

Grand Valley State University Human Research Review Committee Procedure	
Subject: <i>Investigators not otherwise affiliated with GVSU in GVSU approved research activities.</i>	
Section: 18.0	This procedure supersedes those previously drafted
Initially adopted as procedure on June 18, 2007	Approved by: Dean of Graduate Studies and Grants Administration, 11-15-2007.
Related Sections:	

Human subjects research is conducted by GVSU as an assured institution, that is, research involving human subjects is permitted under the FWA approved by the OHRP. Research collaborations outside the University may involve the following two types of collaborating individual investigators:

A. A collaborating **independent** investigator is:

1. not otherwise an employee or agent of the assured institution;
2. conducting collaborative research activities outside the facilities of the **assured** institution; and
3. not acting as an employee of **any** institution with respect to his or her involvement in the research being conducted by the assured institution.

B. A collaborating **institutional** investigator is:

1. not otherwise an employee or agent of the **assured** institution;
2. conducting collaborative research activities outside the facilities of the **assured** institution;
3. acting as an employee or agent of a **non-assured** institution with respect to his or her involvement in the research being conducted by the **assured** institution; and
4. employed by, or acting as an agent of, a **non-assured institution** that does not routinely conduct human subjects research.

C. The Individual Investigator Agreement (IIA) is the sole assurance option for collaborating investigators at GVSU. The IIA is used to extend the applicability of the

GVSU FWA for one or more research protocols to cover either collaborating **independent** investigators or collaborating **institutional** investigators. OHRP permits GVSU to extend its FWA to investigators not otherwise affiliated with GVSU provided all of the following conditions are satisfied:

1. The principal investigator at GVSU directs and appropriately supervises all collaborative research activities to be performed by the collaborating investigator outside the assured institution.
2. The FWA coverage is extended by a written IIA agreement for each collaborating investigator who will be engaged in the research being conducted by the assured institution. Copies of the IIA must be included in the protocol file in the HRRC office.
3. For collaborating institutional investigators, the appropriate authorities at the non-assured institution state in writing that the conduct of the research is permitted at their institution.
4. GVSU and the HRRC approve the extension of the assurance through the IIA.
5. The following documents are made available to the collaborating investigator:
 - (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (see <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>) or other internationally recognized equivalent (see section B.1. of the *Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions* on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>);
 - (b) the HHS regulations for the protection of human subjects at 45 CFR part 46 (see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) or other procedural standards designated by a non-U.S. institution under its FWA (see section B.3. of the *Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions* on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>);
 - (c) the FWA and applicable terms for GVSU; and

(d) the relevant HRRC policies and procedures for the protection of human subjects of the assured institution.

6. The collaborating investigator understands and accepts the responsibility to comply with the standards and requirements stipulated in the documents referenced in the preceding paragraph and to protect the rights and welfare of human subjects involved in research conducted under the IIA used by GVSU.

7. The collaborating investigator agrees to comply with all other applicable federal, international, state, and local laws, regulations, and procedures that may provide additional protections for human subjects participating in research conducted under the IIA or other written agreement used by the assured institution.

8. 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 terminate participation in designated research activities conducted under the IIA.

9. The collaborating investigator agrees to complete any educational training required by GVSU and/or the HRRC prior to initiating research covered under the IIA.

10. The collaborating investigator agrees not to enroll subjects in research under the IIA prior to the research being reviewed and approved by the HRRC.

11. The collaborating investigator agrees to report promptly to the HRRC any proposed changes in the research conducted under the IIA and further agrees not to initiate changes in the research without prior HRRC review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

12. The collaborating investigator agrees to report immediately to the HRRC any unanticipated problems involving risks to subjects or others in research covered under the IIA.

13. The collaborating investigator, when responsible for enrolling subjects, agrees to obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by the HRRC.

14. The collaborating investigator acknowledges and agrees to cooperate with the HRRC in its initial and continuing review, record keeping, reporting, and certification for the research covered by the IIA and to provide all information requested by the HRRC in a timely fashion.