Multi-site Research: Institutional Decision Making at the University of Michigan

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IRBMED Seminar Series
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Multi-site Research

- More than one site is participating in the research study
  - Performance sites
  - Coordinating centers
- Each site would normally conduct an IRB review of the research
- Single IRB review is required or requested
  - Policy (NIH now; Common Rule later)
  - Request (not required but may be more efficient)

Single IRB (sIRB) Mandates:

Use of a research

- Single IRB in multi-site research is now a requirement for NIH funded
- NIH sponsored
  - January 25, 2018

- Common Rule: federally sponsored
  - January 20, 2020

  (Note: This Common Rule element is not on hold/delayed)

NIH Policy Mandate

Effective January 25, 2018 sIRBs are required for:

- NIH sponsored, multi-site research
- Conducted at US sites
- Identification of sIRB will be responsibility of applicant/PI
- Some exceptions for specific contracts and competing grants

NIH (and general) Premise for sIRB

- Enhance and streamline IRB review for multi-site research
- Maintain high standards for human subjects protections
- Allow research to proceed effectively and expeditiously
- Eliminate unnecessary duplicative IRB review
- Reduce administrative burden
- Prevent systemic inefficiencies
- Compatible with final revised Common Rule requirement to use single IRBs for multi-site studies

Institutional Options

- Agree to cede IRB oversight to another IRB
    - Commercial
    - Academic
    - Health system
- Agree to accept IRB oversight
    - Academic site(s)
    - Any other performance site

Institutional Obligations Accepting *or* Ceding Oversight

- Assure compliant conduct of the research
    - Regulatory obligations
    - Monitoring
- IT support
    - eResearch application types
        - Ceding
        - Multi-site/Coordinating center
- SOPs for consistent operations
    - Accreditation
    - FDA

Reliance Agreements

- Master Agreements (MSA)/IRB Authorization Agreements (IAA)
  - Commercial IRBs
  - Consortia
  - Academic Institutions/Medical Centers/Other FWA holding entities
  - SMART IRB participants

- Individual Investigator Agreements
  - Single researchers
  - Entities without a FWA

Reliance Agreements continued

- Collaborating institutions complete the agreement document
  - Not signed by the PI or the IRB
- Roles and responsibilities are apportioned between IRBs and the institutions
- Assure all internal institutional documents are in alignment with the arrangements
  - Standard Operating Procedures
- Does not require OHRP or FDA signature or approval

Process for Accepting Oversight

- Intake of information
  - Grant application
  - Reliance request
  - Study-specific information
- Review
  - UMOR
  - IRB Administration
  - IRB Leadership

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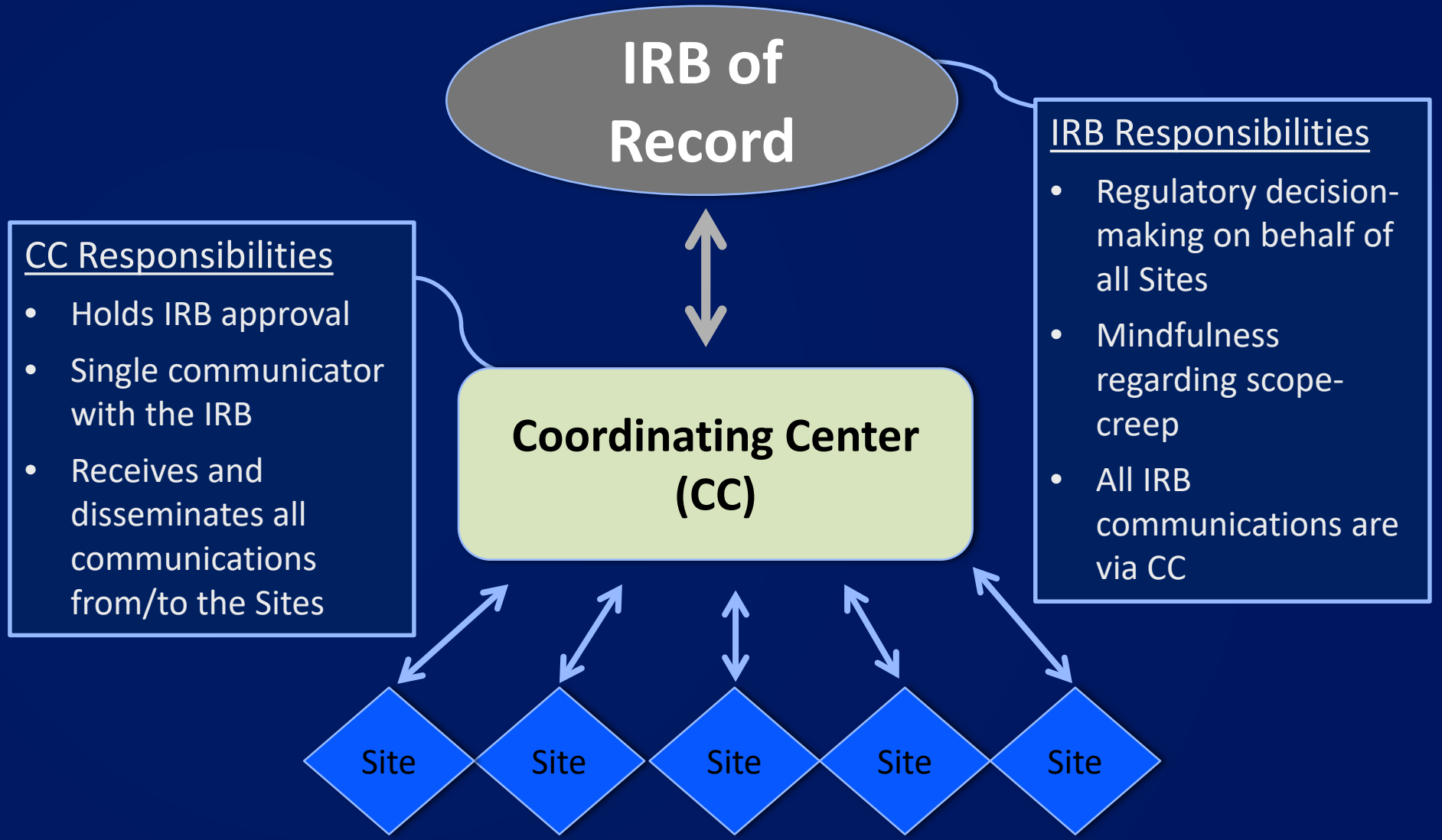
Institutional Considerations - Accepting Oversight

- Type of study
    - Phase
    - Investigator-initiated here/elsewhere
    - Who holds IND/IDE
- Number of sites
- PI/study team experience
- Available infrastructure of study team
    - Database for tracking
    - SOPs
- IRB expertise in content area
- Budget

Academic IRB of Record – Multi-site Trials



CC Responsibilities

- Holds IRB approval
- Single communicator with the IRB
- Receives and disseminates all communications from/to the Sites

IRB Responsibilities

- Regulatory decision-making on behalf of all Sites
- Mindfulness regarding scope-creep
- All IRB communications are via CC

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Additional Institutional Review Responsibilities - Accepting Oversight

Local Context

- Subject injury language
- State laws/regulations
- HIPAA
- Local PI/contact

Monitoring

- Quality Assurance
- For-cause

External Reports

- FDA
- OHRP

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Institutional Considerations - Ceding Oversight to an External IRB

- Type of study
  - Phase
  - Investigator-initiated
  - Who holds IND/IDE
- IRB expertise in content area
- External IRB accreditation status
  - AAHRPP
  - Other evaluation/self assessment
- Past working relationship
- Necessity

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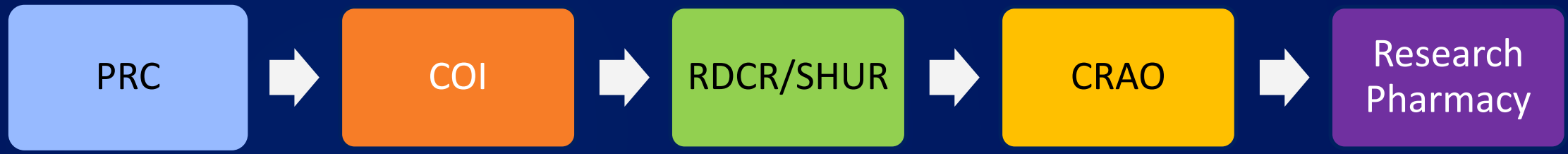
Retained Responsibilities in Ceding

- Local ancillary committee reviews as applicable (e.g., pharmacy, radiation safety, clinical billing, conflict of interest or PRC).



- Ensure that the U-M study teams are appropriately qualified, and have completed educational requirements, i.e., PEERRS
- Local analysis of any specific requirements of state or local laws, regulations, policies, standards (social or cultural) or other factors applicable to the study.

Additional Considerations

PIs/Study teams: new responsibilities

- IRB-specific procedures (ceding)
  - IRB review styles/requirements
  - Informed consent templates

- Site specific procedures (accepting)
  - Communication strategies
  - Dissemination/collection of information

Institutional ‘shared’ responsibilities: reviewing site / relying site

- Monitoring
- Control and accountability

Questions?