

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>IRB Review Fees</i>	
Section: 040	
Approved by IRBPPC: 04/23/2020	Approved by AIO/RIO: 04/27/2020
Effective Date: 04/27/2020	
Related documents: <i>Policy 210: The Determination of Human Subjects Research</i> <i>G-3: Guidance on Research Activities Not Requiring IRB Approval</i>	

## **Policy**

1. IRB review fees are charged to maintain the expertise and efforts needed to perform the numerous components of appropriate review, assessment and approval of research protocols, and to support post-approval monitoring.
2. Fees do not influence the decisions reached by the IRB. If the IRB votes to table or disapprove a research protocol, no additional fee will be charged for reconsideration.
3. Research subject to IRB review fees
  - A. The following human subjects research is subject to GVSU IRB review fees:
    - i. Research conducted by GVSU researchers that is partially or fully sponsored by industry or other for-profit companies and that is covered by a Fee-for-Service Agreement.
    - ii. Research conducted by institutions in which there is no collaboration with GVSU researchers but GVSU serves as the reviewing IRB.
  - B. A request for a fee waiver or fee reduction may be made by contacting the GVSU Office of Research Compliance and Integrity (ORCI); however, approval of such requests is rare.
4. Research excluded from IRB review fees
  - A. The following human subjects research is not subject to this policy:
    - i. Research conducted by GVSU researchers or in collaboration with GVSU researchers that is not sponsored, in whole or in part, by industry or other for-profit companies
    - ii. Research conducted by GVSU researchers or in collaboration with GVSU researchers that is partially or fully sponsored by industry or other for-profit companies and that is covered by a Research Collaboration Agreement stipulating that the IRB review fees are waived

- iii. Research conducted by GVSU researchers or in collaboration with GVSU researchers that includes students conducting the research as part of a for-credit course (e.g., capstone course, undergraduate research course, etc.).
- iv. Research conducted by GVSU researchers or in collaboration with GVSU researchers that is partially or fully sponsored by industry or other for-profit companies, but which is funded via federal\*, state, county, and local governments, or not-for-profit organizations (\*refer to NIH exception in Procedures, Section 5)
- v. Research conducted by GVSU researchers or in collaboration with GVSU researchers that is sponsored by funding agencies that prohibit payment of IRB fees

## **Procedures**

1. Fees will be administered by the GVSU ORCI. Fees collected for IRB review will be used by the ORCI to support professional development for IRB members, infrastructure costs (e.g., electronic database management systems), and/or outreach for GVSU researchers.
2. IRB review fee schedule

The fee amounts will be reviewed periodically and are subject to change.

<b>Type of Review</b>	<b>Full Board</b>	<b>Expedited</b>	<b>Exempt</b>
Initial review	\$2000	\$1000	\$500
Amendment	\$1000	\$500	\$500
Continuing Review	\$1000	\$500	\$500
Reportable Event	No charge	No charge	No charge
Personnel Change	No charge	No charge	No charge

3. Requests for fee waivers or fee reductions
  - a The most common reason for a fee waiver or reduction is when the sponsor is supporting the research by providing only certain supplies or nominal support, rather than funding the entire research.
  - b Requests may be made by emailing the GVSU ORCI ([rci@gvsu.edu](mailto:rci@gvsu.edu)). The request for fee waiver or reduction should include all of the following information:
    - i A summary of the study objectives and procedures
    - ii Justification for the fee waiver/reduction, including the amount of the requested reduction if not requesting a complete waiver
    - iii The study budget summary
  - c Requests will be reviewed by the Vice Provost for Research Administration (VPRA). The VPRA may choose to seek additional guidance from other institutional personnel as

needed, including, but not limited to: ORCI staff, the IRB Chair and/or Vice Chair, and the Institutional Official.

- d The Principal Investigator (PI) will be notified of the VPRA's initial decision and given the opportunity to respond and provide any additional information they feel is relevant to the decision. Following the response from the PI, the VPRA will reconsider the decision if necessary, and render a final decision. All decisions by the VPRA are final. The ORCI will inform the requestor in writing of the VPRA's final decision.

#### 4. IRB review and outcomes

- a. The review process and timetable for submissions remains the same for all research, regardless of whether the research is subject to IRB review fees.
- b. Fees are charged for services rendered. Because the IRB and the ORCI commit full resources to each review, the fees are due in full even if the IRB does not approve the study, subjects are never enrolled, or the study is terminated before objectives are achieved.
- c. IRB fees are non-refundable.

#### 5. Direct versus indirect costs for National Institutes of Health (NIH) grants

- a. IRB fees are generally recovered as indirect costs in the Facilities and Administrative Costs rate.
- b. If the GVSU IRB will serve as the single IRB for multi-site research funded by the NIH, incremental costs incurred that exceed the indirect rate may be charged as a direct cost.

### **Background**

1. NIH expects that all sites participating in a non-exempt multi-site research study funded by the NIH will use a single IRB for that study. If the costs incurred to provide single IRB oversight exceed the indirect cost allowance, the additional expenses may be charged as direct costs with appropriate budget justification. Refer to the following NIH documents:
  - a. NOT-OD-16-094: "Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research"
  - b. NOT-OD-16-109: "Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research"
  - c. NIH FAQs on Single IRB Policy for Multi-Site Research
2. Types of Agreement
  - a. Fee-for-Service Agreements: These agreements are legally binding contracts used when GVSU expertise is applied to solve problems within the business community. They include

GVSU standards and terms of conditions that enable entities to conduct relevant work, the results of which will be owned by the business.

- b. Research Collaboration Agreements: These agreements are a written contract between GVSU and one or more organizations that help define the relationship during a research program. This agreement develops the intent to share data and research materials, as well as publication of research findings. Generally, these forms also include terms and conditions on how the results of the research will be shared between parties.
- c. More information about agreements can be found on the GVSU Technology Commercialization Office website (<https://www.gvsu.edu/tco/agreements-17.htm>).