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	Approved by RIO/HRPA: 2/16/2012 Revision approved: 09/10/2013 Revision approved by AIO/RIO: 3/6/2017 Revision approved by AIO/RIO: 3/13/2020
Related documents: *110: Ethical and legal standards & practices for HS research* *120: Compliance with applicable laws and regulations* *320: Researcher conflict of interest* *341: Unapproved research* *1010: Modifications to approved protocols* *1030: Research non-compliance* *1040: Research post approval audits* *OP-4: GVSU Conflict of Interest Policy* *GVSU Policy on Research Integrity*	

Policy

1. GVSU faculty and staff may serve as the Principle Investigator 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 serve as a co-investigator in conducting covered human subjects research when an appropriately trained, qualified and authorized faculty research advisor serves as a Principal Investigator to supervise the research to assure the safety of research procedures and compliance with all relevant IRB directed requirements including data security.

3. All GVSU faculty and student, affiliated researchers, and research staff must document 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; competency to conduct research related procedures and interventions such that risks to the safety and welfare of study participants are minimized.

4. A determination of researcher competency to conduct covered human subjects research related procedures and interventions is the responsibility of and shall be made by the IRB in accord with the memorandum of understanding from the GVSU office of general counsel (February, 2012).

5. The Principal Investigator is ultimately responsible for the conduct of a study, although they may delegate tasks to other members of the research team. Responsibilities of the

Principal Investigator include, but are not limited to:

a. Full responsibility for the conduct of a study
b. Oversight of the research study and the informed consent process
c. Supervision of the research team
d. Assuring compliance with applicable GVSU policies and regulations
e. Assuring compliance with applicable Federal Policy Regulations
f. Assuring that confidentiality of data and protection of subjects is maintained
g. Assuring safety of research participants by using ethical and sound research design
h. Seeking IRB approval prior to engaging in research activities
i. Notifying IRB of changes to the protocol during the approval period
j. Complying with continuing review and audit requirements.

6. Responsibilities of researchers and research staff include, but are not limited to:
    a. Knowing what constitutes human subjects research
    b. Knowing under what circumstances approval from the IRB and/or another IRB is required
    c. Acquiring all necessary approvals of research activities *before* commencing such activities
    d. Knowing the duties, requirements, and accountability as an investigator
    e. Knowing the GVSU policy on Research Integrity

7. 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. 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
    d. Be granted access to the protocol file on the GVSU IRB submission platform beginning with the initial submission of the protocol.

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 in the form of an approved training program as required by the IRB
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. Documentation of Required Standards
    a. The unit authorization procedure (authorizing official's signature or other process) shall be understood to attest that each of the following have been considered and determined to meet the requirement standards.
        i. Qualified Leadership. All researchers must meet the minimum qualifications required by the policies and practices of the unit authorizing the research.
        ii. 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 department chair and to the IRB.
        iii. Regulatory compliance. All proposed research activities must undergo a systematic review by the principal investigator 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:
            1. Human Research Protections (IRB approval and policy compliance)
            2. Animal Research Protections (IACUC approval if appropriate)
            3. Biosafety Requirements
            4. Chemical Safety Requirements
            5. Laboratory Safety Requirements
            6. Social Security Number Security
            7. Confidentiality Agreement and Security Policy
            8. Privacy Rule (HIPAA/ HITECH)
            9. Data Security
            10. Intellectual Property
            11. Conflict of Interest
            12. Family Education Right and Privacy Act (FERPA)
            13. Laboratory Safety Checklist (OSHA)

3. Modifications to Approved Protocols
    a. Any proposed changes in key personnel or other modifications to approved protocols must be in compliance with IRB **policy *#1010: Modifications to approved protocols***. This includes IRB approval of a new principal investigator or other key personnel prior to their participating in an approved study.

4. Required Reporting Adult Abuse: MCL
    a. Adult Abuse: MCL §§ 400.11(a) http://legislature.mi.gov/doc.aspx?mcl-400-11a
        i. This statute defines the reporting requirements for suspected adult abuse, neglect or exploitation. It applies to the following persons who "suspect or ha[ve] reasonable cause to believe that an adult has been abused, neglected, or exploited":
            1. "[a] person who is employed, licensed, registered, or certified to provide health care, education, social welfare, mental health, or other human services;"
            2. "an employee of any agency licensed to provide health care, education, social welfare, mental health, or other human services;"
            3. "a law enforcement officer;" or
            4. "an employee of the office of the county medical examiner"
        ii. This law requires the individual to "make immediately, by telephone or otherwise, an oral report to the county department of social services of the county in which the abuse, neglect, or exploitation is suspected of having or believed to have occurred."
    b. Child Abuse: MCL §§ 722.623 defines individual required to report child abuse or neglect.
        i. Individual are required to report child abuse or neglect; report by telephone or online reporting system; written report; contents; transmitting report to centralized intake; copies to prosecuting attorney and probate court; conditions requiring transmission of report to law enforcement agency; pregnancy or presence of sexually transmitted infection in child less than 12 years of age; exposure to or contact with methamphetamine production.
        ii. Sec. 3. (1) An individual is required to report under this act as follows:
            1. A physician, dentist, physician's assistant, registered dental hygienist, medical examiner, nurse, person licensed to provide emergency medical care, audiologist, psychologist, marriage and family therapist, licensed professional counselor, social worker, licensed master's social worker, licensed bachelor's social worker, registered social service technician, social service technician, a person employed in a professional capacity in any office of the friend of the court, school administrator, school counselor or teacher, law enforcement officer, member of the clergy, or regulated child care provider

who has reasonable cause to suspect child abuse or neglect shall make immediately, by telephone or otherwise, an oral report, or cause an oral report to be made, of the suspected child abuse or neglect to the department.

iii. Within 72 hours after making the oral report, the reporting person shall file a written report as required in this act. If the reporting person is a member of the staff of a hospital, agency, or school, the reporting person shall notify the person in charge of the hospital, agency, or school of his or her finding and that the report has been made, and shall make a copy of the written report available to the person in charge.

iv. A notification to the person in charge of a hospital, agency, or school does not relieve the member of the staff of the hospital, agency, or school of the obligation of reporting to the department as required by this section. One report from a hospital, agency, or school is adequate to meet the reporting requirement. A member of the staff of a hospital, agency, or school shall not be dismissed or otherwise penalized for making a report required by this act or for cooperating in an investigation.