Grand Valley State University Institutional Review Board (IRB)	
Title: *Ethical and Legal Standards and Practices for Human Subjects Research*	
Section: 110.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 04/12/2011 Revisied:10/28/2014 Reviewed:10/28/2014 Revised by HRRPPC: 04/24/2018 Revised by IRBPPC: 09/09/2024	Approved by IO: 05/12/2011 Revisions approved: 04/08/2014 Revision approved: 10/28/2014 Revisions approved by IO: 05/23/2018 Revisions approved by IO: 03/13/2020 Revisions approved by IO: 10/25/2024
Effective Date: 10/25/2024	
Related documents: *IRB Policy 120: Compliance with Applicable Laws and Regulations* *IRB Policy 310: Researcher Responsibilities, Qualifications and Training*	

Policy

GVSU has the following written policies for working with research participants, sponsors, researchers, and the Office of Research Compliance and Integrity (ORCI) to uphold legal and ethical standards and practices in research involving human participants. Institutional Review Board (IRB) policies and procedures are available to sponsors, researchers, participants, reviewers and other interested parties via the IRB website and internal documents, as appropriate.

1. Ethical Principles

    a. The primary ethical principles applied to research covered by the ORCI, including protocols that are exempt from the federal regulations pertaining to human subject research, are those set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (Belmont Report). The three main principles are:
        i. **Respect for persons** (e.g., demonstrated by obtaining informed consent, respecting privacy and confidentiality, and adding protections for vulnerable populations)

        ii. **Beneficence** (e.g., demonstrated by balancing risks and benefits)

        iii. **Justice** (e.g., demonstrated by equitable participant selection & distribution of risks and benefits)

    b. In addition, all researchers are expected to adhere to the principles of *expertise* (competent to do the work) and *integrity* (uphold professional principles and standards). Additional ethical principles may be applied when appropriate. Examples include, but are not limited to, the following:
        i. International Council on Harmonization Good Clinical Practice principle on restricted use of placebo-controlled studies;

        ii. Research data management and security; and

iii. Native language or other accommodations for illiterate or non-English speaking participants.

c. Training on the ethical principles and researcher responsibilities are covered in the training tutorials researchers are required to complete (see *IRB Policy 310: Research Responsibilities, Qualifications, and Training*) and in the IRB new member orientation. All sponsor contract templates include explicit notice that ORCI oversight is applicable to all research involving living human participants.

2. Legal Principles

The basic legal principles governing research involving human participants are:

i. Department of Health and Human Services (DHHS) regulations for Protection of Human Subjects (Common Rule) in 45 CFR Part 46.

ii. Food and Drug Administration (FDA) regulations for the Protection of Human Subjects in 21 CFR Parts 50 and 56.

iii. General Data Protection Regulation (GDPR) for research involving European Union participants. See *IRB Policy 120: Compliance with Applicable Laws and Regulations*.

iv. Privacy Rule regulations of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 CFR Parts 160 and 164.

v. Family Educational Rights and Privacy Act (FERPA) for research involving student education records.

vi. Applicable Michigan law. See *IRB Policy 120: Compliance with Applicable Laws and Regulations*.