

# Key Ingredients to Running a Successful Clinical Trial (UM & JHS)

- Describe existing resources for protocol development
- Identify nuances for JHS studies
- Highlight best practices & requisite training

**Speakers:** **Nicole S. McCullough, MS, CCRP**, Director, Investigator Initiated Trial Services at the U (IITS-U), Office of the Executive Dean for Research

**Katuzka Barbery, EMBA**, Director, Office of Research Administration, Jackson Health System

**Karrelyn Wetherington, CCRP, CCA**, Sr. Clinical Trial Disclosure (CTD) Associate, HSRO

*All presenters have indicated that they have no relevant financial relationships with ineligible companies.*

# IRB Grand Rounds 2026 - Virtual Series

Time	Topic	SPEAKER
January 15, 2026, 10-11 am	State of our Union: Updates & Best Practices	ORA, RIC, EHS, IITSU, HSRO
February 19, 2026, 10-11 am	Guardians of the Data in the Digital Age	Data Brokers, AI
March 19, 2026, 10-11 am	Key Ingredients to Running a Successful Clinical Trial (UM & JHS)	IITSU, JHS, CTD
<b>April 16, 2026, 10-11 am</b>	<b>Balancing Act: Biobanking, Big Data &amp; Data Privacy</b>	<b>RI, OTT, CTSI</b>
May 21, 2026, 10-11 am	Beyond the Approval: Building a Culture of Compliance	RQA, DSAM, EC



Describe existing resources for protocol development



# UM Internal Resources Overview for clinical research protocol development

- **Louis Calder Memorial Library** – resources for planning and designing your study
- **CTSI** – provides support and resources for planning & implementation of research, research compass, research navigator and more...
- **HSRO** – templates (link to **Protocol Builder**), guidance on submitting to the IRB and policies on human subjects research.
- **BCCC** - ensure that the appropriate use of statistical methodology is incorporated in research.
- **MSOM ITS-U team** – link to **Protocol Builder**, resource and support for MSOM investigators for clinical trial protocol writing, FDA submissions and general questions about IITs.

# Calder Library Guide for Researchers- Department of Learning, Research, and Clinical Information Services

The aim of the Calder Library is to provide resources such as planning research studies in design, finding collaborators and mentors, compliance and citations management.

**The Calder Library Guide for Researchers** provides links to resources for:

- Planning a study
- Designing a study
- Grants and funding
- Finding collaborators and mentors
- Citation managers

**Website:** <https://spmed.library.miami.edu/subjects/researchers#tab-0>

**Email:** [reference@miami.edu](mailto:reference@miami.edu)

**Phone:** 305-243-6648

**Ask a Librarian:** <http://calder.med.miami.edu/librarianask.html>

# CTSI Resources for Clinical Research Protocol Writing

## Clinical & Translational Science Institute (CTSI)

### One Florida

- Prep-to-research data query, which helps researchers formulate hypotheses and identify trends within targeted populations, or

### Informatics tools

- Tools such as EPIC SlicerDicer can be used to assist investigators with identification of patient cohorts, study design, feasibility analysis.

### Data Science and Research Informatics Services (UHealth IT)

- Services range from provisioning data for research from UChart to data management to comprehensive education and consultations.

**Website:** <https://miamictsi.org/resources/>

**Email:** [CTSIservices@med.miami.edu](mailto:CTSIservices@med.miami.edu)

**Telephone:** 305-243-5096

# UM HSRO Resources for Clinical Research Protocol Writing

The **Human Subjects Research Office (HSRO)** oversees the administrative aspects of Institutional Review Board (IRB) functions and provides the following resources for investigator-initiated studies:

- Templates: Protocol Builder application link (under CommUnIITy), consent/ assent, phone scripts
- Instructions and guidance documents for how to submit to UM IRB
- UM Investigator Manual and policies and procedures for conducting human subjects research (includes strategies for research conduct)
- Office Hours and consultation with senior staff available

Website: <https://hsro.uresearch.miami.edu/>

Protocol Builder link: [Protocol Builder| Research and Scholarship | University of Miami](#)

Email: <https://hsro.uresearch.miami.edu/contact-us/index.html>

Interim Assistant Vice President: Kenia F. Viamonte



# Biostatistics Collaboration and Consulting Core (BCCC)

The aim of the BCCC is to assure that the appropriate use of statistical methodology is incorporated in research.

## Types of Support

- Short Term Support Activities
  - Specific projects, defined questions with relatively small datasets e.g. research proposal development; data analysis on a prepared data set; pilot study design
- Ongoing Collaboration Plan
  - Department may have a "retainer" on biostatistical support.
- Grants
- Office Hours Appointments for Quick Consultation
  - addressing simple biostatistical questions or providing short consultations on statistical advice

**Website:** <https://www.publichealth.med.miami.edu/divisions/biostatistics/bccc/index.html>

**Email:** [MJRodriguez@biostat.med.miami.edu](mailto:MJRodriguez@biostat.med.miami.edu)

**Contact:** Maria Jimenez-Rodriguez

# Investigator Initiated Trial Services at the U (IITS-U)

## IITS-U resources for clinical research protocol development:

- Protocol Builder link
- Regulatory support & services
  - Questions and consultations for IIT planning and conduct
  - Review of clinical trial protocols and CRFs
  - FDA submission preparation services (for INDs, IDEs, etc.)
- Multisite IIT services, including assistance with protocol development

**Website:** <https://med.miami.edu/research/clinical-research/iitsu>

**Protocol Builder link:** [Protocol Builder Application Miller School of Medicine](#)

**Email:** [iitsu@miami.edu](mailto:iitsu@miami.edu)

**Director:** Nicole S. McCullough, MS, CCRP





# Other general CTSI Resources for Clinical Research

The **Research Navigator** is a concierge service that connects researchers to the right resources at UM. It is a one-on-one, centralized support service designed to help researchers focus on research, not roadblocks.

Contact the Research Navigator at [Navigator@miami.edu](mailto:Navigator@miami.edu).

The **Research Compass** is a dynamic new tool designed to guide you to the resources you need to make research and scholarship happen at the University of Miami.

Access the Research Compass at <https://researchcompass.miami.edu/learn/course/research-compass/welcome/welcome-introduction>.



## Welcome to Protocol Builder 2.0

Protocol Builder is now available at the University of Miami. This secure, cloud-based technology can help you write research protocols faster and more easily. It provides organization, guidance, and collaboration tools for your observational or interventional research protocols. It can be used on your laptop.

Click Login below to get started today!

LOGIN



## ProtocolBuilder<sup>®</sup> application (cloud-based) at the University of Miami

- 🍊 16 different protocol templates (increase regulatory compliance & help w/ IRB review)
- 🍊 Guidance for what to write in protocol sections, some boilerplate starter text
- 🍊 User friendly, easy to navigate
- 🍊 Formatting similar to Microsoft Word, shows tracked changes
- 🍊 Automatic version control, automatically creates summary of changes
- 🍊 Export to Microsoft Word or Adobe PDF (working on possible integration with IBIS IRB submission)
- 🍊 Upload references library
- 🍊 Collaboration - automatic formatting, ensure all working on same version, email notifications
- 🍊 Complimentary access to CITI “Research Study Design” & “Observational Prospective Protocols” courses



## INTERVENTIONAL

- NIH and FDA Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials
- Interventional FDA Approved Drug/Biologic
- Interventional Investigational New Drug/Biologic
- Interventional Non-Significant Risk Device
- Interventional Significant Risk Device
- Interventional Combination
- Behavioral Intervention (incl. benign behavioral intervention)

## OBSERVATIONAL

- Chart Review
- QA/QI
- Repository with the use of Broad Consent
- Repository without the use of Broad Consent
- Observational study of a FDA regulated product
- Observational study of individual or group characteristics or behavior, or human factor evaluation

## SOCIAL BEHAVIORAL

- NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans
- Social Behavioral

# External Resources for IIT planning & design

- NIH and FDA IND/IDE Protocol Word Template (can be used for any drug or device study)
  - **UM specific template in Protocol Builder application**
- National Institutes of Health (NIH)
  - Clinical e-Protocol Writing Tool
  - Behavioral & Social Science Research (BSSR) Protocol Word Template - **UM specific template in Protocol Builder application**
  - Many of the NIH Institutes have helpful clinical research templates and toolboxes for protocols, data safety & monitoring e.g NCCIH, NIA, NIAID, NIAMS, NIDCR, NIDDK
- Food and Drug Administration (FDA)
  - Guidance documents
  - Databases on drugs, biologics, biomarkers, devices, etc.

# Overview of IITS-U services

## Regulatory Services & Support

- FDA submissions & support for Investigational New Drug (IND) and Investigational Device (IDE) applications
- Study document review (protocols, CRFs, ICFs, DSM plans)
- Clinical research regulatory guidance & consultations.
- Managing Trial Master File for UM as sponsor

## Clinical Trial Monitoring Services

- Monitoring services for UM or UM investigator-held IITs
- Central monitoring for multi-site IITs

## Project Management Services

(for multi-site IITs)

## Data Management Services

(for multi-site IITs)

## Safety Monitoring (when UM has sponsor role for multi-site IITs)

## Clinical Research Education



# Key Ingredients to Running a Successful Clinical Trial (UM & JHS)

3.19.2026

Katuzka Barbery, MBA  
Director of Clinical Research

# Topics

- ❖ Pre-Submission Tips
- ❖ Post-Submission Tips
- ❖ Post Approval Tips



# Pre-Submission Tips

## TIPS

- ❖ Review all resources and tools available before adding JHS in IBIS and UM ORA's submission, refer to Research Compass and UMs HSRO Ancillary Committee Page [Ancillary Committees | Human Subject Research Office | University of Miami](#)
- ❖ If in need of research rates before submitting a proposal, reach out to JHS ORAs general inbox
- ❖ Ensure drug and device availability and applicability
- ❖ If in need of feasibility data from JHS contact [JHS-CTO-Research-Tickets@jhsmiami.org](mailto:JHS-CTO-Research-Tickets@jhsmiami.org) inbox to get access to the Oneness solution
- ❖ If in doubt of a JHS process reach out to JHS via [JHS ORA Helpdesk](#) or general inbox [JHS-CTO-Submissions@jhsmiami.org](mailto:JHS-CTO-Submissions@jhsmiami.org)

## Benefits

- ❖ Prevent working on the wrong documents or adding the incorrect language
- ❖ Decrease delays in review process by adding JHS from initiation
- ❖ Prevent underbudgeting
- ❖ Increase Clinical trial success
- ❖ Understanding target population

# RESEARCH COMPASS

A dynamic guide to the critical resources needed to make research and scholarship happen here at the University of Miami.



[researchcompass.miami.edu](https://researchcompass.miami.edu)

## Conducting Research with Jackson Health System (JHS)

The University of Miami works with the Jackson Health System (JHS) to conduct studies and perform research activities utilizing JHS facilities, patients, data, and other JHS resources. If a UM study involves Jackson\*, approval is required from both the University of Miami and Jackson Health System prior to the use of any Jackson resources.

### Resources Include:

- Key Contacts for JHS and UM
- Guidance for obtaining approvals for research involving JHS
- Guidance for conducting researching involving JHS
- How to request data
- Links to required forms
- Templates
- JHS systems
- JHS services
- Reporting publications and research findings



# JHS Office of Research Administration Website

## Submission

The Office of Research Administration requires a complete submission of all required documents for the study to be accepted and reviewed by the JHS ORA. Below you will find the resources needed for a successful submission.

### I. Drug studies



### II. Device studies



### III. Chart review/repository studies



### IV. Emergency/Compassionate Use of a Drug or Device



## Forms



Pre-Approval Documents:

The CITI Program is available for JHS Staff to receive a certification to perform research at JHS.

Select your organization affiliation: [Public Health Trust/Jackson Health System Instructions](#):

Register as a "Learner" using the following link: [Research, Ethics, Compliance, and Safety Training \(citiprogram.org\)](#). For more information on which courses to take, contact [JHS-CTO-Submissions@jhs-miami.org](mailto:JHS-CTO-Submissions@jhs-miami.org)

- [JHS ORA Application](#)
- [Study Calendar](#)
- [JHS online EMR Orientation](#)
- [EMR Access Form](#)
- [Workflow Template](#)
- [Pre-submission Budget Request Questionnaire \(workflow TBD\)](#)
- [Pathology Bypass Letter](#)
- Order Set Request Form (coming soon)

Post-Approval Documents:

- [Research Encounter Ticket](#)
- [Monthly Enrollment Report Form](#)
- [Pathology Fee Schedule/Request Form](#)
- [PACS Research Request Form](#)
- [Chart Review Data Request Questionnaire](#)

# Post-Submission Tips

## TIPS

- ❖ Maintain open communication with JHS ORA
- ❖ Respond to clarifications promptly
- ❖ Follow JHS Policies and Procedures
- ❖ Attend JHS meetings
- ❖ Perform In-Service with Clinical teams

## Benefits

- ❖ Process understanding leads to great results
- ❖ Prevent JHS from closing the study administratively
- ❖ Prevent non-compliance
- ❖ Increase understanding of post approval processes
- ❖ Allows understanding of the protocol management and implementation

# Post- Approval Tips

## TIPS

- ❖ Maintain open communication with JHS ORA
- ❖ Follow JHS Policies and Procedures
- ❖ Attend JHS trainings
- ❖ Perform In-Service with Clinical teams

## Benefits

- ❖ Process understanding leads to great results
- ❖ Prevent non-compliance
- ❖ Increase understanding of post approval processes
- ❖ Allows understanding by clinical team of the protocol management and implementation

# Jackson Health System Research: Quarterly Training Sessions



## Target Audience:

- Principal Investigators
- Study Teams

## Topics:

- JHS ORA Oversight & Compliance Governance
- Research Start-Up & Study Oversight Controls
- Participant Enrollment & Billing Safeguards
- Safety Reporting, Devices & Emergency Use
- Medical Records Access & Innovative Therapy Governance
- Audit Readiness & Enforcement



## Key Dates:

- January 28, 2026, noon
- April 29, 2026, noon
- July 29, 2026, noon
- October 28, 2026, noon



Ericka Cheriska-Pacareu, HSE Physician, MHA, MS, ACRP-CP  
Senior Financial Analyst, Research and Grants

Maria Alexa Zambrano, MSc, MHM  
Research Program Coordinator

Katuzka Barbery, EMBA  
Director, Clinical Research

## Contact Us

Office Number: 786-466-2360

Email: [JHS-CTO-Submissions@jhsmiami.org](mailto:JHS-CTO-Submissions@jhsmiami.org)

Website: <https://jacksonhealth.org/administrative/clinical-trials/>

## Zoom Session Details

Meeting ID: 839 8673 2767

Password: 073381

One tap mobile: +1 786 635 1003 US  
(Miami)

The Zoom logo, consisting of the word "zoom" in a white, lowercase, sans-serif font on a dark blue background.

Join our Cloud HD Video Meeting

Zoom is the leader in modern enterprise cloud communications.



General Inquiries

[JHS-CTO-Submissions@jhsmiami.org](mailto:JHS-CTO-Submissions@jhsmiami.org)

EMR, ClickUp, JHS Oneness, Data Request Follow up

[JHS-CTO-Research-Tickets@jhsmiami.org](mailto:JHS-CTO-Research-Tickets@jhsmiami.org)

Consent/HIPAA/Enrollment forms/Invoice questions

[ClinicalTrialsOffice@jhsmiami.org](mailto:ClinicalTrialsOffice@jhsmiami.org)

JHS ORA Zoom Helpdesk

[JHS ORA Helpdesk](#)

Website

<https://jacksonhealth.org/administrative/clinical-trials/>

Jackson  
HEALTH SYSTEM

*Miracles made daily.*

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# ClinicalTrials.gov Requirements & Protocol Development

## Key Resources, Processes, and PI Requirements for Jackson Health & University of Miami

Clinical Trial Disclosure (CTD)  
Karre Wetherington, CCRP, CCA  
Sr. Clinical Trial Disclosure Associate



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# Clinical Trial Disclosure(CTD) Committee



The University of Miami's Clinical Trial Disclosure (CTD) was established in 2013 and provides support and assistance to the research community.



CTD is responsible for ensuring that all Clinical Trials registered on ClinicalTrials.gov are compliant with FDA, NIH, CMS, and ICMJE regulations.



The University of Miami requires registration on ClinicalTrials.gov for all clinical trials, and failure to comply may result in penalties and loss of funding.



CTD offers a university-wide training program and one-on-one support for trial registration and result reporting.



The University of Miami has developed a centralized system/database to track and report metrics related to trial registration and results reporting.

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# Purpose of Today's Session


- Clarify **PI role** in protocol development and IBIS IRB submissions
- Explain **PI (Principal investigator)/RP (responsible party) eligibility** for ClinicalTrials.gov
- Walk through the CT.gov Determination (CTD) process in IBIS
- Review CT.gov requirements for registration, results reporting, and **required protocol elements** for studies that qualify as clinical trials
- Highlight **training, resources, and best practices**

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# Key Nuance at Jackson Health: Who Can Submit to IRB

## Critical clarification:

- **Only UM faculty (must verify through UM workday)** may serve as **Principal Investigator** for IRB submissions and CT.gov RP
- Fellows, Postdocs or Graduate Assistants **cannot** be the PI of a record, they must have a mentor who is UM faculty to be the PI of record and responsible party for CT.gov

 **Why this matters:** The IRB system (IBIS) and the ClinicalTrials.gov organizational account are tied to **UM faculty credentials for verification and HR status in UM Workday.**

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# Key Ingredients for Running a Successful Clinical Trial at UM & Jackson Health

## **Strong PI Leadership & Faculty Oversight**

- UM faculty PI required for IRB and ClinicalTrials.gov
- Clear delegation and oversight

## **A Well-Developed Protocol (CT.gov-Ready)**

- Must include all CTD-required elements
- UM and Jackson Health protocols often lack CT.gov-ready structure

## **Regulatory Compliance & IRB Accuracy**

- NIH 4 Questions must be answered correctly in IBIS
- All drugs, devices, and biologics must be captured in the IRB submission
- Ensure consistency across the protocol, IBIS, and CT.gov

## **Adequate Training for All Personnel**

- Required: CITI, GCP, CT.gov training, and Jackson Health workflow orientation

## **Timely CT.gov Registration & Results Reporting**

## **Operational Feasibility**

- Staffing, space, equipment, and patient population
- Coordination with nursing, pharmacy, and ancillary services

## **Strong Study Coordination**

- Coordinators must be familiar with UM and Jackson systems

## **Secure Funding, Budgeting & Coverage Analysis**

- Correct billing at Jackson Health
- Distinguish research vs. standard-of-care procedures

## **Participant Safety & Monitoring**

- AE/SAE reporting
- Safety oversight

## **Data Quality & Timely Reporting**

- Clean source documentation
- Timely CT.gov updates

## **Communication & Collaboration**

- Regular team meetings
- Strong UM–Jackson partnership

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# PI Requirements for ClinicalTrials.gov

**To be listed as PI in ClinicalTrials.gov under the UM organizational account, an individual must:**

- Be a UM faculty verified in UM Workday
- Complete required CT.gov training and participate in 1:1 assistance or QC review with the CTD team
- Be the **IRB-approved PI**
- Ensure federal funding must be routed through ORA and awarded at UM
- Ensure all CTA's must be routed through UM ORA and fully executed
- Document who is providing or supplying the drug, device, or biologic for the study

Fellows and other research team staff may be allowed a CT.gov account and be listed on the access list in CT.gov Protocol Registration System but **only the IRB-approved PI may serve as the Responsible Party and CT.gov PI.**



# Which Trials Require Registration and or Results Reporting?



**International Committee of Medical Journal Editors (ICMJE):** ICMJE requires prospective registration of all clinical trials—defined per WHO as any research study that prospectively assigns human participants or groups to one or more health-related interventions to evaluate effects on health outcomes—in a public WHO-approved registry at or before first participant enrollment. Registries must include the WHO 24-item minimum dataset. For trials enrolling on or after January 1, 2019, the registry record must also include an Individual Participant Data (IPD) Sharing Plan prior to enrollment.



**Food and Drug Administration (FDA):** Applicable Clinical Trials (ACTs) that start on or after 9/27/2007, or that began before 9/27/2007 but were still ongoing on 12/26/2007. Involve Drug, Device, or Biologic.



**National Institutes of Health (NIH):** The NIH Clinical Trial Dissemination Policy applies to all NIH-funded clinical trials for which applications or proposals were submitted on or after January 18, 2017. NIH requires public registration and results reporting for trials where human participants are prospectively assigned to one or more interventions to evaluate health-related biomedical or behavioral outcomes. Trials must be registered (NCT assigned) within 21 days of first participant enrollment. NIH ASSIST draws from ClinicalTrials.gov to pre-populate required annual progress report information.



**Centers for Medicare & Medicaid Services (CMS):** Under National Coverage Determination (NCD 310.1), Qualifying Clinical Trials (QCTs) must meet CMS criteria.

# Potential Consequences for Noncompliance

Reporting Requirements	ICMJE Guidance	FDA FDAAA 801/FINAL RULE	NIH Policy	CMS
Scope	Registration for <b>any Clinical Trial</b>	Registration and Results Reporting for <b>Applicable Clinical Trials</b>	Registration and Results Reporting for <b>NIH-Funded Clinical Trials</b>	Registration for <b>any Clinical Trial</b>
Phase	All	Phase II - IV	All	All
Intervention Type	All	Drug, biologic, & device products regulated by the FDA	All (e.g. including behavioral interventions)	"qualifying trial" of therapeutic intent evaluating Medicare benefit & enrolling participants with diagnosed disease
Funding Source	Any	Any	NIH	Any
Individual Participant Data (IPD) Sharing Plan	Required at Registration	N/A	N/A	N/A
Initial Registration	Prior to enrollment of first participant.	Not later than 21 days after enrollment of first participant	Not later than 21 days after enrollment of first participant	N/A
Results Reporting	N/A	Within 12 months of primary completion date	Within 12 months of primary completion date	N/A
Enforcement	Refusal to publish	<ul style="list-style-type: none"> <li>Criminal proceedings and civil penalties (up to \$12,462/day/study.</li> <li>Loss of HHS Funding</li> </ul>	<ul style="list-style-type: none"> <li>Suspension or termination of grant or contract funding</li> <li>Can be considered in future funding decisions.</li> </ul>	<ul style="list-style-type: none"> <li>Delayed initiation; Billing delayed or denied</li> </ul>

# How ClinicalTrials.gov Determination Works



## When a study is submitted to the IRB:

- Investigators answer the **NIH 4 Questions** in the *Study Scope* section
- If any answer suggests the study *may* be a clinical trial:
  - **CTD Ancillary Review** is not automatically triggered, the PI or study team will need to add CTD Ancillary Review in the Managed Review tab in IBIS IRB
  - The CTD team evaluates whether the study meets CT.gov registration criteria



## CTD Team Responsibilities:

- Verify accuracy of the NIH 4 Questions
- Confirm whether the study meets **clinical trial** criteria: Is there federal funding, drug, device, or biologic and were those questions answered correctly in IBIS IRB
- If the study meets the CT.gov criteria, then CTD Ancillary Review will review the protocol to make sure all elements are incorporated into the protocol. If the protocol is missing any CT.gov elements required for registration, CTD Ancillary Reviewer will make track changes and add comments of what items are missing and what will need to be added to the protocol.
- Notify the study team of required CT.gov actions and any missing protocol elements will be submitted within the IBIS IRB comments section.

Four Clinical Trial Questions

Human Participants?	Prospectively Assigned Intervention?	Evaluate Effect of Intervention?	Health-Related Outcome?	Study Type
Yes	Yes	Yes	Yes	Clinical Trial
Yes	Yes	Yes	No	BESH
Yes	No	No	Yes	Observational
Yes	No	No	No	Observational

Study Matrix

## Glossary

**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.

**Basic Experimental Studies Involving Humans (BESH):** studies in humans that have the purpose of understanding fundamental aspects of phenomena *without* a direct application towards clinical processes or products.

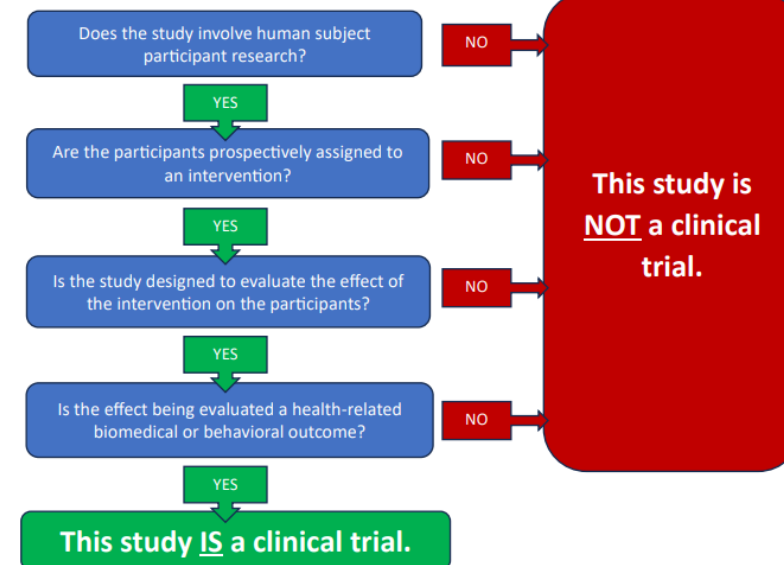
**Observational Studies Involving Humans:** studies in which data are gathered from or about human participants, but the researchers do not perform an intervention. May be performed in real time or retrospectively using existing records or specimens.

# The NIH 4 Questions (Study Scope)

These determine whether a study is considered a **clinical trial**:

- Does the study involve **human participants**?
- Are participants **prospectively assigned** to an intervention?
- Is the study designed to **evaluate the effect** of the intervention?
- Is the effect **health-related** (biomedical or behavioral)?
- **→ If YES to all four → the study is a clinical trial.**

START HERE



**NOTE:** As of the Summer 2026 review round, Basic Experimental Studies Involving Humans (BESH) will no longer be subject to the requirements under the clinical trial definition.

A clinical trial may involve one or more trial designs (e.g., pilot, interventional, behavioral). If the answers to the above 4 questions are yes, your study meets the ORD definition of a clinical trial, even if...

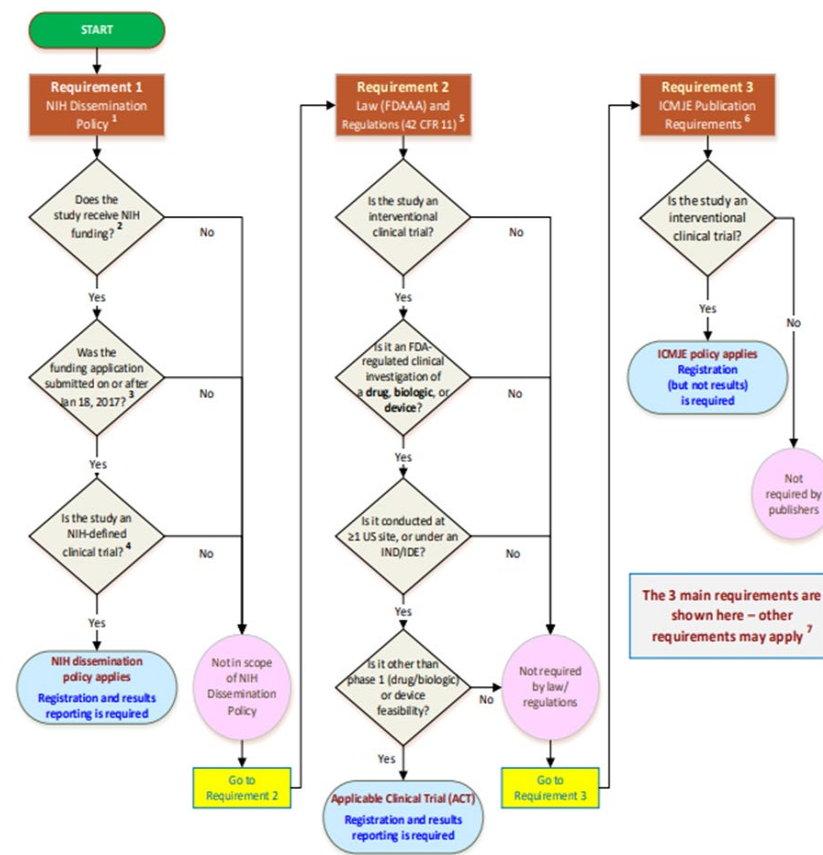
- The study involves only healthy participants.
- The study is single arm or does not have a comparison group (e.g., placebo or control).
- The study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug.
- The study is utilizing a behavioral intervention or measuring intent to change behavior.
- Only one study aim, or sub-aim, meets the clinical trial definition.

# Additional CT.gov Criteria Checked by CTD Team

Beyond the NIH 4 Questions, CTD also checks whether:

- The study is **interventional**
- Participants are **assigned to receive an intervention**
- The intervention is intended to produce a **biomedical or health-related behavioral effect**
- The study has **federal funding**
- The study involves a **drug, device, or biologic**

→ If any apply, CT.gov registration and results reporting may be required.



# Required Protocol Elements for Clinical Trials

Section	Checklist Items
Study Identification	<input type="checkbox"/> English title provided for Spanish titles <input type="checkbox"/> Condition clearly defined and applicable <input type="checkbox"/> MeSH term provided( <a href="https://meshb.nlm.nih.gov/search">https://meshb.nlm.nih.gov/search</a> )
Study Design	<input type="checkbox"/> Primary purpose defined (Treatment, Prevention, Diagnostic, Supportive Care, Screening, Health Services Research, Basic Science, Device Feasibility) <input type="checkbox"/> Drug/Biologic study phase defined (Phase 1, 1/2, 2, 2/3, 3, 4) <input type="checkbox"/> Device feasibility identified (if applicable) <input type="checkbox"/> Interventional Study Model defined (Single Group, Parallel, Cross-Over, Factorial, Sequential) <input type="checkbox"/> Number of study arms clearly defined <input type="checkbox"/> Masking/blinding defined; blinded roles identified (Participant, Investigator, Care Provider, Outcomes Assessor) <input type="checkbox"/> Allocation defined (Randomized / Non-randomized) <input type="checkbox"/> Accrual target & sample size justification provided (power analysis)
Arms & Interventions	<input type="checkbox"/> Arms clearly defined and consistent across protocol <input type="checkbox"/> Interventions identified for each arm <input type="checkbox"/> Intervention description complete (form, sequence, dosage, frequency, duration)
Outcome Measures	<input type="checkbox"/> Primary and secondary endpoints clearly defined and quantifiable <input type="checkbox"/> Metric for each endpoint clearly defined <input type="checkbox"/> Time frame specified <input type="checkbox"/> Exploratory outcomes distinguished from primary/secondary <input type="checkbox"/> For questionnaires/scales: minimum/maximum ranges and interpretation provided
Eligibility	<input type="checkbox"/> Age and sex criteria included <input type="checkbox"/> Comorbidities and concomitant medications defined <input type="checkbox"/> Condition under study included
Adverse Events	<input type="checkbox"/> AE/SAE definitions, classification, time frame, and reporting process provided <input type="checkbox"/> AE/SAE collection approach defined (Systematic vs. Non-Systematic)

# Overview of Phases and Record Stages

Phase	Record Stage
Registration	New PI/study team member needs ClinicalTrials.gov user account.
	Study is approved by IRB.
	Study needs to be registered
	Study record ready for review and approval.
	ClinicalTrials.gov reviewers identify major issues that need to be addressed before study record can be posted.
Maintenance	Record is posted
	Study has changed (started, completed, amended)
	Study is completed.
Results Reporting	Results need to be reported.
	Results entered and study record marked as entry completed.
	Results are unavailable
	ClinicalTrials.gov reviewers identify major issues in results reporting that need to be addressed.

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# Best Practices & Required Training

## Training Requirements

- CITI Human Subjects Research
- GCP (Good Clinical Practice)
- ClinicalTrials.gov training modules
- Protocol writing workshops (UM Research Education)

## Best Practices

- Use **UM protocol templates (working on incorporating CTD elements)**
- Engage mentors early
- Consult CTD team before IRB submission if unsure
- Ensure key elements: Study Design, Arms & Interventions, Outcome measures match **CT.gov formatting**
- Keep documentation consistent across IRB, protocol, and CT.gov

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# Summary

- Only **UM faculty** may serve as PI for IRB and as Responsible Party in ClinicalTrials.gov
- NIH 4 Questions drive CTD review
- CTD team confirms whether CT.gov registration is required
- Clinical trial protocols must include **CT.gov-aligned elements**
- Multiple resources and training are available to support investigators

# Upcoming IRB Grand Round

*April 16, 2026 (10-11 AM)*

## **Balancing Act: Research Integrity and Innovation**

1. Identify Recent Policy Updates
2. Practice Responsible Research Conduct
3. Explore Best Practices for Maintaining Compliance

**Speakers: RI, OTT, CTSI**

***Registration:***



**Please use your Miami email address  
when submitting your request.**



## Continuing Medical Education (CME)

Below please find the claim credit link for session scheduled for 3.19.2026: <https://miami.cloud-cme.com/cme/ClaimCredit?P=850&eventid=18749>



## 2026 IRB Grand Rounds - Continuing Nursing Education (CNE) Credit Registration Form



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!

For additional information about today's presentation,

Please contact [curatingconnection@miami.edu](mailto:curatingconnection@miami.edu) and reference

“IRB Grand Round 2026”.