Human Research Protection Program
Email: irb@wsu.edu
Web site: www.irb.wsu.edu

GUIDANCE FOR UNDERGRADUATE RESEARCHERS

PURPOSE

This document provides information and guidance to undergraduates who will be conducting human subjects research.

BACKGROUND

Human subjects research regulations in the United States were informed by a body of ethical work identifying key components of ethical research practice like the Nuremburg Code, the Declaration of Helsinki, and professional ethical codes. The precursor to the Revised Common Rule (the US federal regulations found at 45 CFR 46) was the Belmont Report.

The Belmont Report identifies three principles that guide human research ethics and builds upon other ethical documents The three principles outlined in the Belmont Report are:

- **Respect for Persons**: "Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection… To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others."
- **Beneficence**: "The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms."
- **Justice**: "Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."

Institutional Review Boards were created as a requirement for institutions who receive federal funding to comply with Public Welfare/ Department of Health and Human Services regulations (Title 45 of the Code of Federal Regulations, subtitle A, subchapter A, Part 46), and the equivalent regulations of other federal agencies collectively known as the Common Rule. The IRB and Human Research Protection Program at WSU are comprised of faculty, staff, and community members who are responsible for making sure that participants in research have their rights and welfare protected.

DO I NEED IRB REVIEW?

The IRB and HRPP **only** review projects that fit the definition of "human subject" and "research" found in 45 CFR 46.102

Human subject – A human subject or participant is a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or
- **Obtains**, **uses**, **studies**, **analyzes**, or **generates** identifiable private information or identifiable biospecimens.

Research – Research is "a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**." Generalizable knowledge is intended to have an impact (theoretical or practical) on others within one's discipline. Additionally, dissemination with the intent to influence behavior, practice, theory, future research designs, etc. are considered contributing to generalizable knowledge.

IRB and/or HRPP review by our office doesn't mean that your project is more important, or scientifically significant, or sophisticated than a project that doesn't need to be reviewed by the IRB. Our ability to review a project is limited by federal regulations and institutional policy.

There are certain types of projects that usually do not meet the federal definition of "research" and don't require IRB or HRPP review. Some examples include:

- Program evaluation or program improvement
- Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. Because this kind of research focuses on specific individuals and their experiences, they can't be generalized out to a larger group and are therefore not human subjects research.
- Public health surveillance
- Collection and analysis of data authorized by law or court order solely for criminal justice or criminal investigative purposes
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- Activities preparatory to research (e.g., testing a research instrument).

WHAT IS A PRINCIPAL INVESTIGATOR?

At WSU, only a faculty member (or staff who have a research requirement associated with their position) may serve as the Principal Investigator (PI) or as the sponsor on a research project involving human subjects. Other individuals, such as research scientists or post- doctoral fellows may be allowed to be the PI at the discretion of the Vice President of Research and/or with approval from their College's dean or Department Chair.

WSU students may not serve as the PI but may serve as a Co-I. They must have an eligible faculty sponsor who fulfills the PI eligibility criteria and who will serve as PI and faculty advisor on the study.

PIs are ultimately responsible for the conduct of research. PIs may delegate research responsibility; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility. As such, PIs on student projects should carefully assess if they will be able to provide meaningful mentorship and oversight on student projects before agreeing to serve in this role.

When selecting your PI, consider the following:

- Do they have time to mentor you throughout the research process?
- Are they familiar with your research interest?
- Have they done human subjects research in the past?
- When you send them an email, do they respond in a timely manner?

CITI TRAINING

For those involved with human subjects research, Collaborative Institutional Training Initiative (CITI) is the national standard for preparing researchers with the proper ethical, logistical, and regulatory training for research specific purposes. WSU maintains a subscription with CITI that allows WSU faculty, students, staff, and affiliates to complete trainings as necessary, free of charge. This training is also recognized at most institutions outside of WSU.

The PI and study team members who are responsible for study design, recruitment, consent, data collections, and data analysis must complete the following training modules as needed:

- **Human Subjects Research (HSR):** Please choose from either the "**Social/Behavioral Research"** course or the "**Biomedical**" course as most applicable to the area of research.
- **Responsible Conduct of Research (RCR):** Please choose from either the "**Social/Behavioral Research"** course or the "**Biomedical**" course as most applicable to the area of research.
- **Good Clinical Practice (GCP):** ONLY required for NIH funded clinical trials

WHAT DOCUMENTS NEED REVIEW?

In addition to the application outlining your research protocol and any supplemental IRB forms, all participant-facing materials need to be submitted for review. These include – but aren't limited to – all recruitment material, informed consent documents, communication sent to participants as follow-up during the study, debriefing material, and participant resource information.

Guidance documents for creating recruitment, consent, and debriefing are available for your use in the Forms section of our website.

RESEARCH ETHICS SUPPORT

The Human Research Protection Program sets aside time throughout the week to meet with students, staff, and faculty to talk about research projects, IRB review comments, and general human subjects research guidance.

The Forms page on our website has an expanding list of guidance documents available to the research community at WSU to provide advice and expertise on a variety of topics, like working with American Indian/Alaska Native communities, education research, creating recruitment and informed consent documents, and more.

CAMPUS PARTNERS

Offices and centers at WSU are helpful partners for you when you are designing your research project. Consider reaching out to the following folks depending on the topic of your project:

- Center for Native American Research and Collaboration
- Native American Health Sciences
- Human Research Protection Program
- WSU Libraries
- WSU Office of Undergraduate Research
- Your instructors and faculty in your program

HUMAN SUBJECT REASEARCH SUBMISSION CHECKLIST

- Work with your thesis advisor/faculty mentor/committee members to develop your research question
- Schedule meeting to talk to HRPP staff about research plans with your PI
- Complete CITI training, and notify your PI that their training must be complete before your project can be reviewed
- Prepare your required materials for submission and save them as .pdf or .docx files:
    - Application (do this last!)
    - Addendums (if needed)
    - Recruitment materials
    - Informed consent materials
    - Study tools and measures
    - Non-WSU approvals, agreements, letters of support (if needed)
    - Non-WSU CITI Certifications (if needed)
    - Debriefing forms (if needed)
- 1-2 months before your intended start date, submit your study materials to irb@wsu.edu

REVIEWER COMMENTS AND THE RE-REVIEW PROCESS

About 2-3 weeks after your submission is complete, you will be hearing back from the HRPP with the results of the project's review. You can monitor the review at www.myresearch.wsu.edu. Depending on the project, you'll receive one of the following:

- A Not Human Subject Research (NHSR) determination
- Exemption certification
- Approval notification
- Revisions required; If revisions are required, your project will need to be re-reviewed. This may result in a delay in approval process. It's important to complete revisions in a timely manner. If you have questions about the reviewer comments or want to go over your edits before re-submitting, please send an email to irb@wsu.edu and we can schedule a meeting with you and your PI.

RESOURCES

- The Belmont Report
- 45 CFR 46
- WSU's Institutional Review
- Board CITI Program
- WSU's MyResearch