Carpe Diem: Dealing with & planning for tight deadlines

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SBS IRB Grand Rounds 2025

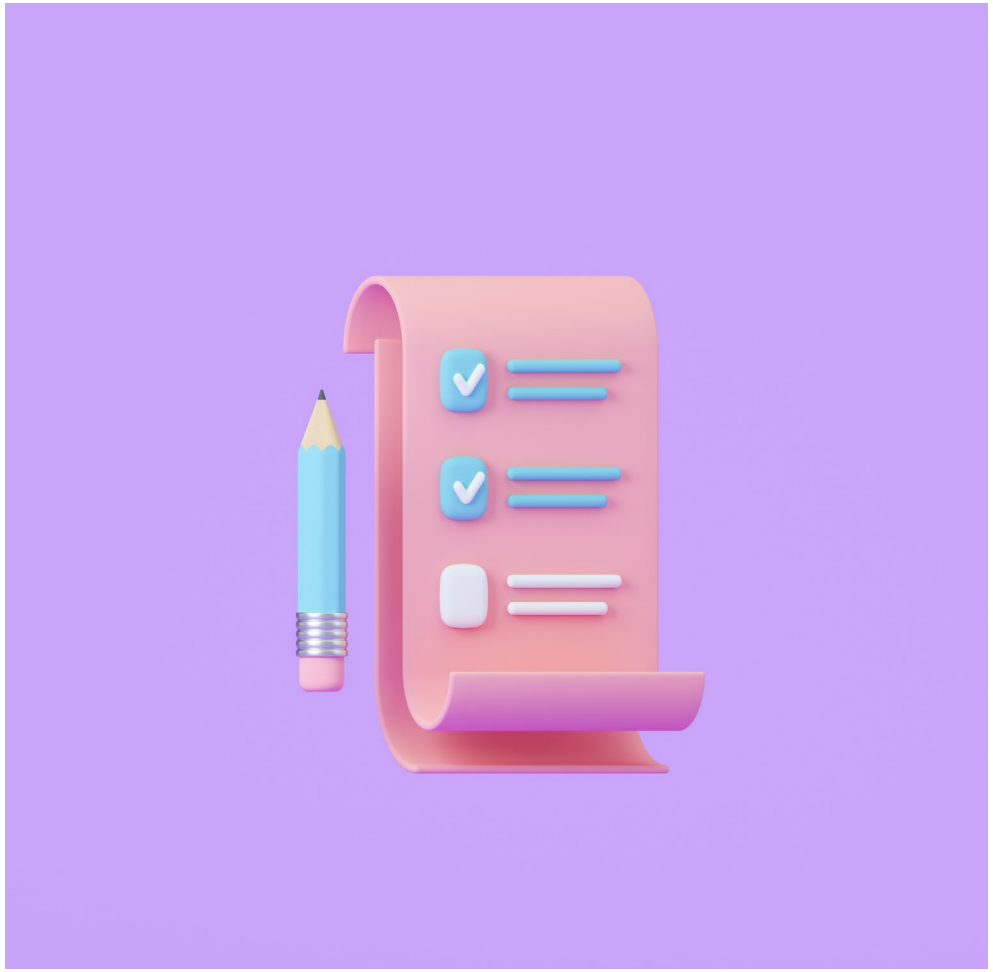
2/12/2025 10-11am	**Building Blocks of Protocol Success**
3/12/2025 10-11 am	Carpe Diem: Dealing with & Planning for Tight Deadlines
4/16/2025 10-11am	Tackling Technology & Data Trends
5/7/2025 10-11am	Keeping the House in Order

Relevant Conflicts

- I DO NOT have an actual or potential conflict of interest in relation to this program/presentation.

Objectives

- Address RNI reporting & CTD compliance reporting
- Discuss Just in Time requirements
- Discuss Reliance requirements & timelines
- Review tips & recommendations



RNI reporting & CTD compliance reporting

Vivienne Carrasco, MPH, CIP
Associate Director, Regulatory Oversight (HSRO)

Principal Investigator Responsibilities

The PI has ultimate responsibility for the conduct of the research, including compliance with the research project's activities, administration, fiscal, and scientific requirements. The PI is also responsible for reading and understanding all IRB letters and HSRO acknowledgment notices, when applicable.

HRP-103 Investigator Manual

Chapter 9
Investigator Responsibilities

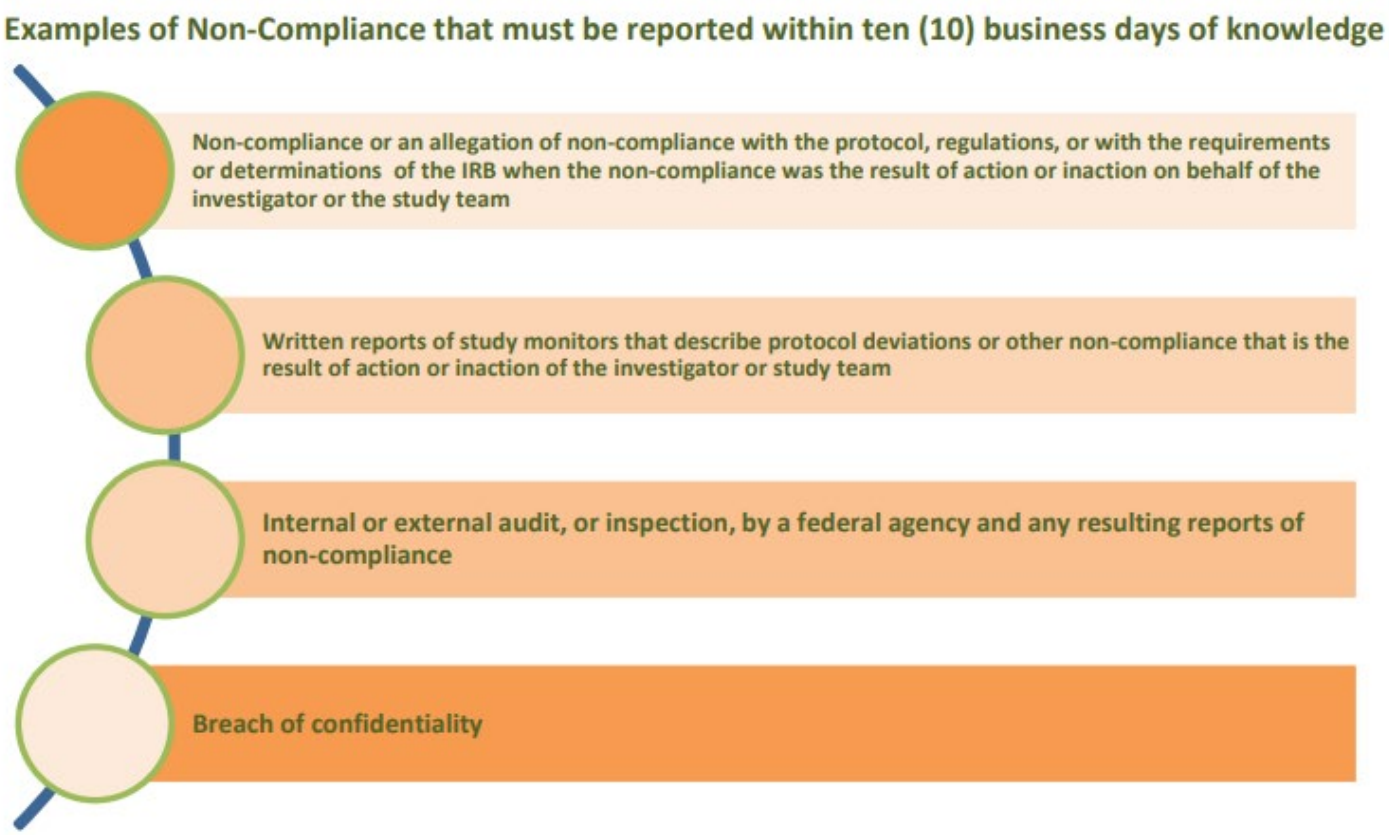
Required Information-RNI Submissions

Category of Information	Information required before reporting to the IRB
New or increased risks (IB*, DIL, Memo, Safety letter) * ***Updated Investigator Brochure or package insert includes revisions to risk profile or expected adverse reactions <u>when an updated consent is unavailable at the same time</u>***	***What risk information is included?*** ***Will there be any changes to the protocol and ICF?*** ***What is the current enrollment status?***
Adverse event that is: unexpected; related to the study; and Indicates there is a new risk to subjects or others that was previously not known.	***Where is the AE from? If local, has the sponsor been informed?*** ***What is the PI's determination? What is the sponsor determination?*** ***Relation?*** ***Expectation (severity/frequency)?*** ***How is the participant doing (outcome)?***
Non-compliance that are the result of action or inaction of an investigator or study team member. "Study team member" includes departments that provide support for the research such as the laboratory, nursing, or Investigational Drug Services.	***Is this non-compliance? If deviation – was the participant placed at increased risk due to the error – if "yes," describe*** ***Root Cause*** ***Steps to correct deviation*** ***Steps to prevent deviation***
Sponsor suspension of study activity (enrollment, dosing, etc.)	***Change of study status*** ***What is the current status?***

8.3 Reports of Non-Compliance (Submit within 10 business days of knowledge)

Investigators must submit reports of non-compliance that result from ***an action or inaction of an investigator or study team member***. If a research participant is frequently or continuously noncompliant with study requirements, you must address the non-compliance or consider withdrawing the participant. Please contact the HSRO for guidance "Study team member" includes departments that support the research, such as the laboratory, nursing, or Investigational Drug Services.

The University of Miami must inform Jackson Health Systems of noncompliance that occurs at a JHS facility. You must report the location of deviations and other non-compliance.



UM does not define major or minor deviation. Please do not submit deviations via CR reports. According to the UM policy, all the deviations should have been submitted within 10 working day timeframe already.

Reminders/Example of Requirements of UM IRB

Type of Review:	Initial Study
Title of Study:	
Funding:	
Number of Subjects Approved	
Consent Requirements	Subjects must sign the most current IRB approved version of the consent document
HIPAA	Subjects must sign a HIPAA Authorization
Investigator Manual	You must follow the requirements listed in the Investigator Manual (HRP-103)

Additional Conditions of Approval - Please Read

1. In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103).
2. This approval is limited to the items in the submission referenced above.
3. Approval from the IRB is required before making any modifications to the research unless the modification is necessary to prevent a subject from experiencing imminent harm.
4. You must submit Reports of New Information as required in the UM Investigator Manual HRP- 103, Chapter 8.
5. You must obtain IRB approval of translated documents before using them.

CTD Registration Requirements

Criteria:

- If the study is federally funded (NIH, DOD, PCORI, NSF, etc.) and deemed a clinical trial **in your grant proposal submission** as well as defined in your federal award terms & conditions
- If your study involves the use of a drug, device, or biologic for study purposes
- If the PI plans to publish in any ICMJE medical journal and your study meets the definition the NIH uses to define a clinical, then CTD is required. Please use the CTD determination tool: Online Survey Software | Qualtrics Survey Solutions
- If the sponsor requires registration regardless if it is observational or interventional this must be documented in the CTA or award and notification to CTD that sponsor is requiring registration and or results for the study.
- If the study meets the CMS requirements for billing and is deemed QCT (Qualifying Clinical Trial)

CTD Registration Requirements

Responsible Party (determination process)

- The **Responsible Party** (RP) for a clinical trial must register the trial and submit results information. A RP can be:
- The **Sponsor** of the clinical trial (as defined in section 21 CFR 50.3) who initiates the study. The University of Miami PI should consult with commercial sponsors to assure that posting of a trial is in accord with terms of the study contract.
- The **Principal Investigator (PI)** of such clinical trial, assuming ALL of Following;
  - the PI is responsible for conducting the trial,
  - has access to and control over the data from the clinical trial,
  - has the right to publish the results of the trial, and
  - has the ability to meet all of FDAAA's requirements for the submission of clinical trial information.
- The **Sponsor-Investigator** (the individual who both initiates and conducts the study or is the IND/IDE holder)

Resource

Registration compliance - SOP on CTD website: Policies and Procedures | Clinical Trial Disclosure |University of Miami
Information for registration: departmental-protocol-review-checklist-20220928.pdf (miami.edu)
Contact for questions/Consultation: Contact Us | Clinical Trial Disclosure | University of Miami

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Understanding JIT and Other Support

K. Brandon Strickland, CRA, JD
Executive Director, Research Administration

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Other Support

What Is Other Support?

- It is documentation provided to the sponsor usually provided in the application or during Just-In-Time. Other Support is also known as current and pending support.
- Other support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the University of Miami.

Why Other Support Matters?

- Sponsors require other support information so they can evaluate if the project under consideration for funding has any programmatic, budgetary or commitment overlaps.
- Not including complete other support information may result in serious consequences including loss of funding and debarment or suspension.

Included As Other Support

- Grant, contracts, awards and any other funding (regardless of whether or not the award is through UM)
- Start up packages from other institutions
- Consulting where the activity is research
- Post-docs, students or other individuals supported by an outside entity performing research activities
- Research collaborations that benefit the faculty member's research endeavors (e.g., experiments done at another institution at no cost)
- Access to lab space, materials and staff at other institutions
- In-kind contributions (technology, chemicals, etc.) that will not be used on the proposed project

Not Included As Other Support

- Start up packages at UM
- Consulting where the activity is not research
- Core facilities and shared equipment at UM
- In-kind contributions that will be used on the proposed project
- Prizes and gifts

Just-In-Time (JIT)

National Institutes of Health

These procedures require certain elements after scientific review when the application is being considered for funding.

The standard elements include:

- other support information (both active and pending) for senior/key personnel;
- certification of IRB approval of the project's proposed use of human subjects;
- verification of IACUC approval of the project's proposed use of live vertebrate animals;
- evidence of compliance with the education in the protection of human research participants requirement

Other program-specific information may also be requested using this procedure.

Disclosure Requirements and Grants

Other Support

- Historically, many investigators only disclosed grants through their institution
- Federal agencies have clarified that ***ALL*** sources of support regardless of whether or not if they have monetary value or are through UM or some other entity must be disclosed
- **Effective January 2022**, NIH requires copies of grants, contracts or other documents for all disclosed foreign other support (translated if necessary)

Disclosure Requirements and Grants

Biosketch

- All academic, professional and institutional appointments including:
  - Any titled position whether or not remuneration is received
  - Full-time, part-time and voluntary appointments
  - Adjunct, visiting or honorary appointments
- Many federal agencies require this level of disclosure now. NIH implemented the requirements in January 2022.
- Some agencies require all appointments and some only require current appointments.

Read and understand the sponsor's requirements

Not Sure?

- Ask your ORA Contact Person!
  - Go to: https://ora.Miami.edu
  - Click on Who is My RA Contact Person
  - Follow the prompts
- Err on the side of caution
- Better to disclose rather than not include something that is required

Transparency is best!

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Foreign Influence

What Is Foreign Influence?

The Federal Government is concerned that foreign entities may be using university research enterprises to compromise the United States economic competitiveness and national security.

Concerns about the Impacts of Foreign Influence

- Loss of intellectual property
- Disclosure of confidential grant application information
- Collaborations with restricted entities or individuals

Disclosure Requirements and Grants

Foreign Components

- Most sponsors require the disclosure of foreign components at the time of proposal, and some require it after award if not included in the application (e.g., NIH)
- Foreign components may include, but are not limited to:
  - Performance of any significant element outside of the US, either by UM personnel or personnel at the foreign site (whether or not funds are expended)
  - Collaborations with investigators at a foreign site anticipated to result in co-authorship
  - Use of facilities or instrumentation at a foreign site
  - Receipt of financial support or resources from a foreign entity

Impacts

- UM ***strongly supports*** international collaborations which are vital to the success of our faculty and our success as a leading research enterprise
- ***Transparency*** about foreign engagements is required by federal and non-federal sponsors
- Transparency also allows UM to assist faculty in identifying potential conflicts or concerns with foreign engagements and to help the faculty manage collaborations

Consequences of Foreign Influence

Consequences to the Individual

- Termination of existing federal awards
- Suspension or debarment from participating in federal funds
- Criminal charges

Consequences to UM

- Withholding payments or not reimbursing for costs incurred
- Loss of expanded authorities
- Suspension or debarment from receiving federal funds (including financial aid)
- Harm to UM's reputation

Questions?

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Reliance Review

Mabel E. Algeciras, Ph.D., CIP
IRB Manager, Human Subjects Research-Reliance

Some basics and why sIRB

Single IRB (sIRB, Central IRB)

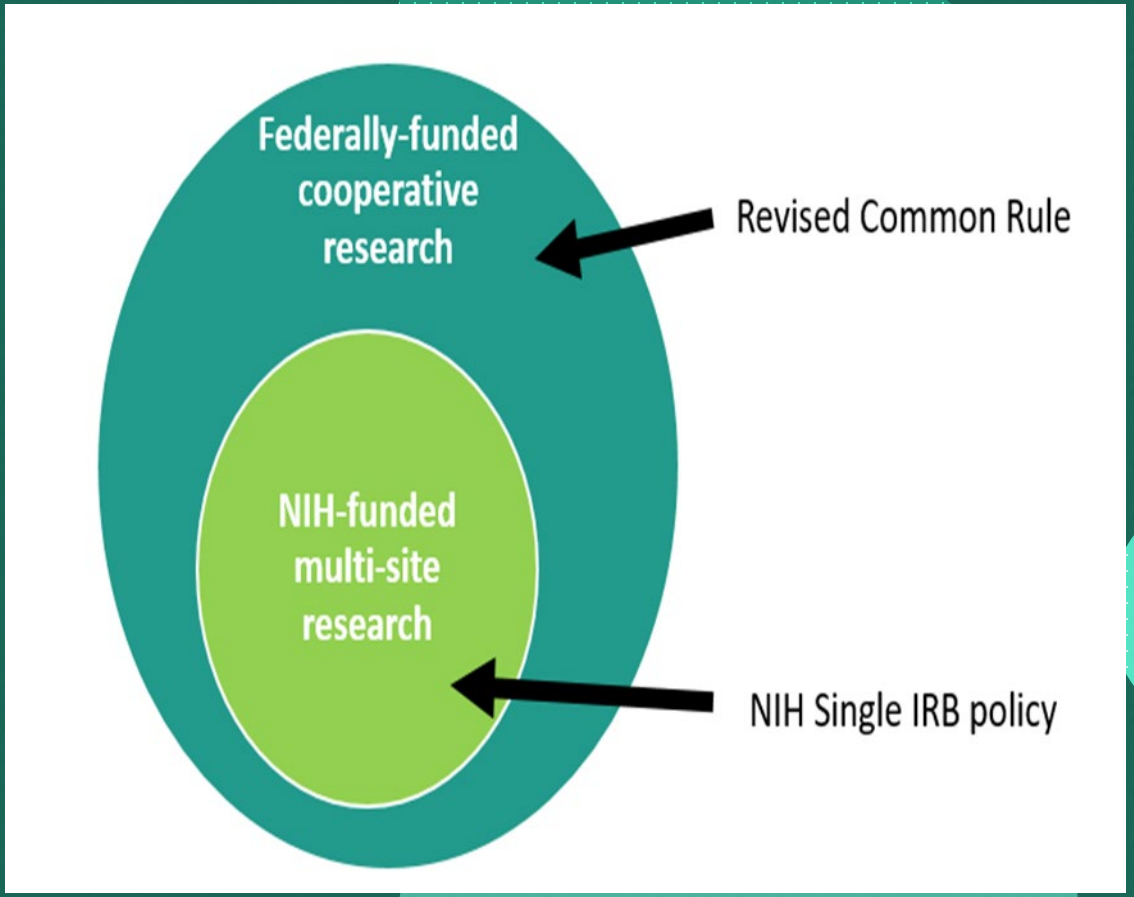
- ❑ IRB of one site provides IRB oversight for other relying sites
- ❑ IRB of record
- ❑ Usually identified by the federal department funding the research

Relying site

- ❑ A site that agrees to rely on the Reviewing IRB and comply with their requirements

Benefits

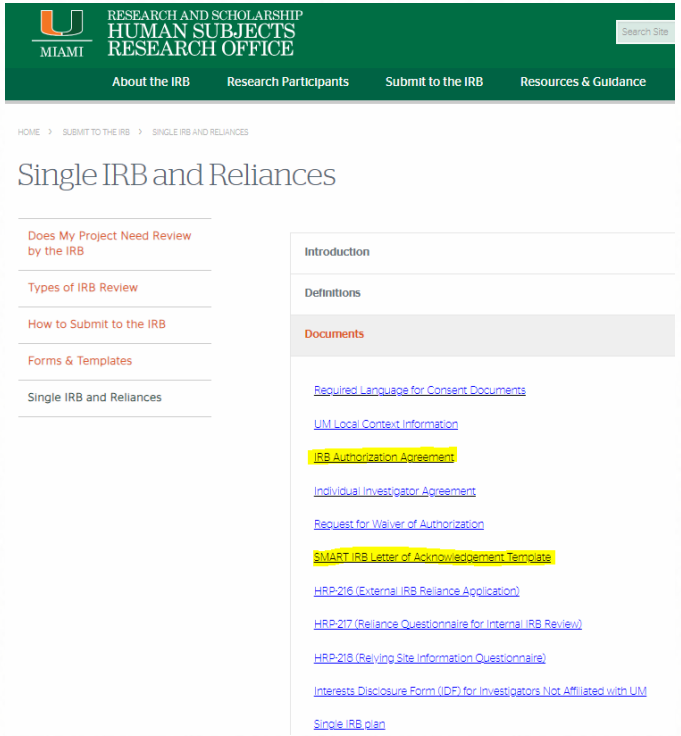
- ❑ Eliminate administrative burden for PIs
- ❑ Avoid duplication of efforts
- ❑ Consistency in the review process
- ❑ Enhance research partnerships
- ❑ Accelerate approval



Reliance Agreement

- ❑ Institutional Authorization Agreement
- ❑ Allow an IRB to rely on another IRB as the IRB of record
- ❑ Outlines specific provisions and responsibilities for each of the parties entering the agreement
- ❑ Types:
  - UM IRB Reliance agreement template
  - Master Reliance agreements
  - SMART IRB

This is a flexible, national IRB reliance agreement that UM and many other institutions have used to cede review



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Responsibilities

Relying site

- ❑ Provide local context (e.g., applicable state or local laws, regulations institutional policies, local factors)
- ❑ Provide study documents with the local/institutionally required language (compensation for injury, payment)
- ❑ Perform ancillary reviews such as conflict of interest review.
- ❑ Review study personnel's education, training and qualifications
- ❑ Submit any change in research in a timely manner
- ❑ Notify the Reviewing IRB of unanticipated problems, potential noncompliance, suspension or restriction, significant subject complaints
- ❑ Comply with the sIRBs determinations

Reviewing site

- ❑ Making IRB determinations for all types of review (initial, continuing, amendments, reportable events, etc.)
- ❑ Review of findings and actions related to reportable issues (unanticipated problems, serious or continuing noncompliance, suspension or termination, subjects' complaints)
- ❑ Report to federal, state or funding agencies
- ❑ Audits (Investigating and determining potential corrective and preventive actions in the event of non-compliance)

Shared

- ❑ Enter into an IRB authorization agreement (IAA).
- ❑ Establish a plan for sharing of information between the site and the IRB, such as establishing a coordinating center or coordinating center liason

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Central IRB Model at UM

Administrative:
Evelyne Bital
Mabel Algeciras

Expedited:
Angel Gallusi
Mabel Algeciras

UM Central IRB

IRB Number: IRB00010711

Member	Primary Scientific or Nonscientific Specialty	Comments
Thomas Sick, Ph.D.	Neurology	*Chair;* Other Scientist; Incapacitated Adults
Gianluca Iacobellis, MD	Endocrinology	*Vice Chair;* Physician Scientist
Evelyne Bital, M.A.	Regulatory Affairs, Liberal Arts	Non-scientist
Gary Feinberg, BA	Liberal arts	Non-scientist
Mabel E. Algeciras, Ph.D.	Regulatory Affairs, Neuroscience	Other Scientist
Daniel Nobel, Pham.D., B.C.P.S.	Pharmacy	Other Scientist; Children

Dr. Behar-Zusman (SBS expertise)

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UM as the sIRB

Requirements

- ❑ Study is federally funded
- ❑ Relying site must be engaged in the research
- ❑ Lead PI is a UM PI or study is conducted in collaboration with a UM PI
- ❑ The engaged site does not have an IRB
- ❑ Site must be domestic
- ❑ Case by case

Exemptions

- ❑ International sites
- ❑ Exempt studies
- ❑ Federal department supporting the research determines that sIRB review is not appropriate
- ❑ Prohibited by tribal or state laws so some sites may not be required to comply

UM as the sIRB

- ❑Set up a reliance consultation with the HSRO to discuss the study plan, expectations, review fees associated with Central IRB review, negotiate the agreement, etc…

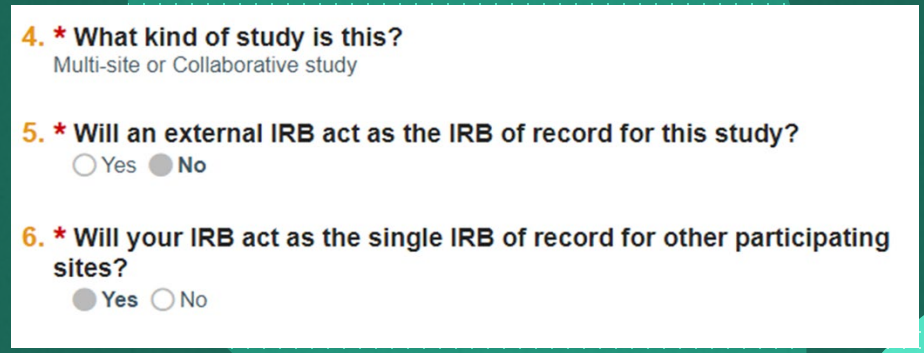
- ❑Submit the study through IBIS.
  - •UM site must always be approved first
  - •Submit as multi-site where all sites are relying on the UM IRB

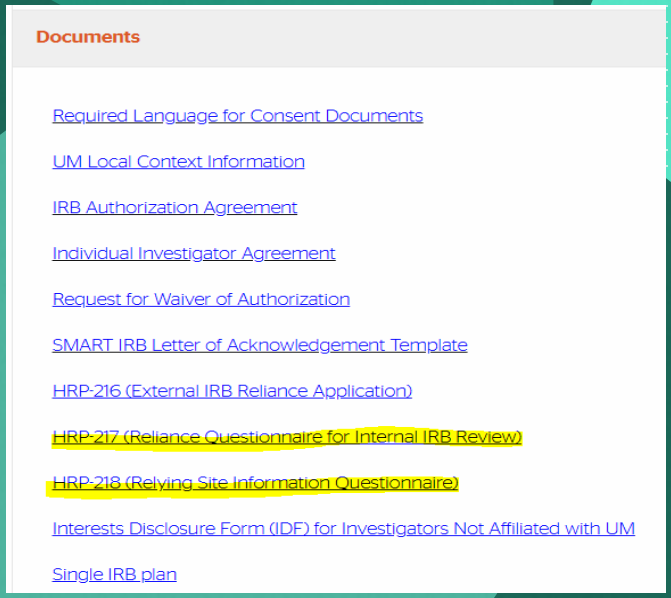
- ❑Include an external site application form **HRP-217:**
  - •UM's role in the research
  - •Relying site's role in the research

- ❑A reliance agreement must be in place with each of the relying sites

- ❑Each relying site must complete the Relying site Information
- ❑Questionnaire form **HRP-218:**
  - •Research personnel involved in the research at the site
  - •Role of the site in the research
  - •Confirmation that all ancillary reviews, training and financial disclosures have been completed
  - •Local context/site's requirements for consent

- ❑Establish coordinating center or coordinating center liaison





UM external IRB model

Study eligibility criteria

- ❑ Federally-funded and external review is required per single IRB mandate.
- ❑ Industry *funded*, multi-site study and the sponsor is requiring the UM to rely on an external IRB as a condition of participation.
  Sponsor must provide a statement requiring external IRB review.
- ❑ Other extenuating circumstances considered on a case-by-case basis.

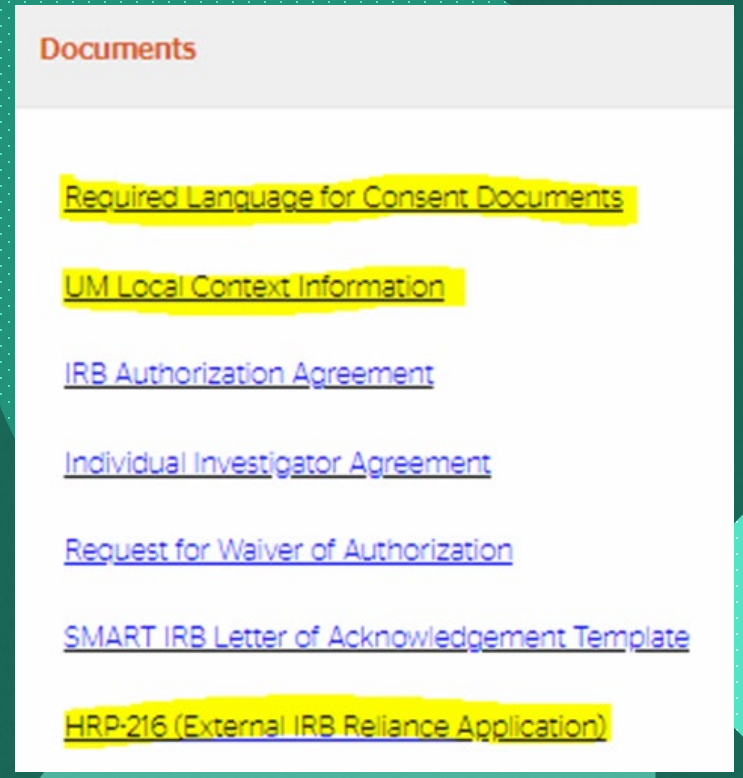
The University of Miami reserves the right to determine if the use of an external IRB for a specific project is appropriate for the institution.

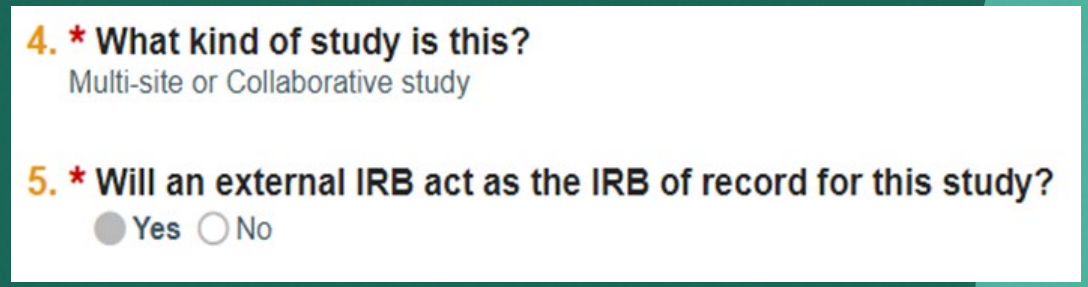
UM external IRB model

- Administrative review
  - ❑ HRP-216 Reliance Application
  - ❑ Rely on External IRB (Sign agreements)
  - ❑ Carry on administrative review functions
    - Approval notice from the external site
    - Ensure that UM consent documents include UM-specific language
    - Provide UM's local context information when requested, including state and local laws
- Ancillary Reviews

Administrative team

Evelyne Bital
Dori Bugallo





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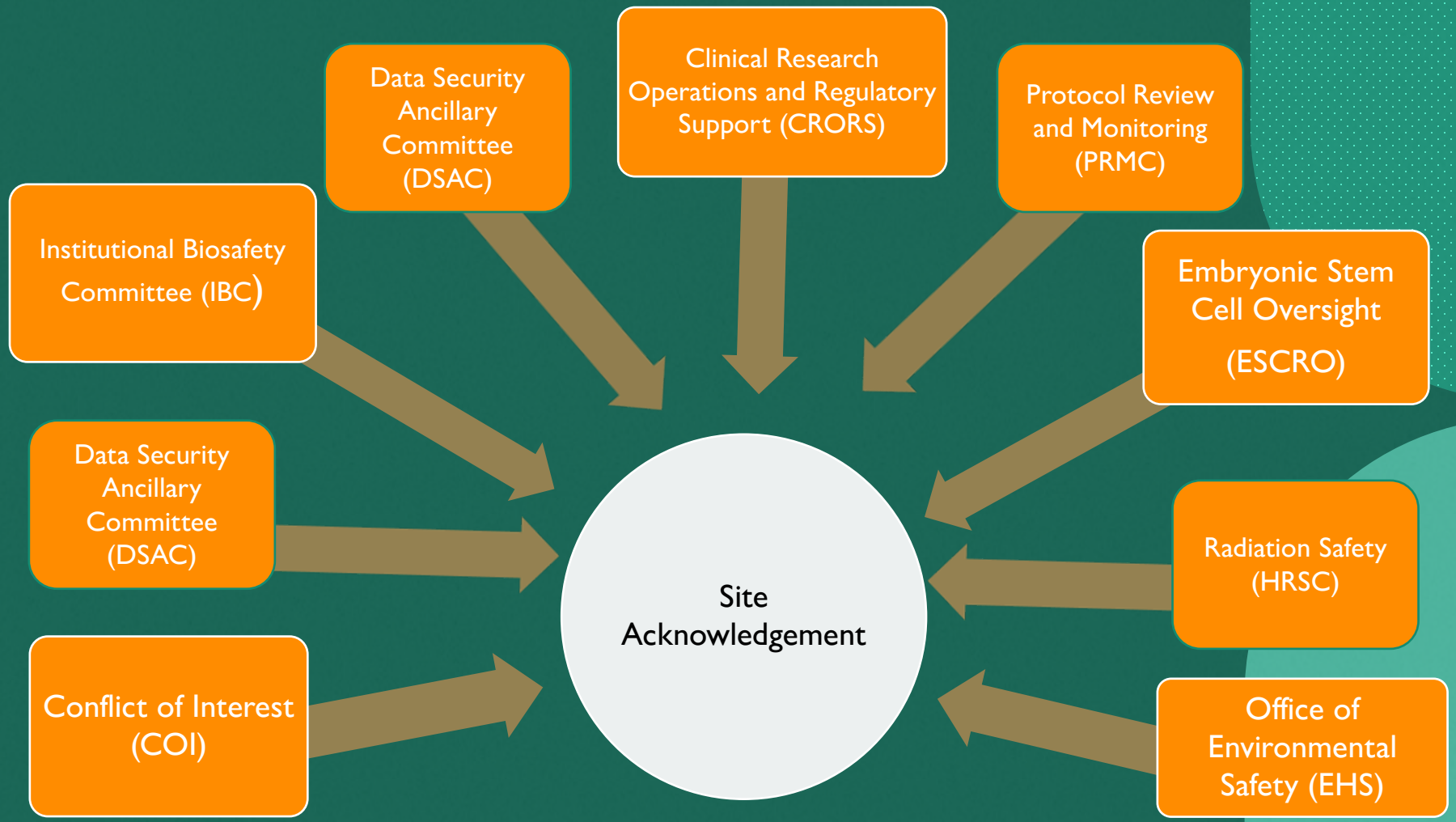
Ancillary reviews required before site acknowledgment by UM



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Ongoing activities after initial acknowledgment

The UM site must submit modifications or RNI in IBIS.

- ❑ The HSRO does not review documents that are uploaded after the local site has been activated. The HSRO will only administratively check that the patient-facing documents are still meeting UM institutional local requirements.
- ❑ Reports of non-compliance that could meet the UM's definition of serious or continuing non-compliance
- ❑ IRB suspensions or terminations of a study
- ❑ IRB determinations of unanticipated problems involving risks to subjects or other

UM does not require continuing reports for studies reviewed by external IRBs.

- Can be reported through : Report Continuing Data activity

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Tips for efficient reliance/review

- ❑ Plan ahead and initiate discussions early
- Early engagement with collaborating institutions and with the UM reliance team
- ❑ Select a suitable sIRB (expertise and experience)
- ❑ Develop a protocol that clearly defines the responsibilities of each participating institution, including data collection, subject recruitment, adverse event reporting, and communication with the reviewing IRB
- ❑ Develop template consent documents
- ❑ Provide training to all research team members involved in the reliance process, including investigators, coordinators, and IRB staff at each site
- ❑ Maintain regular communication with sIRB

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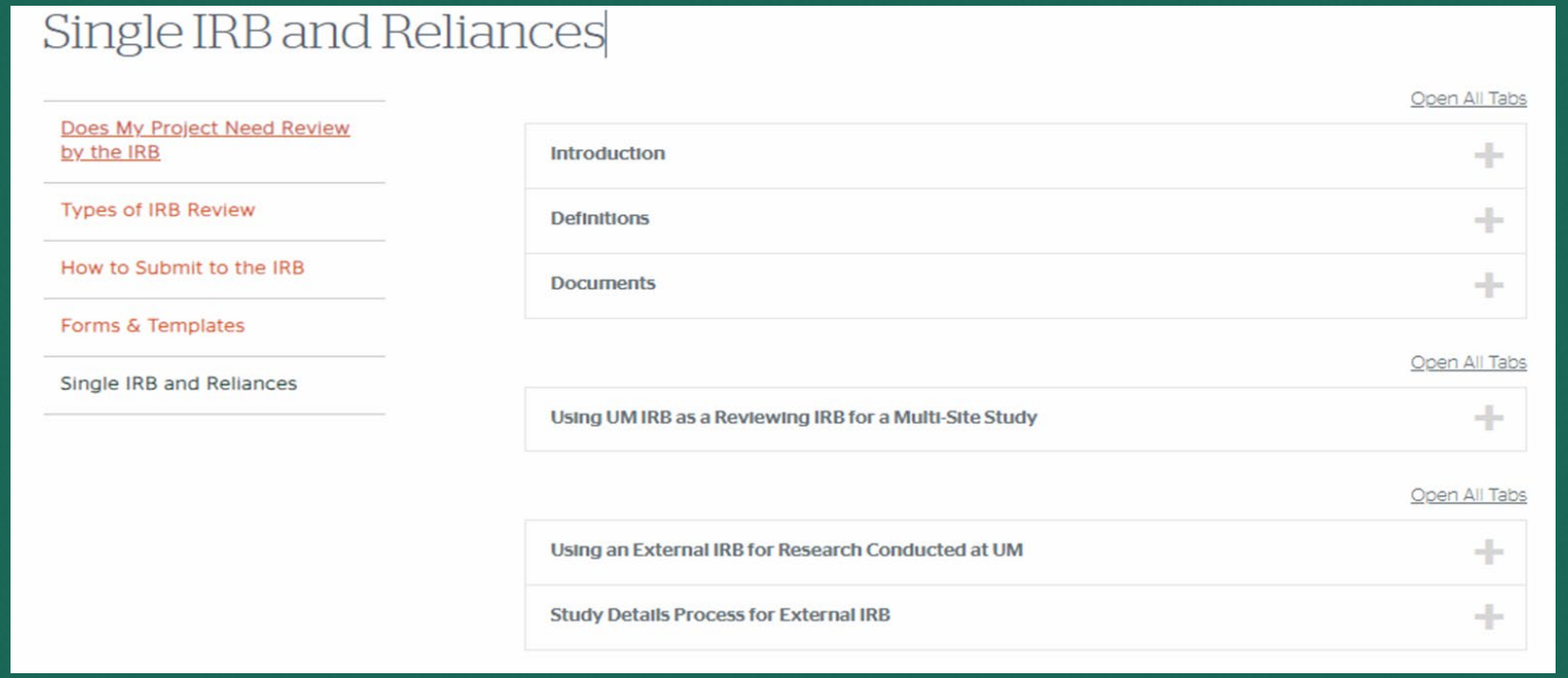
Reliance information on HSRO website



THANK YOU!!!

https://hsro.uresearch.miami.edu/submit-to-the-irb/single-irb-and-reliances/index.html

Investigator Manual:

Chapter 4

Reliances and Cooperative Research for IRB Oversight

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IRB Grand Rounds - Continuing Nursing Education (CNE) Evaluation and Registration

Nursing Continuing Professional Development (NCPD)

The University of Miami School of Nursing and Health Studies is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.

Thank you!/ Questions?

4/16/25 SBS IRB Grand Rounds

Tackling Technology & Data Trends

For additional information please contact curatingconnection@miami.edu and reference IRB Grand Rounds.

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