

PROTECTING HUMAN PARTICIPANTS IN RESEARCH

Submitting an Application

An IRB Application to conduct research can be obtained from the GWU Graduate School office or online at www.gardner-webb.edu/.../irb/policy.../policy-procedure-manual11.08.pdf.

Principal investigators are expected to develop a research protocol that should include the following:

- Specific research objectives
- Research methods and procedures
- Statistical/analytical methods to be used
- How data will be monitored
- Security measures for the protection of research data
- Funding/grant source (if appropriate)
- Human subjects issues such as: potential risks and benefits of the study, informed consent, inclusion/exclusion criteria

ADDITIONAL INFORMATION

Further Reading

Amdur, R. (2003). *Institutional review board handbook*. Boston: Jones and Bartlett.

Bankert, E.A., & Amdur, R.J. (2006). *Institutional review board: Management and function* (2 nd. ed.). Boston: Jones and Bartlett.

Hilton, E. (2005). *Working effectively with and within IRBs: A practical guide for investigators, sponsors, and IRB members*. Hagerstown, MD: University Publishing Group.

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

Contact Us

For additional information, please contact us at the Graduate School Office at 704-406-3020.

Institutional Review Board

Gardner•Webb
University

Pro Deo et Humanitate



What is the IRB?

The IRB exists to support and monitor the ethical research of undergraduate students, graduate students, faculty, and any other researchers requesting supervision.

The IRB supports research ethics as described by the U.S. Department of Health and Human Services, summarized by the following points:

- Research participants must be kept free from harm.
- Research participants must give their informed consent before participating in research.
- Research participants have the right to anonymity. At no time should their name be associated with data.
- Research participants have the right to withdraw without penalty.
- Research participants must be debriefed after their participation is complete.

The IRB consists of members appointed by Chairs and Deans. The IRB then elects its own Chair who serves a two-year term. The Dean of the Graduate School serves as the IRB's Institutional Administrator. The IRB also includes a Cognizant Representative who is selected from outside of GWU. The IRB approves and reviews all research involving human subjects.

All researchers who interact with human subjects to collect data must complete a required educational program on ethics and procedures for the use of human subjects in research before the IRB may approve a proposal.

The IRB policy does not apply to professors and students collecting otherwise “exempt” data for educational purposes in the classroom. Anonymous educational tests and surveys are included in this category. Anonymous publicly available data and program evaluations are also exempt. Any professor may require students collecting “exempt” data to go through the IRB process.



Levels of Review

Exempt Research is conducted in regular classes at Gardner-Webb University under the supervision of a professor. Participation is anonymous and the dependent variable (self-esteem test, stress survey, etc.) is not controversial (surveys not on sensitive subjects, such as sexual behavior or drugs).

Departmental/school IRB representatives (two) may approve research at this level. The activity is initially reviewed by the IRB but is not subject to continuing IRB review if granted exemption.

Expedited Research may be approved at the departmental/school level by two IRB Representatives and the IRB Chair or the IRB Administrator. It does not require discussion at a convened board meeting. This category includes minor changes in previously approved research and research that is considered “minimal risk” (e.g., collecting data on weight or blood samples, test/retest data). Expedited review protocols are subject to continuing review by the IRB on an annual basis.

Non-Exempt (Full) Review Research requires review by the full IRB. This would include research that is more than “minimal risk” in that it could cause harm or discomfort greater than that encountered in daily life or during the performance of routine physical or psychological examinations or tests. Non-exempt research also includes research:

- where informed consent is not possible;
- involving deception;
- involving researchers outside of GWU
- involving vulnerable populations.