WOU Institutional Review Board
Level of Research Review Categories

Exempt Research

A. **Exempt** Research: Exempt research still requires an IRB application.

None of these exemptions apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.

All aspects of the study must fall into one or more of the following eight categories:

1. Research conducted in established or commonly accepted educational settings when it specifically involves normal educational practices, so long as the research is not likely to adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes (i) most research on regular and special education instructional strategies, and (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

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 three criteria is met:

> a) The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subjects;
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> 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
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> c) 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 IRB review to make the determination required by § ll.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality).

3. Research involving benign behavioral interventions -- *which is defined as brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing (HHS 2017)* -- 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 three criteria is met:

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

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) If the subjects' identity can readily be ascertained and if a disclosure of subjects' Reponses has potential to harm subjects, the exemption is permitted if the IRB conducts a limited review and determines that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

Important note about Category 3: Deception is allowed if certain criteria are met. Additionally, this exemption is only for benign behavioral research with adults, and is not applicable to children.

4. Secondary research use of identifiable private information and identifiable biospecimens for which consent is not required, if at least **one** of four criteria is met:

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

b) The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact subjects or try to re-identify subjects;

c) Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes, as those are terms are defined in HIPAA; or

d) The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected.

5. Research supported by a federal agency (not just conducted) is allowed to qualify for this exemption.

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 Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research use of identifiable private information or

identifiable biospecimens for which broad consent is required. This requires that an IRB conduct **limited** IRB review to make the following determinations:

> a) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § ll.116(a)(1)–(4), and (a)(6), and (d);
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> b) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § ll.117; and
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> c) If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, adequate provisions must be in place to protect the privacy of subjects and to maintain the confidentiality of data.

8. Category 8 allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived. The IRB must also conduct a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 46.111(a)(7), and that the use is within the scope of the broad consent. Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.