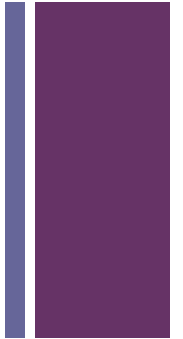




Human Subjects Protections for Qualitative Research



IRB Review and Approval at UW

April, 2017

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UW Human Subjects Division (HSD)



+ Topics for today



- Human subjects regulations background
- Which activities need IRB review
- Different types of IRB review
- How to submit a new application
- Common issues for qualitative research
- Q&A

+ The Belmont Report (1979)

■ Beneficence

■ Assess risks and benefits

- *Is the benefit from the research worth the risk?*

■ Respect for Persons

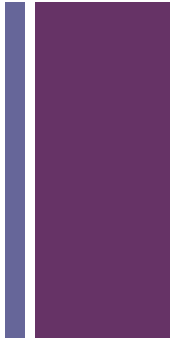
■ Informed consent process

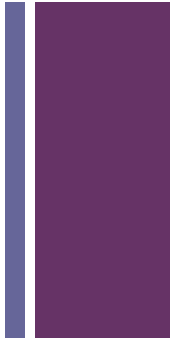
- *Are subjects willing volunteers?*

■ Justice

■ Equitable selection of subjects

- *Are the people in the study also those most likely to benefit?*





REQUIREMENT

All non-exempt research involving human subjects must be approved in advance by an **Institutional Review Board (IRB)**.

+ What is an IRB?

IRB = Institutional Review Board

A group registered with the federal government that is formally designated to review and monitor research involving human subjects.





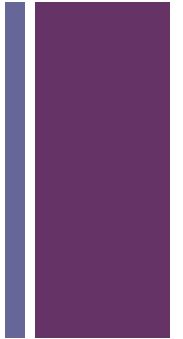
The UW IRB and the Human Subjects Division



- The Human Subjects Division supports the UW IRBs
 - Located in the UW Tower
 - About 45 staff members to provide support
- Four IRB Committees (A, B, D, & J)
- IRB Committee members include:
 - UW faculty, staff, and students
 - Scientists and non-scientists
 - People who are, or are not, affiliated with the UW



+ Where do I start?



+ Consider your activity

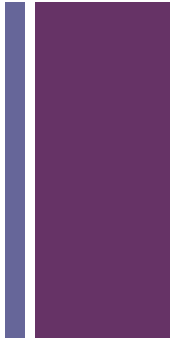


1. Is it research?
2. Does it involve human subjects?
3. Does it qualify for exempt status?
4. What type of review is required?

 *In this order!*



Activities that may not be research



- Case report or case study
- Program evaluation
- Oral history
- Quality assurance / quality improvement
- Public health surveillance

+ 2. Does it involve human subjects?

Human subject = an individual about whom a researcher obtains

- data through interaction or intervention

and/or

- private, identifiable information



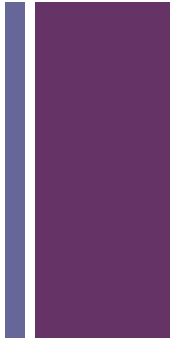
+ Why does this matter?

If it is not “research” and/or if it does not involve “human subjects”, IRB review is not required.





How do I know?



Toolkit for researchers to self-determine:

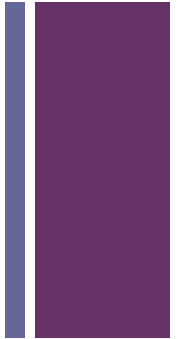
- HSD Website: Is Your Project Considered Research?
 - <https://www.washington.edu/research/hsd/do-i-need-irb-review/is-your-project-considered-research/>
- HSD Website: Does Your Research Involve Human Subjects?
 - <https://www.washington.edu/research/hsd/do-i-need-irb-review/does-your-research-involve-human-subjects/>

When in doubt, ask HSD!

- General HSD email hsdinfo@uw.edu and phone 206-543-0098
- Contact look-up by department available on the HSD website



3. Is it exempt from IRB review?



- Certain types of low-risk human subjects research are “exempt” from the regulations requiring review
- Researchers must still follow principles of Belmont and other, limited UW policies
- 7 exempt categories at UW, based on methods and areas of inquiry
 - 6 for all research
 - 1 for non-federally funded research
- Limited involvement of vulnerable subjects (e.g. children, prisoners)
- Exempt research does not require IRB review, BUT it does require an official determination by HSD
 - HSD Website: Is Your Human Subjects Research Exempt from Regulations?
 - <https://www.washington.edu/research/hsd/do-i-need-irb-review/is-your-human-subjects-research-exempt-from-regulations/>

+ Qual Exemption #1



Research conducted in **established or commonly accepted educational settings**, involving **normal educational practices**, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- **Established or commonly accepted** means sites or settings in which educational activities regularly occur
 - Schools, museums, libraries, online courses, auto-repair shops
- **Normal** means activities that could occur regardless of whether the research is conducted

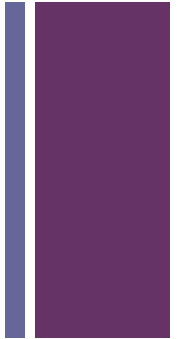
+ Qual Exemption #2



Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures**, **interview procedures** or **observation of public behavior**, if:

- information obtained is recorded in such a manner than human subjects cannot be identified, directly or through identifiers linked to the subjects; OR
 - any disclosure of the human subjects' response outside the research couldn't reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; OR
 - the subjects are elected or appointed officials or candidates for office; OR
 - federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- No child subjects unless limited to educational tests and/or observation of public behavior when the researcher does not participate in the activities being observed.

+ Qual Exemption #3



Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens, if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- **Existing** means “on the shelf” at the time of application to HSD
- WA State Law **supersedes** this and **prevents** the use of state agency and health records under this exemption

+ Qual Exemption #4

Non-federal. UW only.



Research procedures consist solely of benign interventions, interactions, or observations of behavior that do not involve:

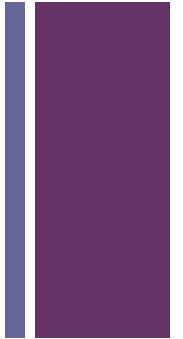
- the collection of biological specimens, or
- the physical assessment of subject's physical characteristics except for standard anthropometrics and vital signs

information obtained is recorded in such a manner that the human subjects cannot be identified, directly or through identifiers linked to the subjects; or any disclosure of the human subjects' responses outside the research couldn't reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

- Only cognitively competent adults



4. What type of IRB review is required?



- There are two levels of IRB review.
- When you submit your application, HSD will assess which level of review your study needs
- **Minimal Risk**
 - Expedited IRB review (“subcommittee review”)
- **Greater than Minimal Risk**
 - IRB review by convened IRB (“full board review”)
- Research reviewed by the IRB must meet specific criteria for IRB approval



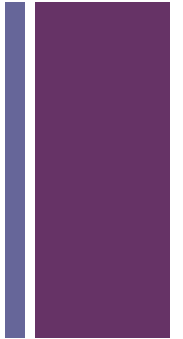
+ Expedited Review

- Definition of “minimal risk”: the probability and magnitude of harm or discomfort anticipated are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
- The review is completed by one “designated” reviewer
- There are 7 categories of expedited review
- WORKSHEET Expedited Review Eligibility
 - <https://www.washington.edu/research/forms-and-templates/worksheet-expedited-review-eligibility/>





Expedited Categories #1 and #2 for Qual Research



Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Collection of data from voice, video, digital, or image recordings made for research purposes.





Expedited Category #3 for qual research



Research on **individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing **survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**



+ Full Board Review

- Typically greater than Minimal Risk
 - Application is reviewed by the convened IRB
 - Board must have a specific quorum number of voting members with varying backgrounds (race, gender, culture, etc.)
 - Board must have appropriate expertise
 - UW IRBs meet every other week (approx.)



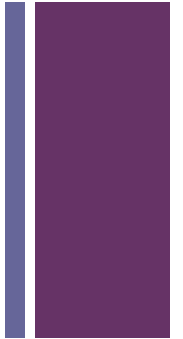
+ Human Subjects Regulations 45 CFR 46

■ Criteria for IRB approval of research

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be obtained or waived
- Informed consent will be documented or waived
- Privacy and confidentiality will be protected
- Data and safety monitoring provisions are appropriate
- Extra protections for vulnerable populations are in place



Common Issues for Qualitative Research

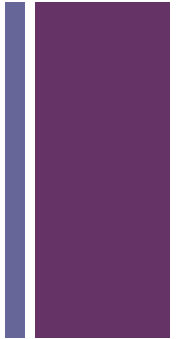


Know your research context and give this information to the IRB

- Ethnography, interviews, etc. doesn't automatically mean it's low risk.
- Are you collecting information that could pose risk to subjects if disclosed?
- Prisoners, employees, socially stigmatized, culturally sensitive issues, etc.
- Identify the probability and magnitude of harm to your subjects from informational disclosure BEFORE you submit to the IRB and incorporate appropriate protections into your study design/plans



Common Issues for Qualitative Research



Develop consent materials and plans that are appropriate to your context and population

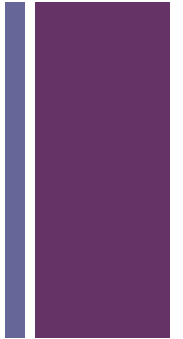
- Language (translations? Literacy?)
- Written or oral
- Short or lengthy – how much time do you have?
- Take advantage of waivers of consent & written documentation

- **Waiver of Consent**
 - Study couldn't be done without the waiver
 - No greater than minimal risk

- **Waiver of Written Documentation**
 - No greater than minimal risk



Common Issues for Qualitative Research



Take advantage of flexibility

UW IRB's are encouraging flexibility for studies based on risk level

- Describe content of recruitment materials, rather than providing the materials themselves
- Describe interview topics to be covered and the most personal/sensitive questions rather than providing every question
- Describe the data you will obtain rather than providing every variable
- For oral consent, provide a list of talking points rather than a verbatim script

+ How do I apply?

The logo for Zipline, featuring the word "zipline" in a bold, lowercase, sans-serif font. The letters are a dark purple color. The text is set against a light gray shadow that is slightly offset to the right and bottom, giving it a 3D effect. In the top right corner of the slide, there is a vertical decorative element consisting of a thin blue line followed by a wider, solid purple rectangle.

zipline

- Zipline is our recently implemented e-IRB System
- Support for Zipline submission can be found on our website:
 - Education:
 - <https://www.washington.edu/research/hsd/training/zipline-online-help-library//>
 - FAQs:
 - <https://www.washington.edu/research/faq/zipline-known-issues/>

+ Registration and Help



PLAN/PROPOSE ▾ SETUP ▾ MANAGE ▾ CLOSEOUT ▾ RESOURCES ▾ COLLABORATION ▾ COMPLIANCE TRAINING



Home > UW Research > Human Subjects Division > Zipline

NOTE: Zipline will be offline for maintenance from 6 to 10 PM on Friday, April 14th. Please save your work and log off before this time.

LOG IN TO ZIPLINE >

zipline

HSDINFO@UW.EDU >

- Sign in with your UW netID and password and update information

- Step-by-step instructions and self help tutorials



Zipline

Welcome to Zipline, the electronic IRB submission system. Click the above button to register for the first time or log in.

In order to access Zipline, you must have a UW NetID. [Click here to see how to get a sponsored UW NetID.](#)



Zipline Online Help Library

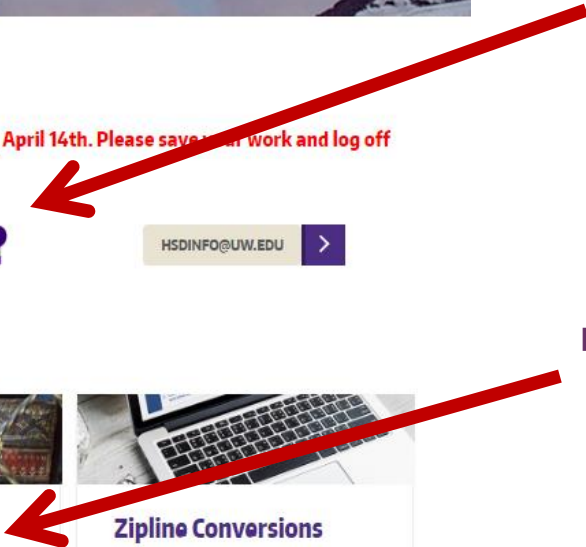
Training materials when you need them, geared towards your role in Zipline.

[General Help](#) - Get started quickly
[Help for Researchers](#) - Learn how to navigate Zipline

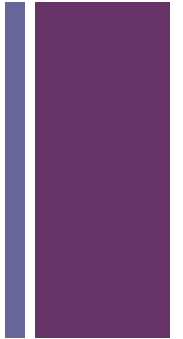


Zipline Conversions

Need to convert a paper study into Zipline? [See our guidance page](#) for helpful tools, tips, and checklists.



+ Submission



- There are three parts to a Zipline application:

1:

Zipline
web-based
SmartForms

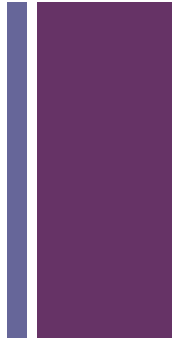
2:

Attached
IRB Protocol
form

3:

Attached
other study
documents

+ Submission (continued)



Main Application Forms to use with Zipline

| | |
|---|---|
| ZIPLINE APPLICATION: IRB Protocol | + |
| ZIPLINE APPLICATION: IRB Protocol, No Contact with Subjects | + |

Other Forms to use with Zipline

| | |
|---|---|
| ZIPLINE ADDENDUM: Study Roles | + |
| ZIPLINE and PAPER SUPPLEMENT: Department of Energy | + |
| ZIPLINE and PAPER TEMPLATE: Confidentiality Agreement | + |
| ZIPLINE APPLICATION: Status Report, Conversion Study | + |
| ZIPLINE APPLICATION: Status Report, Renew or Close | + |
| ZIPLINE REVIEW AUTHORIZATION: External IRB | + |
| ZIPLINE SUPPLEMENT: Department of Defense Involvement | + |
| ZIPLINE SUPPLEMENT: Devices | + |
| ZIPLINE SUPPLEMENT: Drugs, Biologics, Botanicals, Supplements | + |
| ZIPLINE SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC) | + |
| ZIPLINE SUPPLEMENT: Genomic Data Sharing | + |
| ZIPLINE SUPPLEMENT: Participant Results Sharing | + |
| ZIPLINE SUPPLEMENT: Participating Site in Multi-Site Research | + |
| ZIPLINE SUPPLEMENT: RNI | + |
| ALL HSD FORMS | + |

✓ Main Application Form. Two options

✓ Supplemental forms. Depending on study specifics



Other Submission Considerations



■ Ancillary Review

- Faculty advisor must sign off on student research
- Faculty Advisor has to be registered first
- HSD does not require departmental review

■ Conversion

- An entirely different presentation!
 - If you have questions about conversion, call us

+ What do I do after approval?

After the Initial Application

- Status Reports – continuing review/renewal
- Modifications – any/all changes
- Reports of New Information

Fun Fact: In Zipline, these are all called “follow-on submissions”



+ Common Mistakes!

- Incomplete applications
- Missing or misplaced documents
- Not enough info about procedures
- Using too much technical jargon
- Not planning ahead
 - Be sure to leave plenty of time for review
 - Turnaround times are unpredictable



+ Resources



| What | Type | How |
|----------------|------------|--|
| For the Record | HSD e-News | To subscribe: hsdinfo@uw.edu |
| HSD web | Website | www.washington.edu/research/hsd/ |

When in doubt, ask HSD!

- General HSD email hsdinfo@uw.edu and phone 206-543-0098
- Contact look-up by department available on the HSD website

+ Future Changes to the Regulations

- In the works for about 7 years; product of coordination among many federal agencies, regulators, researcher, the public
- Currently on hold by the Trump administration; anticipated effective date: January, 2018
 - No more continuing review for minimal risk research!
 - Federally-funded studies will qualify for exemption under “benign interventions”
 - Small change to what information must be provided to subjects as part of consent
- More announcements to come as HSD analyzes the impacts!



QUESTIONS?