Single IRB (SIRB) Training

Relying Site HRP Education Module | **Trial Innovation Network**

Presenter Names

Presenter Titles

Objectives

Describe the Single IRB (SIRB) Model and Human Research Protections (HRP)

Describe Reliance Process for Relying site HRP

Describe ongoing review and oversight responsibilities

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?

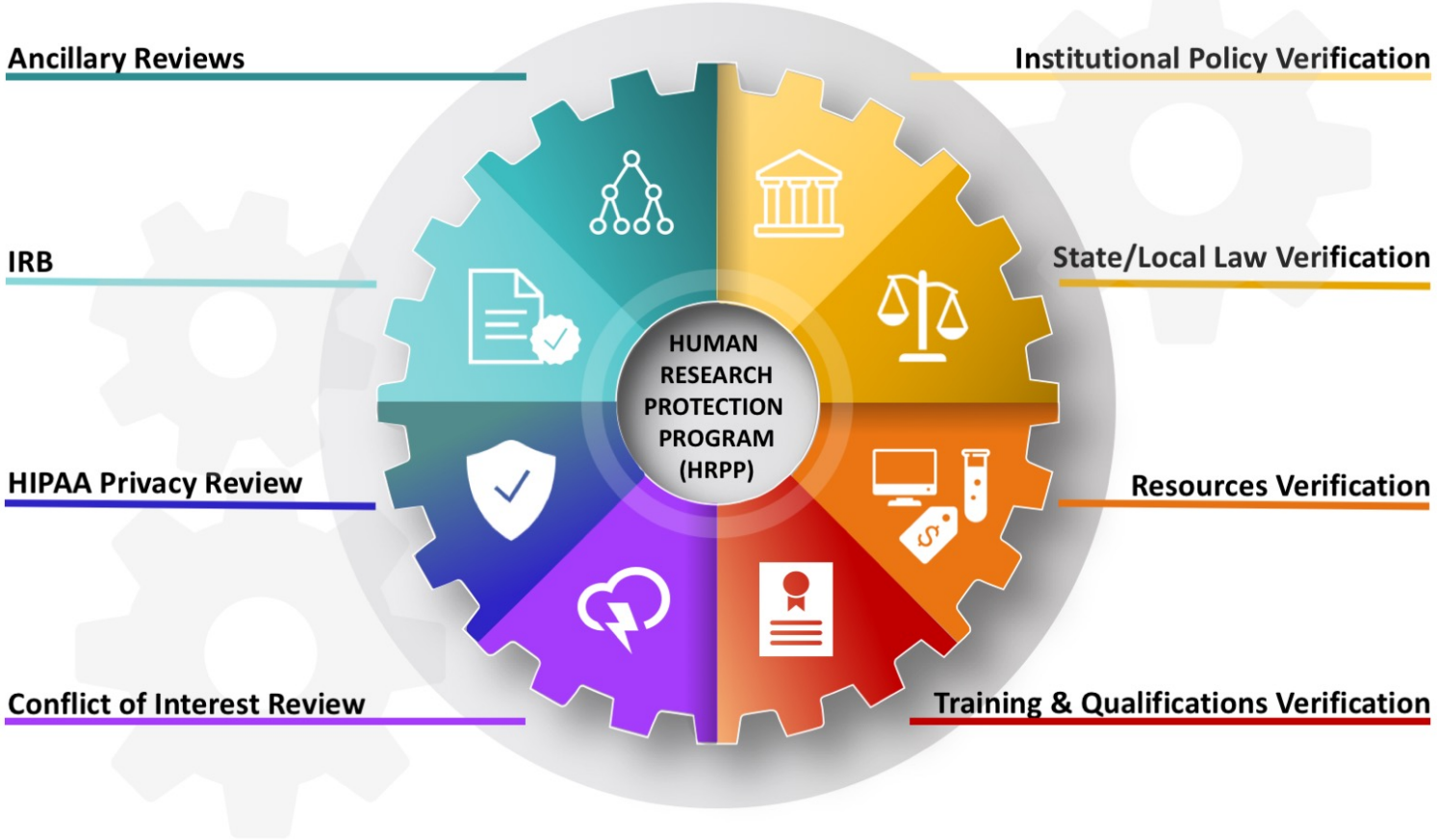
Exempt Research

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

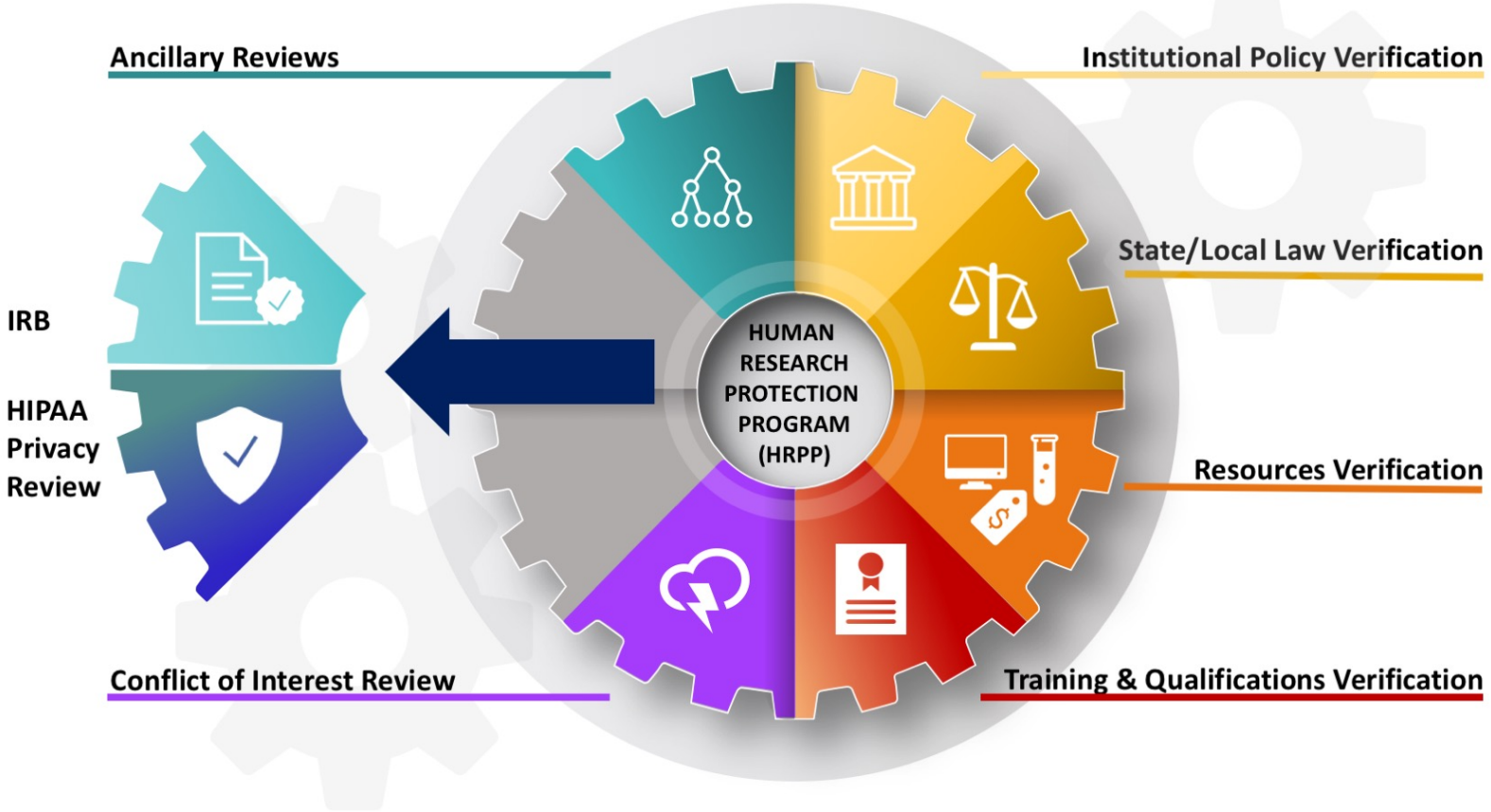
Where local IRB is required by federal, tribal, or state laws

Research conducted under career development, research training or fellowship awards

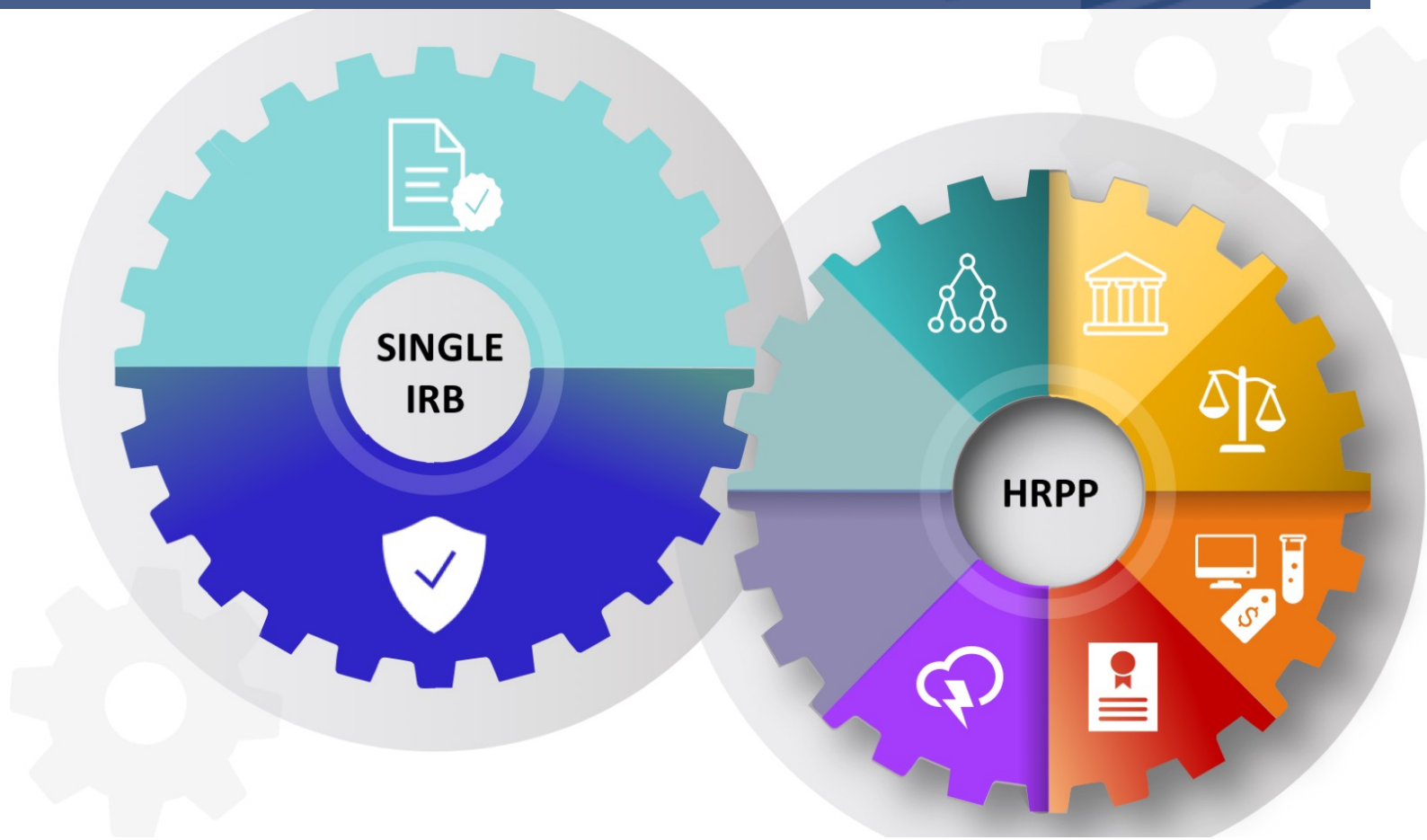
The Full Picture | The HRP



The Full Picture | The HRP



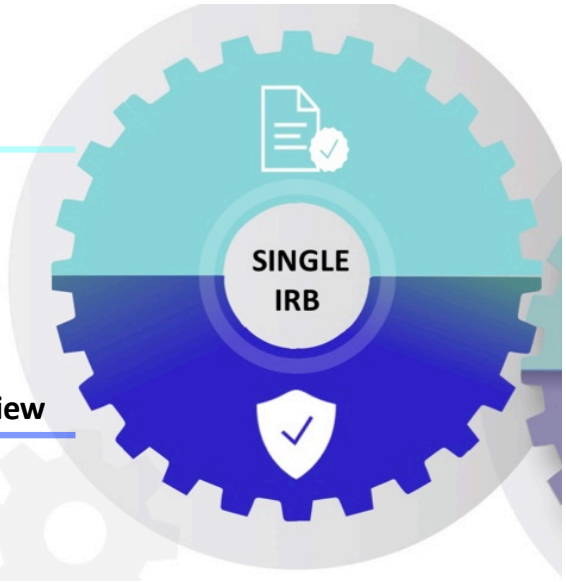
The Full Picture | The HRP



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

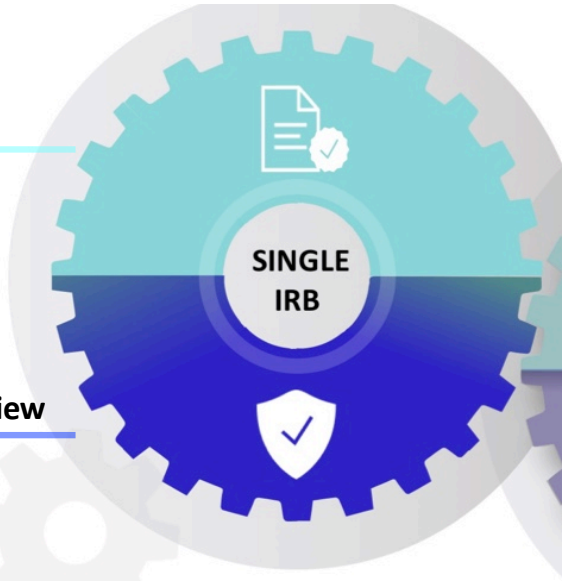
Privacy & confidentiality

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

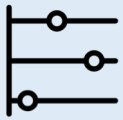
- COI,
- training/qualifications of local research staff,
- ancillary reviews,
- application of local laws and policies

Key Terms

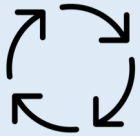
Reliance Agreement	Contract between two IRBs that allows one IRB to rely on the review by the other IRB. Lays out all of the responsibilities. Signed by IRB Director or Institutional Official.
SMART IRB Agreement	A *type* of Master reliance agreement. Organizations sign on through a joinder agreement, 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.

Most Important Takeaway

Develop and Document a Reliance Process



Internal Responsibilities



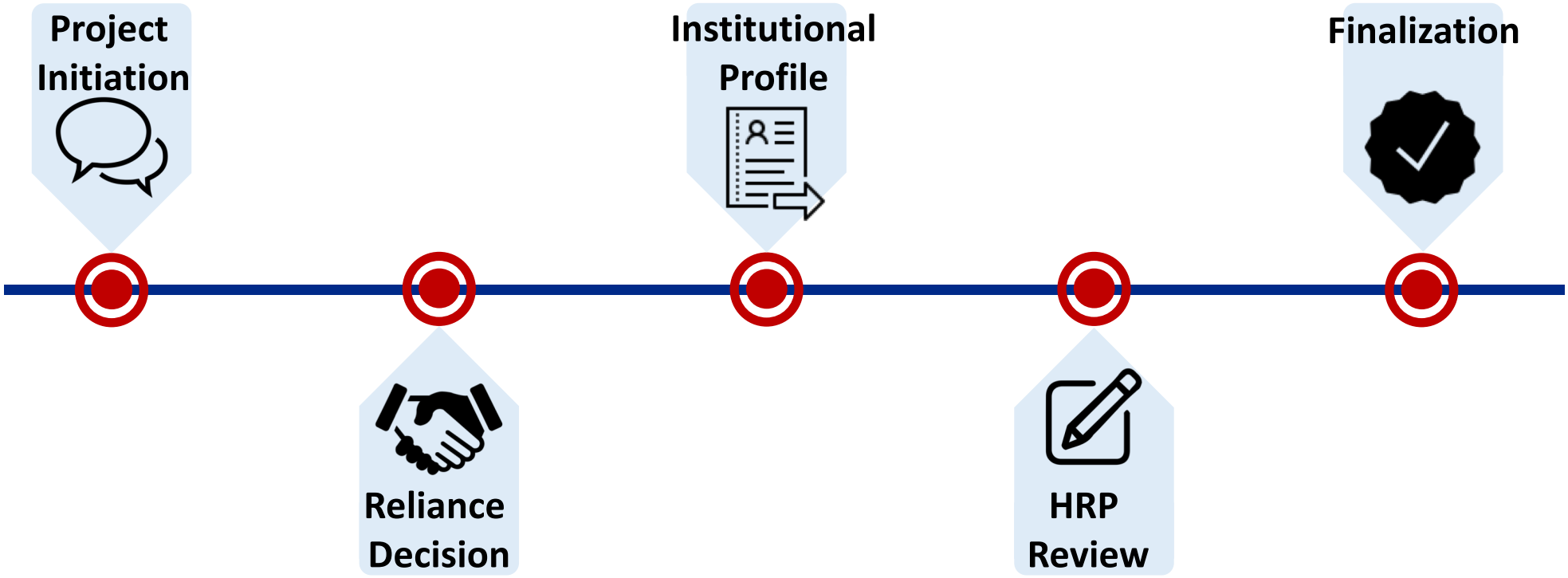
PI Responsibilities

External Communication

Documentation

Points to consider, ideas, and suggestions throughout presentation

SIRB Reliance Components for Relying HRP



Components of Reliance

- **Project Initiation**
- Reliance Decision
- Institutional Profile
- HRP Review
- Finalization

Project Initiation

PI contacts IRB/HRP

New grant submission

How will you learn about a project?

CIRB contacts you

System notification (IREx, SMART IRB Online Reliance, etc.)

Components of Reliance

- **Project Initiation**
- Reliance Decision
- Institutional Profile
- HRP Review
- Finalization

Project Initiation

What does the Relying HRP *need* at this step?

Could be very little depending on your process.
At *most*, need:

- Local PI name ★
- Name of the study ★
- Name of the CIRB ★
- Basic study information ★

Components of Reliance

- Project Initiation
- **Reliance Decision**
- Institutional Profile
- HRP Review
- Finalization

Reliance Decision

Is your institution willing to rely on an external IRB for this study?

- Is SIRB process mandated?
- What is the risk-level of the research?
- Who is the CIRB?

Process to Rely

- Reliance Agreement
- Master Agreement (e.g. SMART IRB Agreement, Network-specific)
- Document individual study decision
- Understand your responsibilities under agreement (e.g. HIPAA)

Components of Reliance

- Project Initiation
- **Reliance Decision**
- Institutional Profile
- HRP Review
- Finalization

Agreeing to rely does NOT mean

- **Relying site has to do whatever the CIRB says**
- **HRP has to agree with whatever determination CIRB makes**
- **HRP does not get to request changes**
- **HRP can't get out of the agreement**
- **Relying site does not review the study**
- **PI does not need any type of approval from Relying site**

Components of Reliance

- Project Initiation
- **Reliance Decision**
- Institutional Profile
- HRP Review
- Finalization

Agreeing to rely means

We are *willing* to rely on the CIRB's review

We will provide CIRB with our local information

We are *willing* to perform responsibilities outlined in agreement

We will provide CIRB any additional information based on our HRP review

We expect CIRB to perform responsibilities outlined in agreement

HRP has final authority to allow research to be conducted at our institution

Components of Reliance

- Project Initiation
- **Reliance Decision**
- Institutional Profile
- HRP Review
- Finalization

Reliance Decision

What does the Relying HRP *need* at this step?

- Local PI name
- Name of the study
- Name of the CIRB
- Basic study information
- Contact info for CIRB ★
- Optional: Draft Protocol & ICF ★

Components of Reliance

- Reliance Consultation
- Reliance Decision
- **Institutional Profile**
- HRP Review
- Finalization

Institutional Profile

CIRB needs your institutional/community information to review Criteria for Approval

Methods

1. CIRB provides you questionnaire/survey (Local Context Survey)
2. You send profile document (Keep one on file)
3. IREx or other online system

What's Included

1. State Laws
2. Consent policies
3. HIPAA Requirements (separate document?)
4. Research-Related Injury language
5. IRB Contact information

Components of Reliance

- Reliance Consultation
- Reliance Decision
- Institutional Profile
- **HRP Review**
- Finalization

HRP Review

Now you have all the information you need – what are you going to do?

1. What are the requirements for the HRP Review?
   - Conflict of Interest review
   - Training/Qualifications review/confirmation
   - Resource review (may include departmental review)
   - Radiation Safety
   - Institutional Biosafety
   - HIPAA (depends on terms of agreement)
   - State Laws
   - Institutional Policies (may include Scientific Review)

Remember Criteria for Approval are responsibility of SIRB

Components of Reliance

- Reliance Consultation
- Reliance Decision
- Institutional Profile
- **HRP Review**
- Finalization

HRP Review – How to do it

What is your application process currently? Does each group have its own application?

- Often IRB application
- May be a separate HRP application
- May be an abbreviated IRB application

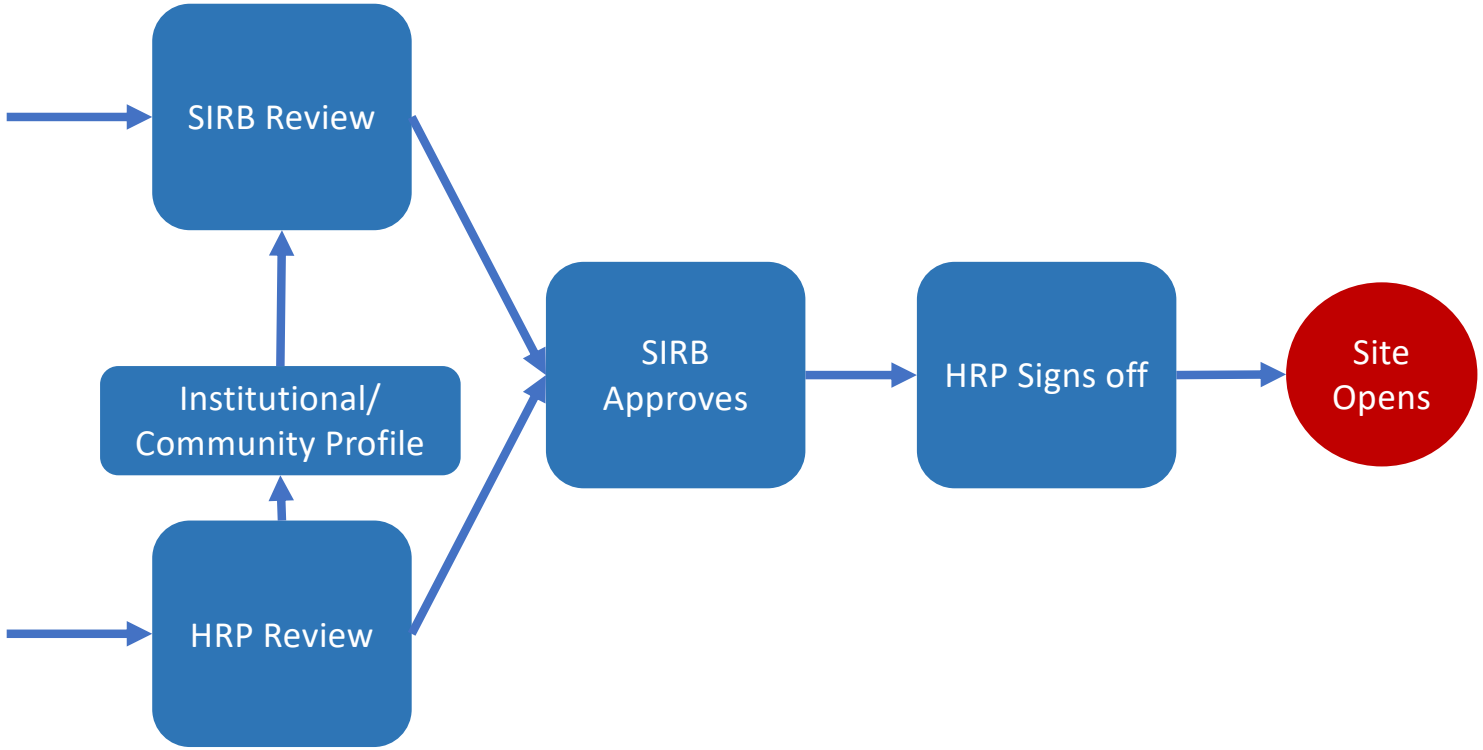
Consider the timing of your process

Based on the regulations and the information you need – SIRB and HRP reviews can occur at same time

Components of Reliance

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

SIRB/HRP Reviews Occurring in Tandem



Components of Reliance

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

Notification of HRP Review

Dependent upon SIRB and HRP process

Option A:

SIRB may want confirmation that HRP has conducted review before they approve the site.

Not necessarily an “approval”, just **completion** and any info SIRB needs to conduct their review is provided.

Option B:

HRP review is responsibility of relying site HRP. Since final authority comes down to HRP, SIRB goes ahead and approves site with or without HRP completion.

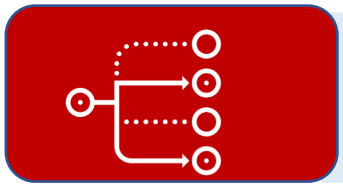
HRP does final review of what SIRB approved and if HRP requirements are not met, site PI has to submit change to SIRB before relying site HRP signs off.

Components of Reliance

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

Finalization

Research cannot begin without approval from SIRB and HRP



SIRB approves site to be added to study

Local HRP activates study at site

Local study team needs to understand that both “approvals” are needed

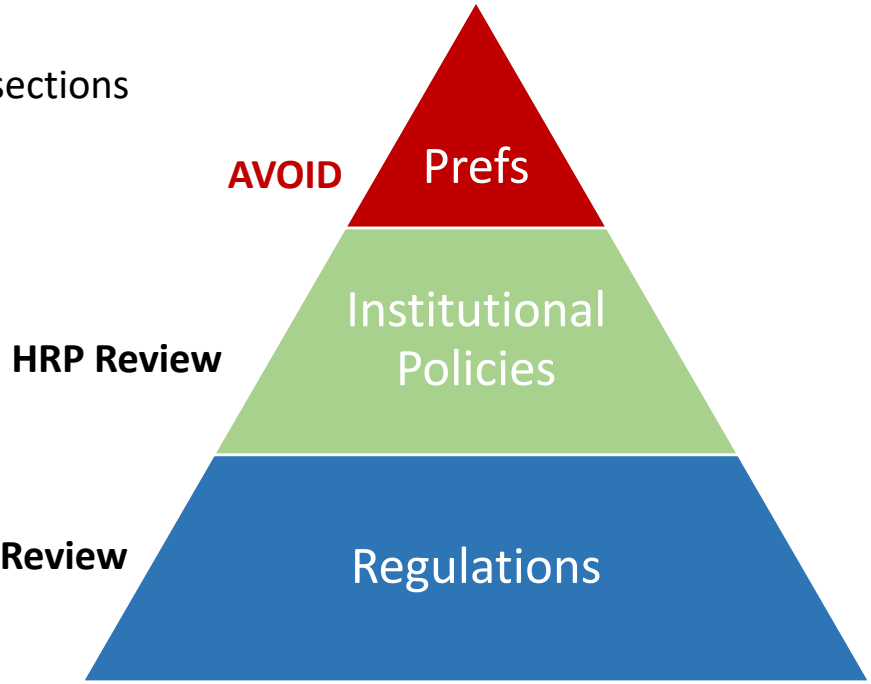
Consent Forms

- Site-specific consent documents
- Most differences are pulled from Institutional Profile/Local Context
- 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)

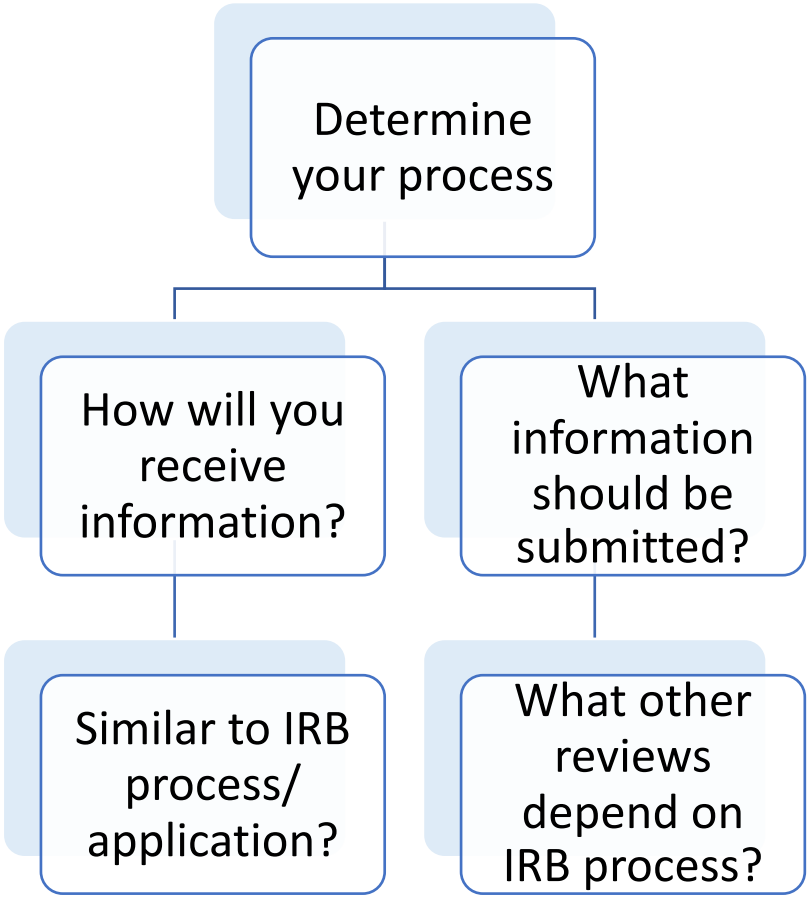


Common areas of institutional differences

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

Ongoing Review & Oversight

Continuing Reviews and Amendments



Regulatory Requirement

HRP only needs ongoing information that impacts the HRP.

- No continuing review requirement
- Does institution require enrollment numbers from IRB system?

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

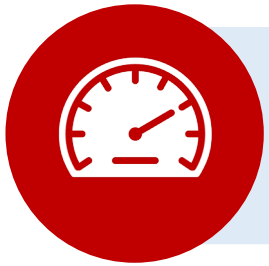
- May be completed by participating site study staff
- Relying site can request documents from SIRB

SIRB may audit any sites

Relying HRPs may audit local site

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

Final thoughts on Ongoing Oversight



Consider the information you actually *need* to provide HRP/institutional oversight – will be institution-specific

Educate your local investigators on your process – what and when to report to the local HRP

Consider responsibilities for reporting and monitoring, may not be that different from normal IRB review