Welcome to the

Single IRB-of-Record (sIRB) – What Research Administrators Need to Know

The webinar will begin shortly.

- Please mute your microphone and turn off your video
- During the webinar, please use the chat function to ask questions

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Single IRB-of-Record (sIRB) – What Research Administrators Need to Know

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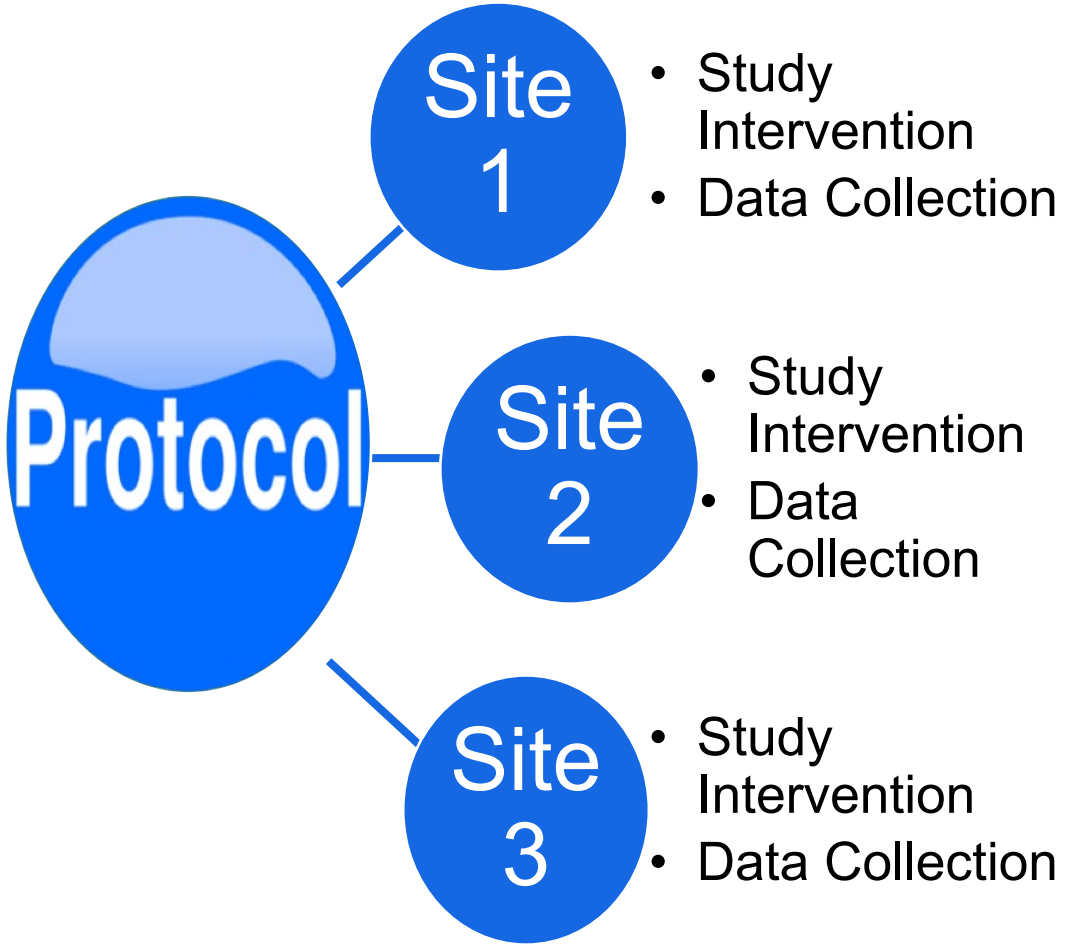
Objectives

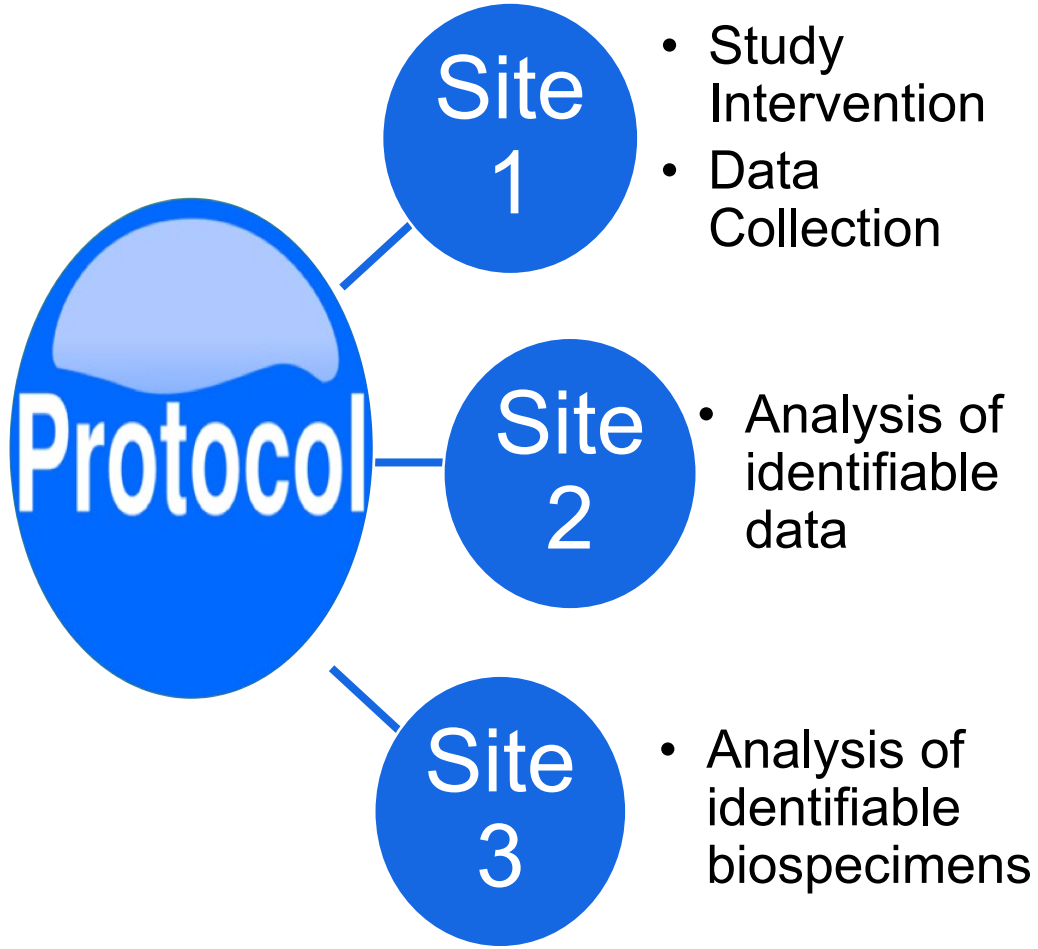
- Key definitions
- Single IRB-of-Record (sIRB)
- New PAF questions and impact on grant preparation process
- sIRB process

What is a Multi-Site Study?

- A project involving collaborators at/from more than one institution (i.e., participating sites) who are involved in the conduct of the same research protocol
- NIH considers “the same research protocol” to mean that the sites all function to address the same research questions, involve the same methodologies, and evaluate the same outcomes
- Also known as collaborative or cooperative research

Examples of Multi-Site Research





Models for IRB Oversight of Multi-Site Research

1. The IRB of each participating site conducts its own IRB review
2. One IRB, known as the single IRB-of-Record (sIRB), conducts the regulatory review for all participating sites
3. Some sites conduct their own IRB review; some sites rely on an sIRB

What is a Single IRB-of-Record?

- The single IRB-of-Record (sIRB) is an IRB that has been designated to provide IRB review and oversight for all participating sites (collaborating institutions) engaged in the conduct of a human research study
- The sIRB provides the regulatory and ethical review of proposed research
- The participating site is responsible for ensuring the ethical conduct of the research consistent with the sIRB-approved protocol and for any required reviews at its site

sIRB Requirements for Federally-Sponsored Research

NIH (Policy)	Revised Common Rule (Regulation)
January 2018 • NIH established a sIRB policy mandate for multi-site research • Domestic research supported by grants, cooperative agreements contracts or the NIH Intramural Research Program • Does not apply to Foreign Sites, career development (K), research training (T) or fellowship awards (F)	**January 2020** • The Revised Common Rule expanded the sIRB requirement to all cooperative research projects funded/supported by federal Common Rule agencies • Exception – U.S. Department of Justice

Exceptions to Federal sIRB Requirements

- Exempt research projects
- Research collaborators/institutions that are not "engaged" in the conduct of human subjects research
- Research collaborators outside the U.S.
- Research conducted outside the U.S.
- sIRB review prohibited by a federal, tribal, or state law, regulation, or policy
  - In each case, all other sites are subject to the sIRB requirement
- Exceptions permitted by the agencies (rare)

sIRB - Other Sponsors

- Industry sponsors and some foundations may also require use of an sIRB process

Reliance Agreements

- sIRB arrangements are managed via IRB Authorization Agreements (IAAs) (also known as Reliance Agreements)
- The IRBs and the U-M HRPP director determine whether to enter into reliance arrangements and IAAs are signed (i.e., executed) by the **U-M HRPP Director** and the appropriate institutional official for the collaborating institution
- Study teams **do not** have the authority to enter into reliance agreements with other institutions
- U-M is member of the SMART IRB, a national consortium of major research institutions (750+) that have entered into a standardized reliance agreement and standardized procedures

Types of sIRB Arrangements

- U-M as the sIRB (Reviewing IRB)
- U-M ceding oversight to an external IRB (Relying IRB)
  - Independent/commercial/central IRBs
  - Academic/medical IRBs

U-M as the sIRB (Reviewing IRB)

Overall Study

- Initial review and approval of the protocol and/or template documents (e.g., informed consent(s), recruitment documents, other study documents)
- Review of study wide amendments affecting overall protocol, study documents and document templates
- Review of study wide safety reports and reportable events (AE/ORIOs)
- Review of all continuing review data, both study-wide and by site

Participating Sites

- Local context review for site activation (includes local/state laws, special consent information, site-specific requirements)
  - Approval of consent(s) and other study docs for each individual site
- Review of site-specific amendments
  - Site specific document approval
- Review of continuing review data for each site
- Site staff training, qualifications, COI

U-M as the Relying Institution – Ceding Oversight to an External IRB

- Regulatory review is conducted by the external IRB
  - U-M provides local context information to reviewing IRB
- “Review by non-UM IRB” application submitted to route application through ancillary reviews, including Conflict of Interest, and to confirm study team member training
- U-M is responsible for the compliant conduct of the research consistent with the regulatory review by the sIRB

U-M Ceding Oversight to an External IRB (Independent/Commercial/Central)

- U-M has established Master Services Agreements with the following independent IRBs:
    - Advarra (formerly Shulman, Chesapeake, Quorum)
    - Western IRB (WIRB) (formerly Copernicus)
    - Ethical and Independent Review Services (E&I)
    - NCI CIRB
- There are fees associated with the use of independent/commercial IRBs that must be considered as part of the study budget
- Use of other independent/commercial IRBs must be approved by the IRB and the HRPP Director

U-M Ceding Oversight to an External IRB (Academic/Medical Institutions)

- Requests to cede to external academic or medical institutions are reviewed on a study-specific basis
- U-M prefers to use the SMART IRB agreement with other participating institutions

- There may be fees associated with review by an external institution IRB, depending on the nature of the research. (More likely in the case of an NIH multi-site clinical trial, less likely for an NSF-funded collaborative project)

Why does this matter to Research Administrators?

- PIs and study teams must plan for the sIRB requirement early in the proposal development process
- Develop plan with collaborators
- Consult with the U-M IRB regarding serving as the sIRB or ceding to an external IRB
- Consider potential budget impacts

New sIRB Questions in the PAF

5.1.3 *
Is this a multi-site study (i.e., proposed activity involves collaborators at other institutions)?
● Yes ○ No Clear

HELP

5.1.3.2 *
Indicate how the project will be supported by an IRB: (select one)

- ○ The project will involve IRB review by each institution (for non-federal sponsors or for federally-sponsored projects involving international or tribal collaborators).
- ● The project will use an external IRB as the IRB-of-Record (e.g., commercial, academic, or hospital-affiliated).
- ○ The project will request that a University of Michigan IRB serve as the single IRB-of-Record for collaborating institutions.

Clear

HELP

Some sponsors (e.g., NIH) require a single IRB-of-record (sIRB) for multi-site (multi-entity) human subject studies. If an independent, external IRB (i.e, commercial IRB) will serve as the single IRB (sIRB) for all participating sites, budget the IRB fees as a direct cost to the project. See the HRPP sIRB webpage for a list of independent IRBs with whom U-M has a service agreement. Other non-UM IRBs (academic or medical institutions) may also charge fees for IRB review. Consult with each of these IRB options for their review fees.

Before designating a U-M IRB as the single IRB, confirm that your U-M IRB agrees to serve as the sIRB for all participating sites in this project and, if appropriate, obtain the IRB's assistance in developing an sIRB budget for the project. Contact your IRB office for more information.

U-M IRBMED: Single IRB and Multi-Site Research website or irbmedreliance@umich.edu

U-M IRB-HSBS:IRB-HSBS Collaborative Research website or irbhsbs@umich.edu

Formal relationships between U-M and the external IRB are established through written authorization agreements (individual or master agreements) reviewed by the IRB and signed by an institutional official.

5.1.3.3 *
Please indicate the external IRB:

If "Other" is selected, please enter the IRB below:

HELP

Identify the specific external IRB you are using. If you do not recognize the named IRBs, you may wish to consult your UM-IRB for further assistance.

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5.1.3.4 *
Indicate which U-M IRB will serve as the Single IRB of Record for collaborating institutions:

HELP

How will these new questions be used?

- Intent is to remind investigators that they must consider the sIRB requirement as part of the proposal preparation
- The IRBs will receive a report from eResearch when a study team indicates that U-M will serve as the sIRB or if it will cede oversight and will check in with them if the IRB has not been consulted regarding this arrangement

Initial sIRB Request

- Important to discuss options with U-M IRBs early!
- Completion of a single IRB request form is required
- U-M IRBs will determine if it is appropriate to serve as the sIRB for the proposed project

sIRB Support in Grant Application

Requesting U-M IRB as Reviewing sIRB

MUST be approved in advance by IRB leadership

- Contact the U-M IRB as soon as possible
- **At least** 8 weeks prior to the grant application due date

IRBMED: Qualtrics sIRB Request Form
IRB-HSBS: Mary Donnelly (mardonne@umich.edu)

Requesting U-M IRB to cede Oversight to External IRB

- Contact the U-M IRB **at least** 3 weeks prior to grant application due date
- A letter of support is required:
- Email sIRB team for request:

IRBMED: irbmedreliance@umich.edu

IRB-HSBS: Mary Donnelly (mardonne@umich.edu)

Accepting Oversight

Before Grant Application

8 weeks before deadline

- Request sIRB support from the IRB.

IRB Assessment

- The IRB will review the request.

IRB Agrees

- Reach out for letters of support from external sites.
- IRB will draft a single IRB plan, PI reviews it.

Final plan & support

- IRB receives letters of support from external sites.
- IRB finalizes single IRB plan and single IRB letter of support.
- Provides plan and letter to PI for grant application.

IRB Review of sIRB Requests

- Evaluation criteria include:
  - Risk level/complexity of study design
  - Ability of study team and IRB to manage submission volume and communication
  - Number of participating sites
  - Location of participating sites
  - Who holds any associated IND/IDE (for IRBMED)
- U-M IRBs reserve the right to decline being the sIRB and will support research investigators to locate an external IRB to serve in that capacity.

Accepting Oversight

After Notice of Grant Award

IRB Application

- *(Use 'Umbrella' application to **secure funding**; sIRB plan required at this time)*
- Type: Multi-site Research Application
- Required Documents: Protocol, Informed Consent template, Recruitment document templates, Manual of Procedures and other study specific documents.
- Be prepared to provide a list of participating sites, the site PIs and the PIs' emails.

IRB Review

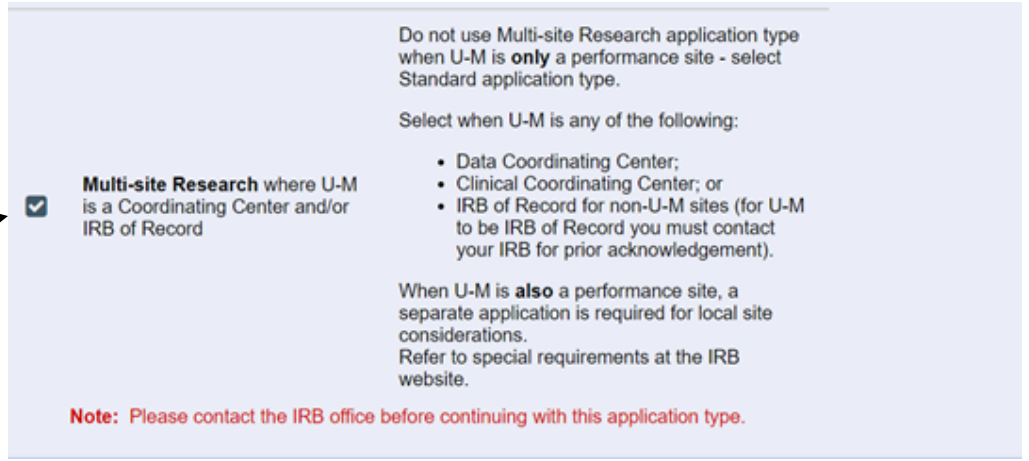
- Full Regulatory review
- Approval of the concept of these performance sites

Post approval

- Communication with external sites will begin
- Participating Site applications are created
- U-M Performance Site Application is created
- Remember external sites are not activated until U-M IRB has reviewed and approved the site individually.

eResearch Application

- Multi-site application type
- Participating site
  - Create
  - Post correspondence
  - Notify (IRB staff only)



Post MSR Approval: Participating Site Activation

Application Initiated

- Information needed: PI name, PI email, Site name and FWA number.
- Friend accounts needed.

Sites Notified

- After participating site applications are initiated they will be notified.
- Directions will be sent out.

Application submitted

- Local Context review is performed.
- Back and forth with study team as needed.

Site Activated

- Review is completed and site is activated.
- All site-specific documents are watermarked.

sIRB Review Activities: Allowable Charges

- PRIMARY ACTIVITIES: Activities associated with conducting the ethical review of the proposed research protocol that will be carried out at all of the participating sites and the review of the template informed consent document describing the study. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html)
  - Charged as indirect costs – no additional recharge
- SECONDARY ACTIVITIES: Activities associated with review of site-specific information, such as investigator qualifications, institutional capabilities, state/local regulatory requirements, and community ethos. Following initial approval, there are additional activities to fulfill IRB oversight responsibilities, including reviewing reportable events (e.g., unanticipated problems, protocol deviations), and, as necessary, reporting them to the Office for Human Research Protections (OHRP) and the funding Institute or Center; receiving and reviewing any complaints that arise regarding conduct of the study; notifying all sites of serious or continuing non-compliance and all other determinations; and communicating with participating sites on matters related to sIRB determinations. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html)
  - May be charged as direct costs with appropriate budget justification

Secondary Activities - Examples

Site-specific/sIRB information

- Investigator qualifications/study team changes
- Unique institutional capabilities
- State/local regulatory requirements
- Community ethos
- Site-specific amendments
- Continuing reviews
- Reportable events (e.g., unanticipated problems, protocol deviations)
  Reporting to Federal agencies and/or funding Institute or Center
- Review complaints that arise regarding conduct of the study
- Notify all sites of serious or continuing non-compliance and all other determinations
- Communicate with participating sites on matters related to sIRB determinations.

Budget Considerations: Accepting IRB Oversight

- **Assessments / Communications**
  - What type of Authorization Agreement is necessary
  - Review of the relying site ‘Local Context’ information
- **Level of Annual Oversight Required (Secondary Activities)**
  - Low
  - Medium
  - High
- **Quality Assurance Reviews**
  - Evaluation of relying site for compliance with U-M IRB requirements

Recharge Rates

- IRBMED has developed recharge rates
- IRB-HSBS plans to develop recharge rates

- NIH grant proposals requesting IRBMED to function as sIRB are provided a draft budget based on the number of sites and expected review complexity

- IRBMED soft-rollout across Summer
- Full-rollout in this Fall

Questions?

- IRB-HSBS

  Mary Donnelly (mardonne@umich.edu) or irbhsbs@umich.edu

  Website: Collaborative Research: IRB-HSBS sIRB Process

- IRBMED

  irbmedreliance@umich.edu

  Website: IRBMED Single IRB and Multi-Site Research

Thank you!

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