

Resources for Complying with Federal HS Guidelines

Methods that minimize risk / are probably exempt from review

- Observing visitors in real time without audio/video (tracking and timing)
- Tracking website and multimedia usage (mining clickstream data)
- Videotaping from far away without audio (as long as visitors are unidentifiable)
- Asking visitors to fill out surveys that ask for no identifying information
- Interviewing adults without asking for identifying information (if questions are innocuous)

Resources for writing protocols

University of California's Committee for the Protection of Human Subjects
Includes full guide for Protocol Narrative and links to other resources
<http://cphs.berkeley.edu/content/forms.htm>

Institutional Review Consulting (IRC) website
Includes information about:

- Informed consent
- IRB approval processes
- Links to other resources

<http://www.irb-irc.com/index.htm>

Exploratorium's Visitor Research and Evaluation Department

- Created an "umbrella" protocol for our common methods
- We can share it

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Steps for setting up your institution to conduct HS Research

1. Find an IRB to work with (see below)
2. Obtain a "Federal-Wide Assurance" (FWA) number for your institution
 - a. See http://ohrp.cit.nih.gov/efile/FWA_start.asp
3. Create a set of internal policies for human subjects protection
 - a. See Human Research Protection Program Plan sheet
4. Plan your study while considering guidelines – try to minimize risks
5. Use decision charts to determine if you must seek IRB oversight
 - a. Talk with an IRB representative, too
6. Using Protocol Form as a guide, write your protocol
 - a. Guides found at UC Berkeley's website or at IRC's site (see below)
7. Submit protocol for IRB review or exemption

External IRBs that will review studies

Institutional Review Consulting (consulting firm)

San Anselmo, California

(415) 485-0717

<http://www.irb-irc.com/>

Basic fees:

\$1800 for Initial Review

\$400 for Annual Review

Response time for review: 1-2 weeks

Portland State University

Portland, Oregon

Human Subjects Review Committee: 503-725-4288 (1-877-480-4400)

http://www.rsp.pdx.edu/compliance_human.php

Basic fees:

\$750 for Initial Review

\$250 for Annual Review

Response time for review: 4-6 weeks

References for learning about the guidelines

The Office for Human Research Protections (OHRP)

<http://www.hhs.gov/ohrp/>

OHRP Guidelines (45 CFR 46 aka Title 45 Code of Federal Regulations, Part 46)

<http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf>

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>

OHRP Decision Charts (for determining if a study constitutes HS Research)

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>

The Belmont Report

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>