr. Salvador Rojas-Murillo
Projects originating in the Fred DeMatteis School of Engineering and Applied Science

Dr. Barbara DeVoe
Projects originating in the Hofstra Northwell School of Graduate Nursing and Physician Assistant Studies

Dr. Janet L. Dolgin
Projects originating in the Maurice A. Deane School of Law

Dr. Rodney Hill
Projects originating in the Lawrence Herbert School of Communication

Paste the link to your **CITI COMPLETION REPORT** here. It is available on the CITI site https://www.citiprogram.org/

Paste **Informed Consent Form** here.

Paste **Assessments, Surveys, Questionnaires and Interview Protocols** here.

Paste **Reference List** here.

Paste **Approval Letter(s) from Other Institution's IRB** here.

Blank page to paste additional documents if needed.

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