



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. Research that is granted exempt with limited IRB review is subject to an additional WSU privacy review focused on ensuring adequate privacy and confidentiality protections of participants when identifiable or potentially identifiable data is collected outside of the privacy protections of HIPAA and/or the privacy standards of research conducted by or on behalf of a Federal department, or agency.

If 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, a limited IRB review is required to examine the protections of the participants' privacy. The limited IRB review is not required if information obtained can be recorded in a manner that the identity of the participants cannot be readily ascertained directly or through identifiers linked to the participants.

IRB approval of an amendment is required for changes that affect (a) how participants are enrolled, (b) the collection of identifiers or (c) the data collected on individuals. The review of these types of changes ensures that the IRB can identify when a study no longer meets the criteria for exempt review and that adequate privacy protections are in place to protect data collected from research participants.

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 as defined in category 4)
- c. Survey or interview techniques with minors (Restrictions are described in category 2)
- d. Children as research participants for any research conducted under exempt category 3.
- e. Any disclosure of participant information that could place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

- f. Research that explore sensitive aspects of a person's own behavior or experience (illegal conduct, abuse, alcohol or other drug use, sexual behavior, suicidal thoughts, etc.) in which personally identifiable information is collected.

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 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, a limited IRB review is required to examine the protections of the participants' privacy. The limited IRB review is not required if information obtained can be recorded in a manner that the identity of the participants cannot be readily ascertained directly or through identifiers linked to the participants.

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.

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.

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:

- (i) The identifiable private information or identifiable bio-specimens are publicly available;
- (ii) Information 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.
- (iii) 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.
- (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 the E-Government act of 2002, and the Paperwork Reduction Act of 1995 if applicable.

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, or possible changes in or alternatives to those programs or procedures, 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 that affect (a) how participants are enrolled, (b) the collection of identifiers or (c) the data collected on individuals. 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.

To Submit for Exempt Review

1. Complete a *Medical Exempt Protocol Summary Form OR a Social/Behavioral/Education Exempt Protocol Summary Form located at www.irb.wayne.edu
2. Complete all associated appendices as directed in the Protocol Summary Form.
3. Complete a HIPAA Summary Form; if accessing or using medical records found at www.irb.wayne.edu
4. Submit a Research Protocol and/or a list of scientific references
5. Provide a list of the kind of data to be collected and/or any data collection tools or instruments, flyers, advertisements and other documents to be used in the research
6. Carefully follow all submission directions provided with the form

***Revised Exempt Protocol Summary Forms will be available January 15, 2018**