



Seven Hills Foundation IRB Manual

(revised March 2023)

Instructions and Procedures for Research Proposals Involving Human Subjects

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Introduction

The organization's Institutional Review Board (IRB) is charged by the Seven Hills Foundation's President with the responsibility of reviewing research proposals for the purpose of protecting the rights of individuals who are subjects of any research, conducted by staff of the Seven Hills Foundation. Federal regulations place responsibility on the organization and the Principal Investigator to insure that high ethical standards are maintained for all research involving human subjects. The Seven Hills Foundation IRB membership shall include the:

- SHF Chief Learning Officer
- SHF Director of Quality Assurance/Program Improvement
- Other SHF Leadership as deemed appropriate based on the research and leadership expertise
- A community professional with expertise in the area of research.

Principal Investigators who are interested in viewing the actual regulations can refer to the Code of Federal Regulations, 45 CFR 46, which can be found on the following website maintained by OHRP (Office for Human Research Protections), the cognizant federal agency for human subjects protections regulation: <http://ohrp.osophs.dhhs.gov/polasur.htm>.

In addition to its mandated review functions, the IRB is committed to serving as an educational resource for the Seven Hills community. Workshops, presentations to faculty and student groups, and consultation can be easily arranged.

This Manual is intended to provide explicit instruction to principal investigators conducting research involving human subjects. Research is defined by Federal regulation as: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR part 46s. 102d). Organizational activities that are solely for program evaluation generally do not have to come before the IRB. However, the burden of responsibility lies with the researcher to consult with the IRB Chair to determine whether classroom activities and/or course assignments fall under IRB regulation.

Instructions for Principal Investigators

Any person proposing to conduct research involving human subjects must prepare a project proposal for review by the IRB. The purpose of the proposal is to describe research purposes, procedures, and protections against risk so that the IRB can determine whether adequate protection of the rights and welfare of prospective research subjects is provided in accordance with all pertinent laws, regulations, and policies.

Research investigators must submit one copy of the complete research proposal to the Chairperson of the IRB. The Chairperson will then determine the appropriate level of review. Proposals may be designated exempt from review, referred for expedited review, or require full review. Please refer to the checklist located on the Seven Hills Foundation web page.

Project Proposal

The project proposal should include the following items: Project Review Cover Sheet, the Project Description, the proposed Informed Consent Form(s), as well as copies of all research instruments and written authorization(s) from cooperating agencies or institutions, if applicable.

Project Description

The project description should be no more than 5 single-spaced pages in length, not including consent forms and instruments. It should include:

- **General Description:** Briefly describe the overall goals of the proposed research and the general procedures to be used.
- **Significance of the Study:** Provide a brief theoretical and empirical rationale for why you believe this study is important.

Subject Population: Describe the characteristics of the subject population. Include their anticipated number, age range, gender, racial and ethnic composition, and health status. Identify the criteria for inclusion in the study. If the study involves special classes of subjects, such as fetuses, pregnant women, children, minors, prisoners or other institutionalized individuals, or others who are likely to be vulnerable, please explain the rationale for their involvement. If the sample is limited to a specific racial or ethnic group or is gender specific, please explain your rationale for exclusion/inclusion. Briefly describe the site(s) from which you will draw your sample(s) and/or locate your research study.

Sources of Research Material: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Subject Recruitment: Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained.

Risks: Describe any potential risks (to confidentiality, physical, psychological and social well-being, legal and financial risks, for example) and assess their likelihood and seriousness.

Protection Against Risks: Describe the procedures for protecting against or minimizing any potential risks identified above and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe provisions for secure storage of data.

Benefits: Discuss the specific benefits to subjects. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

NOTES: Though it is common to utilize the terminology “Human Subjects” to connote an individual who participates as a subject in a research study, it is entirely appropriate to substitute the word “Participant”. Please be sure to define any technical terms in law terminology, including description of special equipment and/or procedures.

Consent Form

If an Informed Consent Form is deemed necessary, research investigators must include copies of the proposed Informed Consent Form(s) with the proposal. You must also submit copies of a written or verbal explanation of the project to be given to subjects. The approved Consent Form is valid for a maximum of one year. In cases where a project is continuing beyond one year, permission to continue use of the Informed Consent Form must be applied for at least 45 days in advance of the one-year anniversary date. Such permission is granted in conjunction with the application for Continuing Review.

If your research study will indicate individuals with linguistic backgrounds other than English, the IRB will generally require that you translate the Informed Consent Form into the appropriate other language. It must be submitted with the other materials you are sending in your application. A “back translation” of the Form should be submitted, as well. In cases where an individual may be unable to read—whether it be English or another language—or has impaired vision, appropriate arrangements must be made to orally convey the contents of the Informed Consent Form. Arrangements must also be made for the individual to give or withhold their willingness to participate in the research project.

Please be sure that your consent form conveys all of the following information, at a minimum:

- A statement that the study involves research, a readily understood explanation of the purposes of the research and the expected duration of the subject’s participation, a simple description of the procedures to be followed, including identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.

- A description of any benefits to the subject or to others which may reasonably be expected from the research and/or findings (if no direct benefit, this should be stated)
- A statement describing the extent, if any, to how confidentiality of records identifying the subject will be maintained.
- As explanation of 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
- For research involving more than minimal risk, 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.
 - Example statement: If you can questions about the research, your rights as a research subject or if you experience any related injury, you should contact [name and contact information of investigator] and/or the Human Protections Administrator at (phone number) NOTE: staff should also include name of and contact information for their research advisor.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- A statement concerning costs or compensation to the subject.

When required by the IRB, the research investigator shall provide one or more of the following elements of information to each subject:

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

Research investigators are responsible for insuring that written consent is documented by the use of a written Informed Consent Form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. In addition, research investigators must insure that each person signing the written Informed Consent Form is given a copy of that form. Research investigators are responsible for the safeguard of consent documents signed by human research subjects for at least three years following the termination of the project.

The IRB may waive the requirement for the investigator to obtain a signed Informed Consent Form for some or all subjects if it finds (as defined by 45CFR46.116):

- (1) There is no more than minimal risk to the subject;
- (2) The waiver or alternation will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without a waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Reasons for a request that consent be waived should be explicitly stated in a cover memo accompanying the research proposal and protocol. When the documentation requirement is waived or altered, the IRB may still require the research investigator to provide subjects with a written statement regarding the research.

Research Instruments: Please submit copies of your research instrument(s).

Subject Recruitment

If you are recruiting subjects from another institution or agency, you may need to get approval from that institution's IRB, as well as from the Seven Hills Foundation IRB. If the institution does not require its own IRB review, you may be asked to provide written documentation of the institution's support for your project.

In cases where a research study poses at least minimal risk and involves vulnerable subjects, the proposal will receive Full Review. A listing of vulnerable subject categories is contained in Project Review Cover Sheet.

Procedures in the Event of Changes to the Protocol or Adverse Effects on Subjects

If a researcher's procedure changes in any way after a research project has been approved, the research investigator must not proceed with the proposed changes without written approval before proceeding of the IRB. IRB notification is also required if your project is discontinued.

In cases where a researcher is seeking approval for the project essentially identical to a project previously approved by the IRB, Renewed Approval should be obtained. This would apply to situations where a researcher submits a previously approved proposal to other funding agencies.

It is the researcher's responsibility to notify the IRB in writing of any adverse effects to research participants within one week of such event(s). If a researcher should encounter any unexpected and serious adverse effects on human subjects, research should be immediately discontinued and the IRB must be notified.

Procedures for Renewed Approval

Any project which exceeds a period of one year in duration must be reviewed and receive IRB approval prior to the beginning of the second and any successive years of the research project. Continuing Review must be sought at least 45 days prior to the anniversary date of approval for the research study.

The Consent Form is also valid for a maximum of one year after its approval. In cases where a project is continuing beyond one year, permission to continue use of the Informed Consent Form must be applied for at least 45 days in advance of the one-year anniversary date. Such permission is granted in conjunction with the application for Continuing Review.

Please complete the Continuing Review Form and submit an original plus one copy to the Office of Sponsored Programs.

Procedures for Project Completion

Upon completion of the research project, it is the researcher's responsibility to submit a Final Report Form. The Final Report must include a description of the plan for destruction of the data or documentation that you have sought appropriate consent from participants to retain the data for future use. The prevailing IRB policy is that research data will be destroyed no later than three years after termination of the research project.

Final Note

It is the responsibility of the research investigator to comply with all IRB decisions, conditions, and requirements.

Proposal Attachments

Proposal attachments include the following:

- Consent Form
- Research Instruments, including but not limited to:
 - Surveys
 - Interview guides
 - Observation tools
 - Psychometric tests,
 - Or ANY data collection tool
- Proposal Checklist

DETAILED DESCRIPTION

Format for letter of consent to participate as human subjects in research is as follows:

An Informed Consent Form must be written in easy-to-comprehend, simple and non-technical language. Also, Informed Consent Forms must not contain any language through which a subject is made to waive any of his/her legal rights. Signed Informed Consent Forms must be retained by the Researcher for a minimum period of three years beyond the end of the project. Any Informed Consent Form that is to be utilized by an individual who is unfamiliar with English must be translated into the language appropriate for that individual. All of the following points must be incorporated into the Informed Consent Form:

- (1) The project title of your research project.
- (2) The date of preparation or revision.
- (3) The researcher's(s') name(s) as well as those of all involved.
- (4) The statement that the project is research and an explanation of the purpose.
- (5) The procedure to be followed and the duration of the subject's participation.
- (6) A description of the reasonable foreseeable risks and discomfort that may result from a subject's participation (if none, state so).
- (7) A description of the benefits to subjects and/or others which may reasonably be expected.
- (8) A statement delineating the voluntary nature of a subject's participation and no retribution for withdrawing or not participating, such as: **Participation as a human subject in this research program is completely voluntary, and your participation, or non-participation, will not affect other relationships (e.g., employer, school, etc) You may discontinue your participation as a human subject in this research program at any time without penalty or costs of any nature, character or kind.**
- (9) The following statement regarding Privacy and Confidentiality: **Every precaution shall be taken to protect your privacy and the confidentiality of the records and data pertaining to you in particular and the research programs in general, disclosure of which may contribute to identifying you specifically to persons not related to this research program.**

- (10) An offer to answer questions sent to Researcher's address and telephone number.
- (11) A statement that the subject has been made aware of any and all possible risks or discomfort.
- (12) A statement that the human subject has read the contents of the Informed Consent Form, has had the opportunity to fully discuss any concerns and questions, and fully understands the nature and character of the subject's involvement in the research program and any attendant risks and consequences. In the event subject is not able to read, appropriate measures to gather consent will be taken with guardian and/or staff member working with the individual.
- (13) Signature spaces as appropriate (e.g., Research Participant, Guardian/Legal representative, Researcher(s), Agency Official, Faculty Advisor, etc.) Where research projects involve children as human subjects, the assent or consent of the child is prerequisite to consent by the parent/guardian, and two Informed Consent Forms should be used—one form for the parent/guardian in adult language and one form for the child in child-appropriate language.
- (14) Identification of individuals conducting the research and their degrees (e.g., R.N., M.D., Ph.D., etc.) The title "Dr." should not be used exclusively.
- (15) The above items may be typed on the letterhead form. You should allow space for the official approval stamp, which must appear on the Consent Form that you use.
- (16) An Informed Consent Form is valid for a maximum of one year after its approval. In cases where the study exceeds one year in duration, a Continuing Review must take place prior to the commencement of the new project year. It is the Researcher's responsibility to submit a Continuing Review request at least 45 days prior to the anniversary of the initial IRB approval or the last Continuing Review approval.

LEVELS OF REVIEW

Upon receipt of your proposal, the IRB Chairperson will designate its review status: either exempt from review, or requiring expedited or full review.

Exempt and Expedited proposals will be reviewed upon submission, and disposition usually requires no more than one week. Full reviews usually require three to four weeks for disposition, as they involve a meeting of a full IRB Committee, and attendance by the primary investigator. The IRB meets as needed to discuss proposals requiring full review. Exempt and Expedited proposals will be reviewed upon submission.

Guidelines for proposal submission are the same regardless of the level of review.

Exempt Status

Only the Chairperson of the IRB can determine whether a research proposal is exempt from review by the full Institutional Review Board. If the project is designated as exempt, you will be asked to submit three copies of the full proposal to the Chair.

Only involvement of human subjects in one or more of the following categories warrants an exemption as outlined in 45CFR46.101(b):

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. Research on regular and special education instructional strategies, or
 - b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.
- (2) Research involving the use of the educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. 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:
 - a. The human subjects are elected or appointed public officials or candidates for public office; or
 - b. 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 project which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate,
 - a. Public benefit or service programs;
 - b. Procedures for obtaining benefits or services under those programs;
 - c. Possible changes in or alternatives to those programs or procedures, or
 - d. 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:
 - a. If wholesome foods without additives are consumed; or
 - b. If a food is consumed that contains a food ingredient at or below the level and for a use 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. Departments of Agriculture.

Expedited Review

If an Expedited Review is designated, submit 1 copy of the IRB proposal to the IRB Chair.

Research for which the IRB may use an Expedited Review procedure authorized in Subsection 110 of 45CFR46 is any research which involves no more than minimal risk to the subjects AND in which the only involvement of human subjects will be in one more of the following categories (carried out through standard methods):

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 110) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, non pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- (3) Prospective collection of biological specimens for research purposes by noninvasive means.
- a. Examples: (a) hair and nail clippings in a non disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
- a. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- (6) Collection of data from voice, video, digital, or image recordings made for purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR. 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB as follows:

- a. Where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Review

If research does not satisfy the guidelines for Exempt or Expedited Review, as designated by the IRB Chairperson, the IRB will meet as a full committee to consider the proposal, and the Principal Investigator/Researcher shall submit to the Chair any additional information required.

The IRB may require that the researcher(s) pass the National Institutes of Health Office of Extramural Research on-line training “Protecting Human Research Participants” prior to the start of the research.

NOTE: Any federally funded project must be reviewed by the full IRB. One copy of the actual application or proposal submitted to the funding agency must accompany the IRB proposal submitted to the Seven Hills Foundation IRB. In addition, principal investigators must provide documentation that all investigators on a federally funded project have completed the federally mandated human subjects’ protections education. Principal investigators should contact the Chair for information on the URL of the training site.

CHECKLIST: (Please complete and attach 1 copy to your IRB submission)

- ☐ Have you described your research protocol in detail?
- ☐ Have you described the subject population from which the sample will be drawn?
- ☐ Have you addressed the rationale for including or excluding any specific group of subjects?
- ☐ Have you clearly described how the subjects are to be recruited?
- ☐ Have you considered the issues of voluntariness and coercion in your recruitment process?
- ☐ In your proposal and consent form, have you addressed the following?
 - Specific activities required of the subjects
 - Risks to the subjects
 - Benefits to the subjects
 - How risks are minimized
 - Protection of confidentiality/anonymity
 - Provision of counseling support or intervention if the study causes psychological distress
 - Ability of subjects to refuse participation or withdraw from the study without penalty
 - Parental/guardian permission and child assent if subject is under 18 years of age
- ☐ Have you considered language and reading comprehension level of the subject population in your consent form?
- ☐ Are copies of research instruments attached?
 - Have you completed, signed and attached the Project Review Cover Sheet?
 - If you have a formal proposal which has a precise description of how human subjects will be involved in the research, on which page(s) can this information be found?

Sample: Project Review Cover Sheet

Instructions: This form must be typed. If there is not sufficient space to answer a question, please attach additional pages.

Investigator(s):

Department/Program:

Daytime Phone #:

Home Phone #:

Research Project Title:

Brief Description:

Is this project being reviewed by any other institution's review board? If yes, provide name and location of institution.

Anticipated date of review? *(Please submit copy of review decision to Office of Senior Vice President).*

Is this project being submitted to a funding agency/organization?

Date by which proposal must be submitted to funding agency:

1.) Please indicate with a checkmark if your project involves any of the following populations

- ☐ Children under 8 years of age
- ☐ Children 8-17 (under 18 years of age)
- ☐ HIV-positive individuals
- ☐ Older adults? (over 65 years of age and have cognitive impairment and/or are institutionalized)
- ☐ Inmates in penal institutions
- ☐ Patients in mental institutions
- ☐ Physically handicapped
- ☐ Mentally/emotionally handicapped
- ☐ Persons incapable of informed consent

Note: If you have checked any of the above-listed categories and your research study involves at least minimal risk, the proposal must receive full review.

2.) If you will be utilizing outside agencies to conduct your research, have you appended the appropriate permission letters on the agencies' letterheads indicating their willingness to cooperate with your research? YES/ NO

3.) Will you be recording any identifiable, private information about individual subjects? YES/NO

a. IF YOU HAVE ANSWERED "YES" TO ITEM 3, PLEASE READ AND SIGN THE STATEMENT BELOW:

I understand that I am obligated to protect and keep confidential any identifiable, private information gathered about individual subjects through the conduct of my research; and I agree to keep such information confidential, unless I obtain the subject's express written permission to do otherwise.

Signed: _____

4.) Will you be collecting audiotapes, videotapes or other media of the subjects in your research? YES/NO

If the answer to Question 4 is YES, please provide a detailed description of what you are doing and why. Also, what will be the disposition of the recorded media after completion of your research? These recordings must be destroyed by a certain date, not to exceed three years from the completion of the research project. You will also need to inform the subject of your intent to record, by including this information on the Informed Consent Form.

5.) If your research involves any conceivable risk or discomfort to subjects, or if your subject pool includes any of the groups identified, or any similarly vulnerable group, then you MUST obtain informed, written consent from your subjects and/or a legally responsible guardian (for children and persons incapable of giving informed consent). If the above is applicable, have you attached a signed and dated Informed Consent Form that you will utilize? YES/NO

- a. When you have completed your contact with the research participant, will there be a debriefing session? YES/NO
If your answer is YES, please describe the procedure that you will utilize.

ATTACHMENTS: If you will be asking questions, testing performance, or manipulating the subject, please append copies of questionnaires, test, interview protocols, or the methods sections of your grant proposal. If you have yet to pick the exact procedures you will be using, then provide specific, concrete examples of the types of test items, treatments, or questions you will use.

ASSURANCES

It is understood that I will keep on file (for at least three years) and make available, on request by the IRB, copies of signed Informed Consent Forms of all subjects participating in this research.

It is the responsibility of the researcher to ensure that a Final Report is filed when the project is completed. Furthermore, any project which exceeds a period of one year in duration must be reviewed and receive IRB approval PRIOR to the beginning of the second and any successive years of the research project.

I have completed any necessary documents regarding financial disclosure, as required, prior to project approval.

In signing this statement I certify to the accuracy of the information provided and reassert my intention to abide by the Foundation's policies and procedures governing research involving human subjects.

SIGNATURE(s) _____
Researcher Date

SIGNATURE(s) _____
Supervisor Date

I have enclosed the following items collated in the order listed:

- A.) Original and copies of this form
- B.) Original and copies of the Project Proposal
- C.) Copies of Questionnaire(s), if applicable
- D.) Original and copies of authorization(s) from cooperating agencies or institutions
- E.) Original and copies of proposed Informed Consent Form(s) signed and dated.
- F.) With any federally funded project, the researcher must submit one copy of the actual application/proposal submitted to the funding agency, in addition to the Seven Hills Foundation IRB materials.
- G.) Copies of the completed NIH Training, if required by the IRB.

NOTE TO INVESTIGATOR: It is the responsibility of the researcher to ensure that a Final Report is filed when the project is completed. Furthermore, any project which exceeds a period of one year in duration must be reviewed and receive IRB approval prior to the beginning of the second and any successive years of the research project.