Phoebe Putney Health System, Inc.

POLICY TITLE: EXEMPT REVIEW

ENTITY: PPMH

---

Approved by: IRB CHAIR
Effective Date: 3-25-2015
Review Period: 3 Years
Review Date: 2-26-2021
Contact Information: IRB COORDINATOR

---

Scope: This policy applies to all human subject research, including behavioral, biomedical and social sciences.

Purpose: To define appropriate circumstances in which a human subject research project may be deemed exempt from review the Phoebe Putney Memorial Hospital ("PPMH") Institutional Review Board ("IRB").

Definitions: N/A.

Policy:

1.) Research Not Eligible for Exemption. The following types of research are not eligible for exempt review:

a. Prisoners as Subjects – When prisoners are being studied as a population.
b. Children as Subjects – Only allowed under certain conditions.
c. Medical Records – With the exception of limited data sets.
d. FDA Regulated Studies – With the exception of taste and food quality and consumer acceptance.
e. Deception studies.

2.) Exempt human subject research needs to fall into one of the exempt review categories. Only qualified IRB staff members are authorized to determine the eligibility for exempt status. Investigators are not authorized to make this determination.

3.) Categories of Exempt Review. Unless the research is covered by other subparts of the federal regulations, requested review for minimal risk research activities in which the only involvement of human subjects will be in one or more of the following categories qualifies for exemption.

a. Category 1 – Research Conducted in Educational Settings and Practices. Research, conducted in established or commonly accepted educational settings (i.e., a school), that specifically involves normal educational practices that are not likely to adversely impact student's opportunity to learn required educational content or the assessment of educators

who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

This category includes research on minors and pregnant women. This category includes research on prisoners if a broader population is used and the research only incidentally includes prisoners.

b. Category 2 - Educational Tests, Surveys, Interviews, and Observations. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

   i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
   ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; or
   iii. The information obtained is recorded by the investigator in such a manner that the identify of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

This category includes research on minors if it involves the use of educational tests or the observation of public behavior under 2(i) or 2(ii) above. This category does not include research on minors if it involves (1) survey procedures, interview procedures, or observation of public behavior when the investigator(s) do participate in the activities being observed; or (2) if it involves research using identifiable information reviewed under a limited IRB review.

This category includes research on pregnant women. This category includes research on prisoners if a broad population is used and the research only incidentally includes prisoners.

c. Category 3 – Research Involving Benign Behavioral Interventions. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

   i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR §46.111(a)(7).

For the purpose of this exception, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

This category does not include research on minors. This category includes research on pregnant women. This category includes research on prisoners if a broader population is used and the research only incidentally includes prisoners.

d. Category 4 - Secondary Research for which Consent is not Required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);
iv. The research is conducted by, or on behalf of, a federal department or agency using government- generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

This category includes research on minors and pregnant women. This category includes research on prisoners if the research is not seeking to examine prisoners as a subpopulation.

e. Category 5 - Public Benefit or Service Programs. Research and demonstration projects that are conducted or supported by a Federal department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

   i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

This category includes research on minors and pregnant women. This category includes research on prisoners if a broader population is used and the research only incidentally includes prisoners.

f. Category 6 - Taste and Food Quality and Consumer Acceptance. Taste and food qualify evaluation and consumer acceptance studies: a) if wholesome foods without additives are consumed or b) if a food is consumed that contains a food ingredient at or below the level and or a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Food Safety and Inspection Service of the U.S. Department of Agriculture.

This category includes research on minors and pregnant women. This category includes research on prisoners if a broader population is used and the research only incidentally includes prisoners.

g. Category 7 - Storage or Maintenance for Secondary Research for which Broad Consent is Required. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR §46.111(a)(8).

This category includes research on minors and pregnant women. This category includes research on prisoners if a broader population is used and the research only incidentally includes prisoners.

h. Category 8 - Secondary Research for which Broad Consent is Required. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR §46.116(a)(1) through (4), (a)(6), and (d);
ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
iii. The IRB conducts a limited IRB review and makes the determination required by 45 CFR §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (i) of this section; and
iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

This category includes research on minors and pregnant women. This category includes research on prisoners if a broader population is used and the research only incidentally includes prisoners.

## Procedure:

1.) If an investigator believes 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 who will make a determinate of exemption. The investigator will be notified in writing of approval or disapproval of exempt status. Studies determined not to be exempt can thereafter be submitted for full board review or expedited review, if appropriate.

3.) Meeting minutes of the next IRB meeting will include all research determined to be exempt and the regulator authority justifying the exemption.

## References:

45 CFR 46.104

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 | 3-25-2015 |
| N/A | Reviewed – No Changes | IRB Committee | 02-28-2018 |
| 1 | The policy was revised to comply with changes in Federal law. | IRB Committee | 2-24-2021 |
| | | PPMH CEO | 2-26-2021 |
| | | | |