

Clinical Research Education Series 2021

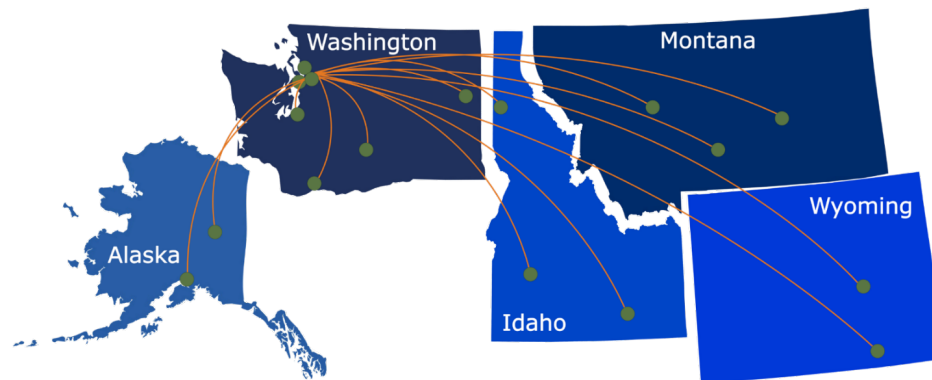
## **A Single IRB: The Promise and the Reality**

Presentation will begin at 12:00 PM (PT)

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# Feedback

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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

**1966 – 1971:** In-house, group peer review model is extended to all research *conducted* by the Department of Health and Human Services (DHHS)

**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 conducted or *funded* research.

**1981:** Common Rule is adopted by most federal agencies

## The Idea of 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.”



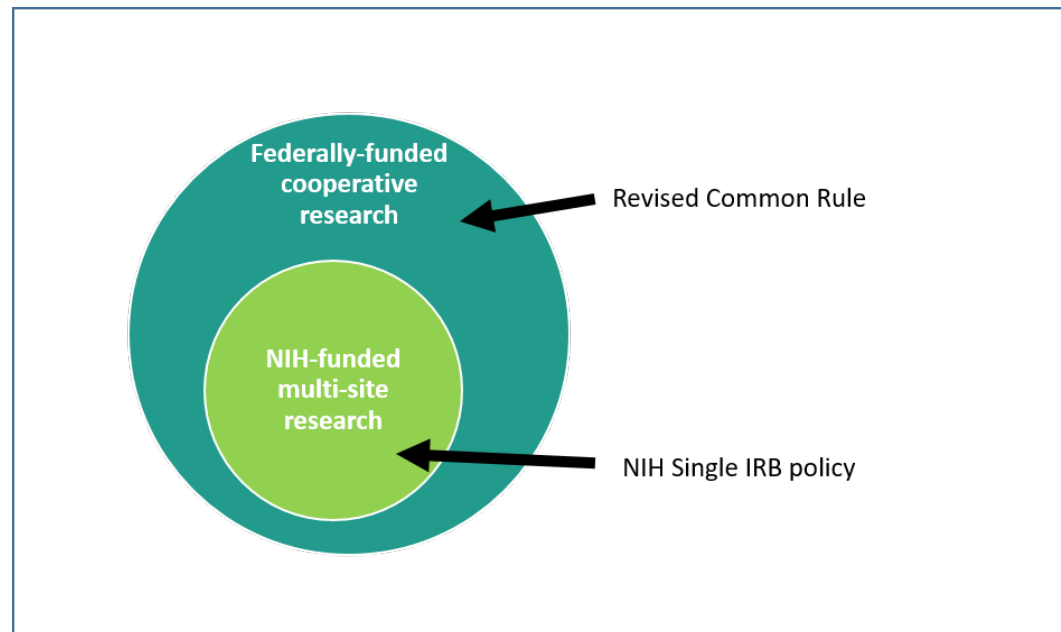
# **THE NEW SINGLE IRB REVIEW REQUIREMENT**

## Rationale for Single IRB Review

“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 met for studies subject to this policy that do not apply to studies under the broader Common Rule requirement

## 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. Work through the program officer.



## Pre-Award Tasks

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 any required information in the funding application. Some notices of funding opportunity require the applicant to describe information about the single IRB.

## Selecting the Single IRB

Not all IRBs are willing to be a single IRB for all research. The IRB of the home institution of the PI should not automatically be assumed to be the single IRB. In order to be a single IRB, the IRB 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

## 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**

There will be additional responsibilities for coordinating single IRB review and requirements throughout the life of the study which may require additional staffing resources.

## Obtaining Confirmation From Sites

In order to avoid problems when the funding is awarded, it is best practice to confirm that all participating sites can and will rely on the selected sIRB prior to submitting a funding application. 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 formal letter of support.

## Providing Single IRB Information in the Funding Proposal

**NIH no longer requires that a Single IRB plan be submitted with all funding proposals.**

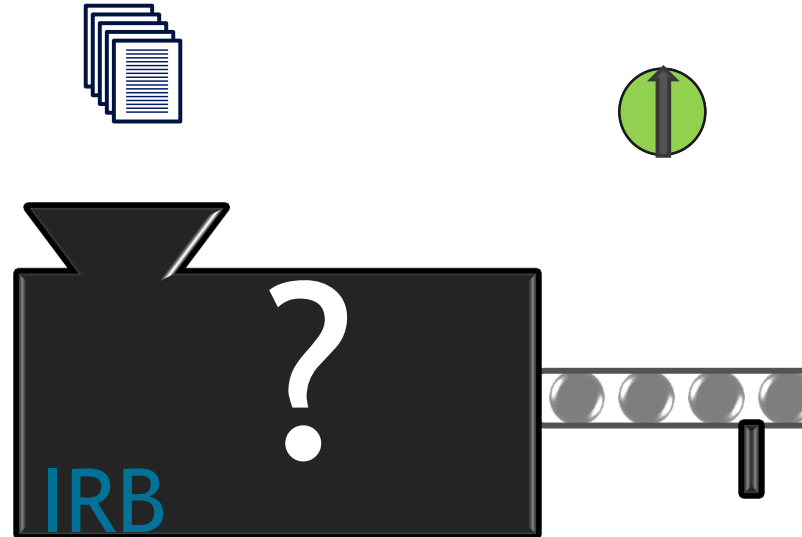
Some individual funding opportunities do require that applicants provide information about the plan for Single IRB review, which might include the name of the selected IRB, and plans for establishing reliance agreements and communicating among sites.

Researchers should carefully read any instructions in the Request for Applications or other notices about the funding opportunity.

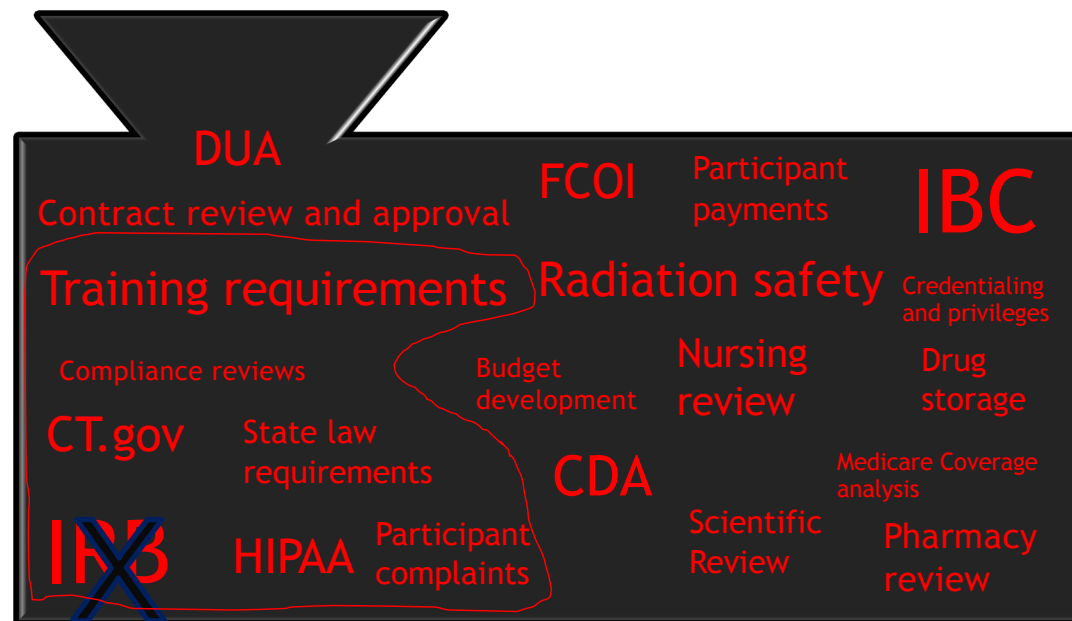


# **SINGLE IRB REVIEW: THE PROCESS**

# Before Single IRB Review



## Reality of Research Review Process





## Single IRB – What is included?

**The IRB reviews 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

## 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

## Part 1: 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

## Part 2: 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. Researchers 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
- Answers to other questions about the study

## Part 3: 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)

## Part 4: 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.



## Part 5: 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 that might impact its considerations (FCOI, Radiation Safety, etc.)

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

## Part 6: 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.



# **SINGLE IRB REVIEW: THE CHALLENGES**

## 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 IRBs

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 for other institutions and handling state laws and institutional requirements 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 Relying Institutions

Institutional IRB review process (and the application itself) is often the center around which multiple other compliance processes are attached. Even if another IRB is reviewing the study, the compliance responsibility stays with the institution. When that institutional process is removed, how will an institution

Without having that institutional review process to attach to, how will an institution ensure that:

- All ancillary reviews (e.g. FCOI, Radiation Safety) are completed
- It's investigators are trained and qualified
- State and local laws and policies are met
- It has enough information about the study to generate required internal reports, communicate among its compliance offices and respond to inquiries and audits
- All of this is done throughout the life of the study

## Challenges for Research Teams

Must comply with the reporting requirements 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 or directly access the application system

No consistency of process or roles from study to study



# Questions?



# Thank You

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Open for Questions

# Feedback Survey

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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.