Exemption Categories

Research that is NOT federally supported[1] and NOT FDA-regulated (Geisinger's New Rule 2018)

Effective May 1, 2018, Geisinger IRB will make Exempt determinations for all research that is neither federally-funded/sponsored or FDA-regulated according to the following 6 Exemption categories:

☐ Category 1 - 45 CFR 46.104(d)(1)[2] Educational Strategies, Curricula or Classroom Management in Educational Settings

Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' 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.

☐ Category 2 - 45 CFR 46.104(d)(2)[2] Tests, Surveys, Interviews, Public Behavior Observation

Please Note: If **FEDERALLY FUNDED or SPONSORED**, the research cannot be exempt if the information collected is both identifiable and sensitive.

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:**

a) The information obtained is recorded by the investigator in such a manner that the identity of the human participant's cannot readily be ascertained, directly or through identifiers linked to the participants;

b) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7)

☐ Category 3 - 45 CFR 46.104(d)(3)[2] Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses

Please Note: If **FEDERALLY FUNDED or SPONSORED**, this category cannot apply.

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 participants cannot readily be ascertained, directly or through identifiers linked to the subjects; or

b) Any disclosure of the human participants' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7) (See Policy #4.003 Limited Review).

For the purposes of this provision, 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.

If the research involves deceiving the subjects regarding the nature or purpose of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category 4 - 45 CFR 46.104(d)(4)[2] Secondary research for which consent is not required

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 are met**:

☐ a) The identifiable private information or identifiable biospecimens are publicly available; or

☐ b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants; or

☐ c) 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) (HIPAA Privacy Rule); or

Please Note - Category 4C cannot apply if any of the following are true:

- The research is federally funded or sponsored.
- GCSOM-paid faculty or students are members of the research team and will have access to identifiable data. This is because GCSOM is not a HIPAA-covered entity.
- The research plans to share identifiable data with a non-HIPAA covered entity.

☐ d) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities...

☐ Category 5 - 45 CFR 46.104(d)(5)[2] Research and demonstration projects

Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to approval of 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, 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.

a) 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.

☐ Category 6 - 45 CFR 46.104(d)(6)[2] Taste and Food Evaluation and Acceptance Study

Taste and food quality 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 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 U.S. Department of Agriculture.

Research that IS federally supported (HHS Common Rule 45 CFR 46.101)

☐ Category 1 - 45 CFR 46.101(b)(1) Educational Strategies, Curricula or Classroom Management in Educational Settings

Category 1 - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

☐ Category 2 - 45 CFR 46.101(b)(2) Tests, Surveys, Interviews, Public Behavior Observation

Category 2 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.

Please Note: Category 2 may be applied to research involving children ONLY if the study: 1) pertains to standardized educational test, or 2) involves observation of public behavior and the investigator does NOT participate in that behavior or activity. This category can NEVER be applied to surveys of children)

☐ Category 3 - 45 CFR 46.104(b)(3) Tests, Surveys, Interviews, Public Behavior Observation - Elected or Appointed Public Officials ONLY

Category 3 - 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 Exempt Category 2, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

☐ Category 4 - 45 CFR 46.101(b)(4) Collection of Existing Data, Documents, Records or Biospecimens

Category 4 - 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

☐ Category 5 - 45 CFR 46.101(b)(5) Public Benefit or Service Research or Demonstration Projects

Category 5 - 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: Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs

☐ Category 6 - 45 CFR 46.101(b)(6) Taste and Food Evaluation Acceptance Study

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

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[1] **Federally supported**: This means that the research is supported by federal funding or other type of federal involvement. GIRB staff members rely upon the information provided by the researcher, except when the provided information is inconsistent or ambiguous about federal support. If there is no indication of federal support, the researcher is not asked for confirmation that there is no federal support. "Federal support" includes any of the following:

- Funding from any federal agency. This means:
  - Awards made to directly support the research;
  - No-cost extensions of awards made to support the research;
  - "Flow through" federal funds that are awarded to a non-Geisinger affiliated institution and then awarded to Geisinger or affiliate through a subcontract.
  - Federal funds that may be indirectly supporting the research such as:
    - Federally-funded training grants;
    - Federal scholarships, fellowships, or other training awards such as "K" grants;
    - Federally-funded program project grants.
- Involvement of federal personnel;
- Use of federal equipment or materials;
- Use of federal facilities;
- Any research team member (including students) whose time on the research is paid or supported (whether directly or indirectly) by any federal award.

[2] ***Final Revised Common Rule 45 CFR 46 Subpart A - Basic HHS policy of Protection of Human Research Subjects (January 18, 2017)*** – while these HHS regulations are not yet effective, Geisinger is implementing these Exemption categories for non-federally funded/sponsored or FDA-regulated research, effective May 1, 2018.