Seven Hills Foundation
Initial Study Assessment

Project Title: _____

Project Investigator: _____

This form is used to determine whether or not IRB review is required for your project. If you have questions, please contact Sonya Bouchard at sbouchard@sevenhills.org.

In order to guide the IRB in its decision, answer questions in Sections 1-3 as best you can. In **Section 4**, you are asked to provide information about the purpose and intent of the study and to attach supporting materials.

SECTION 1: Is the Proposed Project Research?

Research is defined in the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

There are a variety of activities that employ many of the features of research, such as rigorous design, systematic data collection, and statistical analyses, which are not considered research under this definition. The key to distinguishing between research and non-research activities is to determine the primary intent of the project. **The primary intent of research is to generate or contribute to generalizable knowledge.** The primary intent of similar activities that are not research may be to prevent or control disease in a population or to identify methods of improving services for a group of clients or customers.

☐ **Research -** as defined above. (Proceed to Section 2)
Explain: _____

☐ **Program Evaluation Activities -** in which the primary intent is to assess the success of an established program or intervention in achieving its objectives in a specific population, and in which the information gained will be used only to provide feedback to the program, to ensure service quality, or to make improvements in the program, **are not considered research.** (Skip to Section 4)
Explain: _____

☐ **Surveillance Activities -** which involve the regular, ongoing collection and analysis of health-related data in order to monitor the frequency of occurrence and distribution of diseases and/or health conditions in a population, and which are authorized by state statute or regulation which specify the intent of the activity, its purpose, and uses of the data, and in which all the data collected are used only for these purposes, **are not considered research.** (Skip to Section 4)
Explain: _____

☐ **Disease Investigation and/or Emergency Response Activities** - authorized under state statute or regulation which are undertaken to identify, characterize, and solve an immediate health problem, and in which the information gained will directly benefit those participants involved in the investigation or their communities, **are not considered research**. (Skip to Section 4)
Explain: _____

☐ **Quality Assurance and/or Quality Improvement Activities** - in which existing individual-level data will be collected and analyzed and in which there is a formal commitment in advance of data collection to a corrective action plan related to any of a number of possible outcomes of the analyses **are not considered research.** (Skip to Section 4)
Explain: _____

☐ **Other Non-Research Activities -** for example, program audits, resource utilization, service utilization and/or drug utilization studies using existing institutional records, client outcome monitoring in which individual level data are routinely collected and analyzed to determine the extent to which clients are experiencing intended program outcomes, and client satisfaction and needs assessment surveys which collect data from persons eligible to receive program services, **are not considered research.** (Skip to Section 4)
Explain: _____

☐ **Activities Preparatory to Research -** in which individually identifiable personal records and/or protected health information are used by an employee of the department (who otherwise has access to the confidential information for non-research purposes) only to review such information as necessary to prepare a research protocol or for similar purposes preparatory to research, and in which confidential information is not removed from department facilities or computer systems, **are not considered research**. (Skip to Section 4)
Explain: _____

☐ **Activities Conducted Primarily for Educational Purposes -** which fall into one of the non-research categories above, but in which the primary intent is related to training in research methods in partial fulfillment of requirements for an undergraduate or advanced degree, **are considered research.** (Proceed to Section 2)
Explain: _____

SECTION 2: Does the Research Involve Human Subjects as Defined in Federal Regulations?

A **"human subject"** is defined in federal regulations (45 CFR 46.102(f)) as a living individual about whom an investigator obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information. Information which, when used alone or in combination with other available information, may lead to the identification of individuals also requires review.

Are the proposed research subjects living individuals?

- ◯ **No.** If none of the subjects are living, the project **does not** involve human subjects. Please note that if confidential information is required, the project may still require review in accordance with MGL c.111, §24A. (Skip to Section 4)
- ◯ **Yes.** Indicate the type of information about subjects that would be collected in the research.
  - ☐ A If the research obtains data about subjects through interaction or intervention with individuals, including interviews, surveys, physical procedures, manipulations of the subject or the subject's environment, and any other direct contact or communication with the subject, **the research involves human subjects.** (Proceed to Section 3)
  - ☐ B If the research obtains identifiable private information about subjects or information that could lead to identification of individuals from informants or from confidential records, such as medical charts, computer databases, and/or patient registries, **the research involves human subjects.** (Proceed to Section 3)
  - ☐ C The research does not involve obtaining data about subjects through interaction or intervention with individuals, and does not involve obtaining identifiable private information about subjects or information that could lead to identification of individuals from confidential

SECTION 3: Is the Research Potentially Exempt from SHF IRB Oversight?

If the project is considered research (Section 1), and if the project involves "human subjects" (Section 2), it may be exempt from IRB review if the only involvement of human subjects is in one or more of the following four categories. Please select the category (ies) you believe apply to your study and explain, or check the non-exempt box if you do not believe any of the exemptions apply to your study:

☐ A. Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs, or procedures for obtaining benefits under those programs, possible changes to or alternatives to those programs, or possible changes in methods or levels of payment for benefits or services under those programs, provided that:

1. The research relies entirely on information obtained routinely for program management purposes in the course of, and as part of, the ongoing public benefit or service program; and
2. access to identifiable data used in the research is limited to staff of the agency that manages the program. (Proceed to section 4)

☐ B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, provided that:

1. The research does not involve use or disclosure of an agency's non-public information for purposes of contacting human research subjects or prospective subjects; and
2. The information obtained does not deal with sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, or physical, sexual, or emotional abuse, and is not likely to cause the subjects undue stress, fatigue, or other psychological or emotional reactions; and
3. The information obtained is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to subject; and
4. Any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and
5. The research does not involve collecting information from subjects who are unable to provide legal consent for their own participation. (Proceed to section 4)

☐ C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt above, if the human subjects are elected or appointed public officials or candidates for public office. (Proceed to section 4)

☐ D. 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 used by or disclosed to the researchers in such a manner that it is not identifiable, e.g., it does not contain information which reveals or can likely be associated with the identity of the person or persons to whom the information pertains. (proceed to section 4)

Note: All human subjects research which is exempt as specified in A - D of this Section must be conducted in accordance with: (1) The Belmont Report1; and (2) DPH policies and procedures.

☐ **The proposed project is research and is not exempt -** Register with IRBNet, be sure to affiliate with MDPH, and complete the appropriate application materials at www.irbnet.org. You do not need to complete Section 4 or submit additional materials with this form.

SECTION 4: Description of Proposed Project

Attach supporting documents (e.g., applicable parts of a grant application, a contract, a work plan, thesis prospectus, etc.) that describe the purpose and intent of the project. Be sure to include the proposed study methods, the procedures for contacting and recruiting subjects, when applicable, plans for accessing and using confidential records needed to conduct the project, and data collection forms,- including the source of all record information.

(Adapted from Massachusetts DPH)