

## Exempt Categories – Effective January 19, 2019

- **Category 1 - 45 CFR 46.104(d)(1) - expanded:** Research involving 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** such as:
  1. Most 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.
- **Category 2 - 45 CFR 46.104 (d)(2) - expanded:** Research that only includes interaction involving the use of 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 is met:**
  1. Information obtained is recorded by the investigator in such a manner that the identity of human subjects **cannot** be readily ascertained, directly or through identifiers linked to the subjects; **or**
  2. Any disclosure of the human subjects' responses outside of 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**;
  3. **The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).**

Children may only be included in research under this exemption when involving educational tests or observation of public behavior if the investigator(s) do not participate in the activities being observed and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly, or through identifiers linked to the subjects.

- **Category 3 - 45 CFR 46.104(d)(3) - New:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected and at least one of the following is met:
  1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; **or**
  2. 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**
  3. **The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).**

For the purpose 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 (e.g., playing an online game, solving puzzles, etc.). If

the research involves deception, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research and the subject is informed that they will be unaware of or they will be misled regarding the nature or purposes of the research. **Children may not be included in research under this exemption.**

- **Category 4 - 45 CFR 46.104(d)(4) - revised:** 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:
  1. The identifiable private information or identifiable biospecimens are publically available; **or**
  2. 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**
  3. 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 160 and 164, Subparts A and E (HIPAA), for the purposes of "health care operations" or "research" as those terms are defined under HIPAA or for "public health activities and purposes" under HIPAA; **or**
  4. 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.
- Revised to remove word 'existing' and to allow for a HIPAA exemption
- Information must be publicly available, or not identifiable by the investigator directly or through links, the investigator will not contact subjects, and will not re-identify subjects.
- **Category 5 - 45 CFR 46.104(d)(5) - unchanged:** Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads. 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 - 45 CFR 46.104(d)(6) - unchanged:** Taste and food quality evaluation and consumer acceptance studies.

New categories of Broad Consent: Because there is no guidance from OHRP and because of the implications of tracking individuals who do not provide consent and excluding their data from all future research, UWG is not pursuing broad consent at this time.

- **45 CFR 46.104(d)(7):** Storage or maintenance for secondary research for which broad consent is required.
- **45 CFR 46.104(d)(8):** Secondary research for which broad consent is required: Research involving the use of identifiable private health information or identifiable biospecimens for secondary research use.

**Limited IRB Review:** 45 CFR 46.111(a)(7) review will be conducted by the IRB sub-Committee or designee: (1) For exempt categories 104(d)(2) and 104(d)(3) to verify adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data are assessed.