Grand Valley State University Institutional Review Board (IRB)	
Title: *Researcher Responsibilities, Qualifications and Training*	
Section: 310.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revised: 09/10/2013 Reviewed: 10/28/2014 Revised by HRRPPC: 1/26/2017 Revised by IRBPPC: 3/30/2021 Revised by IRBPPC: 4/18/2022	Approved by RIO/HRPA: 2/16/2012 Revision Approved: 09/10/2013 Revision Approved by AIO/RIO: 3/6/2017 Revisions Approved by AIO/RIO: 05/06/2021 Revisions Approved by AIO/RIO: 04/21/2022
Effective Date: 04/21/2022	
Related documents: *050: Records Retention and Destruction* *110: Ethical and Legal Standards & Practices for Human Subjects Research* *120: Compliance with Applicable Laws and Regulations* *210: The Determination of Human Subjects Research* *220: Determining Engagement in Human Subjects Research* *320: Researcher Conflict of Interest* *330: Authorization to Conduct Human Subjects Research* *710: Assessing Risk to Research Participants* *730: Collection, Management and Security of Research Information* *810: Informed Consent: General* *910: Continuing Review and Approval of Selected Non-Exempt Protocols* *1010: Modifications to Approved Protocols* *1020: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events* *1030: Research Noncompliance* *1040: Post-Approval Compliance Review* *1110: Collaborating Researchers Not Covered by an FWA* *1120: Collaborating Research with Investigators Covered by an External FWA* *OP-4: GVSU Conflict of Interest Policy* *GVSU BOT Policy 4.1.10: General Personnel Policies for Faculty and Staff – Obligations of Appointees*	

Policy

1. GVSU faculty and staff may serve as the Principal Investigator (PI) when conducting covered human subjects research if they are appropriately qualified by training and experience for their designated research role.

2. A GVSU undergraduate or graduate student may not serve as the PI of an IRB protocol.

3. Individuals who are conducting engaged human subjects research under the oversight of GVSU as outlined in *IRB Policy 220: Determining Engagement in Human Subjects Research* are required to be named as IRB protocol personnel and approved by the IRB prior to performing human subjects research activities. For additional requirements regarding externally-affiliated (i.e., non-GVSU) researchers performing research under the oversight of GVSU, see *IRB Policy 1110: Collaborating*

Researchers Not Covered by an FWA and *IRB Policy 1120: Collaborating Research with Investigators Covered by an External FWA*.

4. All individuals named on a GVSU IRB protocol must document in the protocol application they are appropriately qualified by training and experience for their designated research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and competency to conduct research-related procedures and interventions such that risks to the safety and welfare of study participants are minimized. All protocol personnel must maintain current training while the study remains active with the IRB.

5. A determination of researcher competency to conduct human subjects research-related procedures and interventions is the responsibility of, and shall be made by, the IRB.

6. The PI is ultimately responsible for the conduct of a study, although they may delegate tasks to other members of the research team. Responsibilities of the PI include, but are not limited to:
    a. Full responsibility for the conduct of a study
    b. Acquiring all necessary approvals of research activities *before* commencing such activities (see *IRB Policy 330: Authorization to Conduct Human Subjects Research*)
    c. Supervision of the research team
    d. Retaining research records, including data, for the minimum required period (see *IRB Policy 050: Records Retention and Destruction*)
    e. Oversight of the research study and the informed consent process (see *IRB Policy 810: Informed Consent: General*)
    f. Assuring compliance with applicable policies and regulations (see *IRB Policy 120: Compliance with Applicable Laws and Regulations*)
    g. Assuring that confidentiality of data and protection of subjects is maintained (see *IRB Policy 730: Collection, Management and Security of Research Information*)
    h. Assuring safety of research participants by using ethical and sound research design (see *IRB Policy 710: Assessing Risk to Research Participants*)
    i. Notifying the IRB of changes to the protocol during the approval period (see *IRB Policy 1010: Modifications to Approved Protocols*)
    j. Complying with continuing review and IRB reporting requirements (see *IRB Policy 910: Continuing Review and Approval of Selected Non-Exempt Protocols* and *IRB Policy 1020: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events*)
    k. Assuring compliance with the GVSU policy on research integrity (see *GVSU BOT Policy 4.1.10: General Personnel Policies for Faculty and Staff – Obligations of Appointees)*

7. Responsibilities of researchers and research staff include, but are not limited to:
    a. Knowing what constitutes human subjects research and under what circumstances approval from the GVSU IRB and/or another IRB is required (see *IRB Policy 210: The Determination of Human Subjects Research*)

b. Acquiring all necessary approvals of research activities *before* commencing such activities
c. Assuring compliance with applicable policies and regulations (see *IRB Policy 120: Compliance with Applicable Laws and Regulations*)
d. Assuring that confidentiality of data and protection of subjects is maintained (see *IRB Policy 730: Collection, Management and Security of Research Information*)
e. Assuring safety of research participants by using ethical and sound research design (see *IRB Policy 710: Assessing Risk to Research Participants*)
c. Assuring compliance with the GVSU policy on research integrity (see *GVSU BOT Policy 4.1.10: General Personnel Policies for Faculty and Staff – Obligations of Appointees)*

8. Researchers who are collaborating with a GVSU researcher and who are otherwise unaffiliated with GVSU must:
    a. Comply with the policies, procedures, and directives of GVSU and the IRB
    b. Complete the same IRB training requirements as GVSU personnel or provide evidence they are appropriately qualified by training and experience for their designated research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant ethical and professional standards; and competency to conduct research-related procedures and interventions such that risks to the safety and welfare of study participants are minimized
    c. Provide evidence of adequate personal liability insurance as applicable and directed by GVSU and the IRB

9. Additional Requirements
   Researchers may be subject to other university and/or professional requirements. These include, but are not limited to, the following:
    a. Unit-Specific Requirements. All researchers must meet the minimum qualifications required by the policies and practices of the unit authorizing the research.
    b. Mandated Reporters. All researchers who are mandated reporters by state law or by professional ethics standards must disclose their reporting obligations when submitting a research proposal to the Authorizing Official, to the IRB in the protocol application, and to research participants in the informed consent document.
    c. Regulatory Compliance. All proposed research activities must undergo a systematic review by the PI that is appropriate to the nature of the research before it is initiated. This review should include consideration of, and assured compliance with, each of the following university or regulatory policies and committee authorizations as relevant to the research:
        i. Human Research Protections (IRB approval and policy compliance)
        ii. Animal Research Protections (Institutional Animal Care and Use Committee approval if appropriate)
        iii. Biosafety Requirements (Institutional Biosafety Committee approval if appropriate)

iv. Chemical Safety Requirements
v. Laboratory Safety Requirements (including Radiation Safety Committee and/or Laser Safety Committee approval if appropriate)
vi. Social Security Number Security
vii. Confidentiality Agreement and Security Policy
viii. Privacy Rule (Health Insurance Portability and Accountability Act [HIPAA]/Health Information Technology for Economic and Clinical Health [HITECH]/General Data Protection Regulation [GDPR])
ix. Data Security
x. Intellectual Property
xi. Conflict of Interest
xii. Family Education Right and Privacy Act (FERPA)
xiii. Laboratory Safety Checklist (OSHA)
xiv. Export Control Regulations

Procedures

1. Evidence of researcher qualifications and compliance
    a. Evidence that researchers have met the required qualifications is provided by, but are not limited to, the following:
        i. Securing the authorization to conduct the research from the appropriate administrative authorizing official prior to securing approval from the IRB
        ii. Providing evidence of appropriate training in research-related procedures and interventions
        iii. Providing evidence of appropriate training in human subjects research protections and responsible conduct of research
        iv. Maintaining appropriate oversight of each research study, as well as research staff and trainees, and appropriately delegating research responsibilities and functions so as to minimize risks to all participants
        v. Following the procedural requirements of the approved research protocol or plan, GVSU policies and procedures, and the requirements or directives of the IRB
        vi. Following reporting requirements in accordance with GVSU policies and procedures, IRB directives, and applicable laws, regulations, codes, and guidance

2. Training requirements for IRB protocol personnel
    a. All protocol personnel must complete GVSU-approved training in both Human Subjects Research and Responsible Conduct of Research. This training is valid for three years.
    b. A lapse occurring in any of the above training requirements for active researchers on an active protocol will be treated as noncompliance according to *IRB Policy 1030: Research Noncompliance*.
    c. The IRB may, at its discretion, require additional training be completed for any protocol member prior to approving that individual to work on a protocol and/or

to perform certain procedures on a protocol.