

Phoebe Putney Health System, Inc.

POLICY TITLE: HUMAN SUBJECTS RESEARCH

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 01-25-2013

Review Period: 3 Years

Review Date: 01-22-2020

Contact Information: IRB COORDINATOR

Scope: The Human Subjects Research Policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: The mission of the Phoebe Putney Memorial Hospital Institutional Review Board (PPMH IRB) is to protect the rights, dignity, welfare and privacy of human research participants.

The PPMH IRB is guided by the ethical principles regarding research involving human participants as set forth in the Belmont Report. The PPMH IRB assures that all of its research involving human participants will comply with the Terms of Assurance for Protection of Human Subjects for Institutions within the United States. This fundamental commitment to the protection of human participants applies to all research involving human participants, regardless of the funding source and regardless of the location of the research.

Definitions: N/A

Research: As defined by the Department of Health and Human Services ("DHHS") any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under the Food and Drug Administration ("FDA") regulations activities are "research" when they involve:

- a. Use of a drug other than the use of an approved drug in the course of medical practice (21 CFR 312.3(b)).
- b. Use of a medical device other than the use of an approved (means approved by the FDA for marketing) medical device in the course of medical practice (Food, Drug and Cosmetic Act 530(g) (3) (a) (i)).
- c. Gathered data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, including a dietary supplement that bears a nutrient content claim or a health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product. (21 CFR 50.1(a) or 21 CFR 56.101(a)).

Clinical Investigation: Any experiment that involves a test article and one or more human subjects, and that is subject to the FDA regulations. FDA regulations consider the terms “clinical investigation” and “research” to be synonymous. The following are considered experiments subject to FDA regulations:

- Any use of a drug, other than the use of an approved drug in the course of medical practice.
- Any use of a medical device to evaluate safety or efficacy of that device.
- Any activity where data are being collection to submit to FDA or to be held for inspection by FDA.

Test article: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.

Human Subject (or Participant): As defined by DHHS: a human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102(f)). If the research involves a medical device, individuals are considered “subjects” when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812.3(p)).

As defined by FDA: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient 21 CFR 56.102(e). If the research involves a medical device, individuals are considered “subjects” when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812.3(p)).

A cadaver is not considered to be a human subject.

Research Activities Involving Human Subjects: Activities that **either** (1) meet the DHHS definition of “research” and involve “human subjects” as defined by DHHS **OR** (2) meet the FDA definition of “research” and involve “human subjects” as defined by FDA. The definition of research and human subjects must consistently reference the *same set of regulations* (i.e., DHHS or FDA) and cannot reference the definition of research from one set of regulations, and the definition of a human subject from the other. **Anyone who plans to engage in an activity that qualifies as “research involving human subjects” requires Institutional Review Board (IRB) review and approval prior to commencement of the research.**

Identifiable: Federal regulations define identifiable to mean that the identity of the individual subject is or may readily be ascertained by the investigator or may be associated with the information.

Institutional Review Board (IRB) is an administrative body established by a local institution to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution.

Interaction: Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant or their private identifiable information.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.

Private Information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to be considered information to constitute research involving human participants.

Policy:

PPMH IRB requires that all human research projects in which a PPMH affiliate is *engaged* must be reviewed and approved by the PPMH IRB or an appropriate IRB prior to initiation. A PPMH affiliate becomes *engaged* in human research when either its employees/agents or others who are permitted to do so at a PPMH affiliate:

- A. Intervene or interact with living individuals for research purposes; or
- B. Obtain individually identifiable private information for research purposes.
- C. Additionally, all projects involving patients, personnel or resources (property or services) of PPMH constitute research in which a PPMH affiliate is engaged.

"Human research" means any activity defined under the DHHS or FDA regulations that meet the definition of "research" and that involve "human subjects" (see Definitions).

The PPMH IRB has the authority to review, approve, disapprove or require changes in research or related activities involving human subjects. As stated in 45 CFR 46.109, the IRB has the authority to:

- Review and approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- Require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116.
- Require documentation of informed consent or waive documentation in accordance with 45 CFR 46.117.
- Notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modification required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision; however, a detailed critique of the protocol is not provided. The investigator may rewrite and submit the study as a new protocol.
- Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.
- Have authority to observe or have a third-party observe the consent process or the research and to review the research documentation.

The IRB also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with serious harm to subjects (45 CFR 46.113). Any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the investigator, appropriate institutional officials, and the Department or agency head in compliance with IRB policies.

The IRB does not have the authority to grant retroactive approval should a research study be initiated without prior IRB review.

No institutional official at PPMH IRB can reverse IRB decisions that involve disapproval, deferral, suspension, or termination of a research study. However, PPMH officials can disapprove an IRB-approved protocol for activation or continuation at PPMH.

Human Subject Research/Non-Human Subject Research Determination

The PPMH IRB has the sole authority to determine whether an activity meets the definition of "Human Subject Research". When activities are conducted that might represent "Human Subject Research", the activities must be submitted to the IRB for a determination.

Investigators do not have the authority to make an independent determination and must submit a "Request for Determination of Non-Human Subject Research" to the IRB. An Investigator may request a determination that an activity is "Non-Human Subject Research," but the final determination will be made by the IRB. The IRB will make a determination whether an activity is "Human Subject Research" by considering whether the activity either:

1. Meets the regulatory definitions of "research" that involves "human subjects," or
2. Meets the regulatory definition of "clinical investigation."

Research involving cadavers must be submitted to the PPMH IRB and the IRB will determine which studies qualify as a "non-human subject."

Non-Research

Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.

Examples of systematic investigations include, but are not limited to observational studies, interviews (including those that are open-ended) or survey studies, group comparison studies, test development; or program evaluation. Examples of activities that would not normally be considered systematic investigations include, but are not limited to training activities (e.g., human subjects being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques) and classroom exercises involving human participants or human participant data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.

Activities are not research if they do not contribute to generalizable knowledge or if the results (or conclusions) of an activity are not intended to be extended beyond a single individual or an internal

program (e.g., publications or presentations). Examples of activities that are typically not generalizable include: biographies and service or course evaluations, unless they can be generalized to other individuals; services, courses, or concepts where it is not the intention to share them beyond the PPMH IRB community; and quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share them beyond the PPMH IRB community.

Thesis, dissertation, or class projects conducted to meet the requirements of a degree are usually considered generalizable and therefore, require IRB review and approval. Medical case studies are usually considered generalizable and therefore require IRB review and approval, unless access to patient health information by practitioners is considered appropriate for treatment or operations purposes and is not for the purposes of research.

Non-Human Subject

Activities do not involve humans as participants if they do not involve the process of obtaining specimens or data through intervention or interaction with individual participants or identifiable private information. Information is considered "not identifiable" if it includes none of the following:

- Name;
- Any geographic subdivisions smaller than a state, including street address, city, country, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of a ZIP code;
- All elements of dates (except year) directly related to an individual (e.g., date of birth, admission);
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voiceprints;
- Full-face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code.

Specimens/data that are received by the Investigator as de-identified stripped of all HIPAA identifiers as noted above. When the Investigator receives the private information or specimens with no code or link that would allow an Investigator to establish identity, this would not involve human subjects. For example, a publicly available, unidentifiable, non-linked cell line qualifies as not involving human subjects. The Investigator may receive coded private information or specimens and qualify for non-

human subject if the following conditions are met:

1. The code is not derived or related to the HIPAA identifiers that must be stripped from the PHI (e.g. patient medical record # + last 4 digits of individuals Social Security Number);
2. **The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and**
3. The Investigator cannot readily ascertain the identity of the individuals to whom the coded private information or specimens pertain, because:
 - a. The key to decipher the code is destroyed before the research begins;
 - b. The Investigator and the holder of the key enter into an agreement prohibiting the release of the key to the Investigator under any circumstances, until the individuals are deceased;
 - c. The private information is received from an IRB-approved repository or data management center that includes written operating procedures that prohibit the release of the key to the Investigator under any circumstances, until the individuals are deceased; or
 - d. There are no other legal requirements prohibiting the release of the key to the Investigator until the individuals are deceased.

Amendments

Any change that might disqualify the activity from a “Non-Human Subject” or “Non-Research” status must be reported to the IRB for review and verification prior to implementation. All “Non-Human Subject Research” is subject to all applicable institutional and IRB policies and procedures.

Procedure: N/A

References: As noted above throughout the Document

REVISION HISTORY

Revision Number	Description of Changes	Approvals	Date
0	Initial release of Policy for PPMH Human Subjects Research. This policy replaces all previous versions.	IRB Committee	1-25-2013
N/A	Policy Review. No Changes. This policy replaces all previous versions.	IRB Committee	2-22-2017
N/A	Policy Review. No Changes. This policy replaces all previous versions.	IRB Committee	01-22-2020