Grand Valley State University Institutional Review Board	
Title: *Exemption Determinations and Research Ethics Standards [Pre-Revised Common Rule Version]*	
Section: 911a.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 05/10/2011 Revisions approved 7/25/2012 Revisions approved 10/11/2013 Revisions approved 01/14/2014 Revisions approved 10/14/2014 Revisions approved 07/14/2015 Revised by HRRPPC: 03/28/2018 Revised by IRBPPC: 03/24/2025	Approved by RIO/HRPA: 05/12/2011 Revisions approved 7/25/2012 Revisions approved 10/21/2014 Revisions approved 02/09/2014 Revisions approved 10/13/2014 Revisions approved 07/15/2015 Revisions approved by AIO/RIO: 4/16/2018 Revisions approved by IO: 06/15/2025
Effective Date: 06/15/2025	
Related documents: *120: Compliance with Applicable Laws and Regulations* *210: Determination of Human Subjects Research* *310: Researcher Responsibilities, Qualifications and Training* *330: Authorization to Conduct Human Subjects Research* *720: Assessing Risk to Vulnerable Participants* *1010: Modifications to Approved Protocols* *1040: Post-Approval Compliance Review* *OP-1: GV charge to the IRB*	

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 46.101 or the University-expanded categories shall nonetheless be governed by research ethics standards.

GVSU does not apply engagement determinations to exempt research; therefore, Institutional Agreement Authorizations are not considered for exempt collaborative research studies. GVSU personnel who are not functioning as a PI are not required to submit materials for exempt determination to the IRB.

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. General Procedures for Determining Exempt Status
    a. 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.

b. The IRB distributes the authority to conduct exempt determinations to designated ORCI staff, per administrative procedures.
c. The IRB Chairperson, at their discretion, may complete a subsequent review of exempt determination reviews conducted by ORCI staff.

2. Submission of Expedited Protocols
    a. The Principal Investigator (PI) makes the preliminary determination that a protocol is eligible for exempt review. The ORCI/IRB Chairperson make the final determination regarding whether a protocol is eligible for exempt review.
    b. The PI is responsible for submitting a completed protocol submission form in ORCI's electronic management system. This submission should also include the following documents, as applicable:
        i. The funding letter, sponsor's agreement or human subjects portion of the grant/application
        ii. Written permission from data collection sites indicating support of the research
        iii. Written recruitment materials, such as flyers, posters, emails and social media posts
        iv. Written permission from the GVSU Athletic Director, if the research will target varsity athletes for inclusion
        v. Informed consent and assent documents
        vi. HIPAA authorization form, if separate from the informed consent document
        vii. Surveys, interview questions and data collection forms
        viii. Any other documentation that may be relevant to IRB review

3. Reviewer Actions
    a. For each exempt protocol, the reviewer will review the protocol submission, document their analysis regarding protocol-specific findings, and provide justification for the determinations.
    b. If the reviewer determines the research qualifies as Not Human Subjects Research, the reviewer will document the rationale for this. If the reviewer determines the research requires non-exempt review, the form will be returned to the PI to resubmit at the appropriate level of review.
    c. For exempt protocols, reviewers may take one of the following actions:
        i. **"Exempt Determination**": The submission meets all the criteria for approval.
        ii. **"Conditional approval"**: The submission will meet the criteria for approval with minor or prescriptive changes or requirements that can be verified by administrative staff or Chairperson without considering the criteria for approval.
            1. Summarize the ORCI's/IRB's required modifications and reasons.
        iii. **"Request Clarifications/Changes"**: The submission does not meet the criteria for approval, and substantial changes or additional information is needed.
            1. Summarize the ORCI's/IRB's reasons (required clarifications and modifications) and recommendations, if any.

4. Chairperson Actions
    a. The Chairperson may review the reviewer's determinations and recommended actions and may at any time identify additional clarifications/changes that need to be addressed prior to an exempt determination.
    b. The Chairperson may prepare the response to the PI, delineating the conditions of approval or requested changes.

c. For protocols that have been conditionally approved: At the Chairperson's discretion, ORCI staff may verify that the conditions required for approval have been satisfied. This verification can be done without requiring further review by the Chairperson.

5. IRB-Required Modifications and Corrections
    a. When the ORCI/IRB requires modifications or clarifications to a protocol in order to comply with federal regulations, research ethics standards, or the minimization of risks to research subjects, it shall inform the researcher of the required modifications and/or clarifications in writing.

6. Exempt Determination Processing
    a. The IRB determination letter is sent to the PI, the PI's Authorizing Official, and the Office of Sponsored Programs (if applicable).
    b. For exempt protocols that are given conditional approval, the exempt determination date is taken as the date that the ORCI/IRB Chairperson confirm the approval conditions have been satisfied.

Guidance

1. Exclusions from Exempt Eligibility
    a. Federal exclusions
        i. Exempt categories do not apply to research involving prisoners
        ii. Survey/interview research on minors is restricted
    b. University criteria for restricting exemption eligibility:
        i. Research that is greater than minimal risk
        ii. Research that is FDA regulated, apart from studies eligible under exemption category 6
        iii. Studies involving a Certificate of Confidentiality

2. Determination of exempt status is made according to the following criteria: 45 CFR 46.101(b):
    a. Exempt Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
        i. Research on regular and special education instructional strategies, or
        ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

    b. Exempt Category 2: Research involving the use of educational tests* (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures** or observation of public behavior, unless:
        i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
        ii. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

    *May include non-invasive interventions (e.g., a measured response to a prompt or manipulations of environment that would have typically required review under expedited category 7), if all other exemption criteria are met. Also applies to category 3 below.

**May include collection of audio and/or video recording data if all other exemption criteria are met. Also applies to category 3 below.

Minors[1]: Research involving observations of public behavior is permissible with minors provided the researcher does not participate in the activities being observed.

c. Exempt Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
    i. The human subjects are elected or appointed public officials or candidates for public office; or
    ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d. Exempt Category 4: Research involving the collection or study of existing data*, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

    *Existing data includes data that exist at the time the research is proposed or will exist in the future for non-research purposes.

e. Exempt Category 5: Research and demonstration projects that are conducted by or subject to the approval of department or agency heads*, and which are designed to study, evaluate, or otherwise examine:
    i. Public benefit or service programs;
    ii. Procedures for obtaining benefits or services under those programs;
    iii. Possible changes in or alternatives to those programs or procedures; or
    iv. Possible changes in methods or levels of payment for benefits or services under those programs.

    *Research and demonstration projects sponsored by the State of Michigan in addition to those conducted by or subject to the approval of the federal Department of Health and Human Services will be eligible for review under this exemption category

f. Exempt Category 6: Taste and food quality evaluation and consumer acceptance studies,
    i. If wholesome foods without additives are consumer, 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.

[1]In Michigan, minors (children) are defined as persons who have not yet reached 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. 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. Researcher-initiated changes to protocols that have received an exempt determination must follow GVSU IRB Policy 1010: *Modification to Approved Protocols*.

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.