IRB Reliance

Conducing multi-site human subjects research

Ask Questions at Any Time

About the Presenter

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- Senior Coordinator
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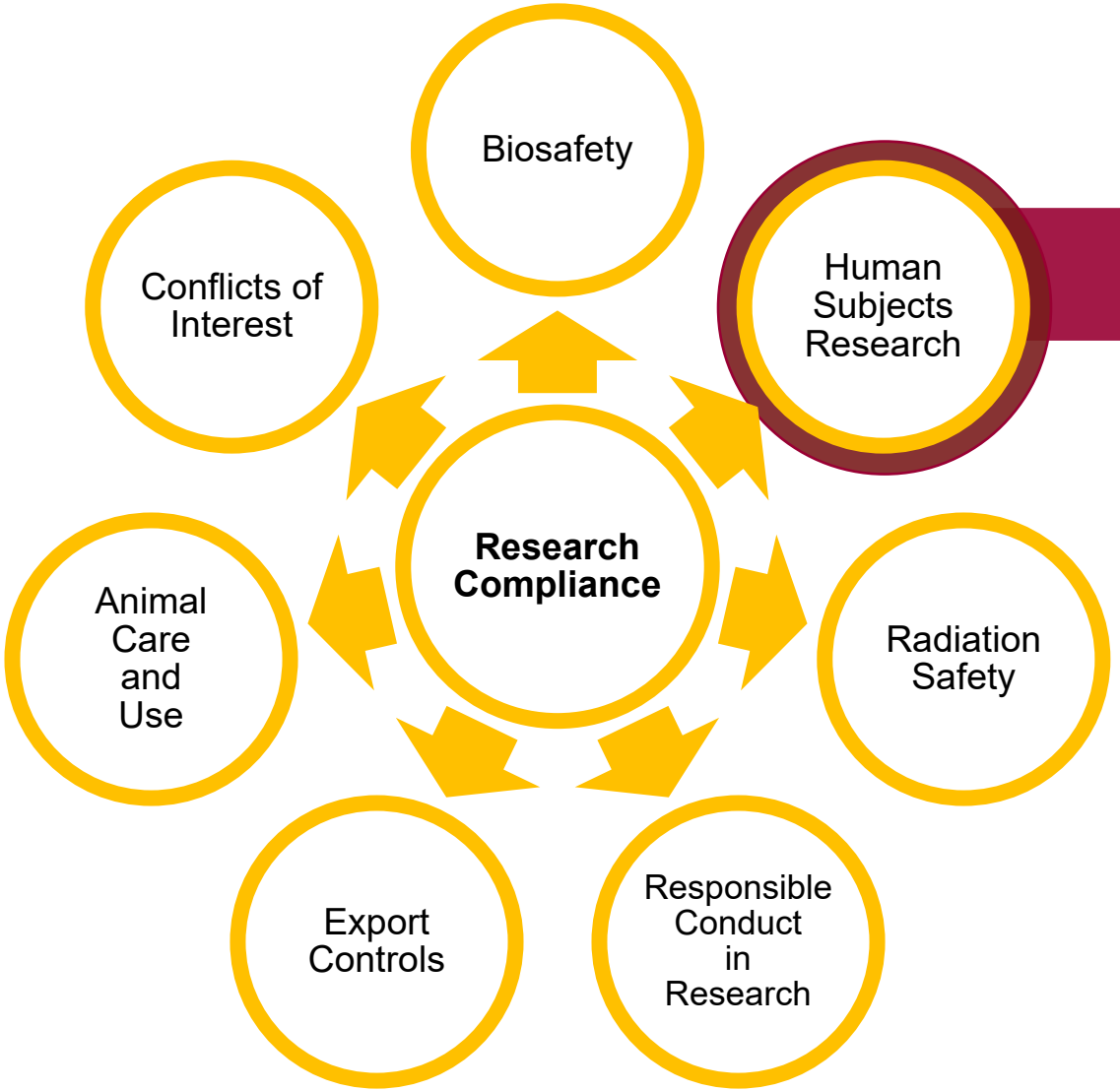
- Previous IRB experience at:

Overview + Definitions

Overview – NU-RES Compliance Areas



Department of Human Research + IRB

The DHR supports the IRB in reviewing **Human Subjects Research** *or* **Clinical Investigations** to document and ensure that the activities are conducted ethically and in accordance with relevant regulatory criteria

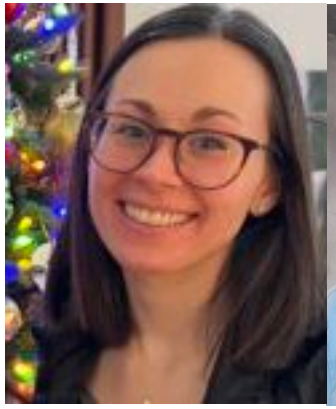
DHR – who is the team?

Anita Balgopal
Executive Director

April Boudreau
IRB Coordinator

Claire Spelkoman
IRB Coordinator

Clarke Dalton
IRB Coordinator



Ashley Strzelecki
IRB Coordinator

Erik Williams
Senor Coordinator

Rae Mwangi
Assistant Director

Maria Voyiatzis
CPS Coordinator

IRB Reliance

Conducing multi-site human subjects research

Learning Objectives

- What is multi-site research?
- What is single IRB review?
  - Brief history
  - When is it mandated/required?
  - What responsibilities are differed?
  - When is someone “engaged”?
- What are the different types of reliance agreements?
- What are the steps for establishing a reliance agreement at NU?

Terms

Single IRB ≈ sIRB ≈ “IRB of Record” ≈ “Reviewing IRB” ≈ “Central IRB”

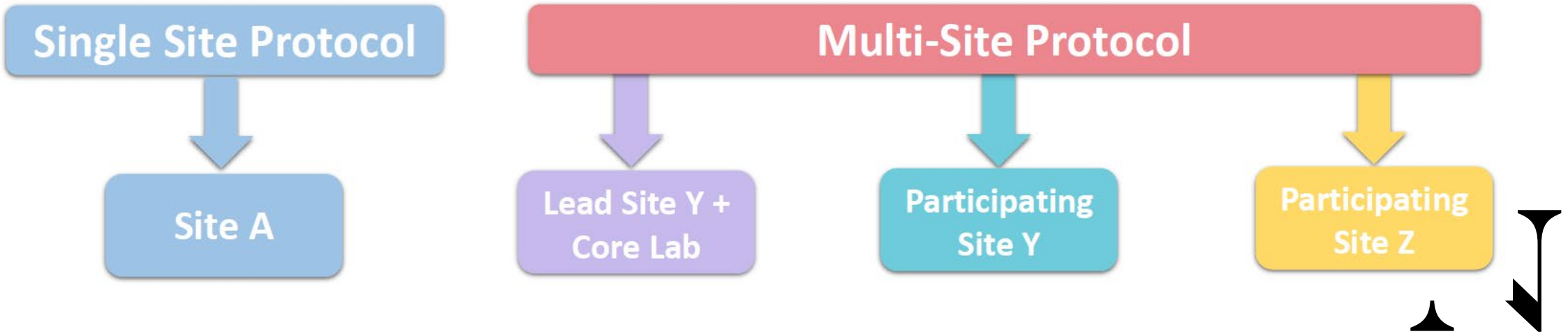
Cooperative research ≈ multi-site research

Differing ≈ ceded review ≈ “relying on”

Terms are loose due to different regulations and the fact many terms were used prior to sIRB regulation.

What is multi-site or “cooperative” research?

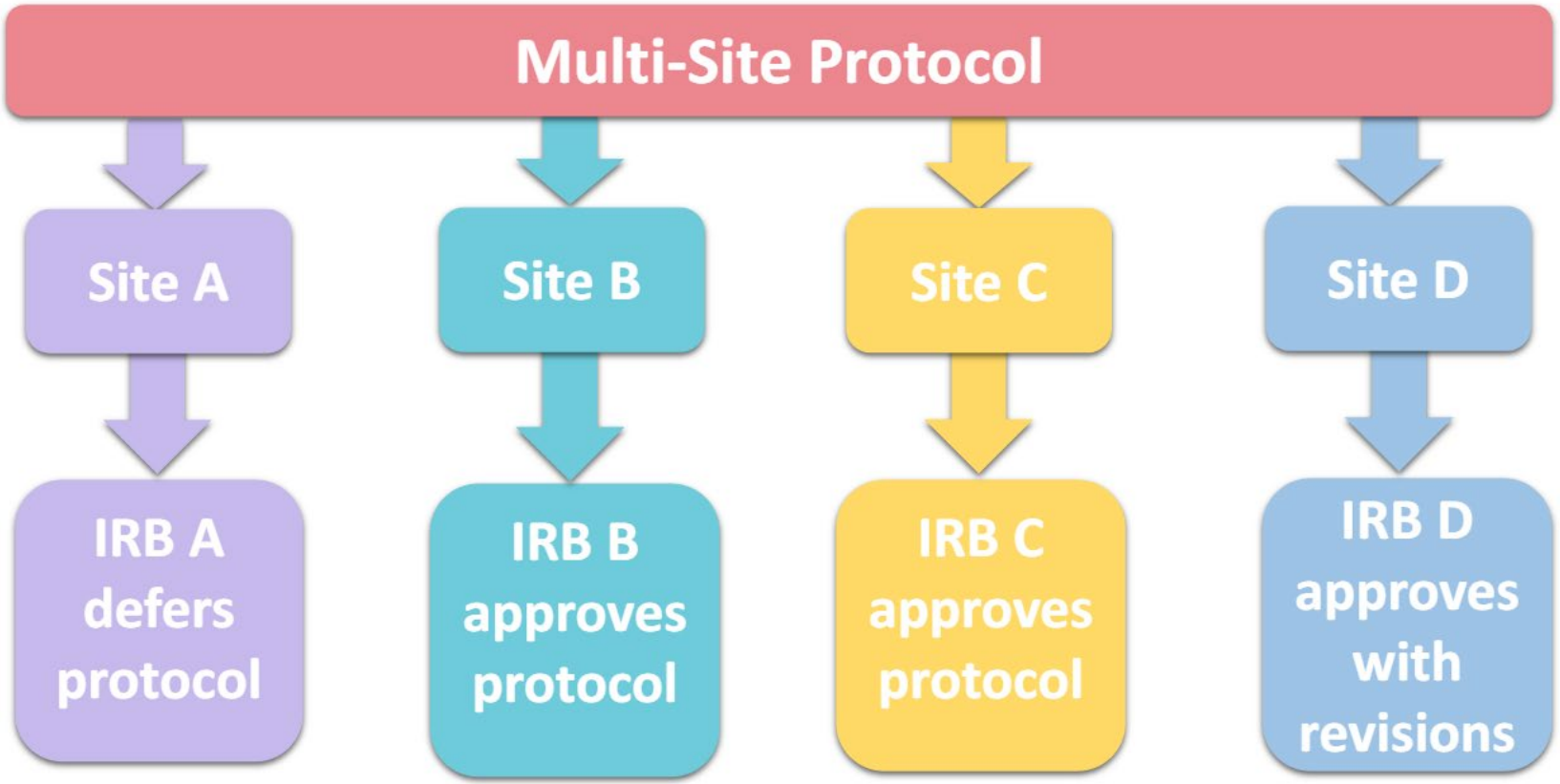
- “**Research projects** (*protocols*) that involve **more than one institution** conducting (*engaged*) the **same human subjects research**” -- NIH
- Note that “research project” is not defined. A grant can contain one or more “projects”.



*Graphic taken from NIH

Before sIRB

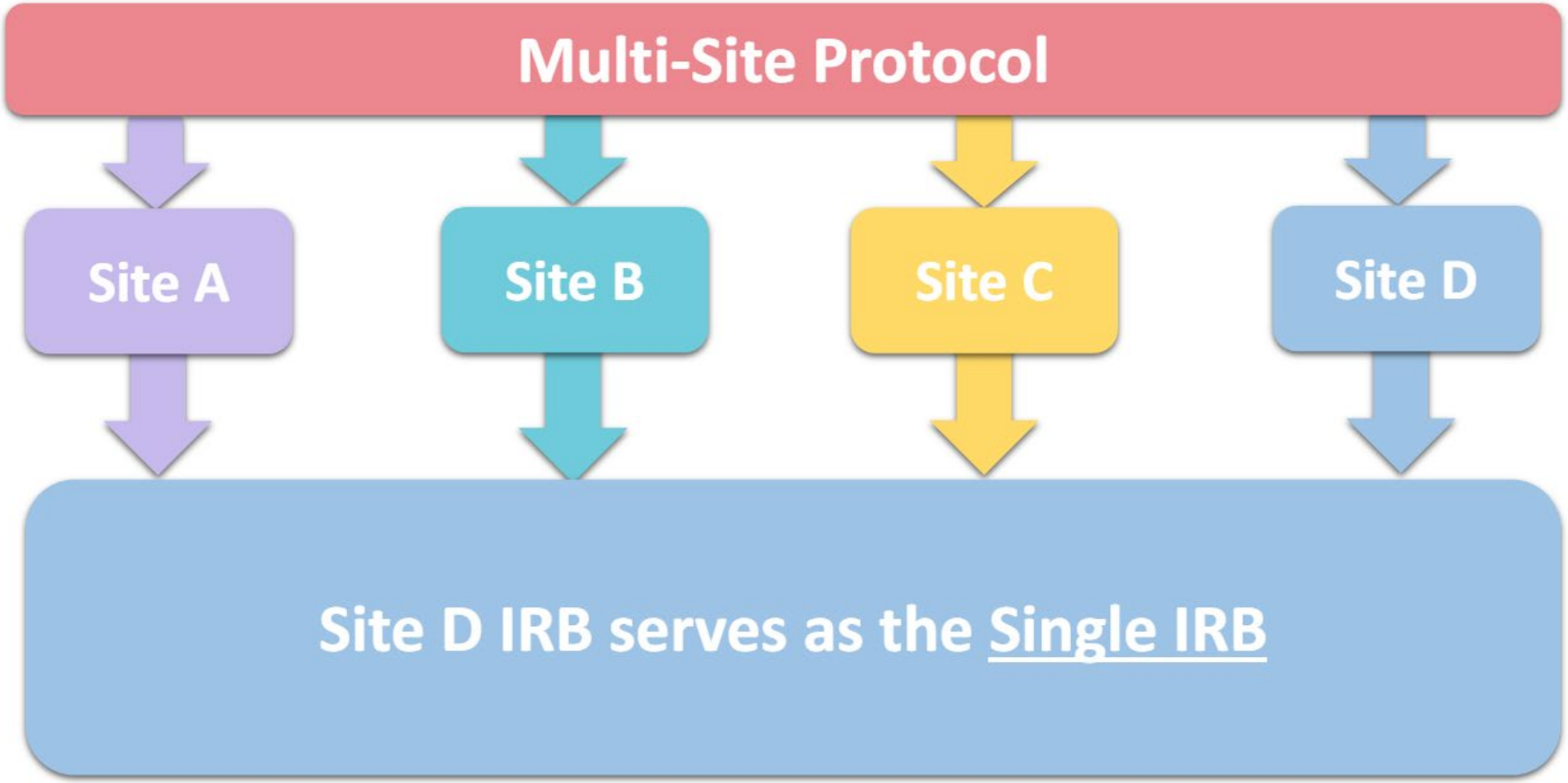
Multi-site studies were subject to different reviews – results varied:



*Graphic taken from NIH

After sIRB

Allows for consistent determinations made by a single IRB



*Graphic taken from NIH

Engagement:
We don’t talk about engagement until we have to

Engagement:

- Regulatory term that defines when an institution requires IRB oversight.
- We can be “involved” in human subjects research but not “**engaged**”.
- ?? “Acting on behalf of the institution” ??

  - Always engaged when we are the prime on the grant or obtaining informed consent.
  - Sometimes engaged when we intervening or interact with participants.
  - Sometimes engaged when we get data or specimens.
  - See Engagement Worksheet on our Reliance Website

The sIRB Mandate

When is single IRB **required**?

Brief History of sIRB

Pre-2018 sIRB was rarely used. Usually limited to research where institutions had a long-standing relationship or clinical trials.

2018 NIH research requires single IRB review

2020 Federally funded research under the revised common rule requires single IRB review

When is sIRB Mandated?

Revised Common Rule

Any institution located in the United States that is engaged in non-exempt cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.

45 CFR 46.114

NIH Policy

All domestic sites must use a single IRB of record to review human subjects research when participating in NIH supported multi-site studies.

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When is sIRB Mandated?

- Most federally funded or supported projects are subject to the revised common rule and, as such, require sIRB:
  - NIH, NSF, DoD, etc…
  - NIJ does NOT require sIRB.
- FDA regulations do not have a sIRB mandate
  - sIRB is not inconsistent with FDA regs.

Exceptions to sIRB Mandate

- Research for studies prior to implementation (review specific regs)
- “Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe)”
- Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
- “Exempt” research (must be “exempt” at all sites)

Deferring Review

The nitty and gritty

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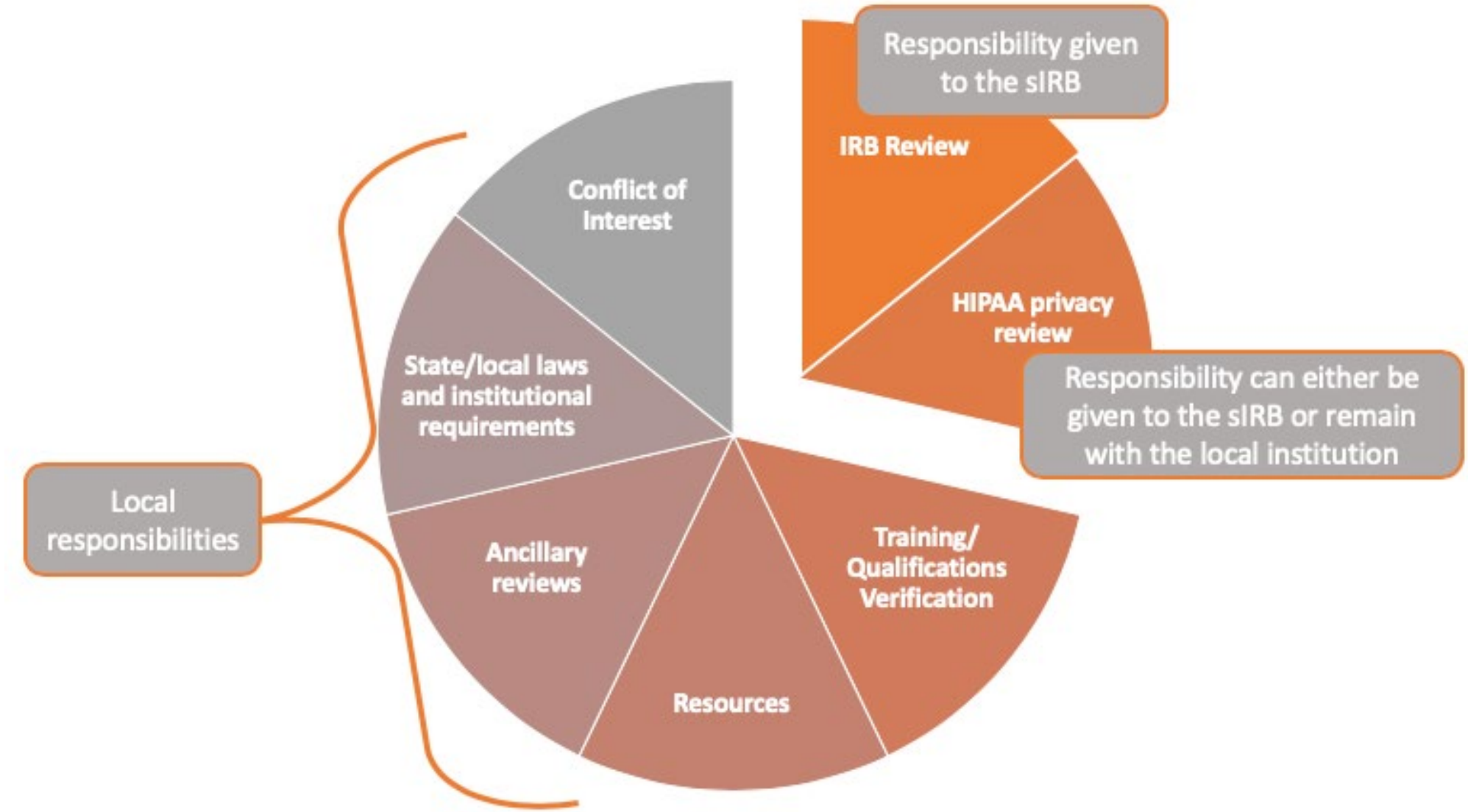
Who establishes sIRB and how?

- Form agreement between two institutions that relies on our Federal Wide Assurance (FWA)
- The reliance agreement is signed by institutional officials at both institutions and outlines roles *and* responsibilities of each/terms of the reliance.
- Terms of reliance can vary from simple to complex.

What responsibilities are part of our review process?

*Graphic taken from PennState

What responsibilities are differed in sIRB?

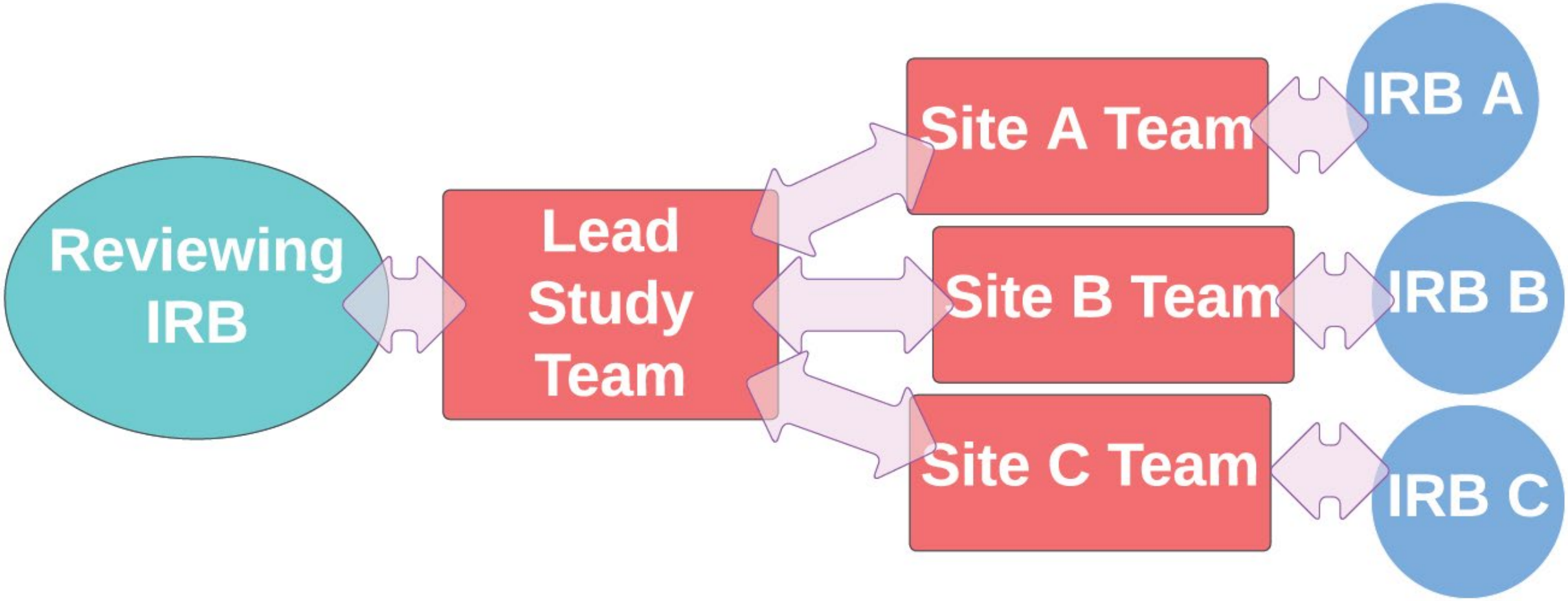


*Graphic taken from PennState

In Practice:
the good, the bad, and the ugly

- Results in more consistent studies.
- Faster ??? most of the time.
- Can result in institutional disagreements that slow down the review process.
- Different IRBs have different processes = very confusing for research teams.
- Little infrastructure and uniform practice = lots of work for research teams.

In Practice:
research team responsibility



Different types of reliance

SMART IRB

Online platform for establishing agreements.

Requests are initiated by research teams.

Streamlined and designed to facilitate easy reliance agreements.

Has a wonderful video: https://smartirb.org/reliance/

SMART LOA is a variation that some institutions require – it is a signed form (PDF, etc) that used the SMART master agreement.

IRB Authorization Agreements (IAA)

Signed agreement (PDF, etc) outline terms of reliance.

Often uses HHS Template, but institutions can have custom versions.

Memorandums of Understanding or Master Agreements

A permanent agreement between two institutions.

Usually part of a larger partnership.

Individual Investigator Agreements (IIA)

Used when collaborating an independent investigator or when the collaborator is not affiliated with a US based institution with a FWA on file.

i.e. research team members who are community members, teachers, or clinicians at local clinics.

Reliance @ NU

Moving forward isn’t always a linear process

Northeastern University
Research Enterprise Services

Step 1

- Identify if a reliance agreement should be used. Use the **Northeastern University Reliance Flowchart**!

Step 2

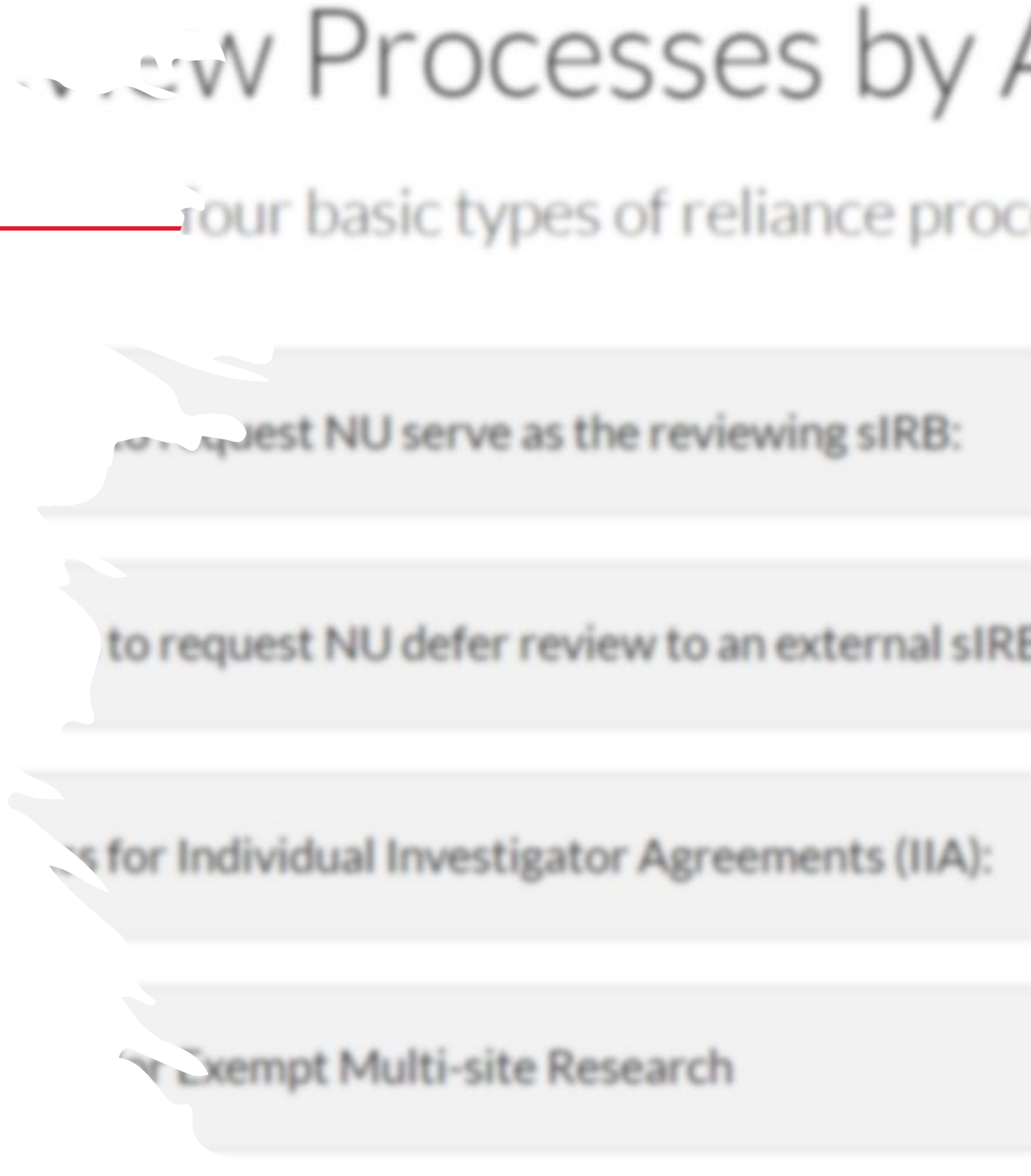
- Identify who should serve as the reviewing IRB and what type of agreement to use.
- Usually the lead institution on the grant, but can be dependent on:
  - Sponsor
  - Funding
  - Intuitional expertise
  - Intuitional infrastructure
  - Intuitional policy
  - Accreditations like AHRPP
  - Scope of work

Step 3

- Develop protocols, consent forms, etc
- Consider best avenues of communication and identify institutional requirements
- Note that NU requirements are minimal to reduce researcher burden.

Step 4

- Navigate the intake process/requirements at all sites.
- @ NU see https://hsrp.research.northeastern.edu/irb-reliance/
- For serving at the IRB of record, recommend executing the reliance agreement as an amendment to an approved study
- For deferring, follow the intake process (2 forms and documents from the reviewing IRB)



Step 5

- Follow the processes and try to identify what might be keeping the agreement from moving forward.

Step 6: Ongoing Responsibilities

- Keep relying IRBs updated with reviewing IRB determinations including:
  - Continuing Reviews
  - Amendments
  - Reports
  - Changes in local research teams

Resources

NU's NEW reliance website:

https://hsrp.research.northeastern.edu/irb-reliance/

IRB Drop-in Hours:

https://hsrp.research.northeastern.edu/

SMART IRB resource library:

https://smartirb.org/resources/

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