

Human Research Requirements At Washington University

Tips for Undergraduate Student Researchers
November 2007

<http://hrpo.wustl.edu>

Student Research The Basics

- Research Faculty Sponsor > Required for ALL Student
- Does my project require HRPO Review?
Scientific Purpose: Systematic Investigation > Generalizable Data will be used for Honors Thesis or presentation (e.g., Undergraduate research award)

Human Subjects: OHRP definition > living & identifiable Data Collected is Private Information about individuals
- If I need HRPO Review, what type of review do I need?
Exempt, Expedited or FULL REVIEW
- What do I need to apply for HRPO review?
- How do I apply for HRPO review?

Outside the Purview (verified in writing by HRPO upon request)

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)

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

You record the data without identifiers

***Per laws of the country*

Details, Details, Details...

You **MUST**:

Obtain HRPO approval **BEFORE** you begin to collect data

Your Study Team (including **YOU** and **YOUR FACULTY SPONSOR**) **MUST**:

Complete WU Human Research education (need User ID & password)

Students: "N" number

Faculty: Employee number

HRPO Approval Steps:

Obtain eIRB User profile and password (Diane Clemens, HRPO)

Create eIRB application and **SUBMIT** to HRPO.

(You must press the "Submit" button.)

Your Faculty Sponsor must approve the eIRB application

Dept. Chair must approve the eIRB application

Details, Details, Details...

HRPO application **MUST** include:

Answers to all required questions.

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

Description of your recruitment process (if applicable).

Description of your consent process (if applicable).

[For non-EXEMPT research: An ICD or WOD of Consent + info sheet.]

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 you will need to complete the eIRB APPLICATION

Info. About RESEARCH METHOD

Participants & Recruitment

Number of Subjects: ESTIMATE

Population: SPECIFY

Recruitment process: SPECIFY

Estimated end date of study: SPECIFY

Consent Process: SPECIFY

Description of any Benefits to participants for their participation in the research

Informed Consent

Informed Consent: BEFORE study begins

A process, not a document.

Several Elements - think of these as Questions:

What is the purpose?

What will happen?

What are the risks?

What are the benefits?

What if you want to discontinue?

Will your responses be kept confidential?

Who can you contact if you have questions later?

What if you want to express a concern?

Informed Consent: AFTER study begins

What if you feel uncomfortable or uncertain?

CITI logon Instructions

Go to HRPO website at: <http://hrpo.wustl.edu>

From the column on the left side, select "Human Subjects Research Training Module (CITI)."

Select "Directions for RAS Non-Wustl Employee Sign-On"

IMPT! You will be prompted to change your password. Use the following formulary: last 2 digits of birth year, first initial of last name lower case, last 4 digits of your SSN. (You will use this same password for eIRB.)

The "Group" you should select for your research activity is, "Hilltop IRB Members and Researchers in Select Departments/Schools."

If you have trouble logging in, contact the Systems Helpdesk
314-935-5707 (hours: 9:00 a.m - 5:00 p.m CST, M-F).

To obtain eIRB User ID

Last Name

First Name

Year of Birth

Last 4 digits of SSN

"N" Number (same as CITI login)

Title (e.g., Undergraduate Student)

Department or Program Name

Preferred Email address

Faculty Sponsor's Name

Email information to Diane Clemens, HRPO

clemensd@wustl.edu

REMINDER:

If you do not obtain HRPO approval

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