PROTECTING HUMAN SUBJECTS IN RESEARCH

IRB Review and Approval at UW

Human Subjects Division
Winter 2019
Today’s Topics

- Historical Background of Human Subjects 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
- The Revised Common Rule – What You Should Know

Questions and Answers
Beneficence

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

Respect for Persons

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

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.
Most research funded by many federal agencies must be approved in advance by an Institutional Review Board (IRB).

This requirement has been adopted by many non-federal funding agencies, such as foundations.

Most universities, including UW, also apply this requirement more broadly to all of their research, even if unfunded.

Note: This presentation focuses on the requirements of the Common Rule promulgated by the Department of Health and Human Services. The FDA also regulates research involving drugs and devices in similar, but not entirely overlapping ways.
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 (race, gender, expertise, etc.) and are made up of:

• UW faculty, staff and students
• Scientists and non-scientists
• Members of the local community
Articulated in the Federal Regulations as:

- 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?

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Articulated in the Federal Regulations as:

- The risks of the study are borne by those who will benefit
- Group harms are assessed and managed
- Safety monitoring plans for studies involving risks.

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

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Articulated in the Federal Regulations as:

- 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 is not necessarily the role of the IRB?

1. Reviewing for scientific merit or improving study design except when there is significant risk to subjects
2. Designing or giving 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
6. Identifying other regulatory approvals you need
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 may 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 may 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.
Many 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 with adults
• Some types of Existing Data
• Benign behavioral interventions
• UW only – Anthropometrics

Limitations: Cognitively competent adults, children only allowed in educational research, no prisoners as target population
# 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.

<table>
<thead>
<tr>
<th>UW Researcher submits an abbreviated application</th>
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<tbody>
<tr>
<td>• UW HSD will review the application to confirm that the study meets exemption criteria.</td>
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<td>• HSD may have questions, especially about privacy and confidentiality.</td>
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<th>HSD issues an exemption determination</th>
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<td>• You will receive a letter documenting that the study is exempt.</td>
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<td>• Determinations are good for the life of the study as long as no significant changes are made.</td>
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<th>UW Researcher manages the study</th>
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<tr>
<td>• Changes to the study don’t need review by HSD unless they impact the determination.</td>
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<tr>
<td>• No continuing review required</td>
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<td>• Follow principles of Belmont Report, obtain consent and other recordkeeping requirements</td>
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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.

- Is the 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, 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

Limitations: No interactions with prisoners. No investigational drugs or devices.
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 typically good for the life of the study, however the IRB may stipulate an approval period.

UW Researcher manages the study

- Changes to the study need review before they are made
- If the IRB has stipulated an approval period, Continuing Review required to renew approval.
- Report to the IRB any new information about risks to subjects

Expedited Review

IRB review is completed by one designated reviewer from among the IRB members.

At UW, HSD staff serve as these reviewers.
Some studies must be reviewed by the full IRB

Types of activities that are typically reviewed

**Greater than minimal risk** research which often involves:
- Testing 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
- High risk survey and interview research

Any research that does not fit into an expedited review category must be reviewed by the full IRB, but may then qualify for future expedited review if the IRB determines that it qualifies.
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
3 Key Changes Introduced by the Revised Common Rule (RCR)

The RCR went into effect on January 21, 2019

<table>
<thead>
<tr>
<th>More studies qualify for exemption</th>
<th>Previous</th>
<th>Now</th>
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<tr>
<td></td>
<td>Survey and interview research with adults only qualified for exemption if the information collected was anonymous or would not put subjects at certain risks of harm if disclosed</td>
<td>Almost all survey and interview research with adults will qualify for exemption as long as there are adequate protections in place for the privacy and confidentiality of subjects.</td>
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<tr>
<td></td>
<td>Benign behavioral interventions only exempt for non-Federal research</td>
<td>Benign behavioral interventions exempt for all research</td>
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<tr>
<th>More studies don't require any kind of continuing review</th>
<th>Approval Periods</th>
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<td></td>
<td>Exempt – None</td>
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<td></td>
<td>Expedited – 1 or 3 year</td>
<td>Typically None</td>
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<td>Full Board – 1 year or less</td>
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<tr>
<th>New Consent Requirements for Expedited and Full Board Studies</th>
<th>Key Information Section for Long Consent Forms</th>
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<tr>
<td></td>
<td>Give subjects more information about future use of data and specimens</td>
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How Will the RCR Impact You?

The RCR went into effect on January 21, 2019

1) Studies approved before January 21, 2019 must follow the old version of the rule. HSD is not transitioning most studies to the RCR. If you have studies approved before that date, you must continue to submit status reports and obtain continuing approval as directed in any approval letters.

2) For new studies, you may be asked to provide more information about your privacy and confidentiality practices in order for our staff to determine whether or not a study is exempt.

3) For new studies, you may be asked to include a Key Information section if your consent form is long. HSD has a guidance document with several examples: https://www.washington.edu/research/policies/guidance-key-information-for-consent-materials/

4) For more information about the RCR, check out HSD’s RCR Webpage: https://www.washington.edu/research/hsd/revised-common-rule/
We’re Here to Help
HSD has many resources for you

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<td>Tools on HSD’s Website</td>
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<td>Zipline Online Help Library</td>
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<tr>
<td>General Email – Monitored Daily</td>
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<td>For the Record, HSD’s monthly e newsletter</td>
<td><a href="https://www.washington.edu/research/manage-your-office-of-research-subscriptions/#hsd-newsletter">https://www.washington.edu/research/manage-your-office-of-research-subscriptions/#hsd-newsletter</a></td>
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questions
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
Know your research context
The IRB relies on you for this information

Are you collecting information that could pose risk to subjects if it is disclosed outside of the research?
• stigmatized behaviors
• criminal activity
• culturally sensitive issues

Are you collecting information about other people?

**Key Issue:** Identify the probability and magnitude of harm to all of your subjects before you submit to the IRB and incorporate appropriate protections into your study design.
Develop consent materials and plans that are appropriate to your context and population.

What language do your participants speak and read?
Will you need an interpreter? Who will do this?
Will your consent process by written or oral?
Short or lengthy – how much time do you have?

**Key Point:** Minimal risk research almost always **does not** require documented written consent.

**Key Point:** The UW Consent Template is recommended, but not required.

**Key Point:** There are many types of research that qualify for a waiver of consent entirely.
Specific Considerations for Medical Records Reviews

In some states, medical records reviews are considered exempt from IRB review. In WA, additional state laws mean that most medical records reviews must be reviewed as expedited.

**Key Point:** Reviews of medical records may use the abbreviated *IRB Protocol: No Contact with Subjects*

**Key Point:** Researchers accessing UW held records without consent may need to sign a UW Confidentiality Agreement in order to meet state law requirements

**Key Point:** Researchers accessing UW Medicine records without consent are responsible for keeping track of and sending in to UW Medicine Compliance their own Accounting of Disclosures logs