

Grand Valley State University Institutional Review Board	
Title: <i>Protocol review agreements with external entities lacking an IRB</i>	
Section: 950.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 09/13/2011	Approved by RIO/HRPA: 09/23/2011
Related documents: <i>010: IRB board composition</i> Updated 09/10/13	

Policy

Requests for human subjects research protocol review agreements will be considered and decided by the IRB with approval of the Research Integrity Officer (RIO) on a case by case basis. Service contracts between GVSU and the external entity must be reviewed and approved by the RIO and other GVSU administrative entities as appropriate. The RIO has the authority to waive the fee schedule in individual cases.

Procedures

1. Considerations for an agreement to perform protocol reviews for an external entity will include, but are not limited to the following:
 - a. Current or desired relationship between GVSU and the external entity;
 - b. How well the external entity's mission coincides with the University's mission;
 - c. External entity's estimated number of protocols needing exempt, expedited and full board review by the IRB for the review period specified in the service agreement;
 - d. IRB's capacity to review and oversee protocols from an external entity;
 - e. Availability of the appropriate expertise for the IRB to conduct the requested protocol reviews;
 - f. GVSU internal support for a protocol review service agreement;
 - g. Acceptance of the IRB oversight authority, all IRB policies, and a service agreement review fee schedule by the external entity.

2. Each contract shall specify the following components of the IRB authorization agreement:
 - a. The service agreement is for IRB *review* of research protocols only, *not* for approval of protocols. There is no guarantee or assumption of approval.
 - b. If the protocol is approved, monitoring and compliance assurance services are included for the entire period over which the approval is extended, usually one year. If the research continues beyond the initial approval period, a continuing review fee shall be due for each subsequent review of non-exempt protocols.
 - c. If the protocol is not approved on initial submission, subsequent submissions of a revised protocol for the same research study are not subject to an additional fee.

- d. Review of proposed changes to an approved protocol are subject to an additional fee.
- e. All fees are due within thirty days after the board has completed its review and issued a final determination letter of approval or lack of approval.

Background

External entities lacking an institutional review board (IRB) sometimes approach the IRB to provide fee-for-service protocol reviews of human subjects research. GVSU seeks to establish and foster mutually beneficial partnerships with external entities as part of its strategic positioning initiatives. The IRB may assist in supporting this goal by extending its professional services to select external GVSU partner entities holding a federal wide assurance, but lacking an IRB.