

Grand Valley State University Human Research Review Committee	
Title: <i>Collaborating research with investigators covered by an external FWA</i>	
Section: 1120.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012	Approved by RIO/HRPA: 02/16/2012
Revisions approved: 10/29/2013	Revisions approved: 11/11/2013
Revised by HRRPPC: 11/28/2017	Revisions approved by AIO/RIO: 04/16/2018
Effective Date: 05/01/2018	
Related documents: <i>110: Ethical and legal standards and & practices for HS research</i> <i>120: Compliance with applicable laws and regulations</i> <i>310: Researcher responsibilities, qualifications and training</i> <i>1110: Collaborating non-GVSU researchers not covered by an FWA</i>	

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 Grand Valley’s HRRC or to the collaborating institution’s IRB via an IRB Authorization Agreement (IAA). This agreement is in lieu of dual-IRB review, which is the useful and default process. The HRRC Chair is authorized to approve IAAs for review of single protocol studies. Durable agreements or multi-project agreements require approval from the University RIO.
2. If the assurances from GVSU and the other institution do not assure equivalent participant protections relevant to the proposed research, it is the policy of the HRRC that the more protective requirements apply. The determination of equivalent protections will be made by the chair of the GVSU HRRC. At the discretion of the HRRC chair, the non-GVSU researcher may be required to submit an Individual Investigator Agreement if that researcher’s activities are not covered by an equivalent FWA.

Procedures

1. Collaborative research involving a Grand Valley *principal or co-investigator* and either non-GV investigators or non-GV controlled research study sites covered by a non-GV FWA

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, scope of assurance applicability (i.e., funded studies and subparts) and expiration date of the FWA
- iii. Institution’s IORG number
- iv. Institution’s accreditation and its expiration date
- v. Contact information for each institution’s IRB office or Chair

2. Collaborative research involving GVSU students, faculty or staff *as key personnel* in a research project led by a non-GVSU Principle investigator
 - a. Any GVSU faculty, staff or student researcher engaged in non-exempt research* as a collaborating key personnel** (i.e. *not* PI or co-PI) under the supervision of a non-GVSU principle investigator (PI) who is employed by an assured institution must either request that the HRRC defer protocol oversight to the other assured institution's IRB, or submit the following materials to the HRRC:
 - i. GVSU HRRC protocol review application that briefly describes the GVSU researcher'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 personally 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. Description of all anticipated risks and benefits to participants;
 - iii. Copy of the consent document(s), if applicable;
 - iv. Copy of current external IRB approval(s);
 - v. Evidence that the non-GVSU PI agrees to open communication with the GVSU HRRC.
 - vi. Any additional materials specified by the GVSU HRRC
 - b. HRRC approval will apply only to the GVSU researchers' activities related to the project. The GVSU researcher may be required to submit additional materials at the direction and discretion of the external institution's IRB.

3. 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 HRRC, 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 HRRC 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 HRRC has identified any additional risks from any site or other relevant source.

**Exempt research is research that has been determined by the chair of an assured IRB, or designee, to qualify as exempt based on the current exemption categories allowed under the federal regulations and as interpreted through OHRP guidance.*

***Key personnel: Individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, including the evaluation and management of benefits and risks, enrolling participants, performing interventions, interactions, or observations, or accessing personal, identifiable information. Key personnel differ from investigators in that they may have a more limited or specific role and may have decreased overall project ownership.*