

Human Research Requirements At Washington University

Review Types
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<http://hrpo.wustl.edu>

Student Research

The Basics: Human Subject Research defined

How do I know if I need HRPO review and approval? Federal definitions:

Research: systematic investigation > develop or contribute to generalizable knowledge

- Data will be used for Honors Thesis
- Data will be presented or published outside of department/program [e.g., Research award from Center for the Study of Ethics & Human Values or Office of Undergraduate Research (Hoopes Award)]

Human Subjects: interaction, identifiable

Data Collected is Private Information about living individuals

Student Research

The Basics: Review Types

When HRPO review is needed, what type of review do I need?

- Outside the purview - activity does NOT meet federal definitions
- Exempt verification
- Expedited review
- Full Board review

Outside the Purview (verified in writing by HRPO)

Activities that do not meet the definition of "human subject research"

Interaction for pedagogical purposes

Interviews about processes or procedures

Collection of existing data that is NOT identifiable

EXEMPT Status (must be verified by HRPO in writing)

Category 1: Most types of Educational Research

Category 2: Most types of Surveys & Interviews

But NOT if:

Participants are prisoners, children**, OR
Sensitive data w/identifiers

Category 4: Existing identifiable data

But ONLY if:

Data are available to the public, OR
PD will record the data without identifiers

***Per laws of the country*

Details, Details, Details...

For Exempt Research

eIRB application MUST include:

Answers to all required questions (see sample application)

A PROTOCOL (i.e., a project description)

Description of your recruitment process

Description of your consent process

For open-ended interviews, a description of the topic and some sample questions

A copy of ANY non-standard survey/questionnaire

A copy of any recruitment letters/flyers. *[Follow Guidelines for Flyers - see HRPO website]*

Collecting Sensitive Data

Whenever possible, sensitive data should be anonymous.

ANONYMITY (vs. CONFIDENTIALITY)

Truly **anonymous data** can only be obtained using one of the following three methods:

- 1) You administer surveys/questionnaires by handing them out or mailing them to a large number of individuals AND no identifiers are recorded AND there is no way to know who provided data and who did not.
- 2) You know (or might recognize) individuals who participated in your study, BUT you have no way of knowing which set of data was provided by which individual.
- 3) You receive existing data that has been stripped of all identifiers (not human research).

What needs to be in your PROTOCOL?

OVERVIEW

Background/Rationale (brief but succinct)

Research Hypothesis and/or Objective(s)

Potential Contribution to Literature/Field

METHOD

Procedure - Provide a brief but thorough description of the entire procedure, including the estimated amount of time required for each participant

Remuneration to participants (if any)

Informed Consent

Informed Consent: BEFORE study begins

A process, not a document. May be oral.

Several elements:

Describe the purpose

Describe what will happen

MUST be voluntary (quit at any time)

Contact info if questions later

Contact info if want to express a concern

REMINDER:

If you do not obtain HRPO approval

You will **NOT** be able to use the data for a
Senior Honors Thesis, publication, or
presentation!