UWO Reference: Revised Common Rule Exempt Categories

Please note that the final rule moved the exempt categories from section 46.101 to new section 46.104. The final rule made changes to five of the six existing exempt categories of research, and added three new categories. Exemption Category 2 & 3 may include criteria for Limited IRB Review to be conducted by an IRB Member to ensure adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of the data. Exemption categories 7 & 8 in the Final Rule identify specific regulatory requirements that must be met (e.g., limited IRB review, use of broad consent) as a condition of being exempt from other regulatory requirements. Since UW Oshkosh did not adopt the use of broad consent under the new rule, Exempt Categories 7 & 8 will not be utilized and is not included in this list. In order for a study to be exempt, it must fit the description of the exempt category and not include any non-exempt research activities.

☐ **Exempt Category #1 .104(d)(1)**

Research, conducted in established or commonly accepted educational settings, which 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 comparison among, instructional techniques, curricula, or classroom management methods.

Note: This is a revised version of existing category 1.

☐ **Exempt Category #2 .104(d)(2)**

Research that includes only 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 following criteria are 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 human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an *IRB conducts a limited review* to make the determination required by 45 CFR 46.111(a)(7) (when appropriate, there are adequate provisions for protecting privacy and maintaining confidentiality of data). ☐

Note: This exemption assumes that the potential risks raised by this category are largely informational and that subjects are aware of them, and thus the most important role that an IRB might play with respect to reducing potential harms is to ensure the application of privacy safeguards. Exempt Category 2(i) and 2(ii) is restricted to research involving educational tests when the investigator does not participate in the activity being observed. Exempt Category 2(iii) is not permitted with children.

☐ **Exempt Category #3 .104(d)(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 are 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 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 subject, and an *IRB conducts a limited IRB review* to make the determination required by 45 CFR 46.111(a)(7) ☐

Note: Exemption 3 is a new category intended to cover research for which IRB review is likely to add little additional protections because the risk of harm is low and subject autonomy is respected by the requirement for prospective agreement. This exemption applies to adults only. 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 criteria are met, examples of such benign behavioral interventions include: having subjects play an online game, solve puzzles under various noise conditions, or 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 purposes 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 study. Excludes medical interventions. See SACHRP's guidance and educational questionnaire tool for this exemption under Attachment B.

☐ **Exempt Category #4 .104(d)(4)**

Secondary Research Use of Identifiable Private Information and/or Identifiable Biospecimens for which Consent is Not Required, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available; ☐ OR
ii. The information is recorded by the investigator in such a way that the identity of the subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact 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 HIPAA 45 CFR parts 160 and 164, subparts A and E (i.e., the use is regulated for purposes of "health care operations" or "research" as those terms are defined at 45 CFR parts 164.501 or for "public health activities and purposes" as those terms are defined at 45 CFR part 164.512 (b)); ☐ OR
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 certain federal statutes. ☐

Note: Does NOT apply to any primary collection of information and/or biospecimens. Unlike current exemption category 4, there is NO requirement that the information/biospecimens be pre-existing at the time the investigator begins the research study. Unlike exemption categories 7 and 8, exemption category 4 does not depend on any consent requirements being met. Permits secondary analysis of identifiable data and biospecimens obtained from subjects who are prisoners, if the research is not designed in a way that seeks to recruit prisoners as a population but rather only incidentally (i.e., not intentionally) includes prisoners.

☐ **Exempt Category #5 .104(d)(5)**

Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency:

- Applies to research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads. Applies to activities that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including, but not limited to: 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.

Note: This exemption DOES apply to research & demonstration projects supported through federal grants or cooperative agreements, even if the federal dep't/agency does not itself administer or conduct the benefit or service program through its own employees/agents. New requirement: each federal dep't/agency conducting or supporting research & demo projects must establish, on a publicly accessible federal website or in another

appropriate manner, a list of the research & demo projects the federal dep't/agency conducts or supports under this provision. The project must be published on this list before beginning the research involving human subjects.

☐ **Exempt Category #6 .104(d)(6)**

Taste and Food Quality Evaluation and Consumer Acceptance Studies:

- This exemption applies if wholesome foods without additives are consumed, or 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 FDA or approved by the EPA or the USDA's Food Safety and Inspection Service.

Note: This category has not changed from previous regulations.
