Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

GUIDANCE - EXEMPT REVIEW

The Prisma Health Office of Human Research Protection staff and members are responsible for determining whether a research project is exempt from 45CFR46 and 21CFR56. Investigators or others within the organization may not make exemption determinations.

REVIEW

In order to fulfill requirements for the proper review of research, the Prisma Health OHRP evaluates and certifies exempt status on appropriate applications. The PI must submit the appropriate application via IRBNet to facilitate IRB review. Exempt status does not mean an application is free from IRB oversight. Exempt studies are governed by all ethical principles pertaining to human subjects research. Occasionally, an alteration of informed consent must still be utilized for certain studies falling into the exempt category for review. Exempt status means the IRB determines the study to possess very little associated risks and only when the project falls into one or more of the exempt categories. Exempt determinations are valid indefinitely unless changes to the risks increase or the population involved alters in such a way as to move the project out of the less than minimal risk review.

In IRBNet, when a study is reviewed as exempt, the reviewer will notate the review type as exempt and submit the exempt letter for approval. Any applicable informed consent forms or alterations of informed consent forms may be stamped without an expiration date as the exempt project will not expire. The project should, however, be given a "next review date" of three years post approval date so that the IRB may determine if the study is still ongoing or if it can be closed.

CATEGORIES

Exemption 1: Normal Educational Practices and Settings

Research conducted in established or commonly accepted educational settings, involving normal education practices that are not likely to adversely impact students' ability to learn required educational content or the assessment of educators who provide instruction. This includes 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.

Exemption 2: Educational Tests, Surveys, Interviews or 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; (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 an IRB conducts a limited IRB review to make the determination required by .111(a)(7). *(*Note: The research cannot be subject to subpart D.)*

Exemption 3: 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: (a) 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 (b) 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 (c) 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 subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7) *(*Note: The research cannot be subject to subpart D.)*

Exemption 4: Research with Existing Data/Samples

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; OR (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 (PHI) when that use is regulated by HIPAA (research or public health activities); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information 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 the E-Government Act of 2002…

Exemption 5: Public Benefit or Service Programs

Research and demonstration projects that are conducted or supported by a Federal department or agency and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

Exemption 6: Taste and Food Evaluation and Acceptance Studies

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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 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 Dept. of Agriculture.

***Exemption 7: Storage or Maintenance of 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 limited IRB review.

***Exemption 8: Secondary Research for which Broad Consent is Required**

Research involving the use of identifiable private information or identifiable biospecimens for secondary research use.

LIMITED IRB REVIEW

Limited IRB Review is required for exempt categories 2, 3, 7, and 8 when identifiable private information or identifiable biospecimens will be retained. In these instances, it is necessary for the IRB to determine that the project has adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of the data being collected. Additionally, if the procedures in the protocol are of a sensitive nature, limited IRB review can be utilized instead of moving the review into an expedited category. For exempt categories 7* and 8*, it is also necessary for the limited IRB review to determine that broad consent requirements are met. Please note that the expedited review mechanism should be used for all limited IRB reviews.

***Please note: Prisma Health does not currently engage with research involving Broad Consent. Please reach out the Prisma Health IRB if you believe your project will fall under Exemption categories 7 or 8.**