# Single IRB (SIRB) Training

Leady Study Team Education Module | **Trial Innovation Network**

Presenter Names

Presenter Titles


# Objectives

Describe the Single IRB (SIRB) Model

Describe Human Research Protections (HRP)

Describe the roles & responsibilities for the Lead Study Team

# Definitions

| | |
|---|---|
| HRP | Human Research Protections |
| Lead Site | Where the lead PI of overall study is; Lead PI has ultimate responsibility for conduct of study; Data Coordinating Center (DCC) may be delegated some of these responsibilities |
| Participating Site/Performance Site | All sites where any of the research takes place (including DCC) |
| Relying Site | Each institution that requires a reliance agreement, dependent on investigator affiliation |
| Data Coordinating Center (DCC) | Group that assists with management of a study/project; may be study-specific or network-related; Lead PI may delegate Lead Site responsibilities so “Lead Site” may be used interchangeably with “DCC”; not applicable for all studies |

# SIRB Requirement

**When is it required?**

## NIH POLICY

**Required for all multi-site, domestic, non-exempt NIH research for grants submitted on or after January 25, 2018.**

## COMMON RULE

**Required for all domestic, cooperative research that is ready for IRB submission on or after January 20, 2020.**

DHHS, DOD, DO Energy, DO Education, NASA, NSF, SSA, DO Homeland Security, USDA, VA, DO Commerce, EPA, Agency for International Development, DOHUD, DO Labor, DO Transportation

# SIRB Requirement

**When is it not required?**

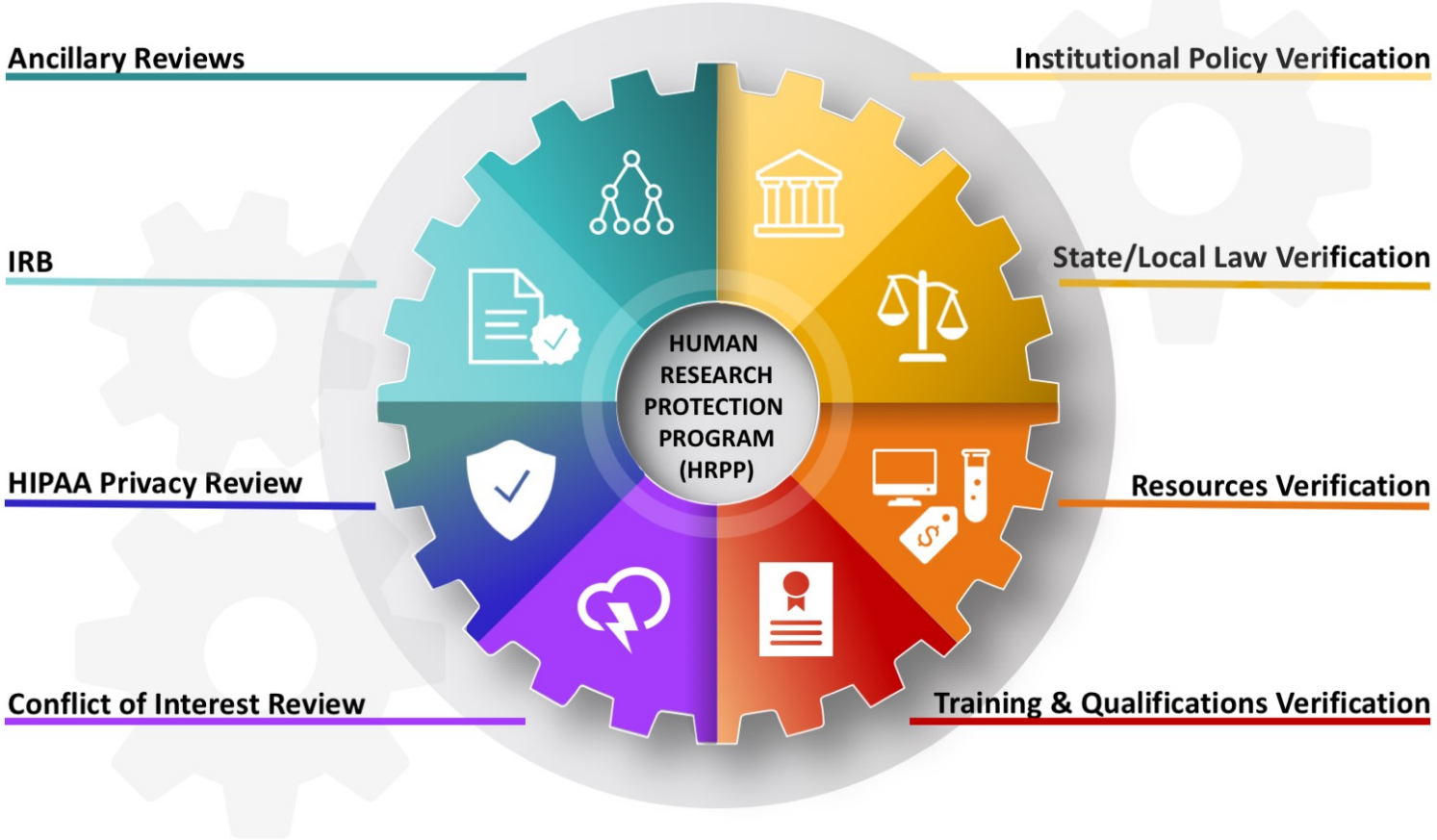
Exempt Research

If the designated SIRB is unable to meet the needs of specific populations

Where local IRB is required by federal, tribal, or state laws

Research conducted under career development, research training or fellowship awards

# The Full Picture | The HRP



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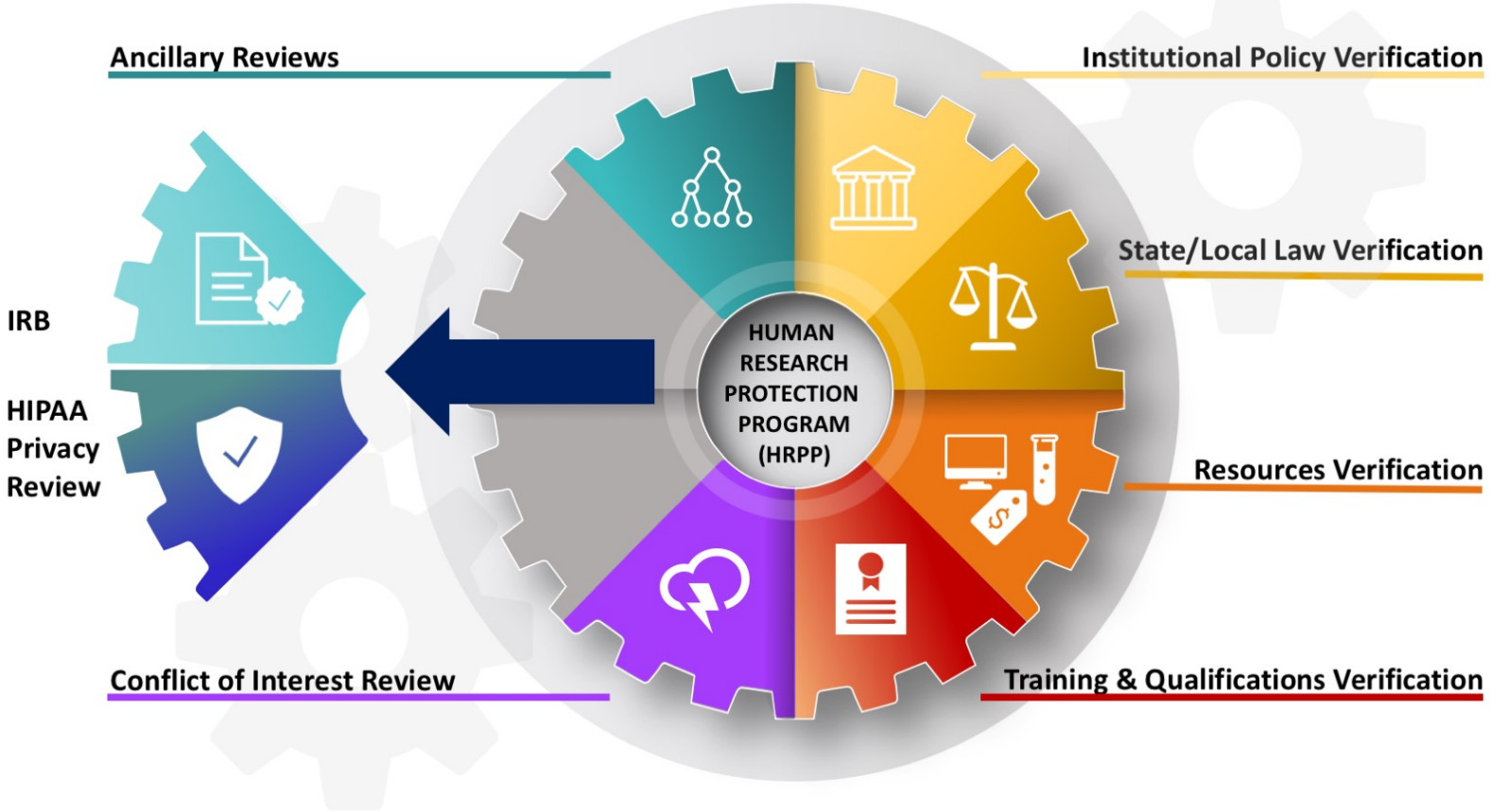

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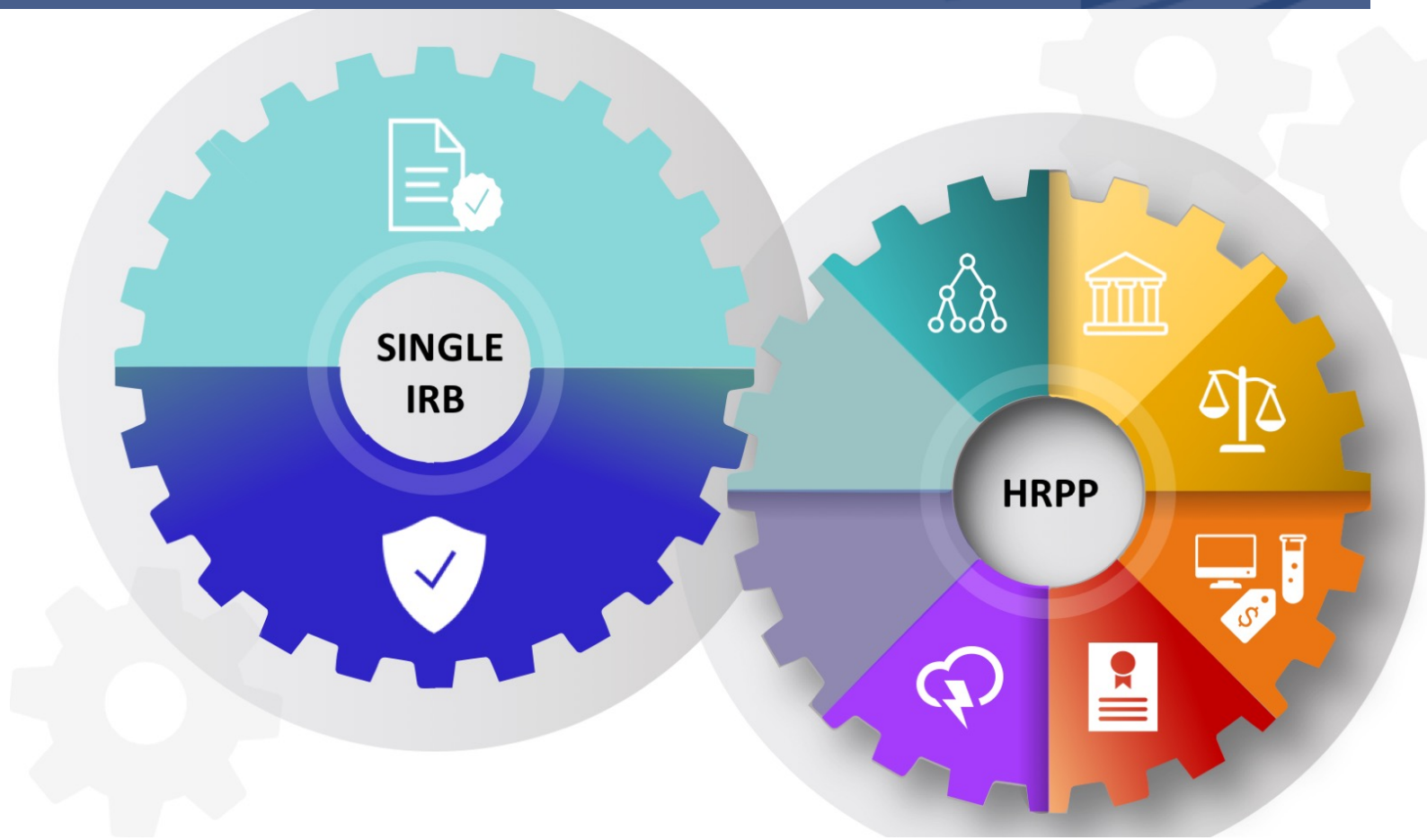
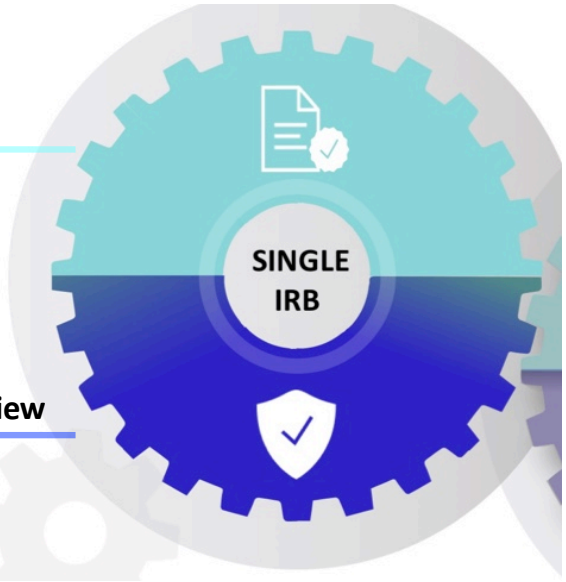


# Single IRB Review Components

**IRB**

**HIPAA Privacy Review**




Minimize risk

Risk-Benefit ratio

Vulnerable populations

Equitable selection

## Criteria for IRB Approval of Research

Informed consent

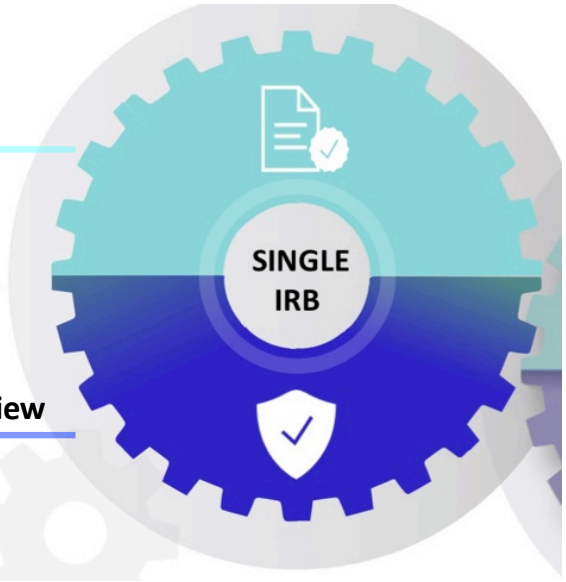
Privacy & confidentiality

Data & safety monitoring

## HIPAA Authorization and Privacy Rule

*45 CFR 164*

# Single IRB Review Components




Minimize risk
Risk-Benefit ratio
Vulnerable populations
Equitable selection

**Institutional/Community Profile**

Information about the site's community and potential participant population that may need to be considered in order to evaluate the **Criteria for IRB approval**. This most often includes relevant characteristics of the local population, and applicable local laws and policies. SIRBs usually only need to ask for this information **once per site**.

Informed consent
Privacy & confidentiality
Data & safety monitoring

# HRP Review Components

A **study-specific review** that needs to occur at the local site. This includes **verification** that the site-specific information is incorporated appropriately for the site in the protocol and consent documents. It also includes the relying site **HRP's review responsibilities** as outlined in the reliance agreement.

This generally includes study-specific confirmation of

- COI,
- training/qualifications of local research staff,
- ancillary reviews,
- application of local laws and policies

# Key Terms

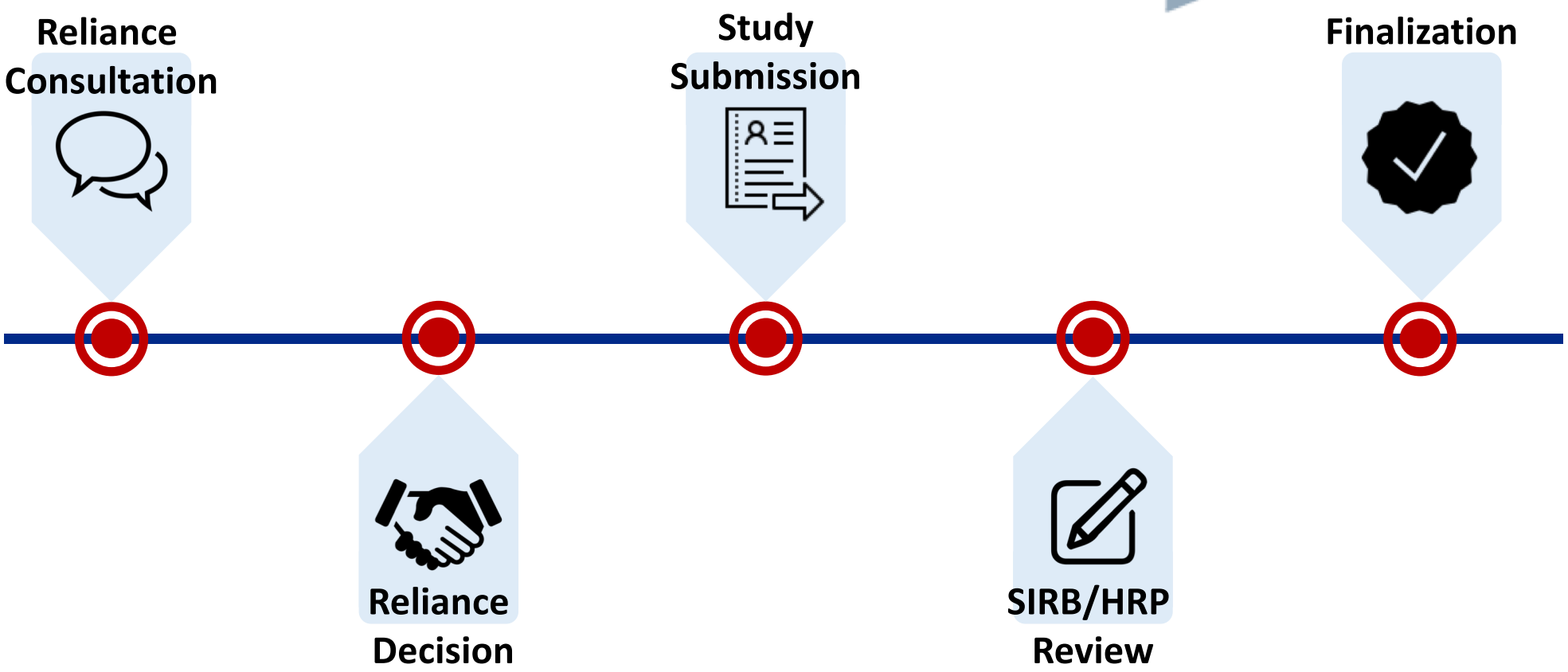
| | |
|---|---|
| Reliance Agreement | Contract between two IRBs that allows one IRB to rely on the review by the other IRB. Lays out all of the responsibilities. Signed by IRB Director or Institutional Official. |
| SMART IRB Agreement | A *type* of Master reliance agreement. Organizations sign on through a joinder agreement, still requires reliance decision to be made for each study. |
| Institutional Profile | Static information about the institution. Provided by relying IRB to reviewing IRB. May be publicly available. |
| Local Context | Information about a relying site's community or local policies. May include study-specific questions. Provided by relying IRB to reviewing IRB. |

# Project Initiation

| Protocol Development | Site Selection | SIRB Selection |
| --- | --- | --- |
| • Responsibility of Lead Study Team<br>• Recruitment Plan<br>• Consent Process<br>• Data and Safety Monitoring | • Approximate number of and names of sites – as comprehensive as possible<br>• Reliance Agreements<br>• Site-Specific Procedures | • Lead/primary research institution<br>• Study sponsor network chooses<br>• Special requirements warrant using particular IRB<br>• IRB has discretion to act as SIRB |

# Project Initiation Process

# Standard SIRB Project Initiation Process



STAGES OF THE PROCESS

**Reliance Consultation**

Reliance Decision

Study Submission

SIRB/HRP Review

Finalization

# Reliance Consultation

- Types: Meeting, Form, Phone Call, Email
- SIRB will determine if single IRB review is appropriate
- Additional topics during the consultation may include:
  - The infrastructure that will be used to implement single IRB review (e.g., agreements and systems)
  - Management of site consent documents
  - Coordination with participating sites and their HRPs

**Following this step, notify relying sites to initiate communication with their HRP**

STAGES OF THE PROCESS

- **Reliance Consultation**
- Reliance Decision
- Study Submission
- SIRB/HRP Review
- Finalization

# Reliance Consultation

## Information Needed

Provide an initial site list with contact information
- Legal Entities, Components, Affiliates

SIRB may require protocol and ICF before moving forward

Plan for managing the study
- DCC
- Communication

STAGES OF THE PROCESS

Reliance Consultation

**Reliance Decision**

Study Submission

SIRB/HRP Review

Finalization

# Reliance Decision

**The SIRB and the relying site HRP will negotiate reliance terms**

- SMART IRB Master Joinder Agreement
- Individual Agreement

**The SIRB process for an individual site may not move forward until that site has officially ceded review. Methods for documenting cede decisions:**

- SMART IRB Master Joinder Agreement
- Individual Agreement

STAGES OF THE PROCESS

- Reliance Consultation
- Reliance Decision
- **Study Submission**
- SIRB/HRP Review
- Finalization

# Slide Title

## Submission Models

**Lead site and other sites can be approved during initial submission**

Additional sites can be added via amendment

**Only lead site approved during initiation submission; all additional sites added via amendment**

**STAGES OF THE PROCESS**

- Reliance Consultation
- Reliance Decision
- **Study Submission**
- SIRB/HRP Review
- Finalization

# Study Submission

**Lead site submits the IRB application to the SIRB according to SIRB policies**

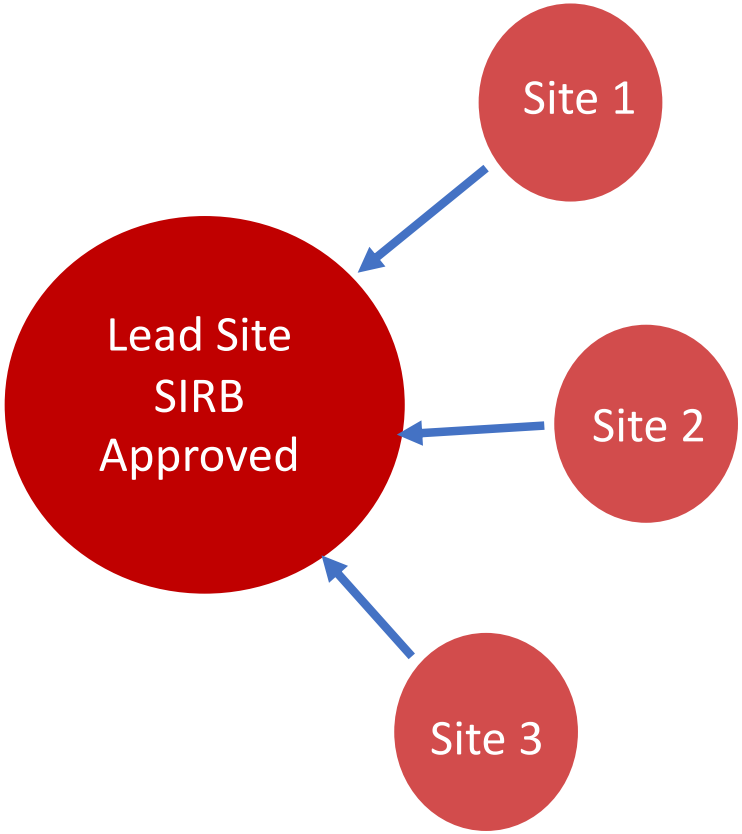
All sites relying on the SIRB (may include the lead site) must submit HRP application according to local policies

- Often looks like a regular IRB application
- Some HRPs will not agree to the Reliance Decision step until the HRP application has been submitted
- Relying sites need to know their HRP's process and requirements for submission

STAGES OF THE PROCESS

- Reliance Consultation
- Reliance Decision
- Study Submission
- **SIRB/HRP Review**
- Finalization

# SIRB Review – Lead Site Approved First




- Will follow standard IRB review process
- Relying sites will be added via amendments/change application once local HRP documentation complete

STAGES OF THE PROCESS

- Reliance Consultation
- Reliance Decision
- Study Submission
- **SIRB/HRP Review**
- Finalization

# HRP Role and Review

## Institutional/Community Profile

1. Information about the community the SIRB needs to complete a review
2. Completed by HRPs – may be form, may be electronic system
3. May be requested only once for each site

## HRP Review

1. Information HRP provides to SIRB *after* completion of study-specific HRP review that impacts SIRB review

STAGES OF THE PROCESS

Reliance Consultation

Reliance Decision

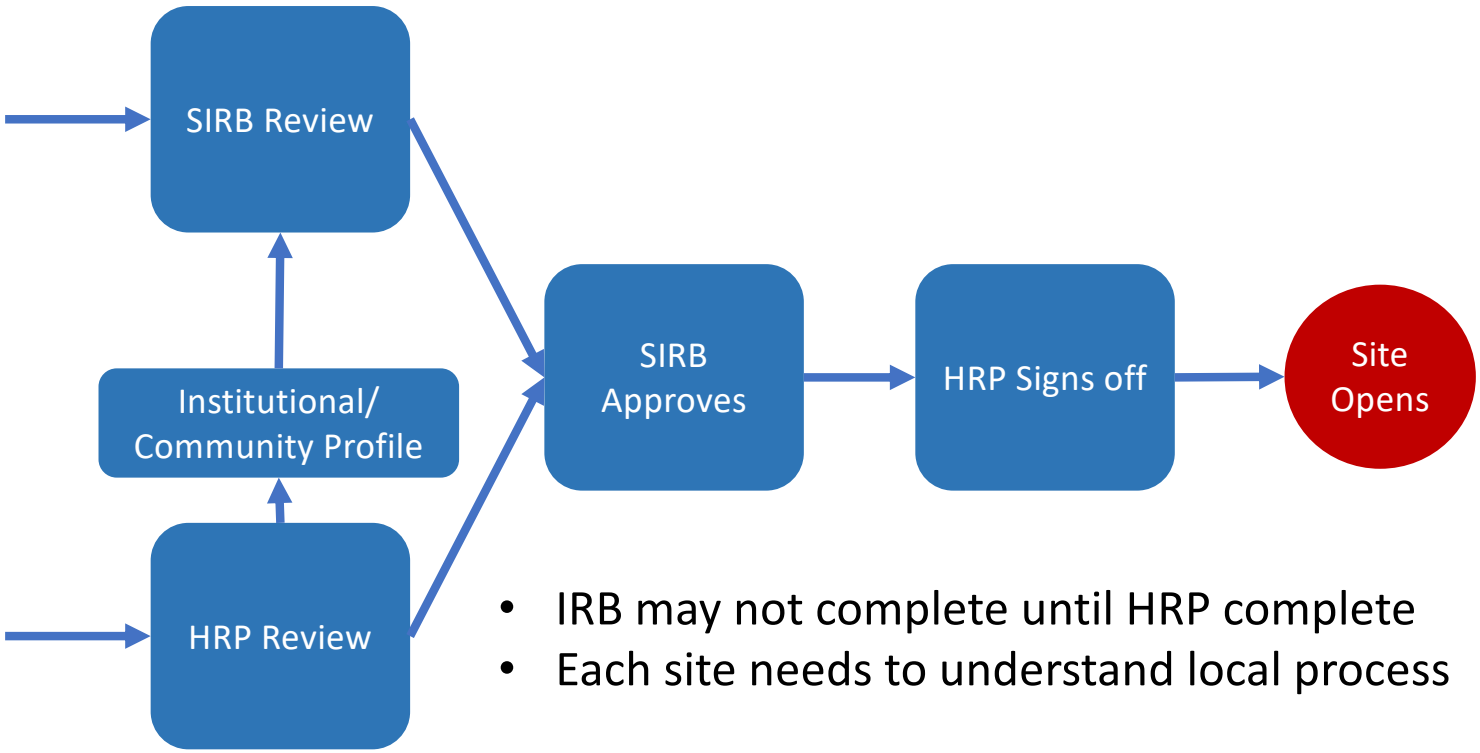
Study Submission

**SIRB/HRP Review**

Finalization

# SIRB/HRP Reviews Occurring in Tandem

SIRB and HRP Reviews may start at the same time



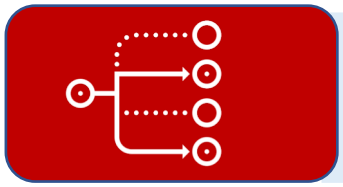

- IRB may not complete until HRP complete
- Each site needs to understand local process

STAGES OF THE PROCESS

- Reliance Consultation
- Reliance Decision
- Study Submission
- SIRB/HRP Review
- **Finalization**

# Finalization

Research cannot begin without SIRB approval and HRP approval/activation



SIRB approves site to be added to study

Each site needs to be approved by SIRB (including site-specific documents)

Lead site's responsibility to distribute IRB notices and documents to other sites, though electronic systems may help automate this function

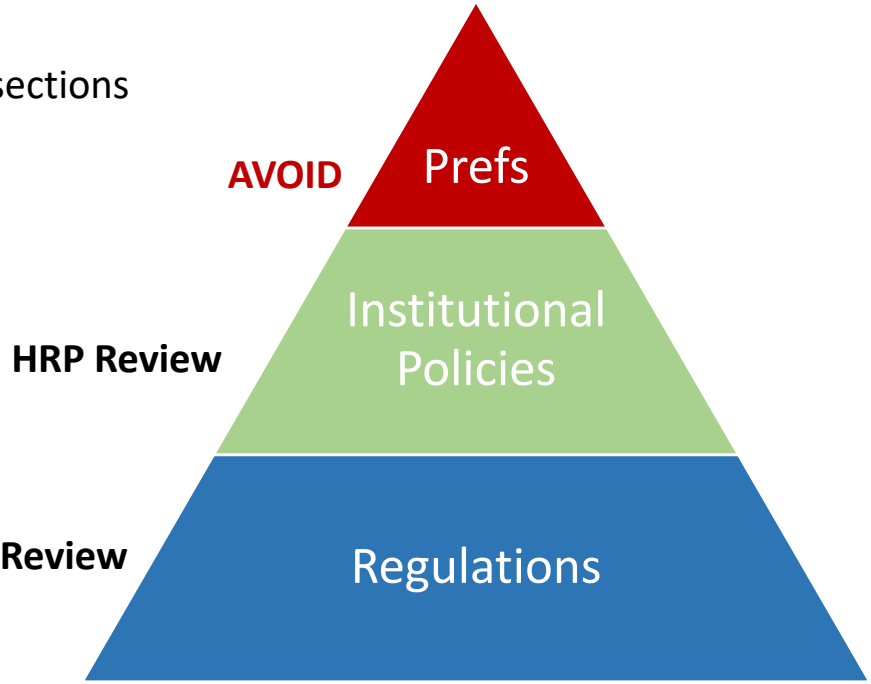
# Consent Forms

- Creation
- Who completes site-specific forms with local info?
- What may be different?
  - Person to Contact
  - Research—Related Injury
  - HIPAA
  - Other

**Limited Changes**

# Policy vs. Preference

- Consent Forms
  - Common Rule
    - IRB requirements based on minimum required sections
    - SIRB review
  - Institutional Policies
    - Costs to participants
    - Headers & Footers (MRN)
  - Institutional Preference
    - Formatting
    - Order of sections
    - Logos (policy vs. preference)



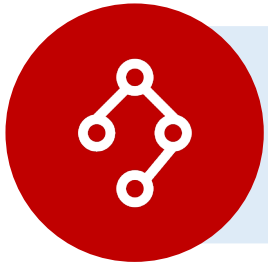
# Other Considerations for Initial Site Approval

| Recruitment | Local Laws |
| --- | --- |
| Institutional Policy | Age of majority<br>Pregnancy regulations |
| Site-specific recruitment plans | LARs<br>Other |

# Ongoing Review & Oversight

# Lead Study Team Responsibilities

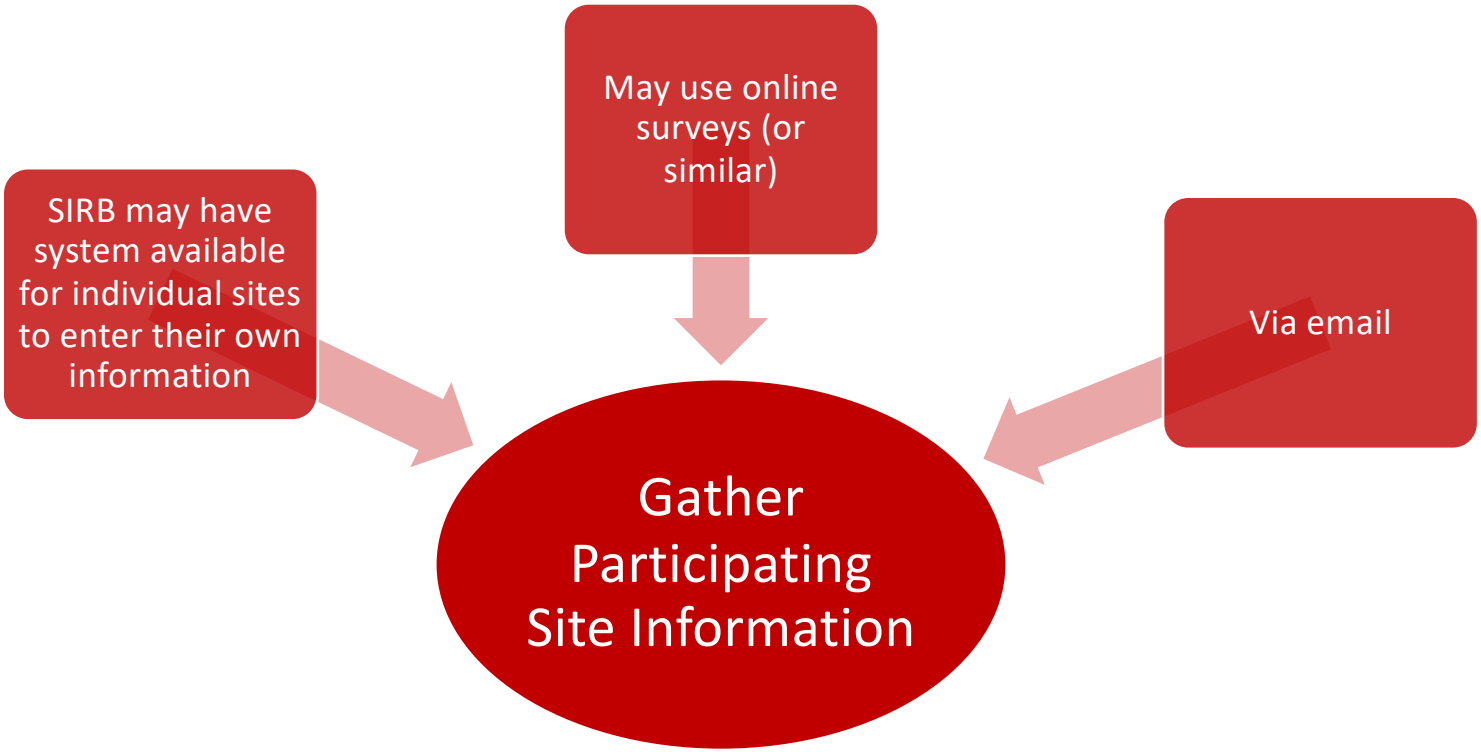
Act as a liaison for communication between the participating study teams and the SIRB



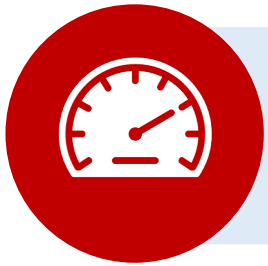
Prepare and/or facilitate the ongoing IRB submissions on behalf of all the sites

Conduct the study in accordance with the IRB-approved protocol

# Continuing Reviews



# Continuing Reviews



Generally every site has the same expiration date

Some SIRBs may provide process where sites that have not provided continuing review information will expire without all other sites expiring

Local HRPs for relying sites may require submission for updates on study status

# Amendments

## SIRB Amendments

- Submitted by Lead Study Team
- Study-wide Amendments - Changes that impact all sites
  - Protocol
  - Consent form updates
- Site-Specific amendments – Changes that impact individual sites
  - Local PI change
  - Local Research Related Injury language change

## HRP Amendments

- Relying sites may only need to submit local change when it impacts relying site HRP review
  - Local Personnel changes (may only be to local HRP)
  - Changes to anything that affects ancillary reviews
    - Drug Storage
    - Radiation
    - Sponsor

**Relying HRP may have additional requirements**

# Reporting

Follow SIRB's policy for reporting requirements

SIRB makes all determinations

Local HRPs may also require reporting

- Problem/event occurs at participating site
- Understand what is occurring locally
- Assist SIRB with follow-up, if necessary

Participating sites must know their local reporting policies

# Auditing and Monitoring

Lead study team/DCC should consider ongoing internal monitoring for all sites

- May be completed by participating site study staff

SIRB may audit any sites

Local HRPs may audit participating sites

- At request of SIRB
- Random
- If need is identified locally