Exemptions – General Information

The "Common Rule" (45 CFR 46 subpart A) defines a set of research activities that may be exempt from its purview, unless otherwise required by Department or Agency heads. Exempt research has very little, if any, associated risk. Note that exempt research still requires completion of a WOU IRB application.

WOU IRB Procedures for Exemption

The IRB Chair or the IRB Chair's designee will determine whether a submitted research project meets the requirements for exemption from IRB review. The IRB Chair or the IRB Chair's designee can require expedited or full review of any research at his/her discretion, even if the research would otherwise qualify for exempt review status. The decision to actually grant exempt review status is initially made by the IRB Chair or the IRB Chair's designee, who must review the full set of documents submitted by the investigator in reaching a decision during an exempt review.

The Principal Investigator must submit all requisite documents to the WOU IRB for consideration for exempt review. These include an initial IRB application and any additional protocol materials such as consent, survey, interview questions, etc., as needed; and any other information known to be relevant. The Principal Investigator must indicate the expected level of review (e.g., exempt) in the initial application.

If it is determined that exempt review is appropriate for a study and the IRB Chair or the IRB Chair's designee wishes to utilize this procedure, the IRB Chair or the IRB Chair's designee will then perform the review. The IRB Chair or the IRB Chair's designee will evaluate research determined to be exempt to ensure that it meets Western Oregon University ethical standards. Such an evaluation might include the following: (1) The research holds out no more than minimal risks to subjects; (2) Selection of subjects is equitable; (3) If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data; (4) If there are interactions with subjects, there will be a consent process that will disclose such information including a) that the activity involves research, b) a description of the procedures, c) that participation is voluntary, d) name and contact information for the investigator, and e) there are adequate provisions to maintain the privacy interests of the subjects.

When a study has been certified as exempt from IRB review, continuing review and approval is not required. Certification of Exemption is effective for the life of the study. However, all modifications to a study that has been certified exempt must be submitted to the IRB for prospective review and certification of exemption prior to implementation. In some circumstances, changes to the protocol may disqualify the project from exempt status.

For projects that include existing data, documents, records, pathological specimens, or diagnostic specimens, "existing" is defined as data that exists prior to the time of the IRB application submission. The Research Plan for projects using existing data, documents, records, pathological specimens, or diagnostic specimens will include the specific dates of the records to be reviewed.

If it is determined that the proposed study is exempt, the Principal Investigator will be provided with a Certification of Exemption that will include under what category of exemption the study was granted. If it is determined that the proposed study is not exempt or additional information is needed to determine exempt status or certification is granted pending acceptance of requested modifications/clarifications, the Principal Investigator will be notified of this information in written form.

Exemption Categories

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 a) most research on regular and special education instructional strategies, and b) 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; 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) 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; provide examples of the types of public benefit and service programs covered by the exemption; and clarify the federal components for which the exempt research is subject to approval (for example, delegated subordinate agencies).

(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); b) broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § ll.117; and 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.