



### Application Checklist for Expedited or Full Review

The following checklist must be completed by the Principal Investigator with the submission of any expedited or full review protocol to the Institutional Review Board for the Protection of Human Participants.

Principal Investigator: \_\_\_\_\_

Department: \_\_\_\_\_

Protocol Title: \_\_\_\_\_

	Attached	N/A
Application Form (with <u>all</u> required signatures).....	<input type="checkbox"/>	
Attachment A .....	<input type="checkbox"/>	<input type="checkbox"/>
Attachment B .....	<input type="checkbox"/>	<input type="checkbox"/>
Attachment C .....	<input type="checkbox"/>	<input type="checkbox"/>
Attachment D .....	<input type="checkbox"/>	
Abstract (limit 400 words) .....	<input type="checkbox"/>	
Protocol Description.....	<input type="checkbox"/>	
Purpose.....	<input type="checkbox"/>	
Source(s) of Subjects and the Selection Criteria.....	<input type="checkbox"/>	
Procedures.....	<input type="checkbox"/>	
Assessment of Risks & Benefits .....	<input type="checkbox"/>	
Protection of Data/Privacy .....	<input type="checkbox"/>	
Debriefing Process .....	<input type="checkbox"/>	<input type="checkbox"/>
Consent Procedures.....	<input type="checkbox"/>	
Investigator Background and other Relevant Information .....	<input type="checkbox"/>	
Draft Consent Form .....	<input type="checkbox"/>	
Draft Assent Form.....	<input type="checkbox"/>	<input type="checkbox"/>
Fliers/Advertisements/Announcements.....	<input type="checkbox"/>	<input type="checkbox"/>
Surveys/Questionnaires.....	<input type="checkbox"/>	<input type="checkbox"/>
Interview Questions .....	<input type="checkbox"/>	<input type="checkbox"/>
Vitas of all Investigators .....	<input type="checkbox"/>	
Copy of Certificate of Completion of Online Training Module for all key personnel.....	<input type="checkbox"/>	
Authorization from Performance Sites.....	<input type="checkbox"/>	<input type="checkbox"/>

**The application checklist, application form and protocol description, and additional materials should be submitted to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at the Office of Sponsored Programs and Research, North House, Second Floor.**



**NYIT Institutional Review Board for the Protection of Human Participants  
 APPLICATION FOR EXPEDITED OR FULL REVIEW**

- This form must be completed for all protocols that do not qualify for exemption. (To request an exemption, review the exempt categories carefully and submit the Request for Exemption form.)
- The Principal Investigator (PI) assumes responsibility for the conduct of the study. Students and non-NYIT personnel may not serve as principal investigators. The PI should complete sections I through IV of this form and attachments A, B, C or D as applicable.
- Submit the application checklist, application form and attachments and other materials as needed to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at North House, Second Floor.

**Protocol title:** \_\_\_\_\_

**I. PERSONNEL**

Principal Investigator: (Last) \_\_\_\_\_ (First) \_\_\_\_\_

Check one:  Faculty  Staff  Other \_\_\_\_\_

Department: \_\_\_\_\_

Address (where you want notification sent): \_\_\_\_\_

Telephone (Home): \_\_\_\_\_ Campus: \_\_\_\_\_

E-mail: \_\_\_\_\_

*If the project has additional investigators, including students, complete **ATTACHMENT A**.*

**II. PROTOCOL**

**1. Assessment of Risk**

Minimal risk (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Moderate risk (minor increase over minimal risk)

Considerable risk (greater than minor increase over minimal risk)

Comments Regarding Risks: \_\_\_\_\_

**IRB USE ONLY**

New Protocol: \_\_\_\_\_ Revised: \_\_\_\_\_

Protocol Number: \_\_\_\_\_ Copies Submitted: \_\_\_\_\_

**2. Type of Review**

Indicate the type of review you are requesting. If you select expedited, check the number of the review category that best fits your research. **Final decisions about the appropriate level of review rest with the IRB.**

I am requesting an EXPEDITED REVIEW under category:  1  2  3  4  5  6  7  8  9

Submit the original and three (3) copies of your application to the IRB.

I am requesting a FULL REVIEW because my research does not fit precisely into any of the expedited review categories.

Submit the original and fifteen (15) copies of your application to the IRB.

PLEASE NOTE: Applications that qualify for Expedited Review are reviewed on a rolling basis. Check the IRB web site for a listing of IRB meeting dates and application receipt deadlines for full review protocols.

**3. Participant Information:** Will data be collected from any of the following populations?

- Minors (Under 18 yrs of age; Specify age range) \_\_\_\_\_
- Prisoners  Staff/Employees
- Fetuses  Students
- Pregnant women  Non-English speakers
- Cognitively impaired (including comatose)  Poor/Uninsured

**4. Research Support:** Do you plan to or have you applied for funding for this project? Please review the sponsor's guidelines carefully and allow sufficient time for IRB review.

Yes Please provide the funding source: \_\_\_\_\_

Program/Grant Number (if Known): \_\_\_\_\_

Please provide one (1) copy of the complete grant proposal or contract.

No

Please check the following as appropriate:

- The above-referenced sponsor intends to fund 100% of the costs associated with participant participation in the research protocol.
- The above-referenced sponsor intends to fund 100% of the costs associated with participant care that is beyond regularly required care. Regular care will be billed to the participant or the participant's insurance.
- The above-referenced sponsor intends to fund only a portion of the total costs associated with participant care. Explain fully in the protocol description.

**5. Financial Conflict of Interest:** Does the principal investigator, any co-investigator or study coordinator involved in the study (or in aggregate with his/her spouse, dependents or members of his/her household):

- A. Have an equity interest in the entity that sponsors this research or the technology being evaluated that exceeds 5% ownership interest or a current value of \$10,000?
  - Yes
  - No
- B. Receive salary, royalty, licensing fees, or other payments from the entity that sponsors this research or the technology being evaluated that is expected to exceed \$10,000 per year?
  - Yes
  - No
- C. Have a license agreement with the University or an external entity that would entitle sharing the current or future commercial proceeds of the technology being evaluated?
  - Yes
  - No

If yes to any of the above, please submit detailed information on a separate sheet.

6. Study site(s):  NYIT-Central Islip  NYIT-Old Westbury  
 NYIT-Manhattan  NYCOM  
 Other (Please specify): \_\_\_\_\_

Please provide letters of agreement and/or complete **ATTACHMENT B**.

7. If this proposal has been submitted to another Institutional Review Board, give the name of the institution and date of review. Supply copies of approval letters and recommendations of that committee.

Institution: \_\_\_\_\_ Date of review: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

8. **Timetable:** What is the estimated duration of the entire study?

Begin: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ End: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

9. **Participant time commitment.** What is the time commitment for each participant participating in the study? Indicate the number of visits/sessions and the time involved per visit/session.

Visits/Sessions: \_\_\_\_\_ Time per visit/session: \_\_\_\_\_

10. **Compensation.** If compensation to participants is intended, indicate how much and in what form (cash, taxi fare, meals, etc). The amount of compensation is subject to IRB approval.

Is any form of compensation being provided?

Yes Describe: \_\_\_\_\_  
 No

**III. PROTOCOL DESCRIPTION**

Please respond to the following requests on a separate sheet.

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study. Briefly discuss the background and rationale for the study. Is the study design appropriate to prove the hypothesis? Provide references for the background information. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.

2. Describe the source(s) of participants, the selection criteria and the recruitment methods. Selection of participants must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. Provide a detailed description of the participant population including criteria for inclusion/exclusion, number of participants involved in the study, age, sex and health status. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential participants **must be attached**.

3. Provide a detailed description of the procedures to be followed. If applicable, include a detailed description of all drugs to be used including dosages, dosage changes varying from manufacturers' recommendations, frequency of use, FDA status of a formerly approved drug being used for new therapies, IND# of all new drugs and all other drug information necessary. Include copies of questionnaires and/or interview protocols, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of participants' involvement. Include a time line for the study.

4. Describe any potential harms or benefits to be derived by participants, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety. Discuss how risks will be minimized and additional safeguards for vulnerable subjects.

5. Describe the specific methods by which confidentiality or anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.

6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

7. Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent. Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent forms. When the consent form to be used will be in a language other than English, an English translation must be provided. Use the Informed Consent Checklist (**ATTACHMENT D**) as a guide in drafting your consent form.

8. Please provide information about your background. You may attach a CV or resume for all investigators.

#### IV. CERTIFICATION AND APPROVAL

By signing this document, I certify that in my opinion the protocol and safeguards described in this application meet the standards of the New York Institute of Technology (NYIT) and all Federal regulatory requirements concerning experiments that use human participants. I accept responsibility for assuring adherence to Federal and NYIT policies relative to the protection of the rights and welfare of participants in this study. I certify that my participation and the participation of any co-investigators does not violate the NYIT policy on conflicts of interest.

By signing below, I certify that I have undergone training in basic human participants protections and will ensure that all key personnel complete this training before working on this protocol.

<b>PI Signature</b>	_____	<b>Date:</b>	____/____/____
<b>Department Chair</b>	_____	<b>Date:</b>	____/____/____

*If students will be involved in the project, complete **ATTACHMENT C**.*

**ATTACHMENT A:**

**ADDITIONAL INVESTIGATORS AND KEY PERSONNEL**

*Fill out this section if additional investigators will work on this project. Attach additional pages as necessary.*

**1. ADDITIONAL INVESTIGATOR/KEY PERSONNEL**

Check one:

Student  Faculty  Staff  Other \_\_\_\_\_

Name: (Last) \_\_\_\_\_ (First) \_\_\_\_\_

Department: \_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**2. ADDITIONAL INVESTIGATOR/KEY PERSONNEL**

Check one:

Student  Faculty  Staff  Other \_\_\_\_\_

Name: (Last) \_\_\_\_\_ (First) \_\_\_\_\_

Department: \_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**ATTACHMENT B:**

**RESOURCES**

The following consultants and service departments (e.g. Radiology, NYIT/NYCOM Academic Health Care Center [AHCC], Hospital Department, Medical Records, School Principal or Superintendent, Counseling Center Supervisor, etc), affected by elements of this protocol, have been consulted and agree to participate to the extent required by the protocol. Any protocol involving the NYIT/NYCOM Academic Health Care Center (AHCC), Old Westbury, and/or the NYIT/NYCOM Family Health Care Center (FHCC), Central Islip, must be reviewed by the Medical Director of the AHCC/FHCC. The investigator is responsible for submitting the protocol to the AHCC/FHCC Medical Director for his/her signature.

This project  does  does not involve the NYIT/NYCOM Academic Health Care Center (AHCC).

This project  does  does not involve the NYIT/NYCOM Family Health Care Center (FHCC).

**Service or Consultant** (Please print)

Department/Organization: NYIT/NYCOM AHCC Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: NYIT/NYCOM FHCC Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

*Letters of agreement may be substituted for signatures here.*

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**HIPAA Certification**

On April 14th, 2003, privacy regulations went into effect that regulate the access and handling of medical information. The investigator, not the IRB, is responsible for understanding and ensuring that the regulations are followed. If the protocol involves any unit of the Academic Health Care Center at NYIT/NYCOM, you must discuss the protocol with the compliance officer of NYIT/NYCOM, currently Nancy Bono, DO, in the Old Westbury Academic Health Care Center. If there is any doubt whether this applies, please discuss it with the HIPAA compliance officer. If the project involves medical records at any other institution, you must discuss your proposal with the compliance officer of that institution.

I certify that I have discussed my proposal involving medical records of any kind with the appropriate compliance officer, and understand and will comply with the requirements of HIPAA regulations.

PI Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**ATTACHMENT C:**

**STUDENT PARTICIPATION IN RESEARCH**

**Principal Investigator**

I certify that I have instructed the student(s) listed below in research techniques and human protections standards; I have reviewed the entire research proposal, including any components composed by the student(s); any student role will be consistent with the description I provide in this proposal and in compliance with NYIT Human Protections Policies, to the best of my knowledge.

PI Signature: \_\_\_\_\_ Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**Students**

I certify I am at least 18 years of age and that to the best of my understanding I will comply with the NYIT policies regarding Human Research Protections and will participate in research consistent with the descriptions in the submitted protocol

Student Name (print/type)	Signature	Date
_____	_____	____ / ____ / ____
_____	_____	____ / ____ / ____
_____	_____	____ / ____ / ____
_____	_____	____ / ____ / ____
_____	_____	____ / ____ / ____
_____	_____	____ / ____ / ____

**ATTACHMENT D:**

**INFORMED CONSENT CHECKLIST**

*Please use this checklist to develop your informed consent form(s). Sample consent forms are available at <http://iris.nyit.edu/sponsoredprograms>. Submit **ONE** copy with your copies of the proposal and other forms.*

Unless waived by the IRB, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the participant or the participant's legally authorized representative.

The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by Federal regulations (45CFR46.116). This form may be read to the participant or the participant's legally authorized representative. The investigator should give either the participant or the representative adequate opportunity to read it and ask questions before it is signed. Copies of the consent form should be given to the participant(s).
2. A short form written consent document, stating that the elements of informed consent required by 45CFR46.116 have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there should be a witness to the oral presentation. The IRB must approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness should sign both the short form and a copy of the summary, and the person obtaining consent should sign a copy of the summary. A copy of the summary should be given to the participant or the representative, in addition to a copy of the short form.

Please check one:

- I am requesting a waiver for documentation of informed consent.**  
*Complete **Section 1** below*
- I have enclosed a draft informed consent form and assent form (if applicable).**  
*Complete **Section 2** below.*

**Section 1:**

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either:

- 1). That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
- 2). That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

- A. Does the research present more than minimal risk to the participants?
  - Yes
  - No
- B. Will a waiver adversely affect the rights and welfare of the participants?
  - Yes
  - No
- C. Can this research be practicably carried out without the waiver?
  - Yes

- No
- D. Will participants be provided with additional pertinent information after participation?
- Yes
- No

**Section 2:**

Consent documents must be written in lay language at the 6<sup>th</sup> grade reading level and include the following required elements:

**Included**

- A statement that the study involves research and an explanation of the purposes of the research, the expected duration of the participant's participation, and a description of the procedures to be followed and identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the participant
- A description of any benefits to the participant or to others, which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation will be offered, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled
- Additional elements, as appropriate:

**Included    N/A**

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
- Any additional costs to the participant that may result from participation in the research
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant
- A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant
- If minors are involved, an **assent** form