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

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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
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

IRB of Record

Coordinating Center (CC)

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
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
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
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?