

UNIVERSITY
OF MIAMI



HSRO Monthly Office Hours

Initial Protocol Submissions

Presented by: HSRO Staff

Topics to Cover



Key Elements of an Initial IBIS Submission



Common areas where clarification is often requested



Tips to strengthen your application before submission



Real-world examples and practical takeaways

Key Elements of an Initial IBIS Submission - How IRB Staff Reviews a submission

1. PI Eligibility
2. COI Disclosures
3. Ancillary Reviews
4. Basic Study Information
5. Study Funding
6. Study Team Members
7. Study Scope
8. Local Research Locations
9. Local Site Documents

PI Eligibility

PI Eligible	Case-by-Case Decisions	Not PI Eligible
<ul style="list-style-type: none"> • Tenure-track faculty (full, associate, and assistant professors); and • Non-tenure-track research and clinical faculty (lecturers, full, associate, and assistant professors); • Senior research investigators (Faculty with emeritus status or who are tenured and retired but wish to continue as PI) • The University of Miami BSN or above-prepared Nurses (see specific requirements above) • Jackson employees who are conducting research at Jackson. 	<ul style="list-style-type: none"> • Adjunct faculty • Visiting faculty • Visiting scholars. <p><i>Contact a manager for the Vice Provost for Research + Scholarship or the Associate Vice Provost, Regulatory Affairs and Assessment via email to request permission for such non-PI eligible UM affiliates to conduct research. Please include a letter of support from your Department Chair/Division Chief and, if applicable, IRB Chair decisions/ opinions. Upon approval, upload the confirmation email into the "Other Attachments" section in your electronic submission.</i></p>	<ul style="list-style-type: none"> • Postdoctoral fellows and research assistants (graduate students); • Research associates; and • Graduate and Undergraduate students

Jackson Health System (JHS) employees who obtain approval from the JHS Clinical Research Review Committee (CRR) may also serve as Principal Investigators on studies

COI Disclosures

Clarification

- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy
- Assign IRB
- Manage Ancillary Reviews
- Clinical Trials
- Manage Guest List
- Create Ad Hoc Certifications
- Add Comment
- Add Private Comment
- Copy Submission
- Withdraw
- Discard
- Manage Tags

(IRB - STUDY - In-review)

History Funding Contacts COI Documents IRB Assignment Details Reviews ...

Open Certifications

Filter by ? Discloser First N Q + Add Filter ✕ Clear All ⚙

Discloser First Name	Discloser Last Name	Date Created	Status	Last Profile Update Date
[REDACTED]		3/9/2026 4:20 PM	Awaiting Profile Update	
		3/9/2026 4:20 PM	Under Review	7/15/2025
		3/9/2026 4:20 PM	Under Review	10/13/2025
		3/9/2026 4:20 PM	Awaiting Profile Update	2/1/2024

4 items ◀ page 1 of 1 ▶ 10 / page

Most Recent Certifications

Filter by ? Discloser First N Q + Add Filter ✕ Clear All ⚙

Discloser First Name	Discloser Last Name	Date Created	Status	Last Profile Update Date	Determination Date	Management Plan	Plan Status
[REDACTED]		3/9/2026 4:20 PM	No Review Required	1/28/2026	3/9/2026	No Review Required	
		3/9/2026 4:20 PM	No Review Required	7/28/2025	3/9/2026	No Review Required	
		3/9/2026 4:20 PM	No Review Required	9/27/2025	3/9/2026	No Review Required	



Ancillary Reviews

 Manage Ancillary Reviews

 Clinical Trials

 Manage Guest List

 Create Ad Hoc Certifications

 Add Comment

 Add Private Comment

 Copy Submission

 Discard

 Manage Tags

(IRB - STUDY - In-review)

- History
- Funding
- Contacts
- COI
- Documents
- IRB Assignment Details
- Reviews

There is no Pre-Review to display at this time.

There is no Non-Committee Review to display at this time.

There is no Committee Review to display at this time.

Ancillary Reviews

Review Type	Organization	IRB Reviewer	Person Req Accepted	Instruction Comments	Instruction Documents	Review Comments
Department	UMMG - General Clinical Psychiatry	Evelin Marquina Sari Izenwasser Carola Martinez Audrey Alves Deborah Jones	yes			

Add or update ancillary reviewers. These can be organizations or people.

There are no Committee Member Review Comments to show at this time.



Adding Ancillary Reviewers

The screenshot shows a web browser window with the URL `ibis-research.miami.edu/IRB/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity%5BID%5B673F7821AD58CD4891ABE...`. The main content area is titled "Manage Ancillary Reviews" and contains a table with columns for "Review Type" and "Org". A "+ Add" button is visible above the table. A sidebar on the left lists various actions: "Manage Ancillary Reviews", "Clinical Trials", "Manage Guest List", "Create Ad Hoc Certification", "Add Comment", "Add Private Comment", "Copy Submission", "Discard", and "Manage Tags".

The "Add Ancillary Review" dialog box is open, showing the following steps:

- 1. * Select either an organization or a person as reviewer:**
 - Organization:** A text input field containing "data security".
 - Person:** A dropdown menu showing a list of organizations. The selected item is "IRBAC009 Data Security Ancillary Committee (DSAC)".
- 2. Review type:** A dropdown menu.
- 3. * Is a response required?** Radio buttons for "Yes" and "No", with a "Clear" link.
- 4. Comments:** A large text area for entering comments.

At the bottom of the dialog, there are three buttons: "OK", "OK and Add Another", and "Cancel". A "* Required" label is present at the bottom left of the dialog.

IRB Submission Readiness

Please verify the following prior to submission:



PI eligibility



Sponsored study: ORA
submission (FP/feasibility
review)



Cancer-related studies:
PRMC approval
All Additional Ancillaries



Required documents
completed (e.g., protocol,
consent form, etc.)

Basic Study Information

1. * Title of study:

[Redacted]

2. * Short title:

[Redacted]

3. * Study purpose/objective (2-3 sentences):

The study purpose/objective should be at the same 6-8 grade reading level as the Informed Consent Form. This field will be exported and used by other UM systems/tools, which potential research participants will access to learn about the different research studies at the University of Miami.

[Redacted]

Basic Study Information



Question #1 Title



Question #2 Short Title



Question #3 Study Purpose/Objective *Only 2-3 sentences



Question #4 Single Site or Multi-Site *Depending on how you answer this additional questions may appear



Question #5/6 External IRB/UM IRB of Record



Question #6/7 Local Principal Investigator

Basic Study Information

MOST IMPORTANT!

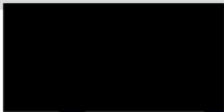
- Question #7 (#8) Attach the Protocol

- Investigator Initiated: Upload a WORD document of the Protocol
- Sponsored: Upload the Sponsor's Protocol AND a Local Site Addendum
- Protocol templates must be used from the HSRO Website

<https://hsro.uresearch.miami.edu/submit-to-the-irb/forms-and-templates/templates/index.html>

- HSRO staff will send back IF there are duplicates, incomplete protocols
- During the review process, when submitting changes back, update the old versions and upload the most recent version as requested by the HSRO

7. * **Attach the protocol:**

	Document	Category	Date Modified	Document History
View	 IRB_Protocol 3-3.docx(0.01)	IRB Protocol	3/3/2026	History

Study Funding Sources

- Unfunded: Cost center, check with your Department
- Funded: List the Funding Source, ID, Upload any Grant Applications or Funding Award

Study Funding Sources

1. * Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
UNIVERSITY OF MIAMI			

If this study is not receiving any external source of funding, it is then “internally” or “intramurally” funded by the University of Miami. Please select the cost center (CC) of the PI's department.

Local Study Team Members

- List all UM staff who will be “engaged” in the study. Engaged means that they are accessing identifiable information or interacting with individuals. Analyzing de-identified information or consulting on the study is not “engaged.”
- It is the PI’s responsibility to ensure that all study team members are CITI Certified and keep a record of expiration dates. The HSRO does not verify this and IBIS can be incorrect.
- If a member does not appear in IBIS, they do not have an IBIS account. They must contact OVPRShelpdesk@miami.edu to troubleshoot any issues.
- Any individual added in this section will be required to also complete the COI Disclosure through udisclose@miami.edu.

Study Scope

This section triggers Ancillary Reviews and other parts of the application to open. If questions aren't answered correctly, it can impact the entire submission.

- Questions 1 & 2: Drugs and Devices
- Question 3: Research Category
- Question 4: Type of Study: records, survey, interview, interventional
 - Interventional triggers Clinical Trial Disclosure Committee review
 - If you are randomizing subjects – “interventional” must be selected

Study Scope

- Question 5: Billing
- Question 6: Data Security Ancillary Committee (DSAC)
 - Collection/Storage of identifiable data anywhere other than UM Box
 - AI/ML Studies
- Question 7: Cancer Related (PRMC)
- Question 8: Specimen Collection (Pathology)
- Question 9: Human Source Materials (EHS)
- Question 10: Radiation (HRSC)
- Question 11: rDNA, gene transfer (IBC)
- Question 12: Embryonic stem cells (ESCRO)
- Question 13: Conflict of Interest Committee (COIC)

Local Research Locations

- Add all locations where the study will be conducted
 - These locations also need to be added via Manage Ancillary Reviews for site approvals:
 - **Jackson Health System**
 - **Clinical Translational Research Site**
 - **UHealth Tower**
 - **Schiff Center for Liver Diseases**
 - **JFK Hospital**
 - **SONHS Simulation Hospital**

Local Site Documents

Local Site Documents

- 1. Consent forms:** (include an HHS-approved sample consent document, if applicable)

Document	Category	Date Modified	Document History
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There are no items to display

- 2. Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History
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There are no items to display

- 3. Other attachments:**

Document	Category	Date Modified	Document History
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There are no items to display

Local Site Documents

- **Consent Forms:** One version of each form that needs review, make sure to add assent forms, proxy forms, pregnant partner forms
- **Recruitment Materials:** Any documents, scripts for recruitment (pre-consent)
- **Other Attachments:** Questionnaires, measures, interview guides, data collection sheets, education materials

Common Areas Where Clarification is Requested

- Protocol Document:
 - Specific inclusion criteria (age range)
 - Step-by-step procedures, instead of just a list of procedures
 - All risks aren't listed, inconsistent with consent form
 - Vulnerable populations, missing children or cognitively impaired
 - Recruitment Methods, who is approaching & where – NO COLD CALLING/APPROACHING ALLOWED
 - Confidentiality & HIPAA, accessing PHI

Common Areas Where Clarification is Requested

- Consent/HIPAA Forms: Most important - use the most recent versions of the UM templates on the website! This eliminates a lot of issues right away.
- Recruitment Materials: Do not include the word FREE or emphasize payment amount, ensure that all site-specific details are included, PI's name, contact info, Especially recruitment posters, Letters from the PI to other doctors and appt reminder cards
- Other Attachments: Upload ALL subject facing materials

Tips to strengthen your application before submission

- Click on Printer Version and review the IBIS submission completely to ensure that all documents are uploaded, all questions are answered correctly and everything makes sense
- Open all of your uploaded documents to make sure they are the correct versions and complete
- Check all Green tabs to see what items are still pending (COI, Ancillary)
- Once the PI or PI Proxy clicks Submit, make sure the study is now in **Pre-Review (not Pre-Submission)**
- Check consistency among all your documents – if your protocol states that there are 2 study visits, then your consent form should not list only 1 study visit.
- All headers should be clean (remove all old protocol watermarks)
- Make sure the PI is faculty or approved to be the PI
- Complete all required training as outlined in the Investigator Manual.
- The study team should determine whether the single IRB policy applies based on the funding source.

Practical takeaways

- Your submission will first undergo Screening and then a Regulatory Review.
- You will receive communication from our office in IBIS. It is important to read the communication thoroughly and follow all of the instructions given to you. We will upload tracked documents and tell you which sections require revision.
- When sending documents back in the system, make sure to click “Update” next to the document and upload the revised version. Don’t delete and don’t add another version.
- Email /Teams us after you review our communication and still don’t understand. Do not just click Submit and send back.
- Only the PI/PI Proxy can click Submit. This must be done after all the changes are made.
- After 7 days, the protocol will be Withdrawn in the system and set back to Pre-Submission. This gives you additional time to make changes.

Real-World Examples – Example Communication

Pending COI Disclosures

-NAME

Pending Ancillary Review

-Department

-DSAC

Basic Study Information Q#7

The protocol must separate out what is research vs. what is part of standard education. If this is research, students must have the option to participate or not and must be fully informed by the consent process. Please clarify and modify your protocol accordingly.

Local Site Documents Q#1

Upload a consent form for this study - verbal consent could be obtained, see template.

Local Site Documents Q#2

Upload any recruitment materials

Local Site Documents Q#3

Upload your interview guide

Real-World Example

- Sponsored Study:
 - Clarifications were requested from the IRB to list the risks in the consent form in bulleted lists because they were listed in dense, giant paragraphs.
 - The sponsor approved the creation of the list and wrote something like "Lists approved as long as the risks listed remain. Site please complete this"
 - The study team sent it back to the HSRO to complete. This should be completed by the study team and then submitted for the IRB to review and approve.

HSRO Helpful Links & Resources

- Does My Project Need IRB Review?

<https://hsro.uresearch.miami.edu/submit-to-the-irb/does-my-project-need-review-by-the-irb/index.html>

- How to Submit to the IRB

<https://hsro.uresearch.miami.edu/submit-to-the-irb/how-to-submit-to-the-irb/index.html>

- Forms and Templates

<https://hsro.uresearch.miami.edu/submit-to-the-irb/forms-and-templates/index.html>

- Investigator's Manual & SOPs

<https://hsro.uresearch.miami.edu/resources-and-guidance/policies-procedures-and-regulations/index.html>

- Ancillary Reviews

<https://hsro.uresearch.miami.edu/submit-to-the-irb/how-to-submit-to-the-irb/ancillary-committees/index.html>