Grand Valley State University Institutional Review Board	
Title: *Collaborating Research with Investigators Covered by an External FWA*	
Section: 1120.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revisions approved: 10/29/2013 Revised by HRRPPC: 11/28/2017 Revised by IRBPPC: 11/04/2024	Approved by RIO/HRPA: 02/16/2012 Revisions approved: 11/11/2013 Revisions approved by AIO/RIO: 04/16/2018 Revisions approved by IO: 12/15/2024
Effective Date: 12/15/2024	
Related documents: *110: Ethical and Legal Standards and Practices for Human Subjects Research* *120: Compliance with Applicable Laws and Regulations* *220: Determining Engagement in Human Subjects Research* *310: Researcher Responsibilities, Qualifications and Training* *1110: Collaborating Researchers Not Covered by an FWA*	

Policy

1. When a GVSU student or employee collaborates to conduct human subjects research with a non-GVSU student or employee who is associated with an assured institution, the IRB review and approval of said research may be delegated to GVSU's IRB or to the collaborating institution's IRB via an IRB Authorization Agreement (IAA). This agreement is in lieu of dual-IRB review. The Institutional Official (IO), or the IO's designee, approves IAAs for review of single protocol studies as well as durable agreements or multi-project agreements.

2. If the assurances from GVSU and the other institution do not assure equivalent participant protections relevant to the proposed research, the more protective requirements apply. The determination of equivalent protections will be made by the IO or the IO's designee. If the non-GVSU researcher's activities are not covered by an equivalent Federalwide Assurance (FWA), the IO may require the collaborating researcher to submit an Individual Investigator Agreement.

Procedures

1. Exempt Research

    a. IAAs are not required for exempt research and no formal agreement is needed. External institutions may accept the exempt determination completed by the GVSU IRB or they may elect to conduct their own review.

        i. If the external institution requires an IAA for an exempt study, the process described below in Procedures 2 will apply.

    b. The non-GVSU investigator will not be listed as a member of the research team on the GVSU IRB protocol application. The non-GVSU investigator is not required to complete the GVSU-required investigator training or conflict of interest disclosure process; instead, they are required to abide by the training and disclosure requirements of their IRB.

c. If an external institution has already determined the research is exempt, the GVSU investigator will submit the IRB protocol application in the electronic document management system and will indicate that GVSU will rely on another IRB's approval.

    i. The GVSU investigator will submit the following materials with their request:
        1. The external IRB's exempt determination letter;
        2. The protocol or IRB application submitted to the external IRB;
        3. Any additional materials relevant to the study, such as surveys or data use agreements.
    ii. The Office of Research Compliance and Integrity (ORCI) will conduct a brief review to verify the exempt determination and will administratively accept the determination if the exempt determination can be verified.

2. Execute the IRB Authorization Agreement (IAA)

    a. For collaborative non-exempt research involving a GVSU investigator and non-GVSU investigator(s), the IAA documents which institution has agreed to serve as the reviewing IRB and which will be relying on that review. Requests for an IRB Authorization Agreement may be initiated by investigators or IRBs at either institution and must include the following information as approved by institutional officials as outlined in the respective IRB policies and procedures:

        i. Name of each institution and its IRB name
        ii. Institutional FWA numbers and, if the research is federally funded, the scope of assurance applicability (i.e., funded studies and subparts) and expiration date of the FWA
        iii. Institution's IORG number
        iv. Contact information for each institution's IRB office or Chair

    b. Unless required by the grant or funding award to enter into a single IRB arrangement, both GVSU and the external institution may choose to enter into a reliance or to conduct their own review.

    c. The IAA negotiation process may occur concurrently with initial IRB review or with a modification. In rare circumstances, it can be completed prior to IRB submission.

    d. If the IAA is not executed, the research will be reviewed by both IRBs.

3. GVSU as Reviewing IRB

    a. When GVSU serves as the reviewing IRB for non-exempt research, the GVSU PI is accepting responsibility for providing oversight of the non-GVSU investigator to ensure compliance with GVSU IRB policies and applicable regulations.

b. When completing the IRB protocol application in the electronic document management system, the researcher will indicate that GVSU will serve as the IRB of record.

c. The non-GVSU investigator will not be listed as a member of the research team on the GVSU IRB protocol application. The non-GVSU investigator is not required to complete the GVSU-required investigator training or conflict of interest disclosure process; instead, they are required to abide by the training and disclosure requirements of their IRB.

d. The non-GVSU investigator is not listed as a member of the research team on the GVSU IRB protocol application and does not complete the GVSU-required investigator training or conflict of interest disclosure process. The non-GVSU investigator is required to abide by the training and disclosure requirements of their IRB.

e. Once the protocol application has been submitted, the ORCI will contact the IRB at the collaborating institution to initiate the IAA, if this process has not already been initiated.

f. The process of negotiating the IAA occurs simultaneously with IRB review. Final IRB approval may be issued before the IAA is executed, although the non-GVSU investigator cannot begin conducting research activities until the IAA has been executed and IRB approval has been issued.

4. GVSU as Relying IRB

a. When relying on another institution's IRB approval, the GVSU investigator is responsible for ensuring compliance with relevant regulations and GVSU IRB policies as well as the IRB policies of the reviewing IRB.

b. When completing the IRB protocol application in the electronic document management system, the researcher will indicate that GVSU will rely on another IRB's approval.

c. The non-GVSU investigator will not be listed as a member of the research team on the GVSU IRB protocol application. The non-GVSU investigator is not required to complete the GVSU-required investigator training or conflict of interest disclosure process; instead, they are required to abide by the training and disclosure requirements of their IRB.

d. The GVSU investigator will submit the following materials with their request:

   i. A brief description of the GVSU investigator's roles and responsibilities in the proposed research project. This description should focus on any direct interaction or intervention with the study participants and/or with the private identifiable information collected from or about study participants. It should be framed within the context of the larger project's overall aims and procedures.
   ii. Informed consent document(s), if applicable;
   iii. Current external IRB approval letter(s);

iv. Any additional materials specified by the GVSU IRB.

e. Once the protocol application has been submitted, the ORCI will contact the IRB at the collaborating institution to initiate the IAA, if this process has not already been started.

f. The GVSU investigator cannot begin conducting research activities until the IAA has been executed and a formal letter documenting ORCI administrative approval has been issued.

5. Multi-Site Research

a. When a *GVSU* investigator is the lead investigator on a multi-site study, the protocol must include a written management plan for coordinating data collection from all study sites and disseminating information to all sites that might be relevant to the protection of research participants. The IRB, other participating institutions and all research study sites must be notified in a timely fashion of significant adverse events or unanticipated problems affecting study participants, regardless of where the event or problem occurred.

b. For a multi-site protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of OHRP Expedited review category (8) (a), (b), or (c) are satisfied for that site. However, with respect to category (8)(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled in the research protocol at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator at a particular site nor the IRB has identified any additional risks from any site or other relevant source.