

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>Compliance with applicable laws and regulations</i>	
Section: 120.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 09/13/2011 Revised 01/14/2014 Reviewed: 10/28/2014 Revised: 04/24/2018	Approved by RIO/HRPA: 09/23/2011 Revisions approved: 01/14/2014 Revisions approved by AIO/RIO: 05/12/2018 Revisions approved by AIO/RIO: 3/13/2020
Effective Date: 05/14/2018	
Related documents: <i>110: Ethical and legal standards and practices for HS research</i> <i>310: Researcher responsibilities, qualifications and training</i> <i>730: Collection, management and security of research information</i> <i>820: Waivers, alterations and exceptions to informed consent process and documentation</i> <i>911: Exemption determinations and research ethics standards</i> <i>950: External entities lacking an IRB</i> <i>1020: Unanticipated problems and adverse events</i> <i>1120: Collaborative research with investigators under and external FWA</i> <i>G-13 Guidance on Multi-institutional Collaborative Research</i>	

Policy

All researchers must comply with relevant laws in the localities where they conduct research on human participants, including US tribal (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe), territorial and foreign localities. In the case of variances between U.S. federal laws and state or local laws, or between U.S. and foreign laws and regulations, the more protective standard typically takes precedence.

Procedures

1. Exceptions
 - a. **Age of majority:** For purposes of consenting to participate in research, the age of majority is determined by the locality in which the participant is physically located.
 - b. **Internet surveys and interviews:** For internet based survey research for purposes of providing independent consent to participate, the minimum age is 18 years. Surveys and internet-based interviews involving persons under the age of 18 require either documented parental/guardian permission, or a waiver from the IRB.
2. Michigan Laws Pertaining to Research on Human Participants
 - a. Michigan has no state statute directly addressing human subjects research. However, both the Michigan *Mental Health Code* and the *Michigan Public Health Code* each reference the protection of human subjects in research in specific contexts, and both require that all covered research comply with the provisions of the Common Rule (45 CFR 46).

- b. In cases of mandated reporting of abuse or neglect, Michigan law requires certain licensed professionals to report suspected abuse or neglect of adults and children. The reporting requirements for licensed professionals do not distinguish between information gained as a care provider or as a researcher. For additional information on these requirements, see ***IRB Policy 310. Researcher responsibilities, qualifications, and training.***

3. Research on Participants in a Foreign Country

- a. To identify relevant foreign laws pertaining to research regulations, including the age of majority, see the Office of Human Research Protections' ***International Compilation of Human Research Standards*** (link available on the GVSU Office of Research Compliance and Integrity web site).
- b. **Foreign Territories.** If the proposed research is conducted in whole or in part in a foreign country or territory then authorization to conduct the study must be provided in the form of an official attestation statement issued by an appropriate official in the local (foreign) jurisdiction that the project is in compliance with local regulations and laws. In most cases this will involve approval of the study by a local IRB.
- c. If there are no relevant regulations or laws in the foreign country pertaining to the proposed research, or no local IRB, then an attestation statement to that effect must be provided in English by an academic administrator or government official from the local jurisdiction. The person providing the attestation may not be a collaborator on the research project with the GVSU faculty or student researcher. In most cases it will be sufficient to have the equivalent of a department head or dean from a local academic institution to provide the attestation statement.
- d. In exceptional circumstances appeals to specific requirements noted in (b) or (c) above may be made to the IRB in writing.

4. Research Involving Non-U.S. Institutions

- a. GVSU researchers who conduct research activities at or collaborate with non-U.S. institutions in human subjects research must meet the requirements of U.S. Federal laws pertaining to human subjects research, as specified in the IRB policies and procedures, as well as any laws that govern research that is conducted in the foreign locality.
- b. Formal review and approval by the IRB is required, including for research that is determined by the IRB to be exempt from the federal regulations. (See *IRB Policy 911: Exemption determinations and research ethics standards*)
- c. Researchers also must provide as appropriate evidence of approval(s) from foreign institution(s) before the research may commence. (See *IRB Policy 1110: Multi-site research and 1120: Collaborative research with investigators under an external FWA*).

5. Research Involving European Participants and/or Being Conducted in a European Country

- a. The General Data Protection Regulation (GDPR), which establishes protections for the privacy and security of personal data about individuals in European Economic Area (EEA)

countries, applies to the collection and use of personal information: 1) through on-the-ground activities in EEA countries, 2) that is related to the offering of goods and services to EEA residents, or 3) that involves the monitoring of the behavior of EEA residents.

- b. The GDPR, as it relates to research:
 1. Establishes the circumstances under which it is lawful to collect, use, disclose, destroy, or otherwise process ‘personal data’;
 2. Establishes certain rights of individuals in EEA countries, including rights to access, amendment, and erasure (i.e., right to be forgotten);
 3. Requires researchers to implement appropriate technical and organizational security measures to ensure a level of data security that is appropriate to the risk of the data; and
 4. Requires notification to data protection authorities and affected individuals following the discovery of a personal data breach, which is a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored, or otherwise processed.
- c. The GDPR defines ‘personal data’ as “any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.”
- d. GVSU and GVSU researchers are required to abide by the GDPR when applicable. Human research studies involving identifiable information are subject to the GDPR if personal data is being collected from one or more research participants who are physically located in an EEU country at the time of data collection (even if the participant is not an EEA resident), and/or if identifiable personal data is being transferred from an EEA country to a non-EEA country.
- e. An active (“opt-in”) consent process with the participant providing a clear affirmative action must be used for all GDPR-covered research.
- f. Any data breach occurring on a project involving GDPR-covered research must be reported **within 24 hours** upon identification of the breach to the appropriate university GDPR compliance official (Vice Provost for Research Administration) and the Office of Research Compliance and Integrity. The breach must also be reported to the IRB as an Unanticipated Adverse Event within 7 calendar days (see *IRB Policy 1020: Unanticipated problems and adverse events*).
- g. In cases where US regulations conflict with the GDPR, the US regulations take precedence. Please contact the ORCI if questions arise about conflicting laws.