The Single IRB Policy

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Coming Soon
Agenda

• The **Single IRB** policy
• UW IRB as a single IRB?
• Information for NIH grants
• Responsibilities: lead site vs. participating site
• Resources
Studies often involve more than one institution

Current federal policies & regulations

• Each institution obtains its own IRB approval
• Reliance agreements allowed: one institution agrees to rely upon the IRB review by another institution
• But not very common for multi-site clinical trials, except industry trials
IRB review for current clinical trials
What is the Single IRB Policy?

Two complementary federal policies Require the institutions participating in a study to rely on the same (single) IRB.
Single IRB policy
Why

Faster overall startup time
More efficient
More consistent
## Single IRB policy

<table>
<thead>
<tr>
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<th>NIH</th>
<th>Common Rule</th>
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<tbody>
<tr>
<td>Implementation date</td>
<td>New grants on or after Sept 25, 2017</td>
<td>Jan 20, 2020</td>
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<tr>
<td>Applies to</td>
<td>NIH-funded multi-site clinical trials</td>
<td>Federally-funded collaborative studies</td>
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<tr>
<td>Exceptions</td>
<td>• Not international</td>
<td>• Not international</td>
</tr>
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<td></td>
<td>• Not VA</td>
<td>• Not VA</td>
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<tr>
<td></td>
<td>• Not tribal involvement</td>
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<tr>
<td>Affects current studies?</td>
<td>No</td>
<td>No</td>
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Today’s focus: NIH policy

Grants for multi-site clinical trials submitted on or after 9/25/17
Why are we talking about this now?

Studies funded by September grants won’t be funded until at least a year from now

1. The grants you submit this fall for multi-site clinical trials must include specific single IRB information – including budget information.

2. Single IRB process is already starting to happen, even though not yet required
Choosing the single IRB

Who can serve as the IRB?
- Potentially any IRB
- Including the independent IRBs like WIRB

Who chooses?
- NIH, lead PI, & PI’s institution
- The selected IRB must agree
If you are the Lead PI or Coordinating Center

Will the UW IRB be the single IRB?
UW IRB as the single IRB?

Most likely scenario

UW IRB will not be the single IRB
- For the first 2 years of the single IRB policy
- Only applies to multi-site clinical trials
- Collect data re workload & cost, then decide

HSD will work with NIH and the PI to select one of the large independent IRBs (e.g., WIRB)
### Why?

<table>
<thead>
<tr>
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<th>Large independent IRBs</th>
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<tbody>
<tr>
<td>Expertise (# &amp; type of IRB members)</td>
<td>Large advantage over UW IRB</td>
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<tr>
<td>Scalability</td>
<td>Large advantage</td>
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<tr>
<td>Staff capacity</td>
<td>Large advantage</td>
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<td>Turnaround time</td>
<td>Faster than UW IRB</td>
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<td>Peer institutions</td>
<td>At least half are making the same decision to use an independent IRB</td>
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HSD staff will still be available to help
HOW DOES IT WORK?
Basic steps: UW PI is Lead PI

<table>
<thead>
<tr>
<th>Grant preparation</th>
<th>Post-award</th>
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<tbody>
<tr>
<td>• <strong>HSD Letter of Support</strong> for a single IRB</td>
<td>• Decision re which IRB</td>
</tr>
<tr>
<td>• <strong>Letter of Support</strong> for single IRB from participating site institutions</td>
<td></td>
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<tr>
<td>• <strong>Personnel</strong>: include an IRB liaison</td>
<td>• <strong>IRB liaison</strong>: identify/hire</td>
</tr>
<tr>
<td>• <strong>Budget</strong>: include IRB fees</td>
<td>• <strong>Zipline</strong>: request to use external IRB</td>
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<tr>
<td>• <strong>Budget</strong>: include IRB liaison</td>
<td>• <strong>Reliance agreement</strong> between IRB &amp; sites</td>
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<td></td>
<td>• <strong>Generic protocol</strong>: IRB review</td>
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<td>• <strong>Each site</strong>: IRB review</td>
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Preparing a NIH grant application for a multi-site clinical trial
NIH grant application:
UW PI is the Lead PI

Letter of Support from HSD
• Contact Karen Moe kemoe@uw.edu

Obtain a Letter of Support from site institutions
• HSD has a template you can provide them

Budget
• IRB fees
• IRB Liaison position

see HSD’s webpage for help
Grant tip
If you name the single IRB in your grant, you **must** include a letter of support from the IRB.

The UW IRB will not honor commitments to be the single IRB made without its knowledge & approval.
Cost of the single IRB review

- It costs money & the grant (lead site) must pay
- The cost is not included in indirect costs (F&A)
- Must be included in grant budget

Two important NIH guidance documents under “Additional Resources” at:
Operational details: Two models

1 - sIRB interacts directly with each site team

2 - sIRB interacts with IRB liaison; IRB liaison interacts with site teams
The grant is awarded!
Now what?
UW Lead PI

When you are funded...

- Contact HSD immediately for help  hsdinfo@uw.edu
- Time and many tasks to get the single IRB established
Decision: which IRB?
- You, NIH, HSD
- This also informs HSD, so we can guide you

Identify your IRB liaison
- If necessary, someone temporary while you hire
Operational details: The reliance agreement

- Each institution has an agreement with the single IRB
- Not the 2-page agreement used in the past!
- Long, complicated, requires attorney review
- One solution: The Smart IRB Master Reliance Agreement prevents the need for a study-specific agreement.

*The UW IRB has signed the Smart IRB agreement.*
What does the single IRB review?

- Generic protocol
- Coordinating center, data center
- For each site
  - Qualifications
  - Site-specific consent form
  - Site-specific procedures
Basic steps: UW is site, not lead

Grant preparation

• HSD Letter of Support for a single IRB

Post-award

• Inform HSD which IRB
• Zipline: request to use external IRB

HSD and/or lead site will let you know what else you need to do
Preparing a NIH grant application for a multi-site clinical trial
NIH grant application:

UW is a participating site

Provide Lead PI with a Letter of Support from HSD, agreeing to rely on a single IRB

- Lead team may provide a template
- Contact Karen Moe kemoe@uw.edu
The grant is awarded!  
Now what?
As soon as single IRB identified:

• Zipline application: Request for External IRB

This triggers the HSD process

• Reliance agreement
• Providing “local” information to the IRB
Lead site vs. participating site

different roles and responsibilities
Participating site responsibilities

- **Zipline**: Permission to use an External IRB
- Information for the IRB provided through the IRB liaison
- Use study consent template, with UW-specific info
- Follow the policies & procedures of the Reviewing IRB
Lead PI and Lead Team responsibilities

- Submit materials to Reviewing IRB, for all sites
- Provide draft study materials to all sites
- Provide IRB-approved materials/determinations to all sites
- Overall study coordination
- Communication & coordination with reviewing IRB
Template Letter of Support
To provide to participating sites

IRB Liaison description
To use for budget justification

IRB review fees: How to budget

Links to NIH guidance about review fees