

Grand Valley State University Human Research Review Committee	
Title: <i>Collaborating researchers not covered by a FWA</i>	
Section: 1110.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revised by HRRPPC: 11/28/2017	Approved by RIO/HRPA: 02/16/2012 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>1120: Collaborating researchers covered by an external FWA</i>	

Policy

As an assured institution, GVSU has the option to extend coverage of its FWA to qualifying collaborating independent and institutional investigators for research projects that are led by a principle investigator from GVSU. Each non-GVSU collaborating researcher must submit a signed Independent Investigator Agreement (IIA) form unless they are covered by an external FWA (see HRRC Policy 1120: *Collaborating researchers covered by an external FWA*). This applies to key personnel involved in the research. The IIA binds the non-GVSU researchers' activities to the GVSU FWA, and to oversight and governance by the HRRC according to its policies and procedures.

The GVSU Federalwide Assurance includes 45 CFR 46 and applies to all non-exempt research activities. HRRC Policy 110: *Ethical and Legal Standards and Practices for HS Research*; HRRC Policy 120: *Compliance with applicable laws and regulations*; and HRRC Policy 310: *Researcher responsibilities, qualifications and training* applies to all HRRC-approved research activities including exempt studies.

Definitions

1. A collaborating *independent* investigator is:
 - a. not otherwise an employee, student or agent of GVSU, and
 - b. not acting as an employee or agent of any institution with respect to his or her involvement in the research being conducted.

2. A collaborating *institutional* investigator is:
 - a. not otherwise an employee, student or agent of GVSU, and
 - b. acting with respect to his or her involvement in the research being conducted as an employee or agent of a non-assured institution that does not routinely conduct human subjects research.

3. *Key personnel* are persons having direct interaction or interventions with research participants or direct access to personally identifiable information collected from or about the participants.

Procedures

1. Requirements for Extension of an FWA

- a. GVSU may extend its FWA to investigators not otherwise affiliated with GVSU provided all of the following conditions are satisfied:
 - i. The principal investigator from GVSU directs and appropriately supervises all collaborative research activities to be performed by the collaborating investigator.
 - ii. The FWA coverage is extended by a written Individual Investigator Agreement (IIA) for each collaborating investigator who will be engaged in the research. Copies of the IIA must be included in the protocol file on ORCI's electronic database management system.
 - iii. For collaborating *institutional* investigators, the appropriate authorities at the non-assured institution, as relevant, state, in writing, that the conduct of the research is permitted at their institution.
 - iv. The chair of the HRRC approves the extension of the assurance through the IIA.
 - v. The following documents are made available by the principal GVSU investigator to the collaborating investigator as relevant and appropriate to the collaborator's role in the study:
 1. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* or other internationally recognized equivalent (see section B.1. of the *Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions*);
 2. HHS regulations for the protection of human subjects at 45 CFR 46 and 21 CFR 50 and 56, or other procedural standards designated by a non-U.S. institution under its FWA (see section B.1. of the *Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions*).
 - vi. The collaborating investigator understands and accepts the responsibility to comply with the standards and requirements stipulated in the documents referenced in v (1) and (2) above.
 - vii. The collaborating investigator agrees to comply with the requirements of the FWA and applicable terms as directed by the chair of the HRRC.
 - viii. The collaborating investigator agrees to make him/herself familiar with all GVSU and HRRC policies and procedures that are relevant to the research and agrees to fully comply with such.
 - ix. The collaborating investigator agrees to comply with all applicable federal, international, state, and local laws, regulations, and procedures that may provide additional protections for human subjects participating in the research.

- x. The collaborating investigator agrees to abide by all determinations of the HRRC and agrees to accept it as the final authority, including but not limited to directives to suspend or terminate participation in research activities conducted under the IIA.
- xi. The collaborating investigator agrees to complete any educational training as required by the sponsoring investigator's unit or the HRRC prior to initiating research covered under the IIA.
- xii. The collaborating investigator acknowledges and agrees to cooperate with the HRRC in its initial and continuing review, record keeping, reporting, post-approval monitoring and certification for the research covered by the IIA and to provide all information requested by the HRRC in a timely fashion.

2. Research Conducted at a Site that Does Not Have an IRB

If non-exempt research is to be conducted at a site that does not have an IRB, investigators must submit evidence of cooperation from an institutional official to confirm that the institution in question approves the conduct of the proposed research at its site. A copy of the letter or other evidence must be dated and include the official's contact information and be uploaded to the protocol file on IRBManager.

3. Multi-Site Research

- a. When a GVSU investigator is functioning as the lead investigator on a multi-site study, the research protocol must include a management plan for coordinating data from all sites and disseminating information to all sites that might be relevant to the protection of research participants. The HRRC, other relevant institutions and all study sites must be notified in a timely fashion of significant adverse events or unanticipated problems affecting research 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 1998 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.

Background

An assured institution is one that holds a federal Office for Human Research Protections (OHRP)-approved Federalwide Assurance (FWA). An assured institution may extend its FWA to cover

collaborating independent investigators and collaborating institutional investigators for any Department of Health and Human Services (DHHS)-conducted or supported human subjects research when:

- a. the research is being conducted under the direction and supervision of a principle investigator (PI) from an assured institution, *and*
 - b. the relevant non-assured institution does not routinely conduct human subjects research, *and*
 - c. the relevant non-assured institution is *not* the primary awardee for a DHHS-supported award for non-exempt human subjects research
- See ***OHRP Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction to the Individual Investigator Agreement***