

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>Exemption determinations and research ethics standards</i>	
Section: 911.	This policy and procedure supersedes those previously drafted
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Related documents: <i>120: Compliance with applicable laws and regulations</i> <i>210: Determination of human subjects research</i> <i>310: Researcher responsibilities, qualifications & training</i> <i>330: Authorization to conduct human subjects research</i> <i>720: Assessing Risk to Vulnerable Participants</i> <i>1040: Post-Approval Compliance Review</i> <i>OP-1: GV charge to the IRB</i> <i>G-15: Guidance on the Use of Deception and Incomplete Disclosure in Research</i>	

Policy

Designated Office of Research Compliance and Integrity (ORCI) staff or members of the IRB shall make the determination of whether research activities are exempt from applicable laws and regulations. Any other party or office may not make the determination.

A determination of exemption from the federal regulations under 45 CFR 46.104 or the University-expanded categories shall nonetheless be governed by research ethics standards.

GVSU researchers seeking to rely on an external IRB's exempt determination are required to submit a reliance request to the ORCI and receive an acknowledgement letter prior to participating in the research. Institutional Agreement Authorizations are not required for exempt collaborative research studies.

Exempt studies are subject to review under the ORCI's Post-Approval Compliance Review Program, per *IRB Policy 1040: Post-Approval Compliance Review*.

Procedures

1. Exclusions from Exempt Eligibility
 - a. Federal exclusions
 - Exempt categories do not apply to research involving prisoners
 - Survey/interview research on minors is restricted
 - b. University criteria for restricting exemption eligibility:

- Research that is greater than minimal risk
- Research that is FDA regulated, apart from studies eligible under exemption category 6

2. General Procedures for Determining Exempt Status

- The Provost has assigned the IRB the authority and responsibility for reviewing all protocols involving human subjects that are conducted at GVSU facilities or by GVSU faculty, staff, students or visiting scientists at any location, domestic or international. The scope of this authority also includes oversight and review of research on human subjects that is otherwise exempt from the federal regulations.
- The IRB distributes the authority to conduct exempt determinations to designated ORCI staff, per administrative procedures.
- Determination of exempt status is made according to the following criteria (45 CFR 46.104(d)):
 - 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 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.
 - 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:
 - 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;
 - 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, or reputation; or
 - 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, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

¹MINORS: Research involving observations of public behavior is permissible with minors provided the researcher does not participate in the activities being observed. Research on minors involving surveys or interviews does not qualify for this exemption.

¹ In Michigan, minors (children) are defined as persons who have not yet reached eighteen (18) years of age. For residents in other locations, the age of majority is determined by applicable law. See also IRB Policy 120: *Compliance with applicable laws and regulations*

- (3) (i) 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:

(A) 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 indirectly 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, or reputation; or

(C) 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, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects 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.

(iii) If the research involves deceiving the subjects 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 subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. For more information regarding the use of deception in research, see *G-15: Guidance on the Use of Deception and Incomplete Disclosure in Research*.

- (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 readily be 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 that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as 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.

*Non-federally funded research will be eligible for review under this exemption if the only contact with potential participants is to obtain Family Educational Rights and Privacy Act (FERPA) consent, and the IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7). Information must still be recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or indirectly through identifiers linked to the subjects, and the investigator will not re-identify subjects from the recorded information.

(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 subjects.

(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 IRB will not allow the use of exempt categories 7 and 8 until processes regarding tracking, in perpetuity, of subjects who opt out of a study and the necessary infrastructure is in place.

- 3. The following research ethics standards are applied to exempt research:
 - a. Risks to participants are minimized and reasonable in relation to anticipated benefits, if any.
 - b. Selection of participants is equitable in relation to anticipated benefit, if any.
 - c. The circumstances of consent minimize coercion and undue influence.
 - d. Provisions for protecting the privacy interests of participants are adequate for the level of risk.
 - e. If personally identifying data are recorded, the data management plan is appropriate for maintaining participant privacy and data confidentiality including the storage, transmission, use, archiving and final disposition of all data.
 - f. Where applicable, the research must comply with all privacy and data protection regulations (i.e., Health Insurance Portability and Accountability Act [HIPAA], Family Educational Rights and Privacy Act [FERPA], General Data Protection Regulation [GDPR]).
- 4. Once determined to be exempt, the following changes must be reviewed and acknowledged by the ORCI prior to implementation:
 - a. Personnel changes
 - b. Alteration in the risk-to-benefit ratio, if there is a potential to increase risk -or- a plan to communicate an increased benefit to participants
 - c. Eligibility for exempt status
 - d. Significant increase in the scale of the project

Questions about whether a proposed change requires review by the ORCI should be directed to the ORCI staff.

- 5. Exempt studies receive a determination rather than an approval; however, modifications may be required in order to comply with research ethics standards. Exempt studies have no approval expiration nor must they be resubmitted in a continuing review application.