



Human Subject Research Guide

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Submitting a Research Protocol to the Human Research Review Committee at Grand Valley State University

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This guide is designed to aid researchers conducting human subjects research through Grand Valley State University (GVSU) with the research protocol review process. The Human Research Review Committee (HRRC) is the body at GVSU which is responsible for approving human subjects research. The HRRC conducts an ethical review of submitted research protocols. This process takes 17 days on average (cf. 2010 Human Research Protection Program Annual Report), and research cannot begin before approval by the HRRC is given.

Submitting a protocol to the HRRC is a multistep process.

Step 1: CITI Training

The Collaborative Institutional Training Initiative (CITI) is a “web based training program in human research subjects protections” (www.citiprogram.org). The training (slide-show format) and short quiz assessments are designed to teach new researchers (and refresh seasoned researchers on) the tenets of research ethics.

The Principal Researcher is expected to complete CITI research ethics training. Other researchers participating in the active research protocol should, but are not required, to complete CITI training.

Online CITI Training Program

- Free online research ethics training
- Encouraged for all researchers
- Register at www.citiprogram.org
 1. Select GVSU from list
 2. Click “Add a Course”
 3. Select Question 1 for new CITI users

To complete CITI training, go to <http://www.citiprogram.org>. Register on their website, and when selecting affiliation, be sure to select “Grand Valley State University” so the HRRC will be able to verify your completion of the program.

Step 2: Write Research Protocol

If you are already planning your research study, this step is likely partially complete already. If you have not yet written your protocol, first consult the new protocol form on the HRRC website: <http://www.gvsu.edu/hrrc> , then click on “IRB Forms and

Documents”, then click on “Application for New Protocol Review” in the table named “IRBNet Forms”.

This form will guide you through the steps of creating a protocol.

One of the items you need to determine is the review level. There are three levels of review: Exempt, Expedited, and Full Board review.

The level of review is a federal definition which is described here: <http://www.hhs.gov/ohrp/> (right-hand column), and in (much) more detail here: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

If you are having trouble selecting a level of review, consider consulting colleagues who have done similar research in the past. In most cases (for example) simple surveys are considered exempt level of review.

Step 3: Submit Research Protocol

When you are ready to submit your research protocol, go to: <https://www.irbnet.org> and register (typically the principal researcher manages files on IRBnet, but other researchers may as well). When you register and are asked for affiliation, be sure to select “Grand Valley State University”.

To submit a protocol, you will need to upload two files:

1. Application for new protocol review
2. Supplemental study materials (e.g. survey instrument, diagram of testing device, etc)

You can contact the HRRC office at any step along the way for assistance:

Phone: 616-331-3197

Email: hrrc@gvsu.edu

You can find answers to Frequently Asked Questions at: gvsu.edu/hrrc , then click on “Frequently Asked Questions”

Instructions on what forms to submit and how can be found on the HRRC website: <http://www.gvsu.edu/hrrc> , then click on “IRB Forms and Documents”. Consult the two tables of downloadable .doc files on that page.

Once you have uploaded the protocol, the principal research will need to electronically sign the package (the package consists of the protocol and supplementary documents). The Authorizing Official (research advisor, department head, college dean, or provost) will also review and sign the package before it is submitting to the HRRC review board.

“Note: The [HRRC] observes all university holidays, and does not process applications during exam week or between academic terms.” (<http://www.gvsu.edu/hrrc>)

Emails will be sent to all researchers attached to the protocol on IRBnet at each step of the review process.

Remember, you cannot begin your research until the HRRC has approved your protocol.

After the HRRC has completed its review of your protocol, we’d appreciate it if you would fill out a short survey about this guide: <http://goo.gl/6UQn>