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
  - Local context review (e.g., Massachusetts' laws)
  - Local signoffs (e.g., nursing, radiation safety)
  - Local investigator requirements (e.g., training, CoI)
  - Local recruitment requirements (e.g., non-readers)
  - Local consent form requirements (e.g., injury, cost)
  - Post-approval monitoring (e.g., audits)

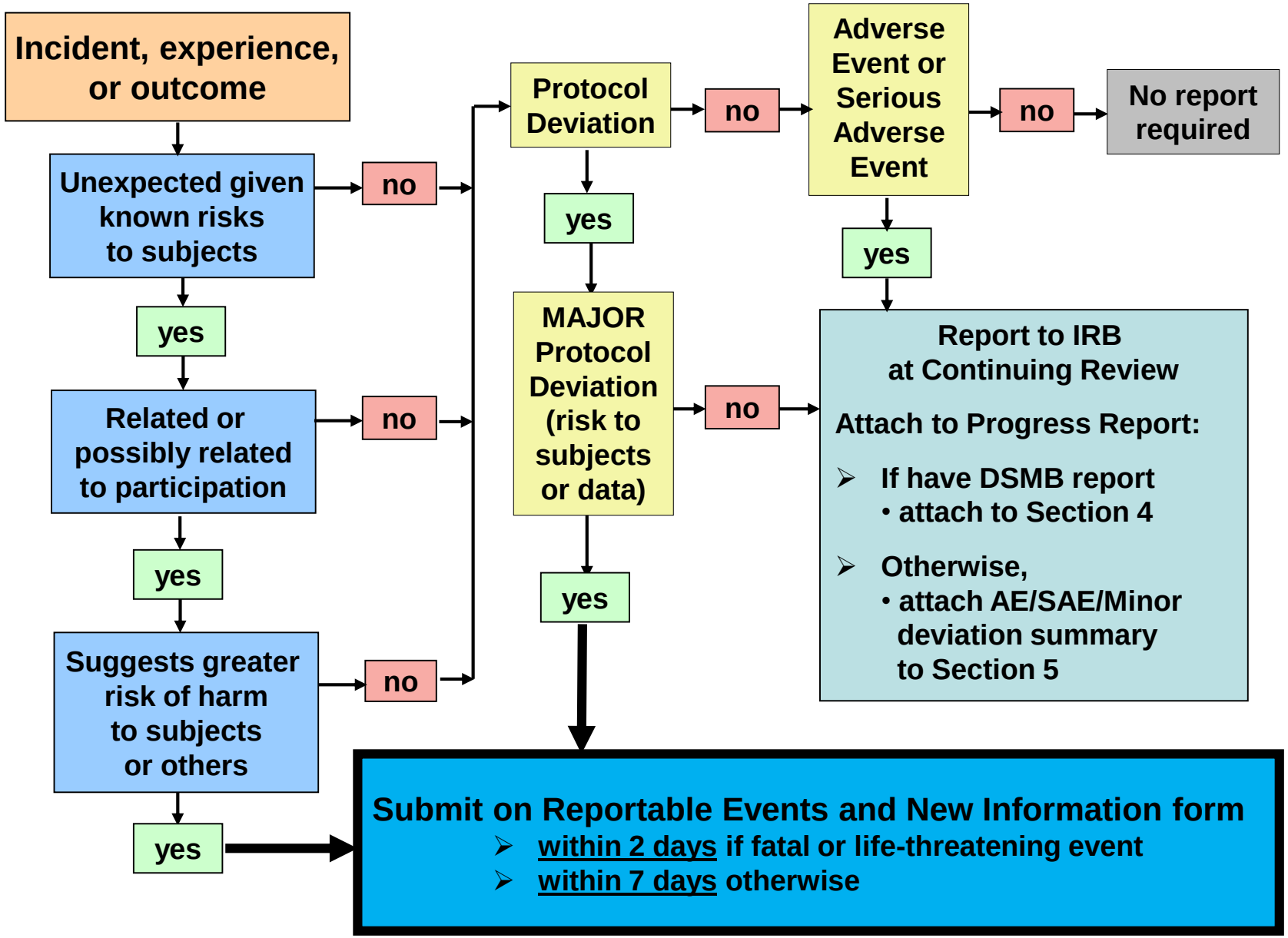
Disadvantages (II)

- Requires Lead PI to communicate with all Local PIs regarding
  - sIRB submission requirements for initial and continuing review
  - sIRB determinations
  - Consent forms
  - Recruitment materials
  - Reporting requirements

Disadvantages (III)

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

Algorithm for Reporting Unanticipated Problems, Adverse Events, and Deviations



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)

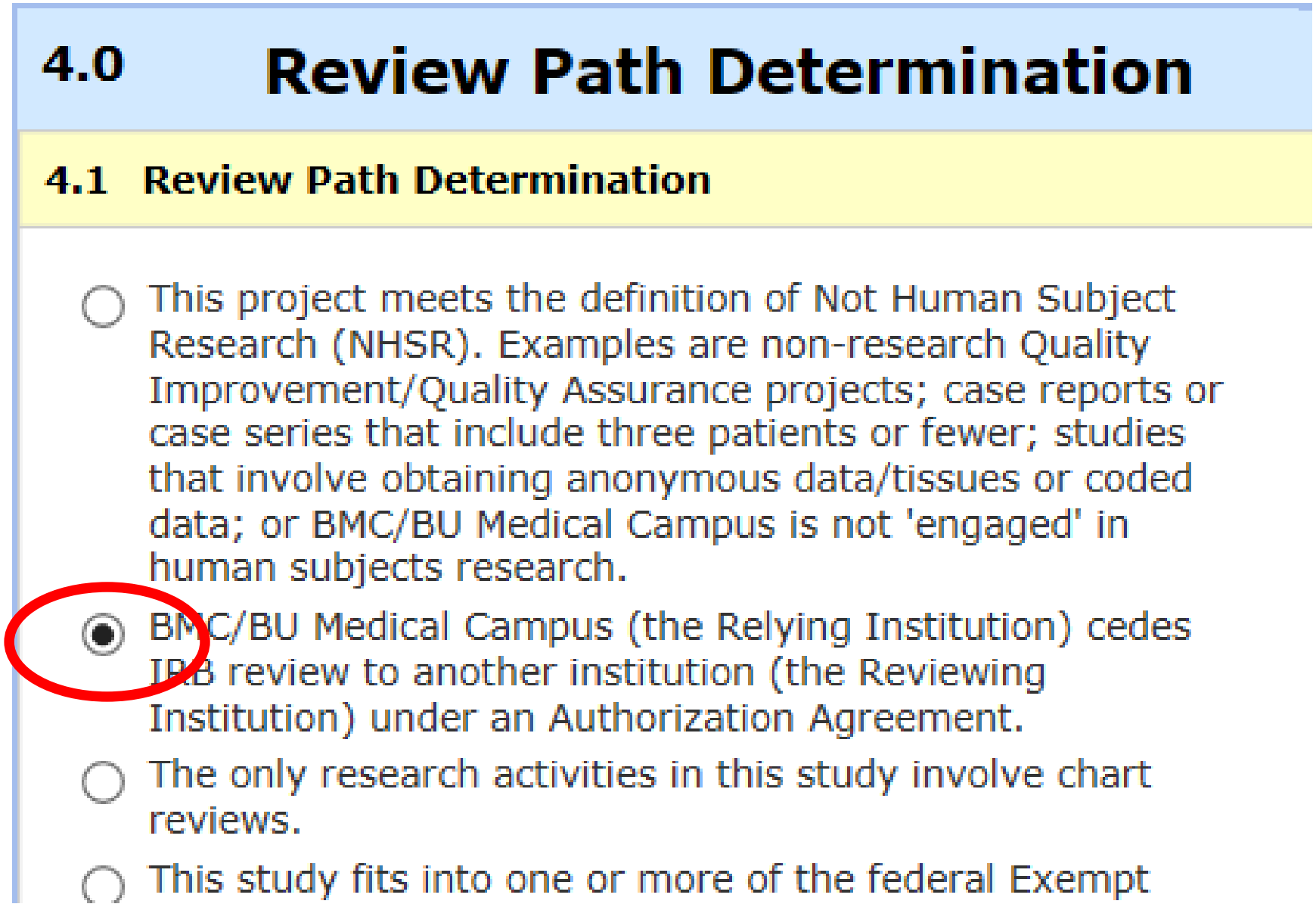
- Electronic platform for reliance agreements
- Includes exempt human subjects research
- 297 participating institutions, including all 64 CTSAs
- Working to promote harmonization among IRBs

➢ 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
  - Use of local facilities
  - VelosCT
- Study personnel
- Drug/device information
  - Storage
  - Drug preparation and dispensing

Same as all submissions

Additional Information in INSPIR (con't)

- Identification of the single IRB
- Special populations
  - students/employees
  - wards
  - cognitively impaired
  - non-English speakers
  - limited- or non-readers
- Consent form "Compensation for Injury" language

Continuing Obligations of Local PI to BMC/BU Med Campus HRPP

- Study personnel changes
  - First submit through INSPIR (so we can check training and Conflict of Interest)
  - Then submit our approval letter for change to sIRB
- Internal Unanticipated Problems
  - 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)
  - Cooperate with QA review
  - 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!