# Building Blocks of Protocol Success


Lory A. Hayes, PhD, CHRC
*Director, Disclosures & Scholarly Activities Management*

Patricia Atkinson, BA, PMP
*Research Navigator, Clinical and Translational Science Institute*

Nelson Vega, BA, RQAP-GCP
*Sr. Quality Auditor, Research Quality Assurance*

Helen Miletic, MA, CHRC, RQAP-GCP
*Director, Research Quality Assurance*

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

# SBS IRB Grand Rounds 2025

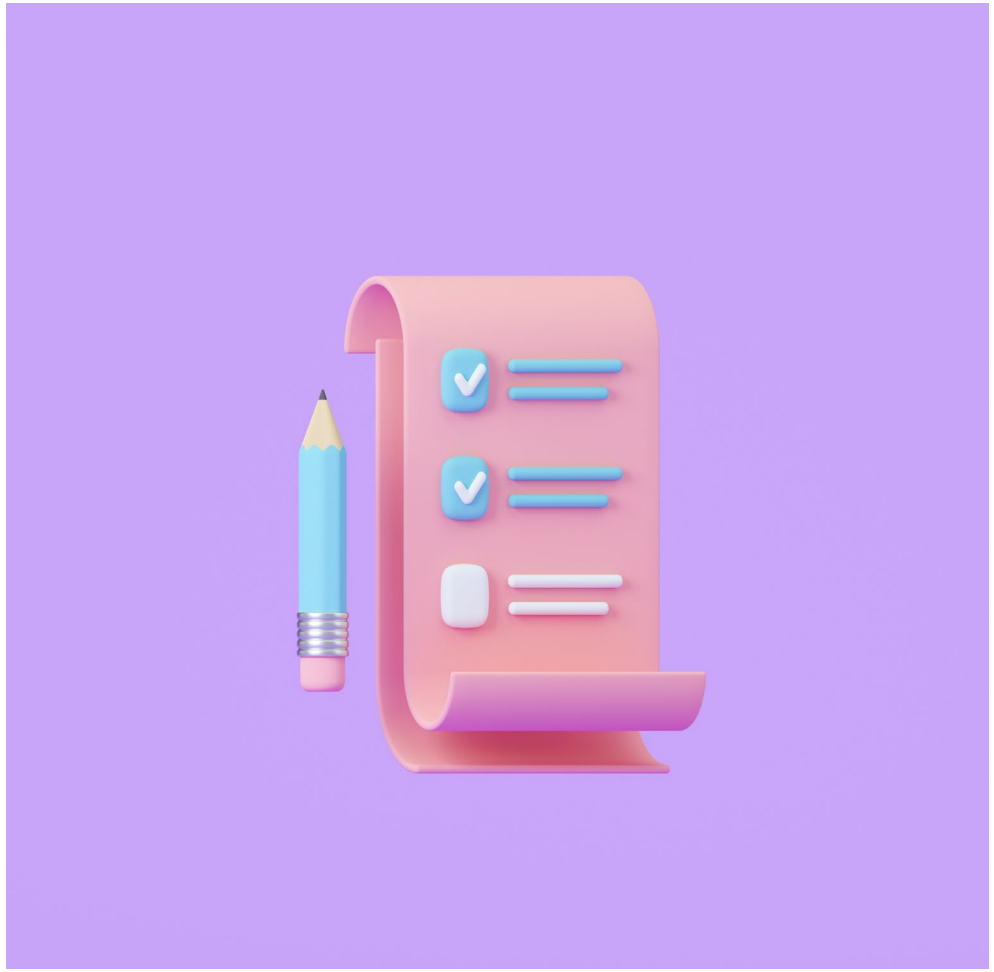
| | |
|---|---|
| **2/12/2025 10-11am** | **Building Blocks of Protocol Success** |
| **3/12/2025 10-11 am** | Carpe Diem: Dealing with & Planning for Tight Deadlines |
| **TBA 10-11am** ***(update coming soon)*** | Tackling Technology & Data Trends |
| **5/7/2025 10-11am** | Keeping the House in Order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

# Relevant Conflicts

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

# Objectives

- Describe institutional requirements including COI & other ancillaries
- Discussion of available resources to ensure a comprehensive/ compliant submission
- Highlight best practices to help avoid potential non-compliance pitfalls
- Identify basic protocol submission requirements



# Ancillary Review

- ***Ancillary review assists the IRB and research teams with matters related to research feasibility, risk, regulatory requirements, and research compliance.***
- ***The ancillary review process is independent of IRB review.***
- ***The ancillary review could be required prior to; simultaneous with; or after the IRB review. Detailed requirements can be found in Ancillary Matrix (HRP-309)***

***Confirmation of readiness from all required ancillary review committees should be obtained before starting enrollment of subjects.***

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# Conflict of Interest (COI) Review

Lory A. Hayes, PhD, CHRC

Director, Disclosures & Scholarly Activities Management

# Conflict of Interest (COI) Committee

- **UM's COI policy requires all team members (TMs) complete before participating and annually:**
  - *Training in UDisclose System: COI10 (policy & process), Researcher, and Research Security Trainings*
  - *Disclosure process; updated within 30 days of changes or acquisition of a new interest; and interests **REMOVED** 12 months after the end of a relationship*
- **Non-UM team members (TMs) must complete UM's Interest Disclosure Form (IDF) process**
  - *Process includes COI training and disclosure of related interests*
  - *Must be completed before TMs can participate on project*
  - *Notify DSAM via Ancillary Review (AR) submission listing the investigator's name and email address*
  - *DSAM contacts non-UM TMs via Redcap, and will contact the PI if no response*
  - *DSAM will close the AR in eProst when the TMs are cleared to participate*
  - *If additional TMs are added, must be noted in a new AR*
- **UM's COI policy requires that *ANY* relationship to a HSR study must be disclosed to participants**
  - *Consulting/teaching/ad board (irrespective of compensation), ownership (equity/shares/options)*
  - *Sponsor/funder/manufacturer of a drug/device used in the study*
  - *ETC*
  - *Method of disclosure is at the purview of the IRB*

**Contact us anytime! DSAM@miami.edu or 305-243-0877**

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# Navigating Research Resources

**Patty Atkinson**

**Clinical &Translational Science Institute**

**February 2025**

CTSI

# Research Navigator Services

- Provides guidance on available resources, services, and expertise
- Assists with navigating administrative processes, policies, and requirements
- Advises on tools and systems for facilitating research
- Provides guidance on research training requirements
- Serves as liaison between faculty, study team, and administrators to expedite research
- Identifies where to go for more in-depth assistance

https://miamictsi.org/resources/navigating-research/research-navigator/

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# Navigator Chatbot

## Quick Guidance & Live Support

- ✓ Available any time
- ✓ Addresses frequently asked questions
- ✓ Includes on-line chat feature (business hours)


**Future enhancements:** Community engagement resources for both academic and community audiences

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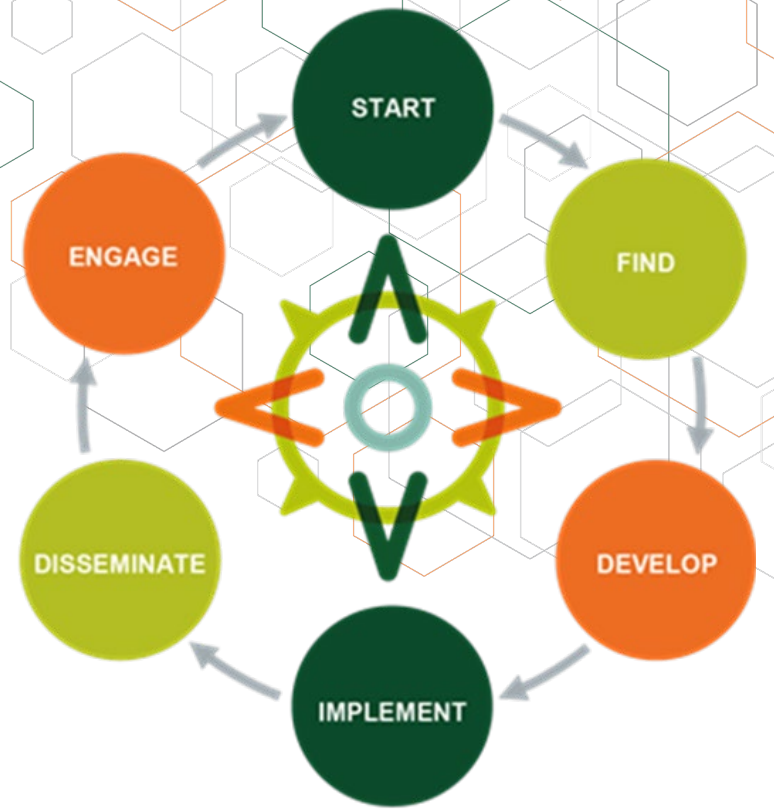
# Research Compass

- Dynamic online tool
- Designed to guide researchers to critical resources and support needed
- Organized around the stages of the research project
- Provides need-to-know information and key contacts
- Includes Getting Started Guides, Tip Sheets, Grant Boilerplates, Guidance Documents and Checklists

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https://miamictsi.org/resources/navigating-research/research-compass/

# Research Compass: Access

- Research Compass is open to all

- Two ways to access the tool
  - Direct access via link; Click and you're in
  - Sign in to the portal to access to additional features
    - Use Search option
    - Add Bookmarks
    - Save Notes

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https://elevate.miami.edu/learn/course/research-compass/welcome/welcome-introduction?page=2

# Research Compass: Getting Started

**Getting Started with Research at the U**

Before initiating research follow the Compass to:

- Learn about the University's research environment
- Meet the key players and research leadership
- Understand research roles & responsibilities at the U
- Find needed research systems and how to obtain access
- Identify what research training is required and how to complete it

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# Research Compass: Protocol Development

- Protocol writing
- Obtaining compliance and regulatory approvals
- Identifying need-to-know policies
- Developing Data Safety & Monitoring Plan (DSMP)
- Working with Jackson Health System (JHS)
- Using ONENESS Data Query Tool (ORS)

| SAFETY MONITORING PLAN | |
|---|---|
| Y ☐ N ☐ | Specific parameters are listed for safety review |
| Y ☐ N ☐ | A frequency of safety observation is given |
| Y ☐ N ☐ | A person has been designated to be responsible for safety review |

## Protocol Writing

- See section on Writing an Investigator Protocol in the HRP Investigator Manual
- Utilize the Forms and Templates that most closely align to your research

### Key Contacts

Human Subject Research Office (HSRO): hsro@miami.edu or 305-243-3195

National Institutes of Health (NIH) -

Checklist for Planning & Writing a Human Subjects Grant Application

Justification for Use of Human Materials

### Tip Sheets

Guide for Obtaining Approval for Studies Involving JHS

Getting Started with JHS Non-Industry Funded Studies

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# Research Compass: Resources & Expertise


## IT Resources for Researchers

The University of Miami has a variety of technological resources available to assist researchers and scholars. Resources are housed across the University's multiple campuses, and each system, service, or resource is overseen by the department or area best suited to manage that resource.

### Getting Started

- Access available resources and services
- Request a consultation to discuss your project's needs

## Library Resources

### Find Expertise

UM experts are here to help navigate library resources throughout the research lifecycle. Researchers can:

- Request a consultation with a librarian in your area of study
- Locate a Research Guide curated by UM librarians and experts to find materials and resources for particular disciplines, courses, and special topics
- Search for expertise via Scholarship@Miami or Pivot

### Find Sources

Search UM Libraries' comprehensive collections of 4 million volumes and over 123,652 ejournals and serials

- Databases - access by format and subject
- Collections, Books, & Articles

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# Miami Clinical & Translational Science Institute
## *Key Resources*

CTSI MIAMI CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

### FUNDING OPPORTUNITIES

- Annual Pilot Awards
- K12 Career Development Program

### INFORMATICS

- Consultative support
- Clinical data for research
- Informatics tools (Epic Slicer-Dicer, REDCap e-consent, etc)

### ADDITIONAL RESOURCES

- Biostatistics consultations
- Grant writing consultations
- Community engagement consultations

### STUDY RECRUITMENT

- Consent to Contact – UHealth patients who consent to be contacted
- UMiamiHealthResearch.org



### EDUCATION & TRAINING

- MS in Clinical Translational Investigation
- Grant Writing training
- Informatics training
- Research Design/Biostatistics education
- Research Mentoring training
- KLUES program for faculty interested in research career development

**The Miami CTSI drives research translation into evidence-based clinical and community practices that improve the health of South Florida's diverse population**

For more information and to sign-up for the mailing list visit:
https://miamictsi.org/

# Key Resources

## WHAT WE HAVE & WHERE TO FIND IT

## Research Navigation Resources

| | | |
|---|---|---|
| **Research Navigator** | ▪ personal 1:1 assistance<br>▪ get connected to resources and expertise | https://www.research.miami.edu/about/admin-areas/rde/navigator/index.html |
| **Chatbot** | ▪ FAQs and chat service | https://www.research.miami.edu/about/admin-areas/rde/navigator/index.html |
| **Research Compass** | ▪ dynamic on-line tool<br>▪ guidance and key contacts for all stages of a research project | https://elevate.miami.edu/learn/course/research-compass/welcome/welcome-introduction?page=1 |
| **Clinical & Translational Science Institute (CTSI)** | ▪ crucial support and resources for researchers implementing studies aimed at improving health of patients and communities | https://miamictsi.org/ |
| **IT Resources for Researchers** | ▪ one-stop shopping for IT resources<br>▪ consultations to assess IT needs and solutions | https://it-resources.research.miami.edu/index.html<br>https://miamictsi.org/resources/data-science-research-informatics-services/ |
| **Listservs & Communications** | ▪ sign up and stay connected with the research community at the U | https://miamictsi.org/newsletter/<br>https://www.research.miami.edu/about/listserv/index.html |

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# Electronic Research Records:

## Timeless Solutions to New Challenges

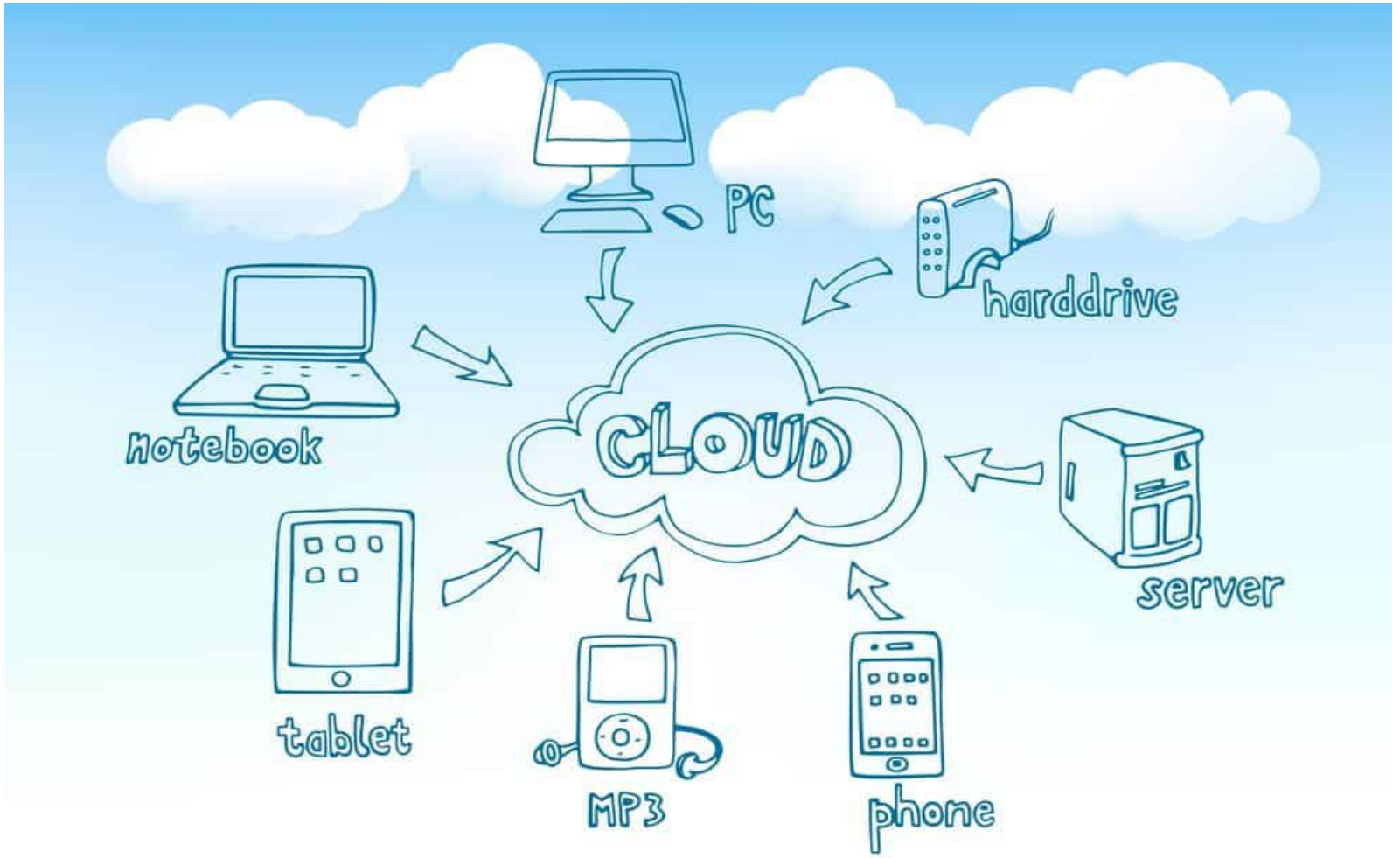
**Nelson A. Vega, BA, RQAP-GCP**

Sr. Quality Assurance Auditor
Research Quality Assurance

# The Good Ol' Days?

# How It Started (pre-COVID, of course)

# How It (Kinda) Went…



# Where We Are Now

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# Trends Noted in RQA Quality Reviews

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## Incomplete Research Records: (Cf. P.I. Manual)

- Missing **FULL** device data (incl. questionnaire responses)
  - Data still on tablets / external partner systems?

- Database (e.g. REDCap?) entries lack
  - Attribution (i.e. who *actually* completed surveys?)
  - Corroboration (where is the raw data?)

# Trends Noted in RQA Quality Reviews

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## Rapid Switch from Paper to E-Data

### Inconsistent Documentation Practices

- Where are the records? (Email accts, Box, Devices)

### Details Matter

- Coordinator Notes / Visit Checklists
- Chain of Custody (Rx / biosamples) Missing

# Where Do We Go From Here?

# Building In Quality / Aiming for Readiness

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## Ensuring Complete & Accurate Records

- Write & Train Staff on SOPs About *__your__* Records
- Storage Platforms: Fewer is Better
- Follow Consistent Data Collection Habits
- Conduct Frequent Data/Records QC

# Building In Quality / Aiming for Readiness

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## Ensuring Complete & Accurate Records

- Request External Data Records (if app.) Regularly
- Conduct Frequent Reviews of Subject Entries
  - ePRO / Symptom Questionnaires
  - QoL Surveys

# Building In Quality / Aiming for Readiness

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## Solid Protocols: Excellence in = Excellence Out

- Protocols as Manuals of Operations
  - Specificity
    - Describe *required* vs *optional* tasks
  - Clarity
    - Say what you want & do what you say
  - Consistency
    - No internal conflicts
  - Concision
    - List critical tasks / instructions **together**

# Building In Quality / Aiming for Readiness

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## Solid Protocols: Excellence in = Excellence Out

- How critical are timelines/visit windows?
- Subject records must show protocol adherence
  - Eligibility (e.g. minimum rating scale scores)
  - Intervention effect / response
  - Completion of required surveys, etc.

# Building In Quality / Aiming for Readiness

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## How Do Your eRecords Compare to Old School Paper?

- Organization & Workflow
- Integration w/ Other Systems & Platforms
- **Ease of Navigation: New Staff / 3rd Parties (e.g. RQA)**

# Final Thoughts

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## ALCOA-C

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete

# Final Thoughts

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www.carsized.com


Reactions
& Ideas?
Thank you
At the U, we transform lives through education,
research, innovation and service.

# Identify Initial Protocol Submission Requirements

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

# Identify Initial Protocol Submission Requirements

***1. Determine the scope of study – Designing Trials Efficiently***

- Is this an observational or interventional trial? Can the objective be achieved by an observational approach?

- Is this project a clinical trial?

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. -NIH Definition of a Clinical Trial

***2. Protocol Write-Up Considerations:***

**Scientific significance:** Feasibility committee, grant award notifications, departmental endorsement, funding

**Initial protocol integrity**: Alignment between study design, aims and supporting outcome measures, target sample size and population, recruitment and study strategies, data collection, quality assurance, safety monitoring, and aim-specific statistical analysis plan)

**Recommendations to plan for success:**

*a. Use appropriate protocol template (HSRO website, protocol builder for investigator-initiated clinical trials)*

*b. Consultation: Mentors, Peers in the department or others with expertise in field, Consultants*

*c. Consideration of applicable regulations/laws – Florida law, Oversight agencies, Privacy Rule, etc*

*d. Site(s) consideration, potential agreement processes*

* ***Complexity*** ⬆ ***Regulations and requirements*** ⬆

# Identify Initial Protocol Submission Requirements

***3. For Industry Sponsored Studies:***

- IRB approval and Sponsored Study Agreement are required before study can begin enrollment.
- Study Agreement (and Budget) need to match IRB approved protocol (and ICF).
- Delays and compliance issues arise if ORA review (and negotiation of Study Agreement) is not aligned with IRB review.
    - Pharmacy, CTRS and Lab units do not provide costs to ORA unless the study is submitted to IRB. Study team is to obtain CTRS budget and provide it to ORA.
    - JHS will not review study unless submitted to IRB.
    - Possibility that Study Agreement is finalized based off wrong protocol version. This could cause billing non-compliance and restarting of budget negotiations.
- Simultaneous submission of Study to IRB and ORA will be required moving forward.

# Identify Initial Protocol Submission Requirements

***4. Research Billing Compliance***

- Billing requirement: Medicare Coverage Analysis (MCA) must be developed, approved, signed by PI and uploaded in Velos before enrollment can start, regardless of the funding source, unless the study is exempted from Clinical Research Revenue Cycle (CRRC) tracking for billing in Velos per CTM Policy.
- Pitfalls: Incorrect answer to Q5 in "Study Scope" in IRB submission and failure to timely follow ORA guidance on required actions provided in ancillary review; not timely submitting MCA Agreement/Amendment to ORA when advised to do so (even if Q5 is answered correctly).
- Best practice: Timely follow ORA recommendations regarding MCA provided in ancillary reviews and collaborate with ORA in MCA development.

Learn more about MCA by attending training "Medicare Coverage Analysis (MCA) in Clinical Research" provided by ORA via ULearn. Two sessions with the same content are scheduled for June 24 and 28.

# Identify Initial Protocol Submission Requirements

***5. When study meets the 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)

# Identify Initial Protocol Submission Requirements

***5 (continued). When study meets the 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)

***6. 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

# Identify Initial Protocol Submission Requirements

***7. Submitting for IRB review:***

If the study is industry-funded, please ensure that the applicable required study documents are submitted simultaneously to

- **IRB and ORA ***

- Verify the thoroughness of the protocol with applicable supporting documents
- Complete the application in the IBIS (ensure consistencies with uploaded materials)
- Update the disclosure profiles and report potential COIs
- Include required Ancillary Review Committees (manually on landing page) *(proactively reach out to applicable ancillaries if you have any concerns)*
- **SUBMIT the study**

  *ORA: CTA and Budget are required. Manage relationship for studies involving contact with ORA

  FEASIBILITY REVIEW APPROVAL (for MSOM studies): Required for submission to ORA and IRB for industry sponsored studies.

  **Complete Clinical Trial information

  For non-IIT studies (provide NCT number).

  For IIT studies, once the registration is complete, update the information via "Clinical Trial information" under the parent study workspace

# 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?

**3/12/25 SBS IRB Grand Rounds**

Carpe Diem: Dealing with & Planning for Tight Deadlines

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

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