Exempt Research Decision Aid
EWU Institutional Review Board for Human Subjects Research

Research Qualifying for Exemption from Federal Regulations for the Protection of Human Subjects
(Quoted from EWU Policy 302-02 and the federal Common Rule (45 CFR Part 46)

(1) 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 education 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.

(2) 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 be readily ascertained, directly or through identifiers linked to the subjects. For 2 iii, a consent form must be used.

(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:
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. For 3iii, a consent form must be used.

(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;
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 be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when the use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 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 nonresearch 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 section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

(5) 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 (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, or possible changes in methods or levels of payment for benefits or services under those programs. *Such projects include, but are 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 such as sections 1115 and 1115A of the Social Security Act, as amended.

(6) Taste and food quality evaluation and consumer acceptance studies if: wholesome foods without additives are consumed; or 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.

(7) Storage or maintenance for secondary research of identifiable private information or identifiable biospecimens for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use must meet the criteria for IRB approval of research outlined in§46.111.

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1)-(4), (a)(6), and (d) and documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.111(a)(7).

Based on both federal policy and university policy, exempt status may only be granted for research that is less than minimal risk as defined below[1]. In addition, if any of the following eight categories apply to the research, it may not be considered exempt.

Yes No

☐ ☐ If any of the subjects are children as defined by state law[2] and parental consent has not been granted (this condition does not include observations and some research under exemption category (1).

☐ ☐ If any of the subjects are confined in a correctional or detention facility.

☐ ☐ If pregnancy is a prerequisite for serving as a subject. Fetuses in utero are subjects in this research.

☐ ☐ If any subjects are presumed not to have adequate decision-making capacity to agree to participate in the proposed research (i.e. not legally competent).

☐ ☐ If personal records (medical, academic, etc.) with identifiers are used without written consent.

☐ ☐ If data from subjects (responses, information, specimens, etc.) are directly or indirectly identifiable.

☐ ☐ If data may be damaging to subjects' financial standing, employability or reputation.

☐ ☐ Behavioral interventions that are not brief in duration.

☐ ☐ Studies involving deception unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research.

☐ ☐ If the intervention or the methods used to collect data introduce risks of harm, physical or emotional discomfort, offense or embarrassment.

☐ ☐ If material from an at autopsy is to be used in the research.

☐ ☐ If alcohol or any other drugs will be ingested.

☐ ☐ If blood or body fluids will be drawn.

[1.] Minimal risk is defined in 45 CFR 46.102(j) Subpart A as: The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

[2.] Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Legal age in the State of Washington is 18. If subjects have the legal status of emancipated minors, or are mature minors, i.e., they may legally be treated as adult for certain purposes, they may be exempt from the restrictions applicable to children.