# **NAZARETH UNIVERSITY**

Human Subjects Research Committee

# Application for Approval of Research Involving Human Subjects

# **Proposal Cover Sheet**

Please save the complete application as Word or PDF file using the following naming convention: “HSRC\_Proposal\_LASTNAME” Use the Principal Investigator’s (PI) last name. Answer all questions and include the informed consent and additional materials as separate documents. Complete the checklist on the last page.

Submit the complete application electronically to the Human Subjects Research Committee Review Coordinator at hsrc@naz.edu with the subject line “NEW\_HSRC\_Proposal\_LASTNAME.

Electronically submit either a scanned copy of the Proposal Cover Sheet with appropriate signatures **or** a completed “Cover sheet only” fillable PDF form with electronic or digital signatures.

Full Title of Project

PI Name:       Date:

[ ]  I have completed the required training modules on the protection of human subjects and received my certificate of completion—available at [www.citiprogram.org](http://www.citiprogram.org). A copy is attached.

[ ]  I agree to conduct this research project in accordance with Federal Policy for the Protection of Human Subjects and with the Nazareth University “Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects.”

[ ]  I agree to conduct the study as approved by the Human Subjects Research Committee and will notify the Committee prior to implementing any changes in the research protocol.

#### Required Signatures

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:

Proposals from those who are **not full-time Nazareth faculty** must be co-signed by a sponsoring full-time faculty member.

Sponsor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:

##### Faculty Advisor Approval (for students’ application only)

Proposals submitted by **students** must be reviewed and approved by faculty advisor prior to submission.

I have read the proposal. In my opinion, all required components of the application and proposal are complete and the informed consent form (if necessary) contains all required elements. I approve this proposal for submission to the Human Subjects Research Committee.

Faculty Advisor Name:       Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:

Application for Approval of Research Involving Human Subjects

# **Proposal Specifications**

**I. Type of Study:**

In accordance with the HSRC instruction, the project meets the criteria for:

[ ]  Category I Research (Risk-free to participants, eg. anonymous, observation, surveys)\*

[ ]  Category II Research (Minimal risk to participants, eg. Interactions, interviews)

[ ]  Category III Research (Risks to participants, eg. invasive measurements, blood draw)

\*For category I research, please use the **Exempt Request** form instead of this application.

**II. Identification:**

Principal Investigator:

Affiliation: College/University/Employer

Department:

Telephone:       FAX:

E-mail Address:

Names of Additional Investigators Associated with the Project:

Complete Title of the Proposed Research Project:

Abbreviated Title:

Anticipated timeline for research. From       to

Funding Agency or Source, and grant # (if applicable):

**If you are a Nazareth University student, please provide the following information.**

**This research is for:**

[ ]  Thesis

[ ]  Course assignment (Give course number and name):

 [ ]  Other:

### III. Project Overview

Abbreviated Title:

 **Research Project Description**

**1. Purpose of study.**

**2.** **Hypothesis or research question.**

**3. Participants and Recruitment**

3.1 Participant

What is the target number of participants? Who will be participating and how will they be selected? Clearly describe the inclusion and exclusion criteria for participation.

3.2. Recruitment

Describe the recruitment procedures. Attach any materials (flyers, advertisements etc) for subject recruitment.

**4**. **Research procedures and Methods**

4.1 Describe the data collection procedures. Indicate where the project will take place. Describe what the participants will do. Describe the duration and frequency of the data collection session. Provide actual and sample material (questionnaire, interview protocol etc)

**5**. **Potential Risks and benefits**

5.1 Describe the potential risks to participants and measures to protect the participants.

5.2 Describe the potential benefit to participants.

**6. How will identity of the participants be protected throughout the project and in dissemination of results?**

**IV. Project Information:**

If the response to any of the following is “yes,” provide an explanation below.

Yes No Does the research involve any of the following?

[ ]  [ ]  a. Deception of participants.

[ ]  [ ]  b. Shock or other forms of punishment.

[ ]  [ ]  c. Sexually explicit materials or questions.

[ ]  [ ]  d. Handling of money or other valuable commodities.

 [ ]  [ ]  e. Extraction of blood or other bodily fluids. (Specify the type of bodily fluid or

 tissue, how it will be extracted, how it will be used, and how it will be disposed of.)

[ ]  [ ]  f. Questions about drug and/or alcohol use.

[ ]  [ ]  g. Questions about sexual orientation, sexual experience, or sexual abuse.

[ ]  [ ]  h. Purposeful creation of anxiety.

[ ]  [ ]  i. Any procedure that might be viewed as an invasion of privacy.

[ ]  [ ]  j. Physical exercise or stress (Specify type of exercise, exertion or stress.)

[ ]  [ ]  k. Administration of substances (food, drugs, etc.) to participants.

[ ]  [ ]  l. Any procedure that might place participants at risk (disclosure of criminal activity; the

 use of invasive procedures such as light, heat, sound, electrical current applied to the

 subject; the use of needles or any other implement that may cause a break in the skin.)

[ ]  [ ]  m. Systematic exclusion of any group, particularly those of minority status. (Explain)

Explanations:

**V. Subject Information**:

 If the response to any of the following is "yes," provide an explanation and details.

Yes No Does the research involve participants from any of the following categories?

[ ]  [ ]  a. Persons under 18 years of age.

[ ]  [ ]  b. Persons over 65 years of age.

[ ]  [ ]  c. Persons who are unable to provide their own legal informed consent.

[ ]  [ ]  d. Persons with physical, mental disabilities.

[ ]  [ ]  e. Pregnant females as target population.

[ ]  [ ]  f. Victims.

[ ]  [ ]  g. Individuals in institutions (e.g., prisons, nursing homes, halfway houses).

Explanations:

**VI. Researcher Information:**

Yes No

[ ]  [ ]  a. Are all researchers aware of the Nazareth University position regarding rights of human

 participants? (See HSRC Instructions. If the answer is "no," provide an explanation.)

[ ]  [ ]  b. Are all researchers aware of plans for responding to any emergencies or other

 problems arising from the research (such as dealing with upset or emotionally

 distraught participants)?

Explanations:

**VII. Risks and Benefits:** the HSRC retains final authority for determining risk status of a project.

Yes No

[ ]  [ ]  a. Are any emergencies or adverse reactions (physical, psychological, social, legal,

 or emotional) probable as a result of the research? (If "yes," provide an explanation.)

[ ]  [ ]  b. Is it anticipated that subjects leave the study or experiment in approximately the same

 emotional state as they began? (If not, then explain how distress will be handled.

 In most cases, this means informing subjects that if they become upset, want to talk

 about the study or related experiences, and so on, you are available. The Principal

 Investigator should provide subjects with his/her office and telephone numbers.)

[ ]  [ ]  c. In research involving deception, did you include a debriefing statement?

 In all research, it is critical to clarify any misconceptions that the participant may develop during the course of the research and to provide a full account of the facets of the study that were not revealed during participation. As the researcher, it is your ethical responsibility to ensure that there are no damaging consequences to the participant. *If your research does not involve deception, please leave it blank.*

Explanations:

**VIII. Informed Consent:** Answer the following questions about the informed consent procedures.

Yes No

[ ]  [ ]  a. Are you using a written informed consent form? (If "yes," include a copy. If "no,"

 explain why and describe how consent will be obtained.)

[ ]  [ ]  b. When disseminating research, do you preserve the confidentiality of participants? Confidentiality is maintained when it is impossible for any person to connect the data provided by the research subject to said subject. (If "no," explain why and describe how you will protect the identity of participants.)

[ ]  [ ]  d. Was the Nazareth University HSRC Informed Consent Checklist used to develop your

 Informed Consent Form? (see HSRC Instructions)

[ ]  [ ]  e. Are you seeking consent from all relevant parties?

Explanations:

**IX. Informed Consent Form**

Include the informed consent as a separate document with the Nazareth University letterhead with logo. Please see sample informed consent templates on the HSRC website.

**X. Additional Materials**

Include additional materials (recruitment flyers, recruitment script, surveys, interview questions etc.) as separate documents.

**XI. Checklist**

Complete before submitting your application.

Please note that **only complete** applications received before deadline will be processed and reviewed.

[ ]  Complete Proposal

[ ]  Cover page with signatures from PI and faculty advisor or sponsor

[ ]  CITI completion report showing modules, scores and expiration date for **all**PIs and additional investigators (if applicable).

[ ]  CITI completion report showing modules, scores and expiration date for faculty advisor (if PIs are students).

[ ]  Informed Consent Form with Nazareth University letterhead with logo.

[ ]  Additional documents as applicable (eg recruitment flyers, email script, surveys etc)