

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>Authorization to conduct research</i>	
Section: 330.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 05/10/2011 Revised: 08/01/2012 Reviewed: 10/28/2014 Revised: 01/26/2017 Revised: 08/29/2017	Approved by RIO/HRPA: 05/12/2011 Revision approved: 08/01/2012 Revision approved AIO/RIO: 03/06/2017 Revision approved AIO/RIO: 09/26/2017 Revision approved AIO/RIO: 03/13/2020
Related documents: <i>110: Ethical and legal standards &amp; practices for human subjects research</i> <i>120: Compliance with applicable laws and regulations</i> <i>321: Researcher conflict of interest when enrolling GVSU students and employees</i> <i>341: Unapproved research</i> <i>OP-1: GVSU charge to the HRRC</i>	

### **Policy**

It is GVSU policy that research activities involving living human subjects, that meet the federal definition of human subjects research as stated in 45 CFR 46.102, must have written approval from both an appropriate administrative official and the IRB prior to the enrollment of any subjects in the research activity.

### **Procedures**

#### 1. Authorizing Officials

- a. The Authorizing Official (AO) or their designee is a designated person with authority who reviews protocols prior to submission to the IRB and verifies that the proposed study is achievable and meets acceptable levels of risk for the discipline.
- b. IRB procedures require that all proposed research protocols must be authorized by a responsible GVSU administrative authority prior to IRB review and approval. IRB review of proposed research will not be initiated until approval from all required authorizing officials (AO) have been recorded on the GVSU IRB submission platform.
  - i. Deans: the AO is the Provost or their designee.
  - ii. Department/Unit/Program heads: the AO is the appointing Dean or their designee.
  - iii. Faculty members: the AO is the academic unit head or their designee.
  - iv. Staff members: the AO is the unit head/supervisor or their designee.
  - v. Research involving teams of GVSU varsity student athletes: authorization from the head athletic trainer is required in addition to all other authorizing official signatures.
- c. The research authorization process at GVSU identifies a university designated person that assumes responsibility for assuring the following considerations:
  - i. Proposed study is feasible: the researcher and supporting department,

- unit, or program have sufficient time, materials, and resources to complete the project as planned and described in the proposal.
- ii. Researchers are appropriately qualified: the researcher(s) and other key personnel are appropriately qualified to supervise and/or conduct this study safely such that risks to participants are minimized.
  - iii. Data are secure: The researcher and the department, unit, or program has the resources to implement the data security provisions described in the proposal.
  - iv. Scientific validity is assured: the study design, procedures and methods of data analysis meet the relevant discipline's standards for scientific merit and validity for academic research.
  - v. Procedures are followed: the researcher has met all college, department, unit, and program requirements for review and approval of this research.
  - vi. Permissions sought: appropriate permissions to access private information for research purposes have been secured.
  - vii. Non-compliance is reported: direct knowledge of noncompliance on the part of the research team will be reported to the Office of Research Compliance and Integrity, the IRB, or the Research Integrity Officer.

## 2. Electronic Signatures

- a. Pursuant to Section 11.100 of Title 21 of the *Code of Federal Regulations*, Grand Valley State University intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, for purposes of authorizing human subjects research activities, are the legally binding equivalent of traditional handwritten signatures.

**Note:** Federal Register/Vol. 62, No. 54/Thursday, March 20, 1997/Rules and Regulations/13457.