Wayne State University
Institutional Review Board (IRB)

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Exempt Review of Research

Exempt research is human participant research of minimal risk where the entire research project falls within one or more of the six specific regulatory categories defined below. Exempt research is NOT excused from IRB review. The IRB grants an exempt status only after review of the proposed research and after confirming that the study falls into an exempt research category.

Full Exempt vs. Exempt with Limited IRB Review:

A study may be granted full exempt status or exempt with limited IRB review, as described in the categories below. Limited IRB review is focused on ensuring adequate privacy and confidentiality protections for participants.

Any proposed changes to exempt research must be submitted for IRB review and approval prior to implementation, unless the change is necessary to protect subjects from an apparent immediate risk of harm.

Research with human participants may qualify for exemption if the project does not involve any of the restrictions listed below and if research procedures/activities meet the criteria detailed in the exemption categories listed below. An investigator cannot determine his or her own research project to be exempt. The exempt determination must be made by the IRB.

Restrictions for Exempt Research

Research may be either restricted or not eligible for exempt review if any of the following are involved:

a. Procedures which expose participants to more than minimum risk (greater than ordinarily encountered in daily life)
b. Prisoners (Unless incidentally included in secondary research aimed at a broader subject population)
c. Survey or interview techniques, or observation of public behaviors, with minors (Restrictions are described in category 2)
d. Children as research participants for any research conducted under exempt category 3
e. Projects that are FDA-regulated, with the exception of category 6

Exempt Research Categories

Category 1 Research conducted in established or commonly accepted educational settings that specifically involve 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 the comparison among instructional techniques, curricula, or classroom management methods.

Category 2 Research that only includes interactions 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 criteria is met:

a. Information obtained is recorded by the investigator in such a manner that identity of the participants cannot be readily ascertained, directly or through identifiers linked to the participants

b. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, reputation.

c. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a **limited IRB review** to examine the provisions to protect the privacy of subjects and to maintain the confidentiality of data.

NOTE: This category can only be applied to research with children when the research involves educational tests or the observation of public behavior (as long as the investigator(s) do not participate in the activities being observed); and either (a) or (b) above is true.

Category 3 Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the participant cannot readily be ascertained, directly or through identifiers linked to the participants

b. Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation

c. The information obtained is recorded by the investigator in such a manner that the identity of the participants' can be readily ascertained, directly or through identifiers linked to the participants, and the IRB conducts a **limited IRB review** to examine the provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving participants 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 participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

NOTE: This category does not apply to research involving children.

Category 4 Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio-specimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable bio-specimens are publicly available;
b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify the participants.
c. The research involves only information collection and analysis involving the investigators use of identifiable health information when that use is protected under HIPAA regulations for the purposes of healthcare operations, research, or public health activities and purposes.
d. 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 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.

Category 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 not 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 using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human participants.

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

NOTE: The WSU IRB has elected to opt out of the optional categories #7 and #8 as described in 45 CFR 46.104. These categories involve research with biospecimens in which broad consent is obtained. Any study with broad consent will not be eligible for exempt review under this policy.

Investigator Responsibilities and Ongoing IRB Reporting:

Investigators conducting exempt studies are required to provide a Status Update of the research project. Investigators are also responsible for updating the IRB of any changes to the study by submitting the Medical/Behavioral Amendment Form. The amendment must have IRB approval prior to implementing any proposed changes. Investigators conducting research determined to be exempt are responsible for ensuring that the rights and welfare of human participants is protected. Exempt status does not lessen the ethical obligations to participants and therefore, depending on the circumstances, researchers performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.