PROTECTING HUMAN SUBJECTS IN RESEARCH

IRB Review and Approval at UW

Human Subjects Division
Spring 2018
Today’s Topics

- Historical Background of Ethics and Regulations
- What Activities Require Review by the IRB
- Different Types of IRB Review
- How to Submit a New Application for Review
- Common Issues with Applications

Questions and Answers
"Respect for Persons

...that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.

"Beneficence

...give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation.

"Justice

...the selection of research subjects needs to be scrutinized in order to determine whether some classes [of people] are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied."
Requirement

Most research involving human subjects that is funded by federal agencies must be approved in advance by an Institutional Review Board (IRB).

Many non-federal funding agencies, such as private foundations, have also adopted this requirement.

Most universities, including UW, also apply this requirement to all of their research, even if unfunded.
The Institutional Review Board

A group registered with the federal government that is formally designated to review and monitor research involving human subjects. In other countries it may be called an Ethics Review Committee (ERC). The Human Subjects Division supports the UW’s 4 IRBs

IRBs must have a specific number of members of varying backgrounds (gender, expertise, etc.) and are made up of:

- UW faculty, staff and students
- Scientists and non-scientists
- Members of the local community
• An Informed Consent Process that is documented
• Additional protections for people with diminished decision-making capacity or who are vulnerable to coercion.

**Key Question:** Are subjects willing volunteers?

**Beneficence**

• Risks to subjects reasonable considering benefits from the study
• Subjects aren’t exposed to unnecessary risks
• Safety monitoring plans for studies involving risks.

**Key Question:** Is the benefit from the research worth the risk?.

**Justice**

• The risks of the study are borne by those who will benefit
• Group harms are assessed and managed

**Key Question:** Are the types of people in the study also those that are most likely to benefit from the results of the study?
What the IRB doesn’t do

1. Reviewing for scientific merit or improving study design except when there is significant risk to subjects
2. Designing or significant advising on consent materials or other study documents
3. Identifying all of the risks of the study
4. Identifying the concerns of the population you will study
5. Editing your materials for grammar and readability
Where Do I Start?
Some Activities Don’t Require Any Review

Ask yourself…

Is the activity research?

A **systematic investigation**, including development, testing, and evaluation, **designed to contribute** to **generalizable knowledge**.

Activities that might not be research
- Single Case Report
- Program Evaluation
- Quality assurance and improvement
- Public Health Surveillance
Some Activities Don’t Require Any Review

Ask yourself…

Does the activity involve human subjects?

An individual about whom a researcher obtains:
• data through interaction or intervention and/or
• private, identifiable information

Activities that might not involve human subjects:
• Public Datasets
• Interviews About an Organization
• De-identified Information
HSD’s Website Walks You Through These Decisions

Step 1. Is Your Project Considered Research?

This is the first of five steps in determining whether your planned activity requires IRB review and, if yes, by which IRB.

Why this matters

• If your activity doesn’t fit one of the definitions of research (below), you do not need to obtain Institutional Review Board (IRB) approval or a determination of exempt status.
• The specific definition (if any) that applies to your activity determines which regulations and requirements govern your research.

Step 2. Does Your Research Involve Human Subjects?

This is the second of five steps in determining whether your planned activity requires IRB review and, if yes, by which IRB.

Why this matters

• If your research does not involve human subjects, you do not need to obtain Institutional Review Board (IRB) approval or a determination of exempt status.
• The specific definition (if any) that applies to your activity determines which regulations and requirements govern your research.
Some Activities That are Research with Humans are Exempt from IRB Review

Ask yourself…

Is the activity exempt from IRB review?

Low risk research that involves:
- Educational practices in typical educational settings
- Common Educational Tests like IQ
- Surveys
- Interviews
- Focus Groups
- Some types of Existing Data
- Benign social/behavioral interventions UW only – for non-federal studies

Limitations: Cognitively competent adults, children only allowed in educational research, no prisoners
Exempt Research

Does not require IRB review and oversight, but does require a determination from the Human Subjects Division (HSD) that the activity is exempt.
HSD’s Website Walks You Through The Decisions

Step 3. Is Your Human Subjects Research Exempt from Regulations?

This is the third of five steps in determining whether your planned activity requires IRB review and, if yes, by which IRB.

Why this matters

- If HSD determines that your human subjects research qualifies for exempt status, you do not need to obtain Institutional Review Board (IRB) approval.
- The answer to this question determines which regulations and requirements govern your research.

And how to obtain a Determination

If you believe your research may qualify for exempt status

Follow these directions for a determination about whether your research qualifies for exempt status. HSD staff are the only individuals authorized at the UW to make exempt determinations.

1. Complete the circled questions on the standard IRB Protocol form or on the No Contact version of the form.
2. In Zipline, create a new application by clicking on the Create a New Study button and following the instructions. Attach your completed IRB Protocol form at the indicated place.
3. HSD will assess your application and issue a formal determination.
There are two types of IRB review based on the anticipated risks to subjects

### 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.

- Daily life of the “average person”. If the subjects are regularly exposed to high risk in their lives, that doesn’t make high risk procedures more acceptable in that population.
- Does not mean there has to be no risk – daily life involves many types of risks of harm
- Includes all types of harms: physical, social, economic, psychological
Some studies qualify for expedited review, also known as subcommittee review.

**Types of activities that qualify**

**Minimal risk** research that involves:
- Data and specimens that have already been collected
- Blood draws under a specified amount in healthy people
- Noninvasive collection of biological specimens
- Clinical studies of low risk drugs and devices
- Noninvasive, routinely used clinical procedures
- Research on social and behavioral characteristics
- Surveys, interviews, focus groups, oral history, etc.

**Limitations:** No interactions with prisoners. No investigational drugs or devices.
Expedited Review

IRB review is completed by one designated reviewer from among the IRB members. At UW, HSD staff serve as these reviewers.

UW Researcher submits an application
- UW HSD will review the application to assess whether it qualifies for expedited review.
- HSD may have questions about risks to subjects in order to make this decision.

IRB member reviews and approves the study
- You will receive a letter documenting that the study has been approved.
- Approval is good for either 1-year (federally supported) or 3-years (most others).

UW Researcher manages the study
- Changes to the study need review before they are made.
- Continuing Review required to renew approval.
- Report to the IRB any new information about risks to subjects.
Some studies must be reviewed by the full IRB

Types of activities that are typically reviewed

**Greater than minimal risk** research which often involves:
- Investigational drugs and devices
- Novel and untested interventions
- Collection of information about criminal or highly stigmatized behavior
- Populations at higher risk of injury, e.g. fetuses and pregnant women
- Vulnerable groups such as prisoners

The IRB may determine that the study qualifies for expedited review if any additional reviews are needed.
UW Researcher submits an application
- UW HSD will review the application to assess whether it requires full board review.
- HSD may have questions about the application as it prepares the study for review by the board.

Convened IRB reviews and approves the study
- You will receive a letter documenting that the study has been approved.
- Approval is typically good for 1 year, but the IRB may require a shorter approval period for high risk or novel research

UW Researcher manages the study
- Changes to the study need review before they are made
- Continuing Review required to renew approval.
- Report to the IRB any new information about risks to subjects

Full Board Review
IRB review is completed by the convened IRB. At UW, each of the 4 IRBs meet every other week.
External IRB Review

In some circumstances, an external, or non-UW, IRB can review UW research instead of the UW IRB. Common external IRBs include:

- Fred Hutchinson Cancer Research Center IRB
- Seattle Children’s IRB
- WIRB
- WA State DSHS IRB

UW Researcher submits an authorization request
- UW HSD will review the request to assess whether it is appropriate for the external IRB to conduct the review.
- HSD may have questions.

HSD authorizes the study for external IRB review
- HSD works with the external IRB to put necessary agreements in place.
- You will receive a letter documenting permission to seek review from another IRB.

UW Researcher manages the study
- UW researcher submits for review directly to the external IRB.
- UW researcher provides additional information such as outcomes of other required committee reviews.
- Report back to HSD if the PI changes or the study closes.
Apply Online

Zipline is HSD’s online submission system. Anyone with a UW NetID can create and submit applications.
Part 1: SmartForm Questions

Zipline has several online questions that ask for basic information about the study. This information is used for routing and metrics.
Part 2: IRB Protocol Form

Complete and upload one of two versions of the IRB Protocol Form. This form collects detailed information about how you will conduct the study.
Part 3: Other Documents

Upload any additional study documents including:

- Recruitment materials
- Consent forms
- Supplemental Forms for the study team and other institutions involved in the study
Don’t Forget

Avoid the 3 most common errors that slow down review.

1. **MISSING QUESTIONS AND DOCUMENTS** Double check your application before you submit to make sure you have answered all the questions and uploaded all required documents.

2. **MISSING FACULTY ADVISOR SIGN-OFF** If you are a student, resident or fellow, you must request that a faculty advisor must sign off on your research.

3. **NOT PLANNING ENOUGH TIME FOR REVIEW** Plan ahead! Median review times vary depending on the type of review:
   - Exempt – 6 days
   - Expedited – 22 days
   - Full Board – 79 days
# We’re Here to Help

HSD has many resources for you

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<tr>
<th>Resource</th>
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<tbody>
<tr>
<td>Tools on HSD’s Website</td>
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Engaging Community Groups

The community you are studying or working with can make many vital contributions to your research. Engage with them and define the role members of the community will play before you prepare your IRB application.

Examples:

- Advising on cultural norms and the acceptability of the study
- Advising on recruitment methods and study design
- Advising on dissemination strategies
- Assisting with assessing foreseeable risk to study participants, especially in sociological research
- Assisting with recruitment
- Working as study team members by obtaining consent and data from other community members
Alcohol Study Barrow Alaska - 1979
Method of dissemination leads to group harm

Native leaders and city officials worried about drinking and associated violence in the community invited a group of sociology researchers to assess the problem and devise a solution. At the conclusion of the study researchers formulated a report entitled “The Inupiat, Economics and Alcohol on the Alaskan North Slope” which was released simultaneously at a press release and to the Barrow community. The press release was picked up by the New York Times, who ran a front page story entitled Alcohol Plagues Eskimos.

The depiction of the community in the article implied to the people of Barrow that they had been labeled a problem. They felt stigmatized. Many of the people of Barrow and in the statewide Native community felt that the researchers had violated their trust by failing to share all results with them first and by not allowing them the opportunity to comment on the results. This led many in Alaska Native communities to doubt that research on alcohol would result in respectful treatment of their communities and created a continuing distrust of researchers and the research process.
Build a flexible application

HSD strongly encourages this for lower risk studies

- Describe the content of recruitment materials rather than providing the materials themselves

- Describe interview topics to be covered and the most personal and sensitive questions rather than every question

- Describe the contents of the data you will obtain and its identifiability rather than providing a list of every variable

- For oral consent, provide a list of talking points rather than a verbatim script

**Key Point:** The lower the risk of the study, the less specific information the IRB needs about the details of the study
Promises in the informed consent can appear to limit an investigator's ability to share data with the research community. In reality, investigators can inform study participants that they are scientists with an obligation to protect confidentiality and still share the study data with the broad scientific community. Many effective means exist to create public-use data files or share restricted-use data files under controlled conditions. That is, data can be modified to reduce the risk of disclosure or shared with additional safeguards while preserving their value for science.

Additionally, in some circumstances, such as unique case studies, it may not be possible to guarantee confidentiality. In such cases, this should be clearly described as part of the consent process.

Finally, in some studies, you may have plans not to mask the identities of study subjects, for example if you wish to attribute quotes to them. Make sure that this is clearly delineated as part of the consent process.
### Sharing study results starts at consent

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<th>Suggested Language</th>
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<td>Avoid terms such as &quot;anonymous&quot; and &quot;de-identified&quot;. They are undefined and left open to interpretation. Instead use descriptive sentences that state what information will not be shared.</td>
<td>Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.</td>
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<td>Avoid promises that the data will be seen or accessed only by the research team. Instead, describe who will have access and when.</td>
<td>Federal or state laws may require us to show information to university or government officials (or sponsors) who are responsible for monitoring the safety of this study. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.</td>
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<td>Avoid language that limits the retention or sharing of data beyond the timeframe of the project. Instead, explain the duration of data storage and what happens to identifiers.</td>
<td>This may include information that might directly identify you, such as your name and address. This information will be kept until state required retention periods are met. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you.</td>
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questions