

Phoebe Putney Health System, Inc.

INSTITUTIONAL REVIEW BOARD (IRB) Policy Regarding Research Involving Children

POLICY NO.: PPMH

Approved by: IRB Chair (April 22, 2015)

Review Date:

Approved by: Phoebe Putney Memorial Hospital Board (May 6, 2015)

Revised Date:

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Contact Information: Institutional Review Board

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SCOPE: These policies and procedures apply to all research involving children submitted to the Institutional Review Board ("IRB") established by Phoebe Putney Memorial Hospital, Inc., which is responsible for oversight of all research involving human subjects conducted on the premises of, or supported by PPMH. Research involving children at PPMH does not include children that are prisoners.

PURPOSE: Special ethical and regulatory considerations apply when research involves children as subjects. Children are inherently more vulnerable than adults, thus requiring a higher level of protection, and are legally incapable of giving valid informed consent. The IRB will apply the requirements and guidance found in federal regulations 45 CFR 46, Subpart D, "Additional Protections for Children Involved in Research" (see SC 503, "Children as a Vulnerable Population"). This includes provision for obtaining assent from the child or minor and permission from the parent(s) or guardian.

DEFINITIONS: (as per federal regulations at 45 CFR 46.402 and 45 CFR 46.403(c))

Assent: A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. The State of Georgia defines children, or minors, as those persons under the age of 18.

Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Parent: A child's biological or adoptive parent.

Permission: The agreement of parent(s) or guardian to the participation of their child or ward in research.

Prisoners: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing

POLICY& PROCEDURE:

I. PERMISSIBLE RESEARCH WITH CHILDREN

The IRB will approve research involving children only if the research presents no greater than minimal risk to children and only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 45 CFR §46.408.

II. CHILD'S ASSENT

A. Assent

In instances where the subject is not legally capable of giving informed consent, the IRB must find that adequate provisions are made for obtaining the assent of the subject when in the judgment of the IRB, the subject should be capable of providing assent.

1. In determining whether subjects are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the IRB deems appropriate.
2. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

B. Wavier of Assent

If the IRB determines that the capability of some or all of the subjects is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subject and is available only in the context of the research, the assent of the subject is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived, in accordance with 45 CFR 46.116.

II. PARENTAL/GUARDIAN PERMISSION

A. Parental/Guardian Permission

The IRB shall determine that adequate provisions are made for soliciting the permission of each child's parent(s) or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient. Permission by parents or guardians shall be documented in accordance with 45 CFR 46.117.

B. Waiver of Parental/Guardian Permission

In accordance with 45 CFR 46.408, the IRB may waive the requirements for obtaining parental or guardian permission for research involving children if EITHER of the following sets of conditions is met:

1. The IRB makes and documents the required findings under either 45 CFR 46.116(c) or 46.116(d) OR

2. The IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), and also finds that: (i) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and (ii) the waiver is not inconsistent with federal, state, or local law.

The choice of an appropriate substitute mechanism will depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

REFERENCES:

45 CFR 46 Subpart D

REVISION HISTORY

Revision Number	Description of Changes	Approvals	Date