

Phoebe Putney Health System, Inc.

POLICY TITLE: INSTITUTIONAL REVIEW BOARD (IRB) INFORMED CONSENT

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 10-26-2016

Review Period: 3 Years

Review Date: 08-28-2019

Contact Information: IRB COORDINATOR

Scope: The IRB Informed Consent policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To ensure that prospective subjects or their legally authorized representatives understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate.

Definitions: N/A

Policy:

1. All Informed Consent Statements must be approved by the IRB prior to the initiation of investigation of a drug, device or behavioral research protocol.
2. Informed Consent must include the following elements:
 - a. A statement that the study involves research, an explanation of the purposes of the research and expected duration of the subject's participation;
 - b. A description in lay language of all procedures, their frequency, and identification of any drugs, devices or procedures used in the study that are investigational or experimental;
 - c. A description of any reasonably foreseeable risks, discomforts, or inconveniences and indication of incidence of occurrence;
 - d. A description of any benefits to the subjects or others which may reasonably be expected from the research (Note: Direct payment or other forms of remuneration are not considered benefits of participation in a research study);
 - e. A statement with regards to the amount or nature of the compensation subjects will receive, if any;
 - f. A description of alternative procedures or courses of treatment, if any, that might be advantageous to the subject and disclosure of any standard treatment being withheld;
 - g. For research involving greater than minimal risk, an explanation as to whether any compensation or any medical treatments are available if the subject is injured and, if so, what they consist of or where further information may be obtained;

- h. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and any exceptions, such as inspection of records by the Food and Drug Administration (FDA);
 - i. A statement that participation is voluntary and the subject has the right to withdraw from the study at any time without affecting future medical care at PPMH;
 - j. The Principal Investigator's and/or Co-Investigator's name and phone number for questions regarding the study and a contact in the event of an research-related injury; and,
 - k. A statement to contact the PPMH IRB and the phone number to call for any questions about rights as a research subject.
3. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if applicable) that are currently unforeseeable;
 - b. 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;
 - c. A description of anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent;
 - d. An explanation of any additional costs to the subject that may result from participation in the study;
 - e. A description of the consequences of a subject's decision to withdraw from the research study and the procedures for orderly termination of participation by the study;
 - f. The approximate number of subjects involved in the study; and
 - g. A statement disclosing an investigator's financial or other interests, when required by the IRB.
4. As a general rule, an Investigator must obtain an Authorization from all research subjects prior to the internal use or external disclosure of Protected Health Information (PHI) for any research related purpose that is not otherwise permitted or required as stated in the PPMH Policy for HIPAA Compliance in Research.
5. It is the responsibility of the investigator to assure that informed consent is received and properly distributed before the study begins. Only the most recent IRB approved informed consent form, date stamped with an expiration date, may be used to obtain consent from prospective subjects.
6. Any changes or revisions to an approved version of the informed consent must be IRB approved prior to use. [See related PPMH policy "Research Revisions and Amendments" for more information]
7. The IRB may approve a consent procedure which does not include some or all of the elements of informed consent as set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents the conditions listed in 7.a or 7.b below. Waiver of informed consent applies in limited circumstances (e.g., medical record reviews). Note: Informed consent cannot be waived for research involving FDA-regulated products (i.e., drugs, biologics and devices) except in emergency situations in accordance with IRB policy. [See related PPMH policies "Emergency Use of a Test Article" and "Planned Emergency Use" policies]
- a. The IRB may approve the waiver or alteration of elements of informed consent set forth above if all four (4) of the following are met:

- i. The research involves no more than minimal risk to the subjects;
 - ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
 - iii. The research could not practicably be carried out without the waiver or alteration; and
 - iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- b. The IRB may approve the waiver or alteration of elements of informed consent set forth above if both of the following are met:
 - i. The research is to be conducted for the purpose of demonstrating or evaluating: a) Federal, state or local benefit or service programs which are not themselves research programs, b) procedures for obtaining benefits or services under these programs, or c) possible changes in or alternatives to these programs or procedures; and
 - ii. The research could not practicably be carried out without the waiver or alteration.
- c. If the IRB has approved a waiver of informed consent for a study, it does not necessarily mean that the study will also qualify for a waiver of HIPAA authorization.

8. Documentation of Informed Consent

- a. Informed consent shall be documented with the use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative (LAR) at the time of consent.
- b. For drug studies conducted with in-patients at PPMH facilities, the investigator will print the informed consents and supply the Hospital Pharmacy with copies of all signed informed consents. The form must allow space for imprinting with the subject's nameplate and Standard Physician's Order designation, which would include the name of the medical center, the name of the investigating physician, and the name of the Protocol.
- c. Space must be allotted at the bottom of the consent form for the signature of the subject (or LAR). If required by the IRB, an impartial witness must be present during the entire consent process and sign the informed consent form. A witness' signature does more than attest to the witnessing of the subject's signature, it attests to the occurrence of the consent process.
- d. The consent form may be either of the following; however, generally, researchers should use the "Long Form" as stated in 8.d.i below. Regardless of the form used, the investigator, or person designated by the investigator, in accordance with state law, must provide the prospective subject or the LAR ample time and opportunity to inquire about the details of the study and to decide whether or not to participate.
 - i. Long Form Written Consent Document: A written consent document that embodies all of the required elements of informed consent and additional elements, if applicable, as delineated above in sections 2 and 3. A copy of the signed informed consent document shall be given to the person signing the form (subject or their LAR).
 - ii. Short Form Written Consent Document: A written document stating that the elements of informed consent have been present orally to the subject or the subject's LAR. This should only be used in certain circumstances, for example, illiterate or blind research subjects. When this method is used:
 - 1. The IRB, or IRB Chair under expedited review, shall have approved a written summary of what is to be said to the subject or the LAR;
 - 2. There shall be a witness to the oral presentation;
 - 3. The witness shall sign both the short form and a copy of the summary;
 - 4. The subject or LAR needs to sign the short form consent only;

5. The person actually obtaining consent shall sign a copy of the summary; and
 6. Both a copy of the summary and the short form shall be given to the subject or subject's LAR.
- e. For research not regulated by the FDA, the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
 - i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Note: In cases where the documentation requirements are waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
 - f. The informed consent process and related circumstances, including the date and time the informed consent was obtained, shall be documented in the patient's medical record. No research procedures, including any screening activities may be performed until after informed consent has been obtained and documented.
 - g. The original Informed Consent Document shall be placed in the subject's medical record. One copy shall be kept in the investigator's corresponding regulatory binders and a second copy given to the patient. Additionally, if applicable, a third copy shall be filed in the appropriate hospital pharmacy or with Materials Management.

Procedure:

1. Upon receipt of the initial study application, the Primary Reviewers will review the proposed informed consent form to determine if all of the PPMH IRB mandated requirements are included. Whenever possible, the Primary Reviewers will communicate with the investigator or his/her designee to resolve any issues regarding incomplete informed consent forms in advance of the IRB meeting date.
2. A "Request for Waiver of Informed Consent" form must be completed for waivers of informed consent, alternations or waivers of some of the basic elements of informed consent (described in Section 8 above) or waiver of the requirement to document consent (described in Section 8.e above).
 - a. For waivers of informed consent or alterations of elements of informed consent, the investigator or his/her designee must clearly describe why:
 - i. The research involves no more than minimal risk to the subject;
 - ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
 - iii. The research cannot practicably be carried out without the waiver or alteration.
 - b. For waiver of the requirement to document consent, the investigator or his/her designee must clearly explain:
 - i. That the only record linking the participant and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality. Further, each subject will be asked whether the subject wants

documentation linking the subject with the research, and the subject's wishes will govern; or

- ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
3. The IRB or IRB Chair (or his/her designee) if the study qualifies for expedited review, will review the proposed informed consent form (or request for waiver) in a manner consistent with the population under study and communicate required revisions to the informed consent form (or its decision with regard to waiver) in writing to the investigator.
 4. The IRB will also make a determination as to whether required revisions to the informed consent form, if any, are substantial or minor in nature. [See related PPMH policy "Research Revisions and Amendments" for more details.]

References:

- 21 CFR 50.25, 50.27
- 45 CFR 46.116, 46.117

REVISION HISTORY

Revision Number	Description of Changes	Approvals	Date
N/A	Initial release of Policy for PPHS Policy Management System (Compliance 360 Program). This policy replaces all previous versions.	IRB Committee	10-26-2016
0	Policy Reviewed – No Changes	IRB Committee	08-28-2019