TO: Human Research Review Committee

FROM: Gayle R. Davis, Provost and Executive Vice President for Academic and Student Affairs

SUBJECT: Revised Charge to the Human Research Review Committee

DATE: July 11, 2016

Protection of Human Subjects in Research. The Human Research Review Committee (HRRC) 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 primary function of the HRRC 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 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 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 HRRC, but not less than once per year, regardless of the source of funding, including no funding. The HRRC may approve research protocols with or without modifications, or may withhold approval of all or any portion of a protocol.

The HRRC 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. The HRRC 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 HRRC 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. An investigation, using approved procedures, will occur following a suspension of a protocol or an investigator’s privilege to conduct research on human subjects.

In cases of alleged research misconduct, the HRRC 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.

Privacy Protections. The HRRC 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 HRRC shall provide comments on draft policies and procedures presented by the GVSU Human Research Review Policies and Procedures Committee. Final approval of policies and procedures shall be made by the Authorizing Institutional Official.