



Application No. _____

Date Received _____

IRB RESEARCH APPLICATION

Two copies of the completed, typewritten, and signed research application should be submitted to the Institutional Review Board, 25 Buick St., Boston, MA, 02215, with two copies of the full grant proposal (including appendices but excluding budgets). Any documents pertaining to the review of the research by another IRB should also be included. Two copies of an informed consent form, and assent form if applicable, must accompany the application.

Attached are synopses of selected parts of the federal regulations governing the use of human subjects in research, which may be useful in preparing applications. Included are important definitions, criteria for IRB approval, and general requirements for informed consent. Two appendices are also included. Appendix A describes categories of research exempt from further review by the Board and appendix B describes categories of research which may be reviewed by the IRB by an expedited procedure, prior to a convened meeting.

Questions concerning this application or the application process should be directed to the Coordinator for the Board at (617) 353-4365.

1. **Category of review (enter N/A if no claim is made):**

_____ **Exempt: Applicants may claim exemption from further review if the research is in accordance with Appendix A (see attached); applicants must cite the applicable regulation.**

_____ **Expedited: Applicants requesting expedited review must cite the applicable regulation in Appendix B (see attached).**

2. **Project Title:**

3. **Principal Investigator (include title, department, university address, email and telephone number):**

4. **Co-Investigators and Staff (include same information as requested in 3 above):**

5. **Granting Agency and Date of Submission (include name, address, phone number, and fax number of program officer as well as the sponsor grant number and Boston University Restricted Fund Account number if available--enter N/A if appropriate):**

Note: Please attach PI and Co-I Conflict of Interest Disclosure forms if the study is not externally funded. For grant-related studies, please indicate whether an investigator conflict of interest has been disclosed to the CRC Office of Sponsored Programs. Yes _____ No _____

6. **Expected Duration of Study:**

7. Description of Project.

A description of various aspects of your project is necessary for the IRB to comply with the mandated criteria for approval of research involving human subjects as set forth in the Federal Regulations and Boston University's policies. The criteria are summarized on page three of this form. Please use numbered continuation pages and address each item below, identifying each item by the appropriate letter.

- A. Describe the proposed research briefly, with attention to:
 - 1. Objective (s) and expected outcome(s).
 - 2. Experimental design, number of subjects, and aspects of the research which are experimental.
 - 3. Materials and procedures, with particular attention to those involving human subjects. (Two copies of all questionnaires, survey instruments, psychological or similar tests, and interview questions which will be used in the project must accompany the application.)

- B. Describe the criteria for the selection of subjects (age, sex, etc.), the method for identifying subjects, and the anticipated number of subjects in each identified subject category. Include a description of any involvement of prisoners, of institutionalized persons, of persons with acute or severe physical or mental illness, or of pregnant women as subjects. Also describe any involvement of subjects who are students, employees, patients, or clients of Boston University or other hospital or institution.

- C. Describe the information that will be provided to the subjects about the research. Include two copies of any ads, posters, or recruitment letters to be used.

- D. Describe the circumstances under which informed consent will be obtained from subjects, including how, when, and by whom consent will be obtained.

- E. Describe any expected benefit(s) for the subject from participating in the study and describe any benefits to others, including society at large. In addition, describe any financial compensation to be provided to subjects.

- F. Describe any reasonably foreseeable risks or discomforts to the subjects arising from participation in the research and any measures to prevent or minimize such risks. This includes physical, psychological, social, legal, and economic risks or discomforts.

- G. Describe what steps will be taken to maintain the confidentiality of records identifying the subjects, including measures to restrict access to such records and to preserve the anonymity of subjects in publication or reports regarding the research.

8. Informed Consent Form(s).

Two copies of each proposed informed consent form, and assent forms for minors when applicable, must be included with each application. The content must be consistent with the basic elements of informed consent as defined by Federal and University policy (see attached). Please note this represents the minimum information to be given a potential subject. The IRB may waive the requirements to obtain informed consent in some circumstances. If a waiver of any requirement for informed consent is requested, please consult with the Coordinator of the Board.

I accept responsibility for assuring that this study will be carried out in accordance with all applicable federal state and local laws and regulations and in accordance with the policies of Boston University, with respect to the protection of human subjects participating in this study.

Signature of Principal Investigator Date

This application has been reviewed and approved for submission to the Charles River Campus IRB.

Chairman/Director of Department Date