Accepting IRB Oversight:
IRBMED as the sIRB

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IRBMED Seminar Series
April 10, 2018
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
Academic IRB of Record – Multi-site Trials

IRB of Record

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

Coordinating Center (CC)

Site  Site  Site  Site  Site
IRBMED as IRB of Record – Multi-site Trials

**Coordinating Center (CC)**
- **CC Responsibilities**
  - Holds IRB approval
  - Single communicator with the IRB
  - Receives and disseminates all communications from/to the Sites

**IRB of Record**
- **IRB Responsibilities**
  - Regulatory decision-making on behalf of all Sites
  - Mindfulness regarding scope-creep
  - All IRB communications are via CC
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)  
slIRB 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
IRBMED as IRB of Record – Multi-site Trials

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Schematic showing the connections between the Coordinating Center (CC), IRB of Record, and multiple sites.
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

IRB of Record

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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?