When a Single IRB Reviews for Multiple Sites: 
The Complexities of “Simplification”

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Learning objectives

• Identify when the use of a single IRB is required for multi-site research and when it is optional

• Explain the obligations of investigators under a single IRB review

• Understand that consultation with the BMC/BU Medical Campus IRB is required when an investigator is the lead on a study that is required to have a single IRB
Nomenclature

• **Cede**: the process by which one institution agrees to rely on another entity for IRB review

• **Single IRB (sIRB)**: the one IRB that reviews for a multi-site study

• **Relying institution**: the institution where research takes place that is reviewed by a different IRB.

• **Reliance Agreement**: the agreement between the relying institution and the sIRB
Nomenclature

• **Local PI**: the Principal Investigator at the relying institution

• **Lead PI**: the overall Principal Investigator, who acts as a liaison between local PIs and the single IRB

• **Multi-site study**: a study using the same protocol at more than one site
When is sIRB Review Required?

NIH funded multi-site studies

• All studies with a receipt date for competing grant applications (new, renewal, revision, or resubmission) on or after January 25, 2018

Other federally-funded multi-site studies

• January 19, 2020
Advantages

• The protocol is only reviewed once
• The sIRB may have more leverage with sponsors to require changes
• The Lead PI submits amendments and continuing reviews on behalf of the local PIs
Disadvantages (I)

• Requires coordination between relying institution and sIRB for
  o Local context review (e.g., Massachusetts’ laws)
  o Local signoffs (e.g., nursing, radiation safety)
  o Local investigator requirements (e.g., training, CoI)
  o Local recruitment requirements (e.g., non-readers)
  o Local consent form requirements (e.g., injury, cost)
  o Post-approval monitoring (e.g., audits)
Disadvantages (II)

• Requires Lead PI to communicate with all Local PIs regarding
  o sIRB submission requirements for initial and continuing review
  o sIRB determinations
  o Consent forms
  o Recruitment materials
  o Reporting requirements
Disadvantages (III)

• Requires Local PI to know and follow sIRB requirements for
  o Process for providing information to join the study (e.g., the format required by the lead PI)
  o Continuing review and closure reports
  o Reporting on Unanticipated Problems, protocol deviations, etc. (e.g., definitions, timeframes)
Algorithm for Reporting Unanticipated Problems, Adverse Events, and Deviations

Incident, experience, or outcome

- Unexpected given known risks to subjects
  - yes
  - Related or possibly related to participation
    - yes
    - Suggests greater risk of harm to subjects or others
      - yes
      - Report on Reportable Events and New Information form
        - within 2 days if fatal or life-threatening event
        - within 7 days otherwise
    - no
    - Protocol Deviation
      - yes
      - MAJOR Protocol Deviation (risk to subjects or data)
        - yes
        - Adverse Event or Serious Adverse Event
          - yes
          - Report to IRB at Continuing Review
            - Attach to Progress Report:
              - If have DSMB report
                - attach to Section 4
              - Otherwise,
                - attach AE/SAE/Minor deviation summary to Section 5
          - no
      - no
  - no
- No report required

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Implications – *Lead* PI

When you are a **Lead** PI

- Consult with us as soon as you know you must use a single IRB
- Identify local PIs and make sure they know how their institutions will cede
- Budget for:
  - Adequate staff to liaison with local sites
  - IRB review costs
- Learn to use SMART IRB
SMART IRB

SMART IRB (not an IRB)

• Electronic platform for reliance agreements
• Includes exempt human subjects research
• 297 participating institutions, including all 64 CTSAs
• Working to promote harmonization among IRBs

➤ Possible to cede outside of SMART IRB, but requires legal review of the agreement
Implications – *Local* PI

When you are a **Local** PI

- Find out from Lead PI how to learn requirements of sIRB
- Submit to BMC/BU Medical Campus IRB through the cede review path in INSPIR
4.0 Review Path Determination

4.1 Review Path Determination

- This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; case reports or case series that include three patients or fewer; studies that involve obtaining anonymous data/tissues or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research.

- BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.

- The only research activities in this study involve chart reviews.

- This study fits into one or more of the federal Exempt
Additional Information in INSPIR

• Special routing
  o Use of local facilities
  o VelosCT
• Study personnel
• Drug/device information
  o Storage
  o Drug preparation and dispensing

Same as all submissions
Additional Information in INSPIR (con’t)

• Identification of the single IRB
• Special populations
  o students/employees
  o wards
  o cognitively impaired
  o non-English speakers
  o limited- or non-readers
• Consent form “Compensation for Injury” language
Continuing Obligations of Local PI to BMC/BU Med Campus HRPP

• Study personnel changes
  o First submit through INSPIR (so we can check training and Conflict of Interest)
  o Then submit our approval letter for change to sIRB

• Internal Unanticipated Problems
  o Submit simultaneously to sIRB and through INSPIR (so we can start any needed action)
Continuing Obligations of Local PI to BMC/BU Med Campus HRPP (con’t)

• QA Reviews (not-for-cause audits)
  o Cooperate with QA review
  o Assist QA review team with accessing sIRB reporting requirements
Continuing Obligations of Local PI to sIRB

• Report study personnel changes after BMC/BU Med Campus IRB approval
• Obtain documentation of sIRB approval of amendments (including revised consent forms)
• Follow sIRB reporting requirements
Key Points

• Being the PI on a multi-site study adds additional layer of responsibility

• Being an investigator on a ceded study requires following the policies of the reviewing IRB and the BMC/BU Med Campus IRB

• sIRB has significant advantages but does not make life simple, just different
Thank you!