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

GUIDANCE - CONTINUING REVIEW NOT REQUIRED

According to the Common Rule, 45CFR46, Subpart A, a project no longer requires annual continuing review if one of the following exceptions may be applied to the project:

1. Research eligible for expedited review in accordance with expedited categories listed in 45CFR46.110[1];
2. Research reviewed by the IRB in accordance with the limited IRB review[2] described in 46.104(d)(2)(iii), (d)(3)((i)(C), or (d)(7) or (8);
3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Note: 1) Even when annual continuing review is not required based on one of these exceptions, the IRB still retains the authority to require continuing review if sufficient rationale exists. 2) Notifications of study modifications, reportable events, and study status updates, including permanent study closure, should be submitted to the IRB for acknowledgement. 3) As part of the administrative processes, the IRB will require check-ins every three years for studies not subject to annual continuing reviews.

FDA REGULATED PROJECTS

The above exemptions do not apply to FDA regulated studies, according to 21CFR56.109(f), and all projects subject to FDA regulations must continue to be reviewed annually until study closure.

EXEMPT AND NOT HUMAN SUBJECTS RESEARCH

Prisma Health IRB policies require that the IRB make the determination as to whether a research project may be approved under the exempt categories[3] or as not human subjects research.

As per the regulations in 45CFR46.104(a), exempt projects do not require regulatory oversight. This means that after an exempt determination is made on a project by the IRB, no further notifications must be made to the IRB unless such modifications would increase the risk to study participants and/or there are significant changes to the project that would cause the study to not meet the exempt requirements as outlined in 45CFR46.104(d) due to an increase in risk.

Research projects that are determined by the IRB to be not human subjects research do not require regulatory oversight by the IRB under 45CFR46. Once the IRB has made the determination that the project either does not involve human subjects, is not considered research by definition, or both, no further reporting is required to the IRB.

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1. See chart A.

2. Definition of Limited Review: There are 4 exempt review categories that are subject to IRB limited review: categories 2, 3, 7 and 8. The IRB is responsible for conducting the review of the proposed project collecting identifiable private information or biospecimens, but instead of requiring an informed consent form, they rely on the provisions put into place that adequately protect the privacy of subjects and the confidentiality of the data.

3. See chart B.

CHART A – EXPEDITED REVIEW CATEGORIES

EXPEDITED CATEGORIES
CATEGORY 1
Studies of drugs and medical devices only when (a) research on drugs for which an IND is not required, or (b) medical devices when (i) an IDE is not required; or (ii) the medical device is being used in accordance with its approved labeling.
CATEGORY 2
Collection of blood samples by finger/heel/ear stick or venipuncture (a) from healthy, non-pregnant adults ≥ 110 lbs, ≤550 ml in an 8 week period, not more frequently than 2 x per week; or (b) other adults and children, considering age/weight/health, collection procedure, amount of blood, frequency collected – may not exceed lesser of 50 ml or 3 ml/kg in 8 week period and not more frequently than 2 x/week.
CATEGORY 3
Prospective collection of specimens for research by non-invasive means – hair, nails, teeth, excreta/secretions, saliva, placenta, amniotic fluid, dental plaques, buccal scraping/swabs, sputum after saline mist nebulization.
CATEGORY 4
Collection of data through noninvasive procedure (no general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays or microwaves. Examples: physical sensors applied to body surface with no input of significant amounts of energy, ECG, MRI, weighing or testing sensory acuity, EEG, US, blood flow.
CATEGORY 5
Research involving data/documents/records/ specimens that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
CATEGORY 6
Collection of data from voice, video, digital, or image recordings made for research purposes.
CATEGORY 7
Research on individual or group characteristics or behavior (perception, cognition, motivation, identity, language, communication, beliefs or practices, social behavior) or research using survey, interview, oral history, focus group, program evaluation, human factors evaluation, quality assurance methodologies.
CATEGORY 8
Continuing review of research previously approved by IRB (a) where (i) it's permanently closed to enrollment (ii) subjects have completed all research related interventions (iii) is active only for long-term follow-up; or (b) where no subjects have been enrolled and no additional risks have been identified or (c) the remaining research is limited to data analysis.
CATEGORY 9
Continuing review of research not under an IND or IDE where categories 2-8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Chart B – EXEMPT REVIEW CATEGORIES

EXEMPT REVIEW CATEGORIES
CATEGORY 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.
CATEGORY 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).
CATEGORY 3
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)
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; 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…
CATEGORY 5

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.
CATEGORY 6
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.
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 limited IRB review.
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.