

**INSTITUTIONAL REVIEW BOARD
(I R B)**

APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH

Step-by-step instructions and other information relevant to filling out this form are contained in CUNY's *Principal Investigator's (PI) Manual for Research Involving Human Subjects*, available at your campus IRB Office or by accessing it on-line at http://www.rfcuny.org/ResCompliance/pi_manual.html.* All Principal Investigators are expected to be familiar with the policies and procedures it contains. Failure to follow the instructions may result in a delay in the approval process. Be sure to sign where indicated by the . See FAQ's page for current IRB LaGuardia Coordinator.

1. **Project Title:** _____

PRINCIPAL INVESTIGATOR INFORMATION (See Page 4 of the PI Manual)

2. Principal Investigator: _____

Department: _____ Phone: _____ Fax: _____

Email (*Required*): _____

3. Co-PI (if any) _____

Department: _____ Phone: _____ Fax: _____

Email (*Required*): _____

4. Status (check one): Faculty Doctoral Student Graduate Student Undergraduate Student
 Other (please explain) _____

For student and non-CUNY researchers *only*, please give your home address and telephone number:

FACULTY ADVISOR INFORMATION (See Page 4 of the PI Manual)

NOTE: The IRB will not review protocols submitted by students without the signature of a faculty advisor on page 8 of this application.

5. Faculty Research Advisor: _____

Department: _____ Phone: _____ Fax: _____

Email (*Required*): _____

* A revised version of the *PI Manual* that includes instructions on the questions in this form related to the Research Authorization required by the Privacy Rule issued under the Health Insurance Portability and Accountability Act (HIPAA) will be available shortly. In the meantime, please refer any concerns you have about these questions to your IRB Chair or IRB Administrator.

For IRB Use Only

Date Received:
(Form Revised March 2003)

Protocol Number:

PROTOCOL INFORMATION (See Pages 4-12 of the PI Manual)*

Yes No

6. Does your study involve individually identifiable protected health or mental health information (PHI), including demographic information and biological specimens identified to an individual, created or maintained by, or received from, a person or an entity covered by the Privacy Rule issued under the Health Insurance Portability and Accountability Act (HIPAA) (e.g., a hospital; a physician, or a practice in psychology, psychotherapy, or social work; a health insurer, HMO, or health plan; or a community clinic, or a social service or mental health agency)?

7. If your answer to question (6) is Yes, please list below or on a separate sheet the PHI that is necessary for your research and that you intend to use in your research.

8. If your answer to question (6) is Yes, please list below or on a separate sheet the name and address of each person or entity that is creating, maintaining or providing the PHI for your research.

9. If your answer to question (6) is Yes, please note that a person or entity covered by the HIPAA Privacy Rule can use or disclose PHI only under narrow conditions. Check below the authority under which you intend to obtain, use and/or disclose PHI in your research.

- You will seek each subject's HIPAA authorization (this HIPAA authorization is required **in addition** to each subject's informed consent). *If so, please attach a copy of the appropriate CUNY IRB HIPAA Research Authorization form prepared by you (PI), or the covered entity's HIPAA authorization, to this application. (These forms are available at <http://www.cuny.edu> under Research and Funding on the Faculty and Staff page.)*
- You intend to request a waiver or alteration of HIPAA authorization. *If so, please attach a copy of the CUNY IRB Request for Waiver or Alteration of HIPAA Authorization form prepared by you (PI). (This form is available at <http://www.cuny.edu> under Research and Funding on the Faculty and Staff page.)*
- The covered entity will provide you with a "limited data set" for your research.** *If so, please attach a copy of the covered entity's Data Use Agreement to this application (consult the covered entity's Privacy Officer for additional information).*

CUNY Investigators whose research involves PHI are required to ask all non-CUNY personnel who will have access to research data (e.g., co-investigators, outside statisticians, contractors) to sign the CUNY Subject Information Confidentiality Agreement, a copy of which is available at <http://www.cuny.edu> under Research and Funding on the Faculty and Staff page.

* Until the revised *PI Manual* that includes instructions on the questions in this form related to the Research Authorization required by the HIPAA Privacy Rule is available, please refer your concerns about these questions to your IRB Chair or IRB Administrator.

** Until the revised *PI Manual* including information regarding "limited data sets" under the HIPAA Privacy Rule is available, please refer your concerns about "limited data sets" to your IRB Chair or IRB Administrator.

10. Does your study involve the collection of data from a vulnerable population?
If yes, please specify type of population:

For a complete list of categories of vulnerable populations, as well as the special safeguards required when conducting research with them, see pages 4-5 of the *PI Manual*. Special Informed Consent procedures are necessary when conducting research with minors. See page 19 of the *PI Manual* for information.

- Yes No
- Children/Minors
- Prisoners
- Fetuses
- Pregnant Women
- Cognitively Impaired Persons
- Other

11. Does this study involve deception (research in which the subject is purposely led to have false beliefs or assumptions)?

- Yes No

12. If the study involves risk to subjects, is the risk greater than that incurred in ordinary life or tasks?

- Yes No

13. Has this study ever been previously approved by this IRB?

- Yes No

14. Is this proposal new or revised in response to previous IRB review?

- Yes No

15. Is funding being sought for this study? If yes, through what sponsoring agency?
Agency: _____

- Yes No

I certify that the research plan and safeguards to human subjects described in this application conform to that which has been submitted/will be submitted to an external funding source.

 Principal Investigator: _____

Date: _____

16. Is this study being reviewed by an IRB at another institution? If yes, please list the institutions below.

- Yes No

Documentation of IRB reviews of this study conducted at other institutions must be provided when it becomes available. **Research may not begin until IRB review has been concluded at all institutions involved.**

17. Have you (PI) completed the federally required CUNY Human Subjects Protection Education Program [see www.rfcuny.org/ResConduct/CBT]?
Documentation needs to be provided only once; if this is your first time submitting an Application for Approval, please attach a copy of your certificate.

Yes No

I certify that each of the following key personnel (as defined in the *PI Manual*) involved in this project either have completed an approved training program for the protection of human subjects in research and have certificates on file with the IRB office, or they will have completed an approved training program and certificates will be placed on file before their participation in the research project actually begins.



Principal Investigator: _____

Date: _____

<u>Name</u>	<u>Role on Project</u>	<u>Date Training Completed</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

18. Please indicate the type of review requested:

The IRB will make the final determination of the type of review.

Exempt

Provide the information requested on pages 5 and 7 and sign pages 4 and 8.

Expedited

Provide the information requested on page 5 and sign on pages 4 and 8.

Full IRB Review

Provide the information requested on page 5 and sign on pages 4 and 8.

ALL Applicants must answer questions 1-8 (See Pages 12-20 of the PI Manual)

All researchers must submit a fully complete application and detailed research protocol to the IRB, addressing all questions, regardless of type of review the researcher is requesting. Please consult pages 7-12 of the PI Manual for an explanation of expedited, full and exempt IRB review and the types of research that may be reviewed under each procedure. The IRB chair will determine the type of review for which your project qualifies under federal guidelines. Research cannot start until written IRB approval notification is obtained. Final judgement rests with the IRB.

Please answer the following questions 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 and indicate whether it has received IRB approval from another institution (*see page 12 of the PI Manual*). **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 subjects and the selection criteria. Selection of subjects 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. Include the number of subjects. (*See pages 12-14 of the PI Manual for a discussion of equity in subject selection and pages 4-5 for a discussion of protected populations*). The text of any advertisement, letter, flier, oral script or brochure used to solicit potential subjects **must be attached**.
3. Provide a description of the procedures to be followed. If available, include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of subjects' involvement.
4. Describe any potential harms or benefits to be derived by subjects, 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.
5. Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to them, and what will happen to data after the study has been completed. (If your study requires a waiver or alteration of HIPAA authorization, you should provide the information requested here on a separate sheet and in the *CUNY IRB Request for Waiver or Alteration of HIPAA Authorization* form).
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 contained in pages 16-20 of the PI Manual.** Describe the oral and written consent processes and attach all informed consent documents, including scripts for oral consent and assent form for research involving minors ages 12-17. When the informed consent form to be used will be in a language other than English, an English translation must be provided. **Unless one or more of the required elements described below is explicitly waived by the IRB, informed consent documents should contain:**
- A. A fair explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - B. A description of any possible discomforts and risks reasonably expected. This includes any potential financial risks that could ensue;
 - C. A description of any benefits reasonably expected;
 - D. A disclosure of any appropriate alternative procedures;
 - E. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
 - F. An offer to answer any current or future inquiries concerning the goals of the research or the research procedures, and to provide a summary of results upon request and information on whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject*;
 - G. An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice.
 - H. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; and
 - I. Provisions for parent or guardian approval for participation of minors or for subjects from vulnerable populations when appropriate.

Upon approval of the study, the informed consent document will be stamped with an expiration date. **Only this document may be used when enrolling subjects.** Studies extending beyond the expiration date must be submitted for a continuation review. **Any changes in the informed consent form must be approved by the IRB.**

8. Please provide any other information that might be pertinent to the IRB's decision.

**If you are requesting exempt status, please continue on page 7.
For expedited or full review, please continue on page 8.**

* **Note:** Questions about the rights and welfare of individuals as participants in human subjects research and notice of a research-related injury should be directed to the IRB Chair on your campus.

For EXEMPT STATUS Requests ONLY (See Pages 7-9 and 20 of the PI Manual)

Following are the categories of research eligible for Exempt Review. Please indicate the category in which you believe your research fits:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - (i) research on regular and special education instructional strategies, or
 - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- (6) Taste and food quality evaluation and consumer acceptance studies,
 - (i) if wholesome foods without additives are consumed or
 - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

FINAL DETERMINATION ON EXEMPTION RESTS WITH THE IRB.

EXEMPT RESEARCH INVOLVING PHI IS NOT EXEMPT FROM THE REQUIREMENTS OF THE HIPAA PRIVACY RULE.

IF YOUR RESEARCH INVOLVES PHI, YOU MUST INDICATE YOUR AUTHORITY FOR OBTAINING, USING AND/OR DISCLOSING THE PHI.

SIGNATURE and CERTIFICATION (See pages 20- 21 of the PI Manual)

I agree to use procedures with respect to safeguarding human subjects in this activity that conform to University policy. If significant change in investigative procedure involving human subjects is called for during the activity covered by this application, I shall seek prior approval for such change from the IRB and agree to follow the advice of the IRB. If my research is subject to the requirements of the HIPAA Privacy Rule, I agree to meet those requirements and to see that other persons and entities from which I obtain PHI also meet those requirements to the extent they assist me in this research. Where required, I will obtain a HIPAA authorization or an IRB waiver of HIPAA authorization. The faculty sponsor’s signature indicates that s/he has reviewed this application and accepts the responsibility of insuring that the procedures approved by the IRB are followed.

Signed:



Principal Investigator _____

Date _____

Co-PI _____

Date _____

Faculty Advisor _____
(required for student research)

Date _____

Before submitting this form, consult pages 21-23 of the PI Manual, “Frequent Oversights.”

For EXPEDITED and EXEMPT reviews, submit the original and 3 copies of this Application together with the informed consent form, recruitment materials, HIPAA Authorization form or Request for Waiver or Alteration of HIPAA Authorization form (where applicable), and other relevant information.

On most campuses, for FULL IRB reviews, submit the original and 10 copies of this Application, together with the informed consent form, recruitment materials, HIPAA Authorization form or Request for Waiver or Alteration of HIPAA Authorization form (where applicable), and other relevant information no less than 12 days prior to the IRB meeting at which you wish your application to be reviewed. Please consult your IRB Chair, IRB Administrator, or grants or sponsored programs officer on your campus for the exact requirements.