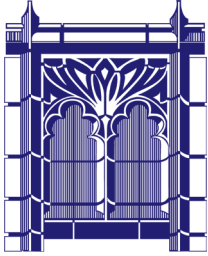


Review of Graduate Student Research by the Institutional Review Board (IRB)



THE GRADUATE SCHOOL **mentor memo** AUTUMN QUARTER 2009

This Mentor Memo, part of a series, responds to graduate students' requests for advice about navigating graduate studies successfully.

The series also addresses topics in career preparation and professional development. For more information and to suggest topics, contact Graduate School Dean Jerry Baldasty at baldasty@u.washington.edu.

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What is the IRB?

The IRB is a committee of scientists, non-scientists, and community members. At the UW and other universities, the IRB reviews research proposals to protect the rights and welfare of human research subjects who participate in research activities conducted under the auspices of the university.

When is IRB review required?

If the proposed study meets the Federal definition of research . . .

"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

and...

If the proposed study involves "human subjects," defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information."

Why is IRB review necessary?

IRB reviews help ensure the safety and protection of research subjects, as well as the ethical conduct of research that involves human subjects.

The IRB review must determine that all of the following requirements are satisfied:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by HSS regulation 46.117.
- The research plan makes adequate provision for the monitoring of data collected to ensure the safety of subjects.

there's more... ►

- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

How does the IRB evaluate research proposals?

The IRB reviews and responds to proposals at three levels, depending on the type of research proposed:

Exempt: Six categories of research involving human subjects qualify for exemption from Federal regulations governing the protection of human subjects. A determination of eligibility for exemption must be made by the IRB or its designee. Exempt research must also comply with state laws, UW policy, and conform to sound research ethics/principles.

Expedited (Minimal Risk): An “expedited” review procedure can be used when research has been determined to be of “minimal risk” to subjects (i.e., “poses no more risk to subjects than would be encountered by the average person in his/her daily activities”) and involves only the procedures listed in the federally described categories of expedited review. All Federal, state and local regulations must be taken into consideration. The standard requirements for informed consent (or its waiver or alteration) apply.

Expedited reviews may be carried out by the IRB Chair, an IRB Co-Chair, or by one or more experienced reviewers designated by the Chair from among members of the IRB.

Full IRB Review: Research that does not qualify as Exempt or for Expedited review must undergo a full review by a quorum of IRB members. The application process is the same as for expedited review; however, it is recommended that researchers allow two to four months from the time of submission until approval. Researchers should also be aware that the initial Full Review process frequently does not result in an outright approval of the research; minor or major revisions and written clarifications are often requested.



This Mentor Memo was developed in collaboration with the Human Subjects Division.

How can I get help?

The Human Subjects Division (HSD) encourages researchers to contact HSD staff during the planning process and, as needed, in preparation of the IRB application. IRB applications are at:

www.washington.edu/research/hsd/forms_paper.php?topic=18

A good starting point: contact the HSD Training Team at hsdtrain@u.washington.edu

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