

<b>Grand Valley State University</b> <b>Human Research Review Committee Procedure</b>	
Subject: <i>Protocol Review for External Partner Entities Lacking an IRB</i>	
Section: 18.2	This procedure supersedes those previously drafted
Initially adopted as procedure on October 6, 2009	<b><i>Approved by:</i></b> Human Research Review Administrator
Related Sections: 18.0; 18.1	

GVSU partner entities who lack an institutional review board sometimes approach the HRRC to provide fee-for-service protocol reviews of human subjects research at their institution. GVSU seeks to establish and foster mutually beneficial partnerships with external entities as part of its strategic positioning initiatives. Among these partnership initiatives is support for high quality research and the assurance of adequate research subject protections. The Human Research Review Committee is committed to supporting these goals through extending its professional services to selected external GVSU partner entities who have a federal wide assurance but lack an institutional review board.

Requests for human subjects research protocol review agreements will be considered and decided by the HRRC with approval of the Human Research Protections Administrator and Research Integrity Officer (HRPA/RIO) on a case by case basis.

Considerations for agreements will include but are not limited to the following:

1. Relationship of the requesting institution to GVSU and its mission;
2. Size and mission of the requesting institution;
3. Expected number of protocols needing exempt, expedited and full board review per year;
4. Availability of technical expertise to HRRC to conduct appropriate protocol reviews;
5. Acceptance of the protocol review fee schedule;
6. GVSU internal support for a protocol review agreement;

GVSU reserves the right to waive the fee schedule in individual cases. Service contracts between GVSU and the external entity must be reviewed and/or approved by the HRPA/RIO and other GVSU administrative entities as appropriate. Each contract shall specify the following components of the service agreement.

1. The service agreement is for HRRC review of covered research protocols only; there is no guarantee or assumption of approval prior to review. If the protocol is approved, updating and compliance assurance services are included in the for the entire period of initial approval, usually one year. If the protocol review and approval is renewed for a subsequent year, a continuing review fee shall be due for the second review.
2. If the protocol is disapproved, and a new protocol is submitted a second review fee shall be charged.
3. The fee is due within thirty days after the board has completed its review and issued a final determination letter (approval or disapproval).