**Phoebe Putney Health System, Inc.**

# INSTITUTIONAL REVIEW BOARD (IRB) EXEMPT REVIEW POLICY NO.: PPMH

**Approved by:** IRB Chair Review Date: 03/25/2015

**Review Period:** Annually Revised Date:

**Contact Information:** Institutional Review Board Approval Date: 03/25/2015 Effective Date: 03/25/2015

**SCOPE:** The Exempt Review policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

**PURPOSE:** To define appropriate circumstances in which a research project may be deemed “exempt” from review by the Phoebe Putney Memorial Hospital (PPMH) Institutional Review Board (IRB).

# DEFINITIONS: N/A

**POLICY:**

1. Federal regulations govern which research projects require oversight by an Institutional Review Board (IRB). Research activities may be exempt if they meet all applicable criteria of one of six categories set forth by federal regulations outlined under section 2 below. [45 CFR 46.101(b)] This means that once the determination has been made that the study is exempt, the IRB will not conduct subsequent reviews of the study.
2. Research activities in which the only involvement of human subjects will be in one or more of the following six categories are generally exempt from IRB review.
   1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
      1. Research on regular and special education instructional strategies, or
      2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
   2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
      1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
      2. Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

NOTE: This exception DOES NOT apply to research involving children, except for research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

* 1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under (b) above if:
     1. The human subjects are elected or appointed public officials or candidates for public office; or
     2. Federal statue(s) require(s) without exemption that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.
  2. 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 recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
  3. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
     1. Public benefit or service programs;
     2. Procedures for obtaining benefits or services under those programs;
     3. Possible changes in or alternatives to those programs or procedures; or
     4. Possible changes in methods or levels of payment for benefits or services under those programs.
  4. Taste and food quality evaluation and consumer acceptance studies;
     1. If wholesome foods without additives are consumed; or,
     2. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environment contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1. Studies that are found not to be exempt from IRB review are eligible for submission to the IRB for review by the full panel or expedited review, if appropriate. [See related PPMH policy “Expedited Review”]
2. The IRB Chair, Vice Chair or one or more experienced reviewers designate by the IRB Chair from among the IRB members will be responsible for the final determination of whether a research project meets the criteria for exemption.
3. The following cannot be exempt from IRB review:
   1. Research that may place participants at risk of physical injury due to intervention(s) performed by the investigator.
   2. Research involving the use of an investigational drug, biologic or medical device that has not received FDA approval or its proposed use is not within the scope of the FDA’s approval (i.e., off-label usage).
   3. Research involving prisoners under Subpart C of the regulations.
   4. Certain research described in section 2, above, which involves fetuses, pregnant women, neonates of uncertain viability, or nonviable neonates under Subpart B of the regulations.
4. IRB members shall be advised of research studies that have been determined to be exempt at the next IRB meeting, and such determination shall be noted in the meeting minutes along with the regulatory authority (i.e., applicable category from section 2 above) justifying the exemption.
5. Meeting exemption criteria does not automatically waive the requirement for subject authorization under the Health Insurance Portability and Accountability Act (HIPAA).

# PROCEDURES:

1. If the investigator feels that his/her research project qualifies for exemption, a completed “Request for Exemption” form and applicable supporting materials should be submitted to the IRB Coordinator.
2. The IRB Coordinator will forward the submission to the IRB Chair, Vice Chair or other experienced IRB member designated by the IRB Chair or Vice Chair. This person will make a determination and the investigator will be notified in writing of approval or disapproval of exempt status. As noted above, studies determined not to be exempt can be subsequently submitted for full board review or expedited review, if appropriate. The procedures outlined in the applicable policy should be followed when resubmitting the study for further consideration.
3. Meeting minutes of the next IRB meeting will include all research determined to be exempt in the interim period and the regulatory authority (i.e., applicable category or categories under section 2 above) justifying the exemption.

# REFERENCES

* 45 CFR 46.110
* 21 CFR 56.110
* 63 FR 60364 – 60367, November 9, 1998

# DOCUMENTATION (Documents & Forms)

1. IRB Request for Exemption

# Other Related Policy/Procedures:

1. Expedited Review

# REVISION HISTORY

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| **Revision Number** | **Description of Changes** | **Approvals** | **Date** |
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