Seven Hills Foundation

Office of Clinical Research

Institutional Review Board (IRB)

Application

(Revised March 2023)

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Seven Hills Foundation
IRB Application

Step 1: Administrative Information

1. **Project Title:** _____

If project is funded and the grant title is different from the project title, please list it here: _____

_____

2. **Please Indicate the Level of Review your Application Requires:**

☐ Full Board
☐ Expedited (see expedited category numbers) **45 CFR 46.110**
☐ *Exempt (see exempt category numbers) **45 CFR 46.101 (b)**

***Exemption category 5 applies only to federal departments or agencies. Studies that involve the audio or video recording of subjects CANNOT be submitted as Exempt.**

3. **Prior IRB Review: If this study has had prior IRB review, outside the Seven Hills Foundation, please describe by listing each approval/review and the instructions.**

4. **Student Research: Please indicate if this is STUDENT research. Student research requires IRB approval unless it is a project designed to train students in the conduct of research without being designed to develop or contribute to generalizable knowledge.**

5. **Principle Investigator's (PI) Information: All correspondence about the study will be sent to the PI's official address or email address on file with the Seven Hills Foundation, or with "home" university or agency.**

Key Personnel/Investigator: _____

Position at Seven Hills or other: _____

Contact Information (address, phone, email): _____

_____

_____

6. **Principal Investigator's Department/Research Unit**

Primary Department/Research Unit: _____

***Application Routing: Emails will be automatically sent to the key personnel/investigators, and Faculty Sponsor (if appropriate). The PI is responsible for confirming that all required signatures are received. After all signers have consented, the PI must then submit this application to the IRB.**

7. **Key Researchers/Investigators: Please list the Seven Hills Foundation researchers involved in the study. Prior to submission of this application, every person listed must verify completion of ethics/compliance training or as required by the IRB, completion of the National Institutes of Health Office of Extramural Research on-line training, *Protecting Human Research Subjects* ,prior to the start of research. As a guide, list people who will "contribute in a substantive way to the scientific development or execution of the project" (co-investigators, consultants, project managers, etc.).**

Key Researcher #1(Name/Role) : _____

Key Researcher #2(Name/Role) : _____

Key Researcher #3 (Name/Role): _____

Key Researcher #4(Name/Role) : _____

Key Researcher #5 (Name/Role): _____

***The Principal Investigator accepts responsibility for the training of all personnel associated with this study in accordance with 45 CFR 46.110. You will be responsible for either UPLOADING or PHYSICALLY SUBMITTING to the IRB Committee the names of researchers along with documentation of compliance training for each researcher.**

8. **Faculty Sponsor (for student research only): If the PI is a student, a Faculty Sponsor at the teaching institution must be listed. This study will not be eligible for final submission until the faculty sponsor approves the study using the IRB Study Listing page. If the PI is not a student, leave the Faculty Sponsor blank.**

Faculty Sponsor: _____

Contact Information (address, phone, email): _____

_____

_____

9. **Department Review Chair (DRC):** If your department has a DRC, and their signature is REQUIRED according to your department's policy, it should be listed below. The DRC must electronically approve this application using the DRC Study Listing page in order for it to be submitted to our office for approval.

Department Review Chair (DRC) Signature: _____

10. **Research Assistant/Project Coordinator: If needed, use this space to list the people who either are involved in or have a need to know about this study and that a protocol is being submitted for IRB approval. Examples of types of people to list here are research assistant, project coordinator, or an assistant to the DRC for your department. Individuals listed here do not have signatory responsibility; they are additional contacts for communication regarding this study.**

Additional Team Member #1 (Name/Role/Email): _____

Additional Team Member #2 (Name/Role/Email): _____

Additional Team Member #3 (Name/Role/Email): _____

11. *** Conflict of Interest*: An investigator is said to have a conflict of interest whenever the PI or IRB member, his or her spouse, or dependent child falls under any of the following conditions:**
    - **Is an investigator or sub-investigator on the protocol (IRB members only, not applicable to PIs)**
    - **If the IRB member, the member's spouse, or dependent children are involved in the conduct of research**
    - **Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest**
    - **Acts as officer, director, or agent of the sponsor**
    - **Has an equity interest in the sponsor or agent of the sponsor that when aggregated for the investigator or member and the investigator's or member's spouse and dependent children, equals $10,000 or greater as determined through reference to public prices (e.g., NYSE or NASDAQ), or any amount if the value cannot be determined through references to public prices, or 5% of the equity of the sponsor.**
    - **Has received payments of other considerations from the sponsor that when aggregated for the investigator or member and the investigator's or member's spouse and dependent children is $10,000 or greater.**
    - **Has identified him or herself for any other reason as having a conflict of interest.**

Do you or does the other researcher hold a patent or license for any material, object, invention, or process used in the study or do you intend to file a patent application at a later date?

- ◯ Yes
- ◯ No

If there is a sponsor for the study, do you own equity or financial interest in the sponsor, give presentations for the sponsor, serve as a consultant to the sponsor, or work in any capacity for the sponsor (such as board member, officer, etc.)?

- ◯ Yes
- ◯ No

To the best of your knowledge, do any of the Key Personnel listed on this study have a conflict of interest associated with this study?

- ◯ Yes
- ◯ No

Please list any other possible conflicts of interest (maximum 4 lines): _____

_____

_____

_____

_____

Step 2: Participants, Recruitment and Compensation

This section requests brief answers to topics that you must cover in detail in your research proposal, consent forms, and other supporting documents. Completing this section does NOT relieve you of responsibility to cover these issues in detail in your research proposal or any other supporting documents.

1. **Types of participants involved in this study:**

- ☐ Academic/SHF Staff
- ☐ Person with disability
- ☐ Person with physical illness/injury/disability
- ☐ Student
- ☐ Minor children (under age 18)
- ☐ Pregnant women or fetuses
- ☐ Prisoners
- ☐ Other – If selected, list all participant types: _____

2. **If the participants are students, is one of the investigators/researchers their instructor or advisor?**

- ○ Yes
- ○ No

3. **If the participants are employees of the Seven Hills Foundation are they directly supervised by the investigator?**

- ○ Yes
- ○ No

4. **Rationale for Risk: If the participants are pregnant women, fetuses, or individuals with mental or psychological disabilities, prisoners, or persons with a physical illness, injury, or disability, give a brief explanation of the need to have these particular individuals participate in this study.**

5. **Subject Age Range: (If the study subjects will be just one age, fill in the same age for both minimum and maximum. Estimate to the best of your knowledge.)**

Minimum Age: _____
Maximum Age: _____

6. **If the participants are under the age of 18, state the rationale for their inclusion in this study.**

7. **Gender of subjects**

- ☐ Male
- ☐ Female
- ☐ Both
- ☐ Transgender

If you are using only one gender population, please mark one of the following:

- ☐ Only the gender selected has the condition (gender specific)
- ☐ Other, please describe (up to 237 characters including blanks):

8. **Does the study require that the subjects be recruited from one or more specific races/ethnicities?**

- ○ No
- ○ Yes, please specify:
- ○ White
- ○ Black
- ○ Hispanic
- ○ Asian
- ○ Native American
- ○ Other, please specify

Reason for specific race/ethnicity:

- ☐ The condition being studied occurs only in the selected group (s)
- ☐ Other, please specify:

9. **How many subjects do you plan to enroll in your study? If using an existing dataset, list the number of subjects in the dataset. (Study will need to be amended PRIOR to INCREASING enrollment size from number given here)**

Number of Subjects: _____

If there is more than one group, please indicate number of groups and number of individuals per group: _____

10. **Explain how you will have access to a population that will allow recruitment of the required number of participants within the proposed recruitment period:**

11. **Time required of each subject (ESTIMATE and round up to the nearest unit. Ex: record 1 hr a week for 5 years as 260 hours and describe in the space provided)**

Minutes: _____

12. **Check any of the following items YOU will be ASKING THE SUBJECTS TO PROVIDE on research forms or in response to research questions (this question pertains to data YOU are collecting):**

- ☐ Name
- ☐ Phone number
- ☐ Address
- ☐ Social Security Number

***Please specify any other information you're collecting that may identify the subjects (up to 237 characters including blanks):**

13. **HIPAA Regulations: Use of Protected Health Information (PHI): Please read the following definition of PHI before answering: PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:**
    - **Identifies or could be used to identify an individual;**
    - **Is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and**
    - **Relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual**

    Health-related information is considered PHI if any of the following is true:

- **The researcher obtains it directly from a provider, health plan, health clearinghouse or employer (other than records relating solely to employment status);**
- **The records were created by any of the entities listed above and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR**
- **The researcher obtains it directly from the study subject in the course of providing treatment to the subject**

Health-related information is not considered PHI if the researcher obtains it from:

- **Student records maintained by a school;**
- **Employee records maintained by an employer related to employment status; OR**
- **The research subjects directly, if the research does NOT involve treatment**

As part of this study, do you:

a. Collect PHI from subjects in the course of providing treatment/experimental care?

◯ Yes
◯ No

b. Have access to PHI in the subjects' records?

◯ Yes
◯ No

If yes to A or B above, complete the HIPPA FORM. After completion, the HIPAA form can be sent to the Office of the Senior Vice President to show how you will satisfy HIPAA requirements for authorization to use PHI in research.

14. Will the subjects be recorded with audio or video equipment?

◯ Yes
◯ No

15. Will students from a class or set of classes, who are to be research subjects, receive class credit or bonus points for participation?

◯ Yes
◯ No

If yes, will the alternative options for getting class credit be explained in full to the students in the consent form or in other material given to the students such as the course syllabus?

◯ Yes
◯ No

Step 3: CONSENT, POPULATION, LOCATION

Completing this section does NOT relieve you of the responsibility to cover these issues in detail in your Research Proposal or any other supporting documents.

1. **Are you using controlled substance(s) in this study?**

◯ No
◯ Yes – please list the DEA drug code number: and expiration date:

2. **If individuals with diseases or conditions are to be specifically included, is there a potential for direct benefit to these subjects?**

◯ No
◯ Yes – please explain (maximum 4 lines)

3. **If individuals with diseases or conditions are to be specifically included AND if the study involves a treatment for their disease or condition, please explain how that treatment will differ from standard care that they would ordinarily receive, or are already receiving, i.e., procedures already being performed for diagnostic or treatment purposes (maximum 4 lines).**

4. **Will any medical procedures (such as lab tests, biopsies, or x-rays, etc.) be performed for the subjects?**

◯ No
◯ Yes – briefly describe (maximum length 110 characters/spaces):

5. **Are there specific medications that MUST be used to meet the requirements of this protocol?**

◯ No
◯ Yes, please list them (maximum length 110 characters/spaces)

6. **Will the study involve:**

☐ Use of human tissue/body fluids
☐ Genetic testing

7. **If yes to Question 6, have you compiled with and/or fulfilled all applicable and necessary Environmental Health and Safety policies, procedures and regulations?**

○ No
○ Yes

8. **If yes to Question 6, have you compiled with and/or fulfilled all applicable and necessary Institutional Biosafety Committee policies, procedures and regulations?**

○ No
○ Yes

9. **Is there sufficient space to conduct the research?**

○ No
○ Yes

If yes, please explain how you will have adequate facilities to conduct and complete the research:

10. **Do sufficient resources exist to conduct the research?**

○ No
○ Yes

11. **Is there sufficient staff to conduct the research?**

○ No
○ Yes

If yes, please explain how you will have adequate numbers of qualified staff:

12. Do you have the necessary equipment to conduct the research?

- ◯ No
- ◯ Yes

13. Do you have the time necessary to conduct the research?

- ◯ No
- ◯ Yes

If yes, please explain how you will have sufficient time to conduct and complete the research:

14. Are women of childbearing potentially to be included in this study?

- ◯ No
- ◯ Yes

If so, is a pregnancy test required?

- ◯ No
- ◯ Yes **– please state who will pay for the test (maximum 100 characters/spaces):**

15. This item is divided into three sections (A, B, and C) all pertaining to subject CONSENT. You must fill out either A, B, or C.

If the study consent plans are for…

- **WRITTEN, SIGNED, INFORMED CONSENT, answer item A**
- **WAIVER OF DOCUMENTATION OF CONSENT – NO SIGNED CONSENT, BUT A WRITTEN COVER LETTER THAT DESCRIBES THE STUDY OR FULL VERBAL INFORMED CONSENT, answer item B**
- **A COMPLETE WAIVER OF INFORMED CONSENT – NO DESCRIPTION, OR ONLY BRIEF ORAL DESCRIPTION OF RESEARCH PROVIDED TO PARTICIPANTS, answer item C**

A. WRITTEN, SIGNED, INFORMED CONSENT:

a. Does the language in the document appropriately match your intended subjects?

- ◯ No
- ◯ Yes

b. Will the document be provided in language(s) other than English?

- ◯ No
- ◯ Yes

***If yes, please describe.**

c. Will you be providing subjects a copy of their consent forms?

- ◯ No
- ◯ Yes

d. Does your document in any way ask or imply that it releases you from any liability?

- ◯ No
- ◯ Yes

e. Who will PROVIDE informed consent?

- ☐ The subject
- ☐ The subject's parent or guardian
- ☐ Other, please explain (maximum 240 characters)

f. Who will OBTAIN informed consent?

- ☐ The Principal Investigator/Researcher
- ☐ Key personnel/co-investigator
- ☐ Other, please explain (maximum 240 characters)

B. WAIVER OF DOCUMENTATION OF CONSENT -- NO SIGNED CONSENT, BUT A WRITTEN COVER LETTER THAT DESCRIBES THE STUDY OR FULL VERBAL INFORMED CONSENT

a. Describe how you will protect the participants' privacy interests:

b. Describe how you will maintain the confidentiality of participant data:

c. Explain how you will adequately inform all persons assisting with the research about the protocol of their research-related duties and functions:

d. If participants need ancillary resources as a consequence of taking part in the research (e.g. psychological counseling, or emergency treatment), explain how these will be made available:

e. Is there a person (other than the Principal Investigator) or a group that will be responsible for reviewing unanticipated problems and other issues related to the safety of the study?

- ◯ No
- ◯ Yes: please describe data safety monitoring procedure

f. Will the data collection for this study take place at Seven Hills in Worcester, MA?

- ◯ NO: Please list location(s) such as agencies or school districts below and indicate the number of subjects per site in the text box below.
- ◯ YES – please list department, building, or site in text box below:
- ◯ Both at SH and off campus – please explain in the text box below

***If data collection takes place at any site off campus, please indicate in the text box below:**

Contact information for the site: _____

Whether the site has an IRB (if the site's IRB has approved the research, please upload their approval letter: _____

Whether the site granted permission to conduct the research there: _____

g. Is this a multi-site study where you are the lead investigator or is a University research partner the coordinating center?

- ◯ No
- ◯ Yes

If yes, please describe how you will manage information that may be relevant to the protection of research participants, such as reporting of unspecified problems, protocol modifications, and interim results: _____

C. A COMPLETE WAIVER OF INFORMED CONSENT – NO DESCRIPTION, OR ONLY BRIEF ORAL DESCRIPTION OF RESEARCH PROVIDED TO PARTICIPANTS

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):

a. There is no more than minimal risk to the subject

- ◯ No
- ◯ Yes

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects

- ◯ No
- ◯ Yes

c. The research could not practicably be carried out without a waiver or alteration; and

- ◯ No
- ◯ Yes

d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

- ◯ No
- ◯ Yes

Step 4: FINANCIAL SUPPORT and INCENTIVES

1. **Is there financial or material support for this study?**

If this grant is from the NIH, upload the Certificate of Consistency here.

- ◯ No
- ◯ Yes – please state the type of sponsorship and whether it has been obtained or is pending:

Details of funding type:

2. **Will the study provide reimbursement of the subjects' expenses?**

- ◯ No
- ◯ Yes – state amount: $

3. **Will compensation be provided?**

- ◯ No
- ◯ Yes

***If yes and compensation will be prorated, describe the prorated amounts and schedule. If compensation is provided but will NOT be prorated, explain WHY (maximum 4 lines):**

4. **Explain here any incentive (financial, gifts or other items of value) that will be given to persons who identify or refer subjects for enrollment.**

5. **Study-specific costs and compensation:**

If you are providing any type of treatment to the subjects, will the treatment be provided free of charge? Explain below:

If an agency/3rd party is paying for ADDITIONAL treatment for the subjects (such as lab tests, biopsies, or x-rays) briefly describe by listing the agency/party responsible for payment.

Who (or which agency) will pay for the specific medications used as part of this study for treating participants?

Step 5: ADDITIONAL DOCUMENTATION

Email Additional Documentation:

If you have additional documentation to include with your study, please email documents to sbouchard@sevenhills.org Keep in mind, if you are emailing a document in an unusual format (a word processing package other than Microsoft Word for instance) others may not have the necessary software to view it. At a minimum, you must provide the research proposal and the consent form.

Examples of Additional Documentation include:

- RESEARCH PROPOSAL
- Questionnaire
- Cover Letter
- Email Recruitment Message
- Site Letter (if off campus)
- Grant Proposal (DHHS)
- Prior IRB Review Letter
- Consent Form (req'd unless waived)
- Survey
- Recruitment Flyer
- Telephone Script
- HIPPA Form
- Certificate of Consistency (DHHS)
- Other Documentation

Upload Documentation

☐ **I CERTIFY THAT I HAVE EMAILED ALL DOCUMENTATION REQUIRED TO EVALUATE THIS STUDY TO KJORDAN@SEVENHILLS.ORG.**

Step 6: COLLECT SIGNATURES

If this is an Exempt study you are indicating that you, as the Principal Investigator, understand and accept the conditions outlined in the PI Assurance Statement. Please send an email to key personnel asking for their review. After all CO-PI's, DRC's and faculty sponsors have approved the application, it will be routed to the IRB.

COLLECT SIGNATURES!

Please remember that only the person listed as the Principal Investigator on the study is able to submit it to the IRB.

Principal Investigator Sign Here: _____ Date: _____

Faculty Advisor/Sponsor Sign Here: _____ Date: _____

Community Site Sponsor Sign Here: _____ Date: _____