

**Instructions for completion of the Human Study Protocol Application
HSL Institutional Review Board**

Please answer all questions on the application form. If any questions are not applicable, please put N/A in the correct section.

1. **Title:** Please type the complete title of the study
2. **Principal Investigator:** Please complete all of the information in this section. If an administrator/coordinator/manager is responsible for submitting IRB paperwork, please be sure to include his/her name and contact information in section 2b. Please note that the IRB requires a copy of human subjects protection certification for the PI. The certification training can be found online at: <http://phrp.nihtraining.com>.
3. **Required Signatures:** Please note that a Human Study Protocol Application will not be reviewed unless it has the original signature of the Principal Investigator.
4. **Co-Investigators/Key Personnel:** Please be sure to complete all information in this section. Please note that the IRB also requires a copy of human subjects protection certification for co-investigators. This certification training can be found on-line at: <http://phrp.nihtraining.com/>
5. **Is HSL the Grant Sponsoring Institution?:** If no, list the institution through which the grant has been awarded. Please attach a copy of the scientific section of the grant application (Section A-D of NIH grants) plus the Human Subjects section (Section E). A copy of the IRB approval letter and current approved Consent Form from this institution must be also be attached.
6. **Project Funding:** Please complete sections a-c on the application. For 6b, department funds may include sources such as HSL Women's Auxiliary or Men's Associates, and these sources should be listed in 6c along with other Agencies that may be funding the project.
7. **Conflict of Financial Interest:**
8. **Summary of protocol:** This section should be as concise as possible. Please include a 1-3 sentence summary of each of the following categories: hypothesis, study design procedures and methodologies, participant selection, randomization to control/intervention groups, and the plan for confidentiality. Alternatively, please note, that you may attach a 1-2 page summary of the protocol with the information.

9. **Research Participation Information:** It is important to complete each question (a-m) in this section. If any question is not applicable, please put N/A in the appropriate space. Please note that any recruitment materials to be used (such as brochures, flyers, and e-mails) must be submitted with the IRB application for review and approval. If any materials are not yet developed, prior to implementation, these materials must be submitted for IRB review.

If the participants are low literate, please describe how investigators will ensure the participants' understanding of the research.

Please note that if the **participant is not fluent in English** or is unable to read English you may need to provide recruitment, consent and educational materials in the language best understood by the participant for the HSL IRB's review and approval, prior to implementation. Please note that back-translations may be required for non-English documents.

If participants are employees, students, fellows, or staff of HSL, please state the investigator's involvement in the participant's education/employment. Please note that an employee/student/fellow may not participate in any protocol conducted by his/her immediate supervisor/mentor

9d. **Expected Duration of Protocol:** Please provide the month, day and year of the start and end date from the study commencement through data analysis.

9k. **Briefly describe the structure/plan to report adverse events to HSL IRB:** Please indicate how any serious adverse events will be reported. Please note that prompt submission of each DSMB report is required. Definition of Adverse Event = An undesirable and unintended, although *not necessarily unexpected* result of therapy or other intervention (e.g. headache following spinal tap or intestinal bleeding associated with aspirin therapy). Please note that HSL IRB has a standard Adverse Event reporting form located on the common drive.

9m. **Please describe how abnormal medical findings that require further follow up will be handled:** Please provide a description of the protocol for following up with any abnormal medical findings encountered during the study.

10. **Informed Consent:** The Informed Consent form should have the following *mandatory* sections: Study Purpose, Sponsorship, Procedures, Risks, Benefits, Alternative Treatments, Confidentiality, Compensation, Costs, Authorization For Use and Disclosure of Your Protected Health Information, Questions, Study Withdrawal, and Signature area. An example of the Informed Consent Form is located on the research common drive and on the web. This section of the application requests a description of the process of how Informed Consent will be presented and discussed with participants.
11. **Investigational New Drug or Device 30-Day Delay Requirement:** Please complete each question in this section. If any item is not applicable, please put N/A in the appropriate space.
List All Drugs to be Used and Dosages: Please complete this section, regardless of whether a drug is investigational, prescription or over the counter. If this is not applicable to the study, please put N/A in the appropriate space.
12. **Radiation to be Used:** Please complete this section, even if the radiation to be used is part of a routine clinical examination.
Please note that if ionizing or non-ionizing radiation will be used, the test, as well as the associated risk, must be identified on the informed consent.
13. **Data Sources:** Please be sure to complete each question (a-e) in this section. If any question is not applicable, please be sure to put N/A in the appropriate space. Please note that any materials – either written or oral, to be used with participants (such as interview questions/scripts, surveys, and ethnographic study question/questions guides) must be submitted with the IRB application for review and approval prior to implementation. Any materials not yet developed upon IRB review must be submitted as an amendment for review and approval prior to implementation. Please indicate whether materials are attached, forthcoming, will not be used in this study or other. *Please note: Any materials, assessment instruments or questionnaires developed or used in a study must be submitted to the IRB for review.*
14. **Genetic Analysis:** If this study involves genetic analysis, please be sure to answer each question in this section. Please note that the items in this section must also be included in the informed consent form, unless the samples are de-identified already existing samples.
15. **Application for Exemption.** Certain research activities may be exempt from review. If you believe that your research constitutes one of the types of research which may be exempt from review, please make sure that your description in #8 includes (1) the specific category under which the research may be exempt, (2) the human material to be reviewed, and (3) the manner in which all subject

materials will be identified to the researchers and in all records made by the researchers.

16. **Application for Expedited Review.** Some categories of human subjects research that do not qualify for exemption qualify for expedited review. Complete this section if you would like to apply for expedited review.

The HSL IRB staff are happy to answer any questions you may have, if you need assistance in completing the application or have questions about informed consent materials please e-mail the IRB Coordinator, Kala Jakobsen, at irb@hsl.harvard.edu or call at 617-971-5311. Generally, the more pertinent information provided, the smoother the review process will likely be.