



Office of the Provost
3090 Zumberge Hall
Maria C. Cimitile, Ph.D.
Provost and Executive Vice President
for Academic and Student Affairs

MEMORANDUM

TO: Institutional Review Board

FROM: Maria C. Cimitile, Provost and Executive Vice President
for Academic and Student Affairs *MC*

SUBJECT: Revised Charge to the Institutional Review Board

DATE: January 21, 2019

Protection of Human Subjects in Research. The Institutional Review Board (IRB) is assigned the authority and responsibility to perform, in an independent and autonomous manner, the key protocol review functions of Grand Valley State University (GVSU) and its affiliates engaged in human subject research. The IRB has final authority to disapprove human subject research at GVSU. No entity or institutional official may overrule IRB disapproval, but GVSU may choose not to support or permit research that the IRB has approved.

The primary function of the IRB is the prospective and continuous review and approval of all GVSU research involving living human participants. Its objective is to ensure that the rights and welfare of research participants are adequately protected and that all activities involving human subjects are in compliance with applicable GVSU policies, external regulations, and research ethics standards.

In partial fulfillment of its obligation under its federal wide assurance, GVSU assigns the IRB 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 approval of research on human subjects that is otherwise exempt from the federal regulations. It further includes the authority to observe the informed consent process and all aspects of the conduct of the research pertaining to the protection of human participants.

All protocols that involve human subjects shall be reviewed at intervals appropriate to the degree of risk as determined by the IRB, regardless of the source of funding, including no funding. The IRB may approve research protocols with or without modifications, or may withhold approval of all or any portion of a protocol.

The IRB is assigned the authority to, and shall review, reports of suspected or alleged protocol violations, participant complaints, potential violations of applicable external regulations or GVSU policies, and other potential non-compliance and unanticipated problems involving risks

to participants or others, per IRB policies. The IRB Chairperson has authority to take action based on committee recommendations, including suspension of a protocol or an investigator's privilege to conduct human subject research. In cases of suspension, the IRB will immediately notify the affected investigator(s), the relevant college dean, school director, the Research Integrity Officer, Authorizing Institutional Official, and other internal and external institutional officials as appropriate. In cases of alleged research misconduct or non-compliance, the IRB shall comply with GVSU policies and procedures on research integrity and provide assistance to the Research Integrity Officer as requested and within its confidentiality policy.

The IRB, at its discretion, may delegate the above outlined responsibilities to staff of the Office of Research Compliance and Integrity in accordance with approved GVSU IRB policies.

Privacy Protections. The IRB also shall serve as the GVSU Privacy Board to ensure compliance with the privacy rules defined in the Health Insurance Portability and Accountability Act (HIPAA). As such, it acts upon requests for waivers or alterations of the Authorization requirements under the Privacy Rule for uses and disclosures of protected health information for research purposes.

Comments on proposed changes to policies and procedures. Upon request, the IRB shall provide comments on draft policies and procedures presented by the GVSU Institutional Review Board Policies and Procedures Committee. Final approval of policies and procedures shall be made by the Authorizing Institutional Official.