Career Development Series 2020

A Single IRB: The Promise & The Reality

Presentation will begin at 11:00 AM (PT)

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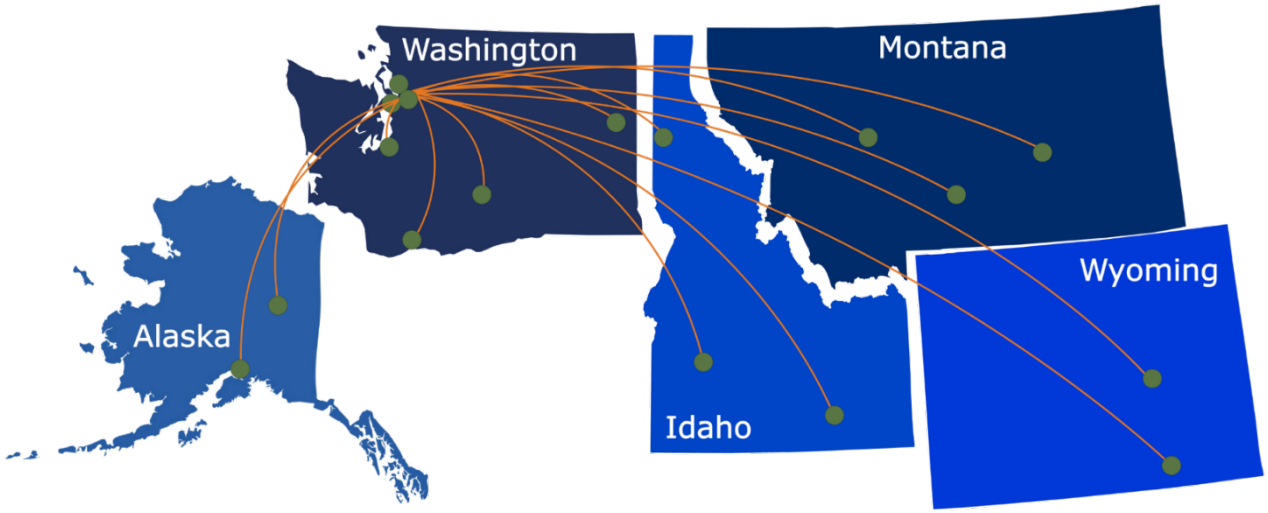

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2. **Community Engagement:** Members can connect with regional and community based practice networks

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Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

A Single IRB: The Promise & The Reality

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Learning Objectives

1. Understand what single IRB review is
2. Recognize what kinds of studies must comply
3. Explain the overall process for obtaining single IRB review
4. Plan for single IRB review for a multi-site research study

BACKGROUND

A little history….
how *Institutional* Review Boards came to be

1953: NIH Clinical Center starts in-house, group peer review for ethical integrity for some research it conducts

1966 – 1971: Group peer review model is extended to *all* DHHS-conducted research

1974: First version of what is now called the Common Rule introduces the term "*institutional* review board". Presumption is that a similar, in-house group peer review model will be required for all DHHS-funded research conducted by other organizations.

1981: Common Rule is adopted by most federal agencies

The Idea of a Single IRB Review is Not New

Regional ethics organizations for protection of human research participants

- Anne Wood, Christine Grady & Ezekiel J Emanuel, *Nature Medicine* (2004)

"…we propose an innovative reform to the structure and process of research review: abandoning **institution**-based review and consolidating all independent reviewing, monitoring, training and ethical policy formulation into a system of approximately 20 **Regional** Ethics Organizations (REOs) for the entire United States.

Under this proposal, all activities related to human research participants' protections for one geographic region of the United States would be consolidated under a REO."

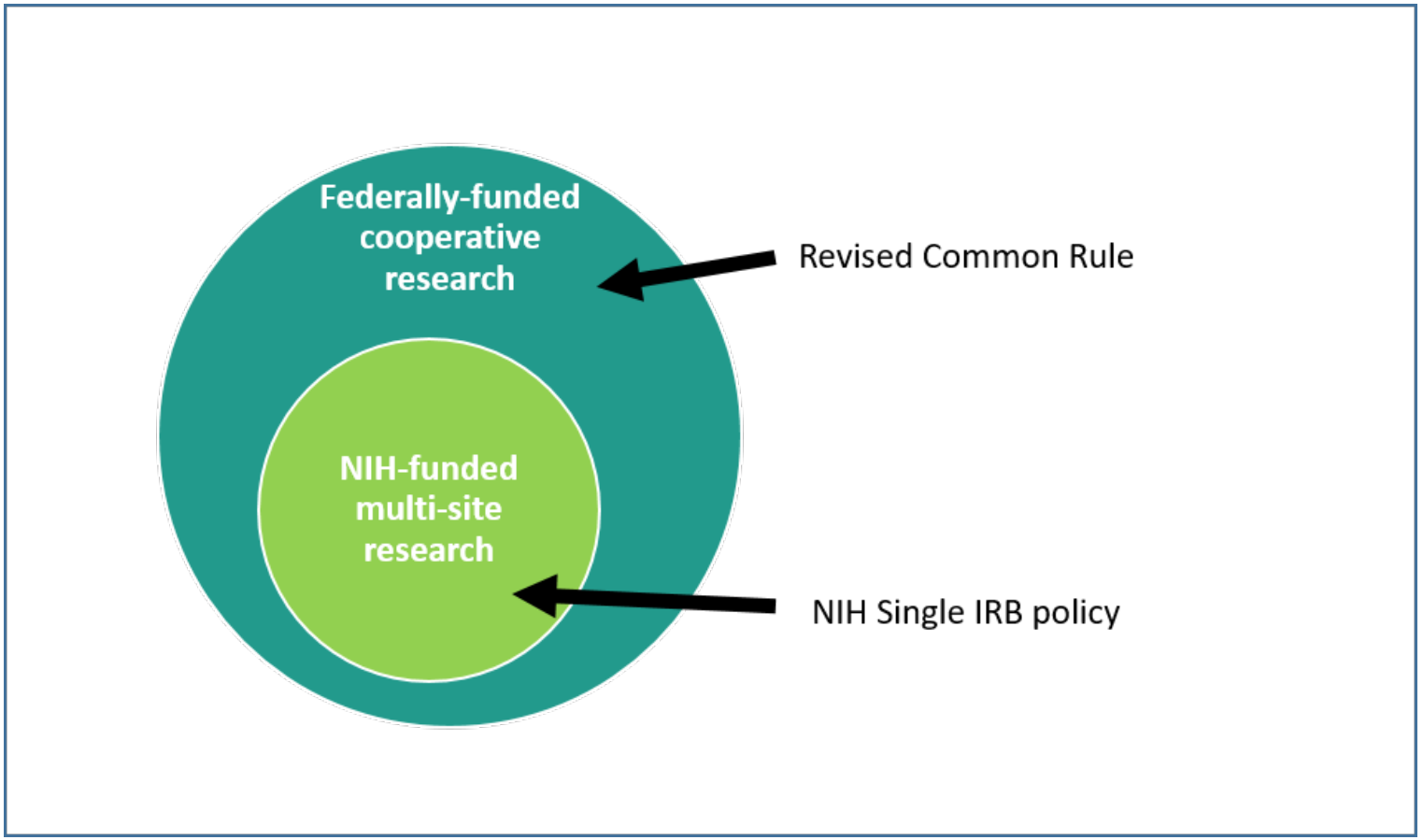
THE NEW SINGLE IRB REVIEW REQUIREMENT

Overarching Rationale

"The use of a single IRB of record…will help streamline the IRB review process by **eliminating the unnecessary repetition** of those reviews across sites. The goal of this policy is to enhance and streamline the IRB review process for multi-site research so that **research can proceed as quickly as possible** without compromising ethical principles and protections for human research participants."

NIH Single IRB Webpage

Single IRB - Two Mandates



Single IRB - Two Mandates

Revised Common Rule

Collaborative, non-exempt human subjects *research* that involve multiple institutions must be reviewed by a single IRB. This applies to almost all federally-funded or supported research. It went into effect January 21, 2020.

NIH policy

Most new *grants and contracts* submitted to NIH that involve *multi-site*, non-exempt human subjects research.

Multi-site research is a subset of *collaborative* research. It is important to identify when a project must comply with the NIH policy because there are specific, NIH requirements that must be present in the grant or contract applications for studies subject to this policy that do not apply to studies under the broader Common Rule requirement

NIH Multi-site Research

"**Multi-site"** means that the same research procedures (i.e., protocol) are being conducted at one or more domestic sites and that each site is under the control of a local participating investigator.

Sites can vary due to local context, for example specific requirements for recruitment.

If a study involves a separate site for study coordination or coordination of data and statistical analyses and the site is conducting the same protocol as the other participating sites, then all sites would be expected to rely on the designated single IRB.

Single IRB – Policy Exceptions

- Exempt human subjects research.
- Foreign sites
- Sites involving tribal nations
- Sites for which review by the proposed sIRB is prohibited by a federal, tribal, or state law, regulation, or policy
- All HHS-funded research that was approved by an IRB prior to January 21, 2020. This means that at least one IRB has approved any part of the study. This exception does not apply if the study must comply with the NIH multi-site policy.

Single IRB – Funding Agency Exceptions

Funding agencies can issue exceptions for a class of research or for individual projects:

NIH: work with the program officer to request an exception. Requests are reviewed by NIH's NIH sIRB Exceptions Review Committee (ERC).

- *There must be a compelling justification. Exceptions will be rarely granted.*

Veteran's Affairs: work with the VA IRB office. Exceptions frequent.

Other agencies: No formal process established or guidance issued.

NEW PRE-AWARD RESPONSIBILITIES

Preparing a Funding Application - Two Roles

Lead Institution

- Often the Primary awardee for smaller studies
- May also involve a coordinating center or CRO for larger studies

Participating Sites (Institution)

Some studies may not have a clear lead, for example multiple-PI funding structures, however it will be important to identify which site will play the lead in regards to IRB review arrangements.

NIH Mandate – Lead Sites

1. Select the IRB that will serve as the single IRB (sIRB) for the project.

2. Identify and budget for any costs associated with sIRB review. Include any sIRB fees and sIRB-related personnel costs in the grant budget.

3. Obtain preliminary confirmation from all participating sites that they are willing to rely upon the selected sIRB.

4. Provide required information in the funding application. The lead PI must prepare a Single IRB Plan for the grant/contract application and complete the appropriate human subjects forms.

1. Selecting the Single IRB

In some cases, NIH (or another funding sponsor) may specify the sIRB in the FOA or RFP funding announcement. However, for most funding opportunities, the funding agency expects the lead PI to select the sIRB, subject to the acceptance of the agency.

Any IRB with a federal registration can serve as a sIRB. This includes independent IRBs such as WIRB and Advarra that are not affiliated with any institution that conducts research. The sIRB may or may not be affiliated with any of the institutions involved in the research.

The IRB of the home institution of the PI should not automatically be assumed to be the single IRB.

1. Selecting the Single IRB

Not all IRBs are willing to serve as a single IRB for all research. In order to be a single IRB, they must have:

- Appropriate IRB member expertise
  - Special populations (children)
  - Special types of research (Exception from Informed Consent)
- Capacity
  - Application system that can accommodate studies with large number of sites
  - Process for reviewing single IRB studies
  - Enough staff to manage requirements of large studies

2. Identifying and Budgeting for Costs

IRB Review Fees

The costs for IRB review of research conducted at a single institution by that institution's IRB have typically been considered an indirect cost covered under an institution's Facilities and Administration (F&A) rate However, many institutions who will serve as single IRBs will charge fees to review other sites. Additionally, fees charged by independent IRBs, such as WIRB or Advarra, will not be paid for by the institution. The fees are the responsibility of the lead site and should be included in the grant budget as direct costs.

Additional Study Personnel

The lead site will have additional responsibilities for coordinating single IRB review and requirements throughout the life of the study which may require additional staffing resources.

3. Obtaining Confirmation From Sites

NIH requires that the lead PI attest in the funding proposal that all participating sites have agreed to rely on the selected the single IRB (sIRB). In most cases, investigators are not authorized to commit an institution to rely on a particular IRB, instead that commitment must come from the institution's IRB office, or other research regulatory office or official.

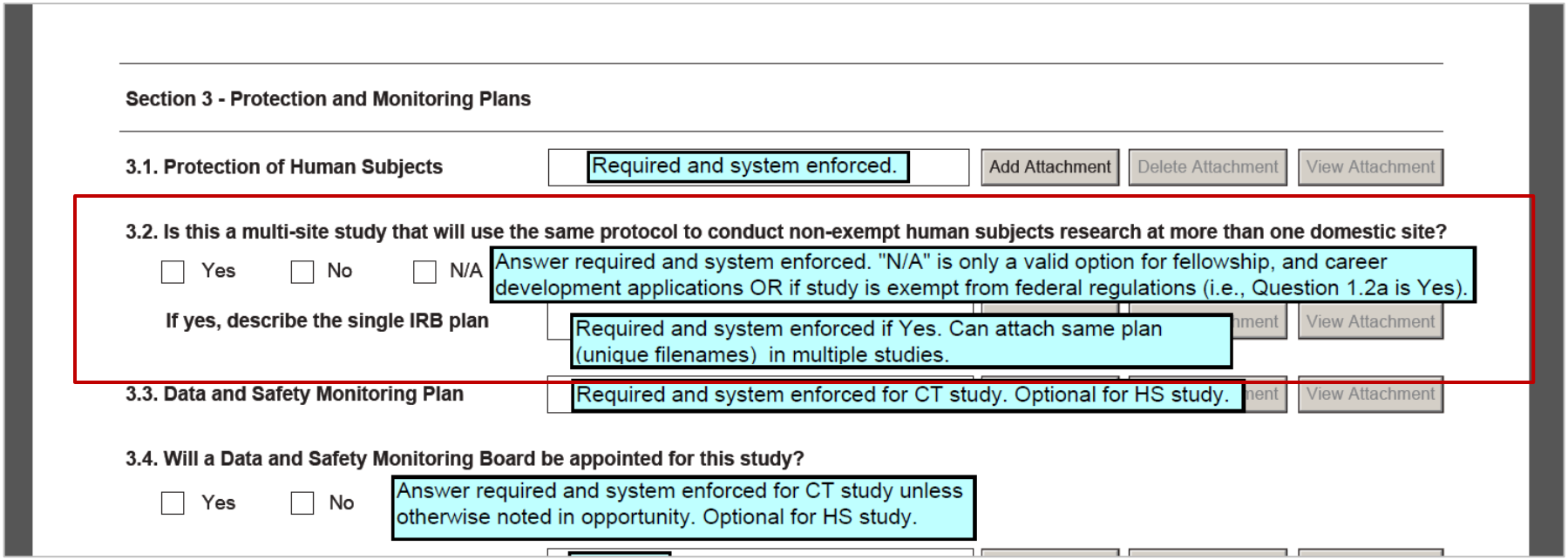
Most sites with IRB offices will have a process for obtaining this confirmation – at UW, HSD provides a letter of support.

4. Providing a Single IRB Plan

- How you will comply with the NIH Single IRB (sIRB) policy.
- The name of the sIRB
- Confirmation that all participating sites have agreed to rely on the proposed sIRB.
- A description of any exceptions you are requesting.
- Confirmation that all participating sites will sign a reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- How communication between sites and the sIRB will be handled.

4. Providing a Single IRB Plan

PHS Human Subjects and Clinical Trials Information Form



Common Rule – Lead Site

No Guidance from federal agencies on what is require. Strongly recommend PIs still complete the following:

1. Select the IRB that will serve as the single IRB (sIRB) for the project.

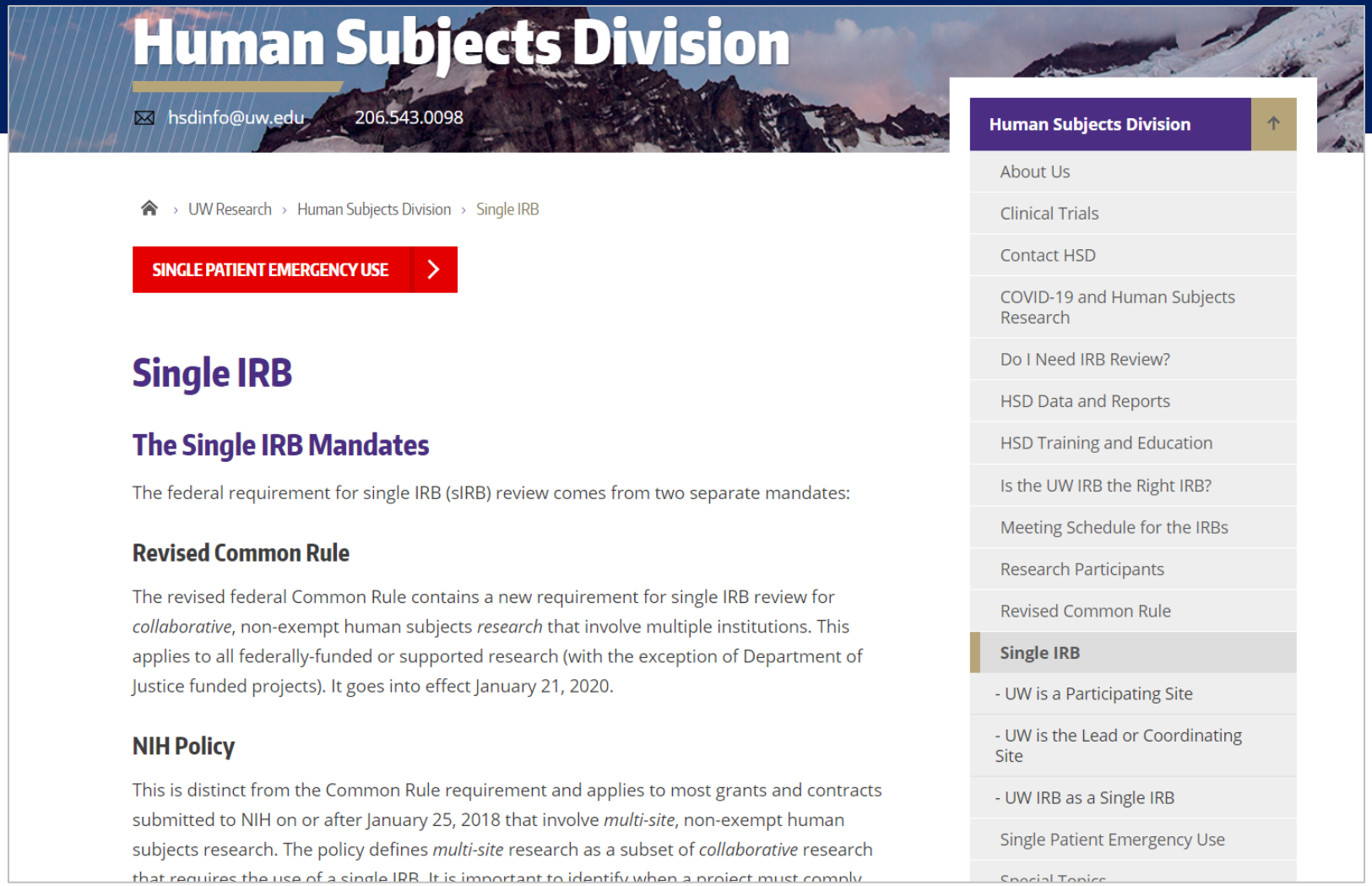
2. Identify and budget for any costs associated with sIRB review. Include any sIRB fees and sIRB-related personnel costs in the grant budget.

3. Obtain preliminary confirmation from all participating sites that they are willing to rely upon the selected sIRB.

Common Rule or NIH - Participating Sites

Typically only role is to obtain confirmation from their IRB or Research Compliance offices that the selected IRB is acceptable.

UW Resources



UW Resources

1. How to identify and select the IRB

►List of options

►Considerations when there are multiple options

2. Identify and budget for any costs associated with sIRB review

►sIRB liaison job description

3. Obtain preliminary confirmation from all participating sites.

►Template letters of support

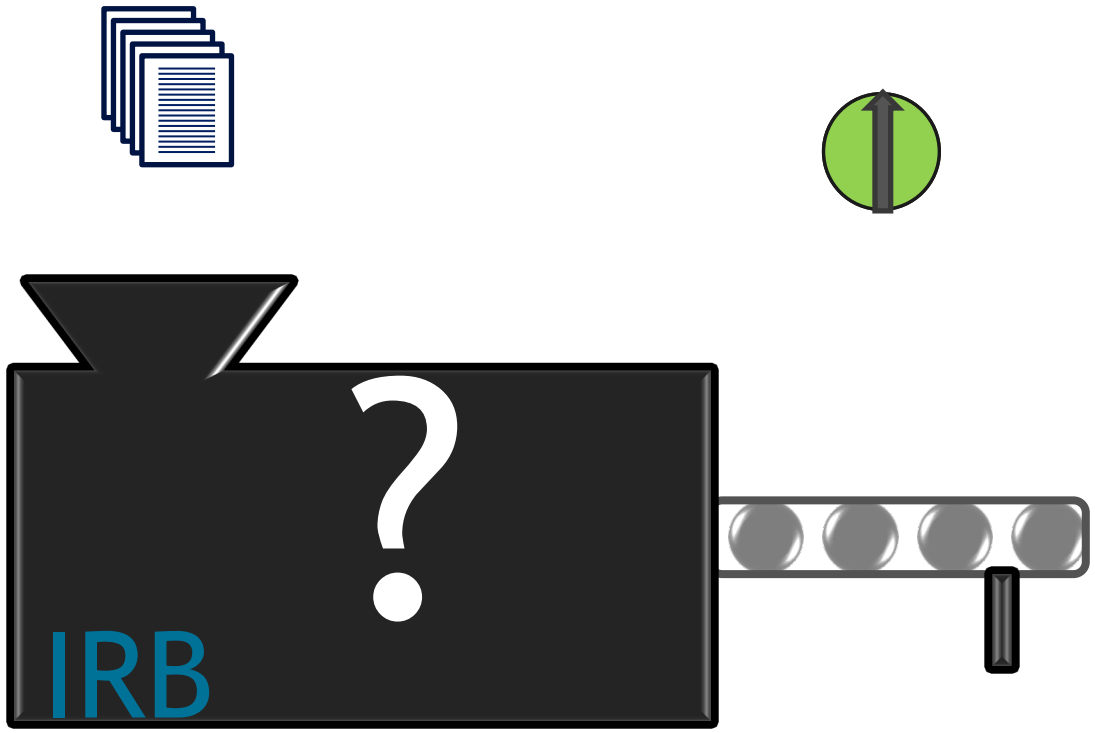
3. Provide Single IRB Plan

► Template Plan language

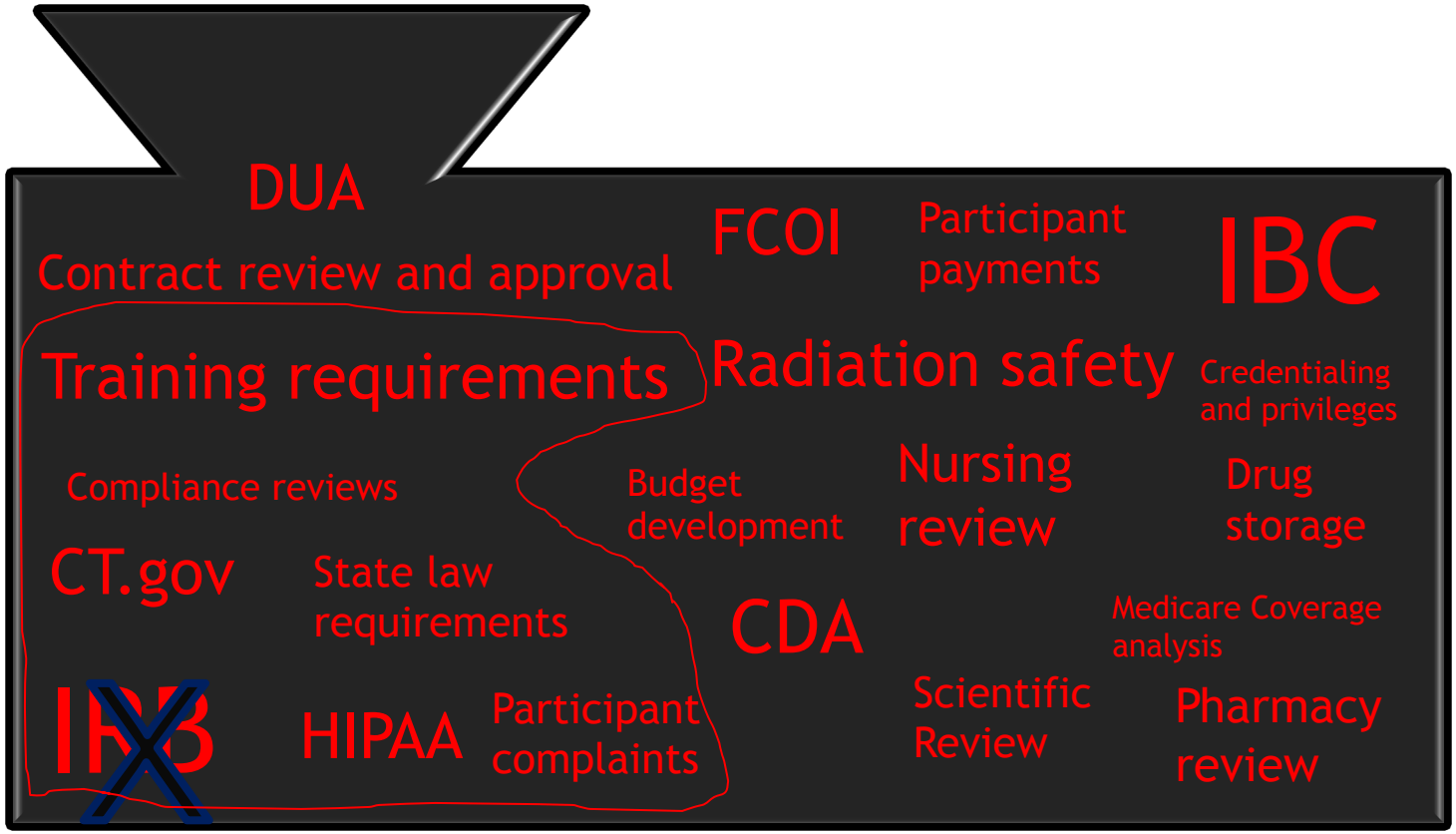
UW HSD WEBSITE
https://www.washington.edu/research/hsd/single-irb/

SINGLE IRB REVIEW:
THE PROCESS

Before Single IRB Review



Reality of Research Review Process



Single IRB – What is included?

Review the study and all sites for:

- The requirements of the Common Rule, the FDA and of funding agencies
- Need for HIPAA authorization or HIPAA waivers (most IRBs, not universal)
- Specific information communicated to it by the sites (impact of state laws, outcomes of ancillary reviews)

Single IRB – What is not included?

Each institution is still responsible for its own compliance with non-IRB requirements such as:

- Financial Conflict of Interest
- Radiation Safety
- HIPAA
- Training and Qualifications of Study Teams
- Post-approval monitoring
- Fielding subject complaints

Single IRB

Not less work, just different work

The Single IRB Review Process

Universal **parts** of the process, however there is no universal agreement on:

- The order of the steps in the process
- Who completes some specific steps in the process
- What specific information is required for each step
- How information is collected (via email, online systems, paper)
- Communication structures

Universal parts of Single IRB review

1) Submit overall protocol and template materials for IRB review
2) Request reliance from relying site IRB/HRPP offices
3) Establish a reliance agreement/arrangement
4) Creation of consent materials for sites
5) Obtain local context information from sites
6) Obtain IRB Review of the participating sites

Submit overall protocol for IRB review

The overall protocol for the study is typically reviewed by the IRB prior to the review of any participating sites. The protocol will need to address how the study will, in general, be carried out across the study:

- Identifying and recruiting subjects
- Consent process
- Study interventions and data to be collected
- How data will be transmitted and stored
- Template materials (consent documents, recruitment materials) for use across all sites

Request Reliance from Sites

Although each site may have already agreed to rely on the single IRB, this does not constitute a formal reliance agreement. For each study, the IRB or HRPP office of each participating site must formally confirm that the study can be reviewed by the single IRB.

Most institutions with an IRB office have a process by which investigators can formally request reliance on an "external" IRB. May need to provide:

- A written description of the research (protocol, grant)
- Documentation of approval of the overall protocol
- Copies of template consents, for tailoring to the site's requirements
- Answering other questions about the study

Establish Reliance Agreement/Arrangement

Reliance on an IRB not operated by the institution requires that an institution establish what is called a reliance agreement. Although some institutions have entered into standing agreements, often the flexible terms of these agreements must be clarified on a study-by-study basis

- Establishing a formal reliance agreement
- Clarifying the specific terms of reliance under a Master agreement
- Completing study specific documents, which may include letters of indemnification.
- Clarifying additional institutional roles and responsibilities under the reliance (Genomic Data Sharing certification, Post-approval Monitoring, HIPAA waivers)

Creation of Consent and Recruitment Materials for Sites

When consent materials will be used for the study, they will often (though not always) be generated based off of a template approved by the single IRB along with the review of the overall protocol.

There is no universally agreed process for the creation of these documents for each site

- In some cases, the site study team may be provided with the template and asked to complete it (in consultation with their IRB office)
- In some cases, the site's IRB office will be asked to provide standard institutional language and the site-specific materials will be generated by the IRB or by the coordinating center or CRO
- The site may be allowed to edit all of the consent template, or only specific sections.

Obtain Local Context from Sites

In addition to reviewing the study according to federal requirements, the single IRB must take into consideration "local context", or information specific to the participating site, this includes:

- State and local laws that impact the research
- Whether there will be any changes to the overall protocol to accommodate how the study will be carried out at the site
- The qualifications of the site study team and resources available at the site
- The outcomes of local "ancillary" reviews (FCOI, Radiation Safety, etc.)

There is no universal standard for how this information is collected.

IRB Review of Sites

After the IRB has reviewed the overall protocol it will review and approve the addition of sites, typically under expedited review. It will need:

- Any documents required as part of the reliance agreement
- All site specific materials (consent documents, recruitment materials)
- A site-specific application
- Local context information

There is no universal standard for how this information is collected and who submits these materials to the IRB.

Challenges for Everyone

No guidance from federal regulators or funding agencies on the Common Rule requirement

- Can budgets contain IRB fees as direct costs?
- Does the funding proposal have to name the IRB?
- What if sites disagree on whether the study is exempt or requires IRB review?
- What if sites disagree about whether the study is subject to the mandates?
- How will this change requirements to release funding as part of JIT?
- How does an investigator obtain an exception? What kinds of studies might qualify?

Challenges for Everyone

Most academic medical center, research institute or hospital IRB's are geared toward reviewing research done by their own institution.

To be a single IRB:

- Revise all policies and procedures to address review of other institutions
- Establish processes for regularly reviewing other institutions (how to collect local context robustly) they are unfamiliar with
- Overhaul application systems to accommodate large numbers of sites and/or need for access to the system by individuals unaffiliated with the institution
- Educating non-institutional researchers on their policies and processes
- Post-approval monitoring considerations

Challenges for Research Teams

Must comply with the reporting requirements, processes and policies of different IRBs

- How will you keep track of what is required for each study?

Must still comply with the reporting requirements of their home institution?

- Does the IRB/HRPP office require any check-ins or updates?
- Will the study team have to report to the Privacy Office if breaches of confidentiality?

May not be able to communicate directly with the reviewing IRB

No consistency of process or roles from study to study

Questions?

Thank You

Open for Questions

Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.