Grand Valley State University Human Research Review Committee	
Title: *Exemption determinations and research ethics standards*	
Section: 911.	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	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
Effective Date: 05/01/2018	
Related documents: *120: Compliance with applicable laws and regulations* *210: Determination of human subjects research* *310: Researcher responsibilities, qualifications & training* *330: Authorization to conduct human subjects research* *720: Assessing Risk to Vulnerable Participants* *1040: Research post-approval audits* *OP-1: GV charge to the HRRC*	

Policy

Designated Office of Research Compliance and Integrity (ORCI) staff or members of the HRRC 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 HRRC.

Exempt studies are eligible for quality assurance monitoring.

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
        - Studies involving a Certificate of Confidentiality

2. *General Procedures for Determining Exempt Status*

a. The Provost has assigned the HRRC 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 HRRC distributes the authority to conduct exempt determinations to designated ORCI staff, per administrative procedures.
c. Determination of exempt status is made according to the following criteria: 45 CFR 46.101(b):

(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.

(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.

[1]MINORS: 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 may not qualify for exemption except under the following University-declared provisions:

- For non-federally funded research studies that are conducted on GVSU campuses, that involve currently enrolled GVSU students, and that otherwise qualify for review under exemption category #2, seventeen year old regularly-enrolled students may consent to research on their own authority without their parent's permission.
    - Dually-enrolled high school / college students who are not yet eighteen years of age may **not** enroll in research determined to be exempt under category 2.
    - If the investigator wishes to include dually-enrolled students as participants the protocol must receive expedited review (usually under category 7) and

[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 HRRC Policy 120: *Compliance with applicable laws and regulations*

signed parental permission forms are required unless a waiver has been granted by the HRRC.

(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.

(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.

(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.

(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.

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, major changes to a study that potentially may affect any of the following must be acknowledged by the ORCI prior to implementation:*
    i. 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
    ii. Eligibility for exempt status
    iii. Significant increase in the scope of the project

    All other changes are considered minor and may be implemented without notifying the committee. Questions about minor vs. major changes 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.*