Institutional Policies and Procedures for Review of Research

Part I: Introduction and General Guidelines

Purpose and Guiding Philosophy of the Research Review Board

As mandated by federal laws and national policies, West Virginia Wesleyan College has established a Research Review Board (RRB). The purpose of this board is to protect the rights and welfare of human subjects and to assure the humane treatment of vertebrate animals used in research and the classroom. The Research Review Board:

- Develops policies and procedures regarding research or classroom studies of humans and vertebrate animals.

- Maintains and disseminates guidelines for faculty and students who plan research with humans or vertebrate animals.
- Reviews all proposed research and classroom studies involving humans and vertebrate animals to assure compliance with appropriate statutes and standards of care.
- Evaluates proposed studies to ensure that they comply with general ethical principles.
- Monitors ongoing studies to ensure compliance with established policies, procedures and applicable statutes.

The purpose of proposal review by the Research Review Board is to assure in advance and during the study that appropriate steps are taken to protect the rights and welfare of human or animal research subjects. The RRB therefore fulfills the duties typically given to Institutional Review Boards *and* Institutional Animal Care and Use Committees. The functions of the Review Board are administrative, educational and consultative. The committee's primary purpose is to facilitate optimum protection of human or animal subjects while also ensuring the academic freedom of researchers and instructors.

To meet this objective, the RRB uses group deliberations to review and approve research protocols and related materials (e.g., informed consent documents, protocols and study-related materials) to ensure that:

1) risks to human or animal subjects are minimized by using sound research design,
2) the risks to human or animal subjects are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be expected to result,
3) the selection of humans subjects for participation in research is equitable, and that of animals, appropriate for the research question;
4) the informed consent of human subjects is obtained in advance,
5) where appropriate, the research plan makes provision for monitoring of data collected to ensure safety of human or animal subjects, and

6) there are adequate provisions to protect the privacy of human subjects and the confidentiality of data collected from them.

Definition of "Research"

"Research" is defined in the Code of Federal Regulations as "a systematic investigation designed to develop and contribute to generalizable knowledge." Wesleyan's Research Review Board extends that definition to reflect the following:

“Research is any project using systematic methodology to collect, analyze, and draw conclusions from data. Whether the results are generalizable or published is not the issue; it is the investigator’s approach to the research question that is important in defining research.”

This definition of research includes

1. Research conducted by faculty, students and staff of the College, or supported by the College and who are acting in connection with their responsibilities and relationships to the College, or who intend to use the name of the College in any report of research activity; or
2. Studies conducted "off-campus" by a faculty member, student or staff member who is the principal investigator or co-principal investigator; or
3. Studies conducted by the use of College records by faculty, staff or students; or
4. Studies that are conducted by students and intended to enhance student learning in a particular subject area, whether carried out by students independently or during class time; and
5. Studies conducted by individuals outside the College when such studies involve College students or employees as their main subjects, or when such studies involve use of student or personnel records.

Composition and Responsibilities of the Research Review Board

The Research Review Board consists of a minimum of five faculty members, one member from the community not employed by the College, nor a student at the College. A physician or veterinarian is a consulting member of the board and will provide medical or veterinary advice and recommendations as needed; however, voting membership is limited to the faculty and community member.

The full Research Review Board meets at least twice a semester to review proposals, and the dates of such meetings are announced in advance. Additionally, the RRB revises College policies regarding research as needed and provides guidance to faculty, students and staff who are preparing proposals. At least once a year, animal care facilities are inspected by a subcommittee of the RRB to ensure compliance with applicable regulations and accepted standards of care. The RRB makes required reports concerning protection of humans and animals involved in research at WVWC to Federal or State agencies or to other organizations that may fund research at the College.

All proposals, submitted materials, and reviews by the board are housed in the IRRB organizational repository on Blackboard until otherwise changed by the IRRB Chairperson or Provost.

Review Categories

Research to be reviewed by the Board falls into one of the following three categories:

Exempt from RRB Review
Expedited Review
Full Board Review

Criteria for studies to be reviewed under these categories are discussed separately under the "Protection of Animals in Research" and "Protection of Human Subjects in Research" sections of this document. In all cases, researchers must submit required forms or documentation; however, the documentation required for "exempt" studies is minimal, and "expedited" studies will be reviewed rapidly by a subcommittee of the board. Researchers, in consultation with their Department Chairs, make the initial determination of review category. If the Board determines that a particular study should be reviewed under a different category, the principal investigator will be notified immediately and may be asked to provide additional documentation.

General Guidelines for Submitting Proposals

The Institutional Research Review Board (IRRB) adopts the following guidelines for its consideration of applicable research proposals and the format for the submission of applicable research proposals. These guidelines shall be subject to periodic review and change as deemed appropriate by the Review Board.

The general guidelines are supplemented by specific procedures and formats discussed separately in the "Protection of Animals in Research" and "Protection of Human Subjects in Research" sections of this document. Investigators should consult both the general guide and the area specific to the proposed project.

1. No research involving humans, covered vertebrates, or endangered species may be conducted without prior approval by the IRRB.

2. Copies of these policies and guidelines will be made available electronically on the IRRB page on the wvwc.edu website and housed in the IRRB organizational repository on Blackboard.
3. Research proposals can be submitting on a rolling basis, however, with the Monday of the 14th week of the semester as the final week applications can be submitted.
4. The principle investigator(s) shall apply using the Google Form listed on the IRRB webpage. Students submitting proposals must include the faculty advisor information on the application. Faculty advisors will receive a copy of the application from the IRRB Chair and confirm the submission.
5. The principle investigator(s) and co-investigators must complete Collaborative Institutional Training Initiative (CITI) training modules as part of the application process and prior to RRB approval.

6. A quorum of more than half of the Review Board membership must be present for the consideration of any proposals or other relevant matters.
7. A majority vote of board members present is necessary for approval of full reviews and for actions unrelated to proposals. Proposals approved by less than the full Board under the "Exempt" or "Expedited" categories will be reviewed periodically to ensure that guidelines are being followed.
8. Principal investigators may, at their own discretion or the RRB's request, attend the meeting during which their proposals are considered.
9. The Chair of the RRB shall provide written notification of the Review Board's actions. This notification shall be sent to the principal investigator when the RRB acts on a proposal.
10. The format for submission of research proposals shall be as specified in the "Protection of Animals in Research" and "Protection of Human Subjects in Research" sections of this document. Each proposal should be as brief as possible and still address each of the pertinent concerns indicated in those sections.
11. Faculty who include faculty-designed research components in courses or who carry out their own research with student assistants must submit a proposal in the usual manner prior to initiating a project. Faculty who wish to repeat an approved project in subsequent classes need only submit a "Request for Continuing Use…" form unless substantial changes are made in the project.

Reporting Requirements for Approved Projects

For a continuing project (or lab exercise repeated in subsequent semesters), the principal investigator should file an extension form ("Request for Continuing Use…") once annually, during September. This allows the Review Board to keep track of projects for reporting purposes. If the methods or other aspects of the project change substantially, then a new application is required. When the project is complete, the

principal investigator should file a brief form indicating completion of the project. All forms are available in Appendix A and electronically.

Part II: Protection of Human Subjects in Research and the Classroom

Introduction

General Information

These policies are designed to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of West Virginia Wesleyan College. "Research" is defined earlier in this document to include scholarly research, institutional research, and certain types of class assignments. Use of human subjects for research or instructional purposes is subject to review and approval of the Research Review Board (RRB). The guidelines, in compliance with applicable federal statutes, must be followed whenever human subjects are involved.

Regulations

Research with human subjects at WVWC is carried out in compliance with the U.S. Department of Health and Human Services (HHS) and other Federal agencies' regulations. The **Code of Federal Regulations (45 CFR 46)** requires this provision for the protection of human subjects in research, and applies to all studies in all locations, whether funded or unfunded, and whether conducted by faculty, students, or staff. It also applies to persons unaffiliated with the College who wish to investigate subjects under the protection of the College. No such study may begin before it has been so approved, and may not continue past its approved term. Further information concerning the protection of human subjects is available through the Office of Protection from Research Risks at the National Institutes of Health (OPRR, 1998a).

Guidelines for Proposals Involving Human Subjects

Exempt from Review

These research activities involve no more than minimal risk and may include classroom studies, surveys, observation of public behavior, non-invasive collection of physiological data, or analysis of existing data that involves human subjects. Whether or not a study is exempt from full review, it must meet accepted standards of protection of privacy and the subject's right to refuse participation without penalty.

Exempt studies are reviewed by a member of the RRB to determine whether the study meets the criteria for exemption. If so, the study is approved. If the study does not clearly meet the criteria, it is referred back to the author for submission under the expedited or full review procedures. Faculty and staff who conduct research using public, secondary data sets where confidentiality is assured, need not submit a proposal.

If a research project qualifies for exemption from review under the criteria listed below, the researcher must still complete the standard research proposal application to be submitted to the IRRB committee. The IRRB committee will make the final review-type designation.

A project is exempt if all the research activities belong in one or more of the following categories:

A. Research involving the collection or study of existing data including documents, records and pathological or diagnostic specimens if:

1. these sources are publicly available or
2. the information is recorded by the investigator in such a manner that human subjects cannot be identified

B. Research conducted in established or commonly accepted educational settings and involving normal educational practices. This includes:

1. research on normal and special education instructional strategies

2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management techniques

C. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to the subjects.

1. cognitive, diagnostic, aptitude or achievement tests if the data are recorded so that subjects cannot be identified
2. none of the investigator's current students are subjects *unless*
   a. The study is conducted solely for program assessment, or
   b. The study is a class assignment whose sole purpose is to enhance student learning.

D. Research involving only the observation of public behavior if

1. The behavior does not place the subject at criminal or civil risk.
2. The behavior does not deal with sensitive or personal behavior.

E. Research involving only surveys or interviews if the project does not deal with:

1. sensitive aspects of behavior or
2. highly personal behavior of the subjects themselves.

F. Research involving only surveys and interviews with public, appointed or elected officials

G. Research involving only taste and food quality evaluations

H. Recording data from subjects 18 years of age and older, using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance, and do not involve input of matter or significant amounts of energy to the subject, or an invasion of the subject's privacy. It also includes such procedures as weighing, measurement of sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, and use of diagnostic electromagnetic radiation outside the visible range (for example, x-ray and microwaves).

Expedited Review

Expedited review is the review of a protocol by two or three members of the RRB, and it is used only for low or minimal risk research. Researchers whose projects are subject to expedited review must submit a full project description, following the guidelines established by the RRB. If the study does not clearly meet the criteria set forth below, the researcher will be notified and the entire board will review the proposal.

Definition of minimal risk:

Minimal risk means that the probability of physical or psychological harm does not exceed that encountered in the ordinary daily life or during routine physical or psychological examinations or tests. Examples of activities that pose minimal risk include:

A. Collection of hair, and nail clipping, in a non-disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction; collection of surface cells from the skin or mouth if done without injury.
B. Voice recordings made for research purposes, such as investigations of speech defects.
C. Moderate exercise by healthy volunteers.
D. Collection of blood samples by venipuncture, in amounts not exceeding 450 millimeters in an eight-week period. and no more often than two times per week, from subjects 18 years of age or older, and who are in good health and not pregnant, and

E. Studies involving only minimal risk of psychological harm related to deception concerning the purpose of the study.

Board Review (Full Board)

Full Board review is required for research involving risk of physical or psychological harm greater than that encountered in daily living or during routine examinations or tests. Research involving experimental medication protocols, or research involving potentially harmful deception requires full board review.

Format for submitting proposals involving human subjects

All submissions must include a cover sheet (see Appendix A) and a proposal appropriate to the category of review. Each proposal should be as brief as possible and still address each of the pertinent concerns

indicated in the following section. Proposals that fall under the "Exempt" category need to file only the "Application for Exemption" form with attachments, as stated above. Proposals that fall under the "Expedited" or "Board Review" categories should follow the format, below:

Format For Expedited Or Full Board Review of a Proposal Involving Human Subjects

1. Title
2. Name of the principal investigator(s) [Note: If the principal investigator is a student rather than a faculty member, then the faculty member supervising the research proposal, course number and title are to be indicated.]

3. Overview or Abstract
4. Brief summary of purpose(s) or goal(s)
5. Methods
    A. Materials and/or procedures to be used (Include copies of questionnaires, if applicable.)
    B. Procedures for identification of subjects
    C. Method of subject selection
6. Ethical considerations:
    A. Informed consent by subjects (How is this obtained? Include a copy of the consent form.)
    B. Address any other ethical concerns specific to this study
7. Description of procedures for subject withdrawal without prejudice.
8. Relationship, if any, to course credit for subject participation.
9. Explanation of risk of physical and/or psychological harm
10. Privacy, confidentiality, and anonymity (How does the study protect privacy?)
11. Explanation of any deception used, including the purpose of the deception
12. Provisions for subject debriefing as appropriate
13. Reporting of results (How and where will results be reported/used?)
14. Retention of records and/or results
    A. What records will be retained?
    B. How will data be stored?
    C. How long will individual data be retained?
    D. How will data be destroyed?

Reporting Requirements for Approved Projects

Follow the guidelines in the "General Information" section to report on continuing projects and to notify the Review Board of completion of a project. Use the form specific to research with human subjects for requesting continuation of a project involving human subjects.

Guidelines for Recruitment and Conduct of Research with Students

I. Whenever possible, solicitation of students for research participation should be done in public areas, such as the library, dining hall, mall, etc.

II. When solicitation of students as research participants is done in class, the following are desirable: A. Request for volunteers for research to be conducted outside the classroom

It is preferable that requests for volunteers for research that is to be conducted outside the classroom come at the end of class periods. This allows students who wish not to participate to leave without having to disturb class and without having to draw attention to themselves by nonparticipation as they await the resumption of class. In addition, it is preferable for faculty members not to solicit directly their own students for participation, as this may imply to students that participation is in some way linked to their class evaluation. If the research is the faculty member's own, it may be preferable to have someone else (such as a paid or volunteer assistant) do the requesting while the faculty member absents him/herself from the process.

B. Requests for volunteers for research to be conducted in class during class time

When possible, it is desirable for research to be conducted outside of class time. This is not always possible, nor is it always desirable. Important time constraints often make it reasonable to take some time in class, and in many disciplines the participation in research can be a meaningful part of the learning experience.

If research is to be conducted during class time, it is again preferable for faculty members not to solicit directly their own students for participation. In addition, it is preferable for someone other than the faculty member to actually conduct the study. This reduces the potential coerciveness of the volunteering process and the implicit pressures to remain in the study. For the same reasons, it is preferable to conduct the research at the end of class periods.

C. Provision of incentives for participation of students

1. **Monetary incentives:** If participants are to be paid, payment must be made as long as the participant agrees to participate and begins to do so. That is, payment is contingent on any degree of participation and not on the completion of the study.

2. **Extra credit as incentive**: For many students, a valued incentive is the possibility of earning extra credit in a class for participation in research. Many faculty members will find this an acceptable practice. However, in order not to make the offer of extra credit overly coercive, the following guidelines should be considered:

   a) Receipt of the extra credit is to be contingent on any degree of participation and not on the completion of the study;

   b) An alternative way of earning the same extra credit might be provided, with the alternative being no more time consuming or effortful than the study itself; and

   c) The means of record keeping for the extra credit do not violate the requirements of confidentiality or anonymity.

III. A cover letter explaining the project must be provided to subjects. Cover letters must include:

- ❑ Purpose of the study
- ❑ A statement that the subject's responses will be kept confidential
- ❑ Explanation of how written or taped responses will be stored during the study and disposed of after the study
- ❑ A statement that subjects do not have to answer every question
- ❑ A statement that class standing, grades or other status will not be affected by participation in the study. If extra credit is offered for participation, include a statement specifying such credit and indicating that credit will be given whether or not students complete the survey or other task

- ❑ A statement that participation is voluntary

IV. Subjects must give informed consent, as indicated by signing a consent form. A model consent form is included in Appendix A.

V. Adequate provisions must be made to maintain students' privacy and to keep their responses confidential. If possible, data collected from students should not contain information that can identify individuals. Where identification at some level is required by the research design, that information should be minimal. Forms or computer files including such identification must be accessible only to the researchers specified in the proposal. To further assure confidentiality, data to be discarded must not be in readable form or accessible to others.

Literature Cited

Office of Protection from Research Risks, National Institutes of Health. 1998a. OPRR Human Subject Protections. <http://www.nih.gov/grants/oprr/library_human.htm>. Accessed 4/23/98.

Appendix A: Sample forms

(Please see separate forms folders for human and vertebrate animal research. These are available on the same server as this policies document.)