Grand Valley State University Institutional Review Board (IRB)	
Title: *Compliance with Applicable Laws and Regulations*	
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 by HRRPPC: 04/24/2018 Revised by IRBPPC: 01/31/2023	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 Revisions approved by AIO: 02/06/2023
Effective Date: 02/06/2023	
Related documents: *110: Ethical and Legal Standards and Practices for Human Subjects Research* *310: Researcher Responsibilities, Qualifications and Training* *730: Collection, Management and Security of Research Information* *820: Waivers, Alterations and Exceptions to Informed Consent Process and Documentation* *911*: *Exemption Determinations and Research Ethics Standards* *950: Protocol Review Agreements with External Entities Lacking an IRB* *1020: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events* *1120: Collaborating Research with Investigators Covered by an External FWA* *G-13 Guidance on Multi-Institutional Collaborative Research*	

Policy

1. 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.

2. 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.

3. 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. This applies to all modalities of research, including virtual, online, and in-person.

    b. Formal review and approval by the IRB is required for such research, 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: Collaborating Researchers Not Covered by an FWA* and *Policy 1120: Collaborative Research with Investigators Covered by an External FWA*).

4. Research Physically Conducted in a Foreign Country

    a. If the GVSU researcher(s) will be physically located in a foreign country or territory to conduct the research, 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 indicating the project is in compliance with local regulations and laws. In some cases, this will involve approval of the study by a local IRB/ethics board.

    b. If there are no relevant regulations or laws in the foreign country pertaining to the proposed research, or no local IRB/ethics board, 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.

    c. Appeals to waive/modify the specific requirements noted in (a) or (b) above may be made to the IRB in writing with proper justification (e.g., researcher is originally from the foreign country and/or has extensive experience conducting research within the country).

5. Research Subject to the European General Data Protection Regulation (GDPR)

    a. An active ("opt-in") consent process with the participant providing a clear affirmative action must be used for all GDPR-covered research.

    b. 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: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events*).

Procedures

1. The IRB will review protocols in accordance with applicable federal, international, state, and local laws.

2. The Office of Research Compliance and Integrity and the IRB rely on GVSU's Office of General Counsel for assistance, as needed, in the determination of applicability and the interpretation of Michigan law and the laws of any other jurisdiction where research with human subjects is conducted.

Guidance

1. To identify relevant foreign laws pertaining to research regulations, including the age of majority (i.e., the age at which an individual is legally considered to be an adult), researchers should consult the Office of Human Research Protections' International Compilation of Human Research Standards.

2. Age of Majority

    a. The age of majority varies by country and sometimes within a single country. In the United States most, but not all, states utilize 18 years old as the age of majority.

    b. For purposes of consenting to participate in research, the age of majority is determined by the locality in which the participant is physically located.

    c. Laws governing age of majority may change over time. As such, if you are unsure about a locality's age of majority, it is recommended that you conduct an Internet search to determine the answer. If you need assistance, please contact the Office of Research Compliance and Integrity.

    d. <u>In-Person Research</u>
    For research involving physical interventions, researchers are responsible for determining the minimum age of consent for the locality where the research is being conducted.

    e. <u>Internet-Based Research</u>.

        a. If the researchers are recruiting participants from a specific locality (e.g., surveys or interviews of citizens in a particular country), the researchers are responsible for determining the age of majority for that location.

        b. If the researchers are not targeting recruitment of participants from a specific locality (e.g., surveys in which respondents can participant from any location), the age of majority cannot be guaranteed with certainty prior to recruitment. As such, when confirming the age of the participant during enrollment in such research interventions, it is best practice to ask the participant to confirm that they are of the age of majority (or, "a legal adult") in the location from which they are participating. Phrasing the question in this manner is preferred over asking participants to confirm that they are over the age of 18, as some locations utilize an age of majority of 19 or older.

        c. Surveys and internet-based interviews involving persons under the age of majority require either documented parental/guardian permission or a waiver of this requirement from the IRB.

3. 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 shall at a minimum 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 mandated reporters, see IRB *Policy 310: Researcher Responsibilities, Qualifications, and Training*.

4. Guidance on Research Subject to the GDPR

a. The GDPR establishes protections for the privacy and security of personal data about individuals in European Economic Area (EEA) countries and 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 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. 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.