Accepting IRB Oversight: IRBMED as the sIRB

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IRBMED Seminar Series

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Accepting IRB Oversight

- ✓Institutional decision-making
- ✓Reliance agreements in place

- ❑Coordinating Center responsibilities (generic term)
- ❑Performance Site responsibilities
- ❑IRB responsibilities

IRBMED Intake for Accepting IRB Oversight

- Complete an Intake Form (found on the IRBMED website to be updated by 4/13)
- Be sure to indicate prior negotiated arrangements
  - Consortium
  - Network
- IRBMED acceptance based on
  - Type of study
  - Number of sites
  - PI/Study team experience
  - Infrastructure
  - IRB expertise
  - Budget
- If declined, use commercial IRB or other multi-site partner

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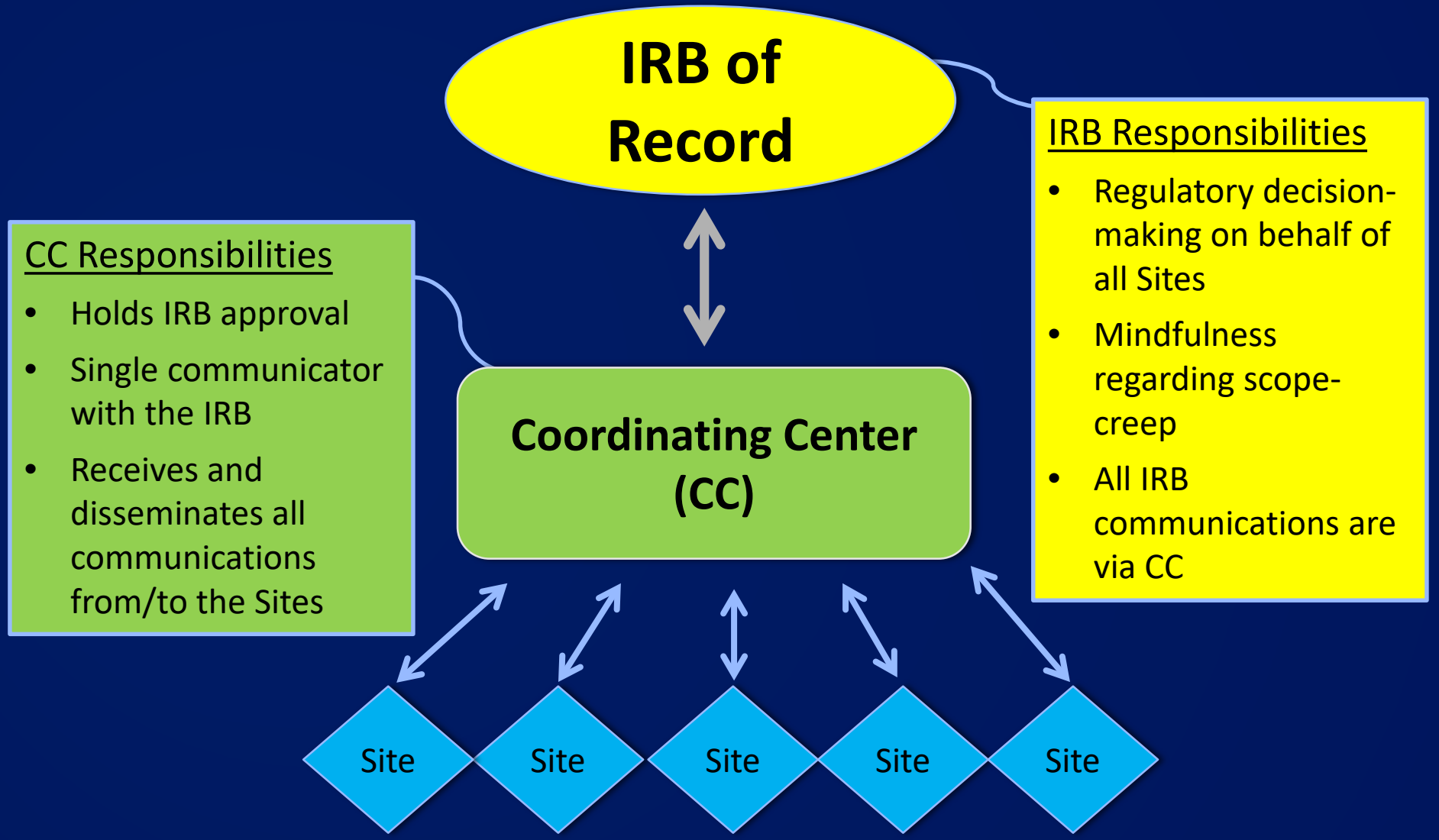
Academic IRB of Record – Multi-site Trials



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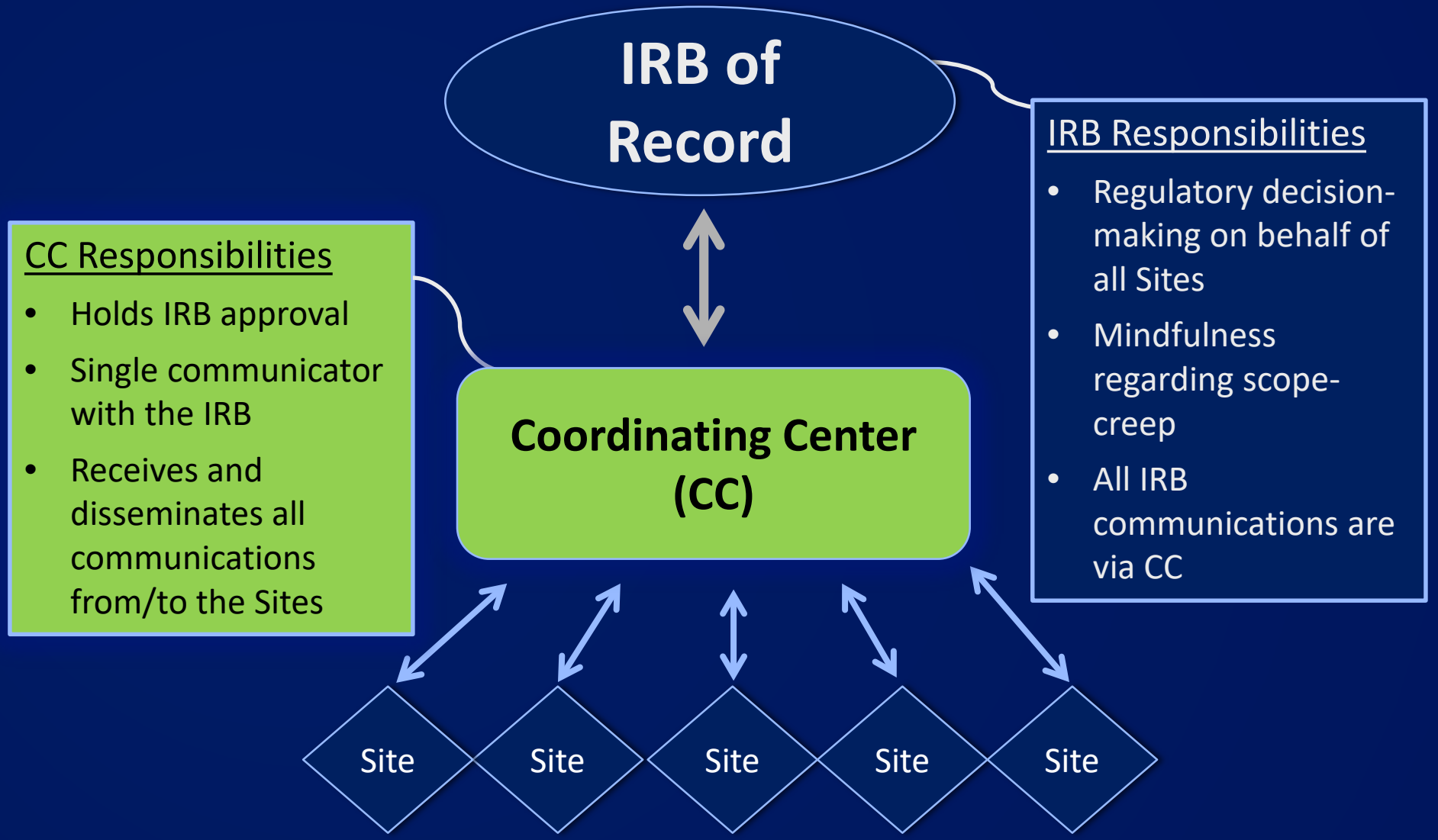
IRBMED as IRB of Record – Multi-site Trials



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Coordinating Center (PI/Study Team) sIRB Responsibilities – Part 1

- Training of sites to IRB procedures
- Communicate promptly
  - With the reviewing IRB (IRBMED)
  - With the performance sites
  - With other external entities (e.g., sponsor, federal entities as appropriate)
- Initial Review Materials (prepare and disseminate after IRBMED approval)
  - Protocol
  - Adverse Event / ORIO reporting (usually as part of protocol)
  - Informed consent
  - Recruitment materials
  - All other necessary materials (including those for Ancillary review)

Coordinating Center (PI/Study Team) sIRB Responsibilities – Part 2

- Ongoing Materials (receive and process)
  - Requests for Amendments
    - Site-specific protocol adjustments
    - Recruitment materials
    - Personnel changes
    - Informed consent
  - External Adverse Events/ORIOs
    - Complete information
    - Categorization
    - Submit according to AE/ORIO reporting plan
      - Standard IRBMED plan
      - Study-specific
- Budget

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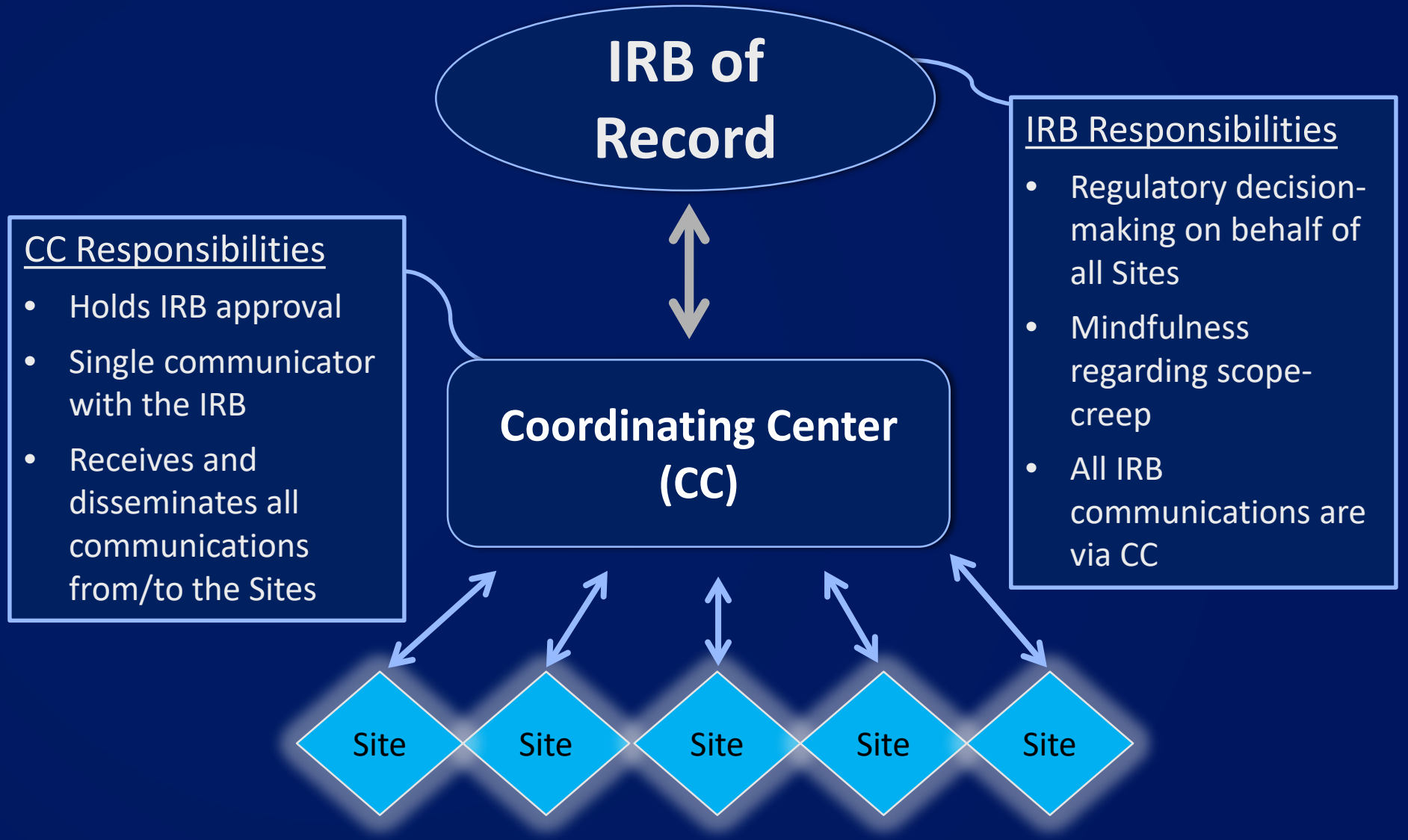
IRBMED as IRB of Record – Multi-site Trials



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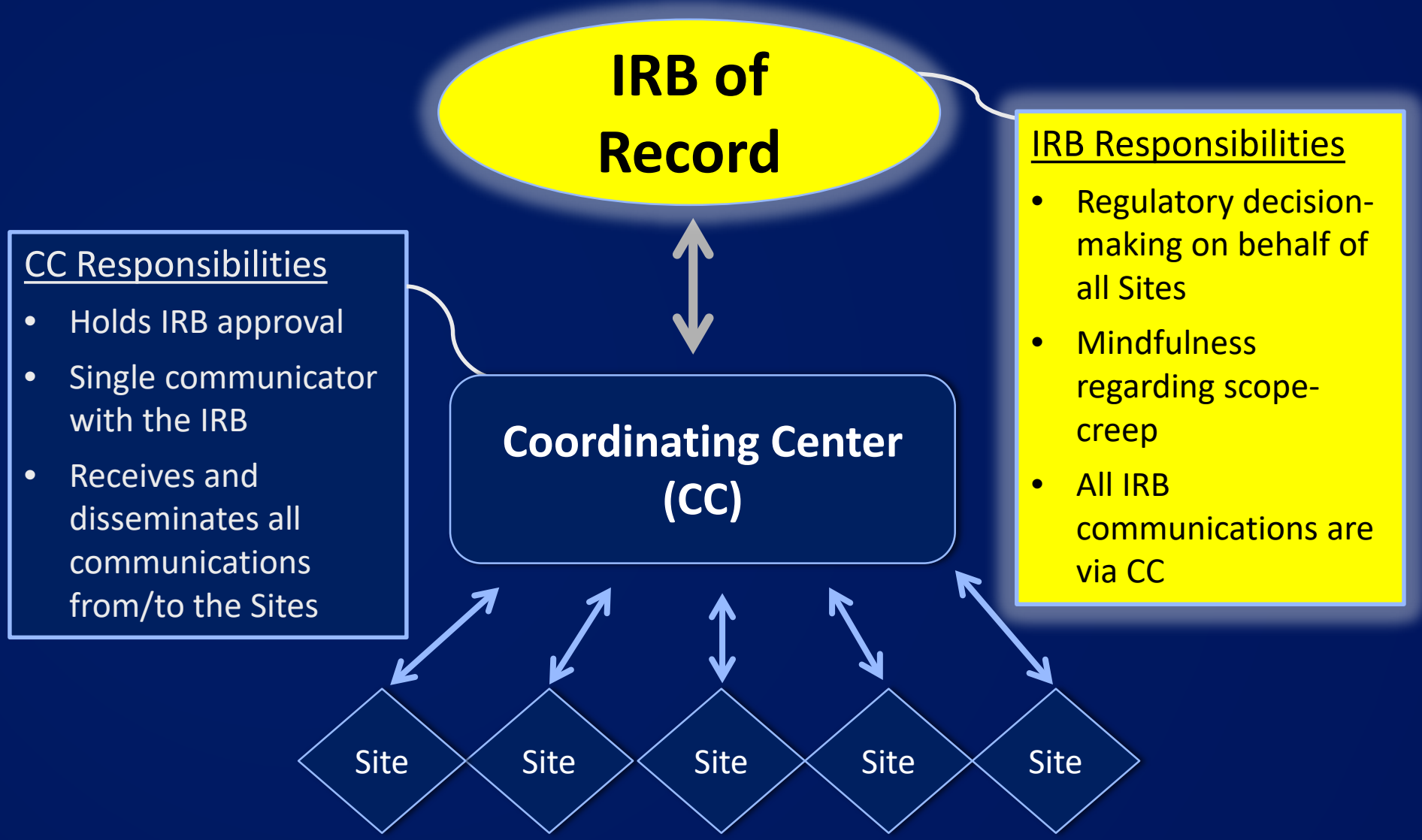
Performance Site Responsibilities

- Follow Reliance Agreement procedures
    - Ancillary committee activities
    - Education
    - Conflict of interest assessment and management
- Communicate with Coordinating Center
- Register the study as necessary at the local site
- Provide local context information and informed consent language
- Understand and utilize all provided materials
- Maintain compliance with local and IRBMED procedures

Academic IRB of Record – Multi-site Trials



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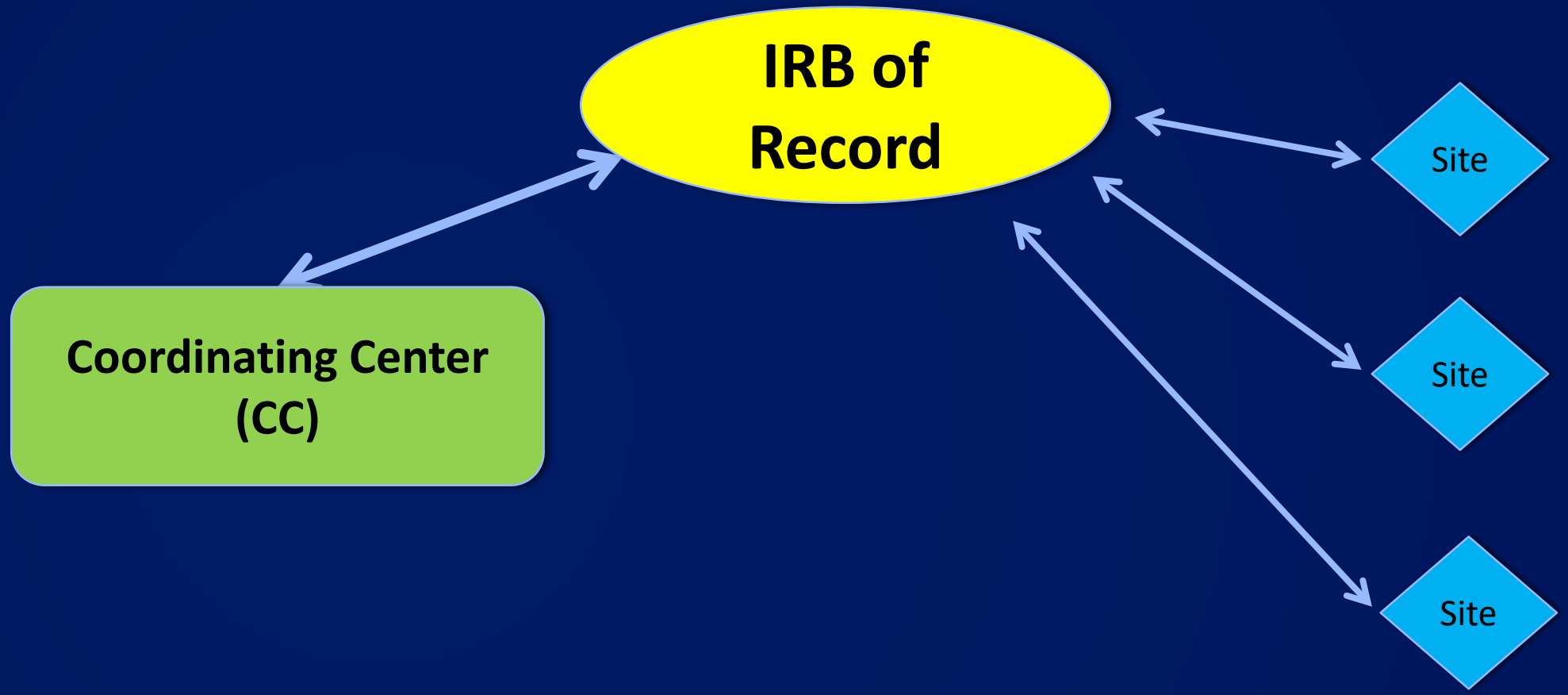
IRBMED Responsibilities / Actions

- Provide reliance agreement(s)
- Collect local context information
- Review all regulatory actions submitted by Coordinating Center
- Provide IRB-approved materials to Coordinating Center
- Provide notification and work with sites on final reports
    - Unanticipated problems
    - Serious and/or continuing non-compliance
- Monitoring of Coordinating Center / Sites

Commercial IRB of Record – Multi-site Trials



Points to Consider When Acting as sIRB

- There are new and significant additional responsibilities
- Working with multiple IRBs requires organization and tracking
- In some cases, sIRB will be mandated
    - NIH (now)
    - Common Rule (2020)

Questions?