# The IRB Roadmap

A step by step guide to navigating Research Approval

# Human Subject Research Office (HSRO)

The HSRO consists of four different teams

- Screening Team
- Expedited Team
- Full Board Team
- Reliance/CIRB Team

# Ancillary Committees

- In some cases, research will involve certain activities that require specialized review. For example, when a study involves radiation, the research must undergo review by the Human Use Radiation Safety Committee (HRSC).
- If your research meets the requirements for one of the ancillary reviews, you must submit the research to that Committee according to the Committee's requirements.

# Ancillary Committees

- The following ancillary reviews **MUST** be completed before the approval letter can be sent:

Human Use Radiation Safety (HRSC)

Cancer Protocol Review & Monitoring Committee (PRMC)

Data Security & Artificial Intelligence Ancillary Committee (DSAC)

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

Clinical Trial Disclosure Committee (CTD)

Institutional Biosafety Committee (IBC)

Embryonic Stem Cell Oversight Committee (ESCRO)

Conflict of Interest Committee (COI)

Environmental Health & Safety Committee (EHS)

# Ancillary Committees

- In addition to IRB approval, the following ancillary reviews are required before any research activities can begin:

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|---|---|---|
| Clinical Translational Research Site (CTRS) | Jackson Health System – Clinical Research Review Committee (CRRC) | Clinical Research Laboratory Services (formerly known as SCCC Research Lab & Satellites- SCCC) |
| UHealth Tower (UHT) | Pathology Review Committee (RPSC) | Cellular Therapy Lab |

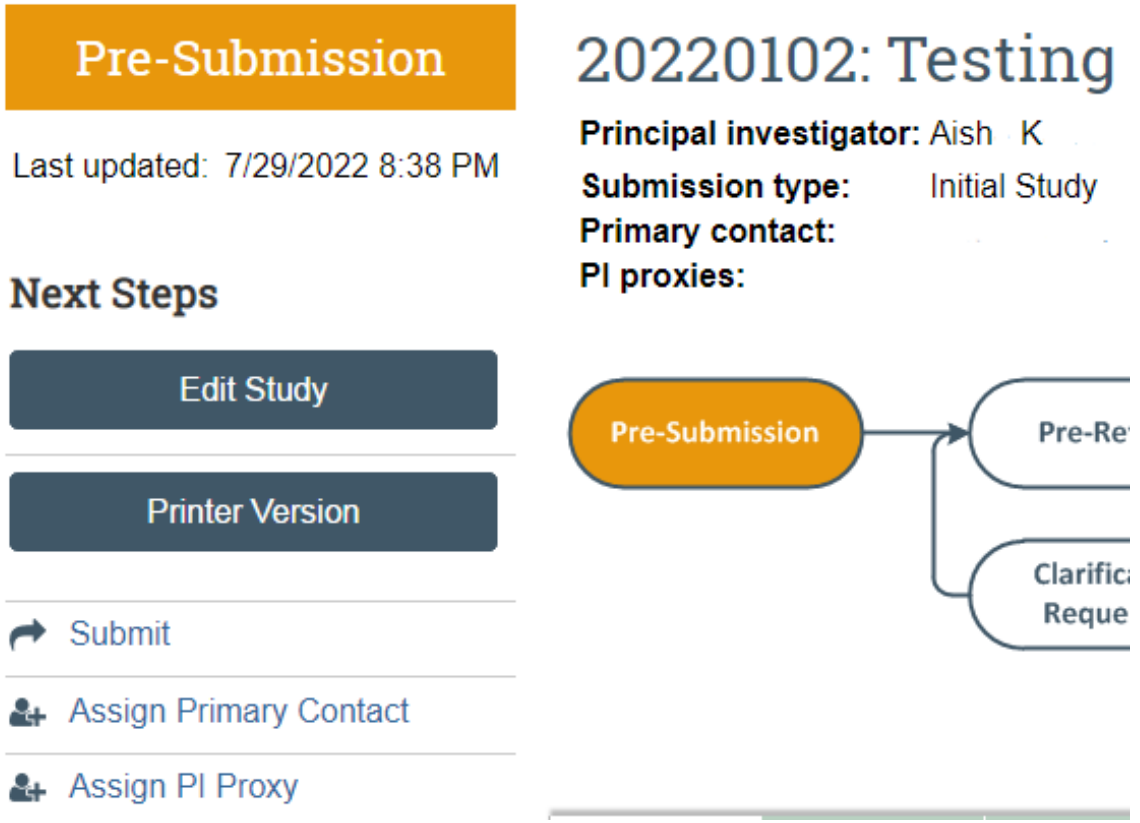
# IBIS Submission Workflow


**A really good walk through guide of this can be found on our website:

https://hsro.uresearch.miami.edu/resources-and-guidance/irb-system-upgrade/training-resources/index.html

# Pre-Submission

- When a submission is in this state, the PI/Study Team is able to make edits, upload documents, and prepare the submission for review
- In order to move the submission to the next step (Pre-Review), the PI or PI Proxy must submit (this can be found on the left hand side of the workspace)



# Pre-Review

- Once the submission has been submitted by the PI/PI Proxy, the submission moves to the Pre-Review state
- Our Screening Team reviews the submission and determines if it moves on to the Expedited Team or Full Board Team
- Then once assigned to an IRB coordinator on either Team, a thorough review is conducted to ensure accuracy and completeness

# Clarification Requested (Pre-Review)

- If during the IRB coordinator's review, clarifications/revisions are required, the submission will move to this state
- The submission is then on the study team/PI side for the requested changes to be made
- To move the submission along in the review process, the PI/PI Proxy must submit it back to the coordinator

# IRB Review (Committee Review/Non-Committee Review)

- After the submission is ready and all clarifications and revisions have been addressed, if the submission is with the Full Board Team, the IRB coordinator will assign it to Committee Review (a meeting)
- If the submission is with the Expedited Team, the IRB coordinator will assign it to Non-Committee Review/Designated Reviewer

# Clarifications Requested (Committee Review)


- When a submission is assigned to board and an IRB Reviewer is conducting their review for the meeting, they may request information and send the submission into this state
- It is important to address their clarifications in a timely manner so that it does not affect the review of the submission at the meeting
- Unfortunately, due to system limitations, the submission is not editable, but the study team/PI can provide the IRB reviewer with information and upload documents via a comment
- In order to move this submission along, the PI/PI Proxy must submit it back once the clarifications have been addressed

# Clarifications Requested (Designated Review)


- When a submission is assigned to Designated Review by the IRB coordinator on the Expedited Team, they may request additional information and send the submission into this state
- It is important to address their clarifications in a timely manner so that it does not affect the review of the submission
- Unlike the Committee Review where revisions cannot be made, the submission is editable in this state. The Study Team/PI is able to make edits, upload documents, and revise the submission accordingly
- In order to move this submission along, the PI/PI Proxy must submit it back once the clarifications have been addressed

# Post - Review

- For Full Board submissions, the submission will move into this state when the post meeting functions have been conducted, and the letter is ready to be sent
- For Expedited submissions, the submission will move into this state when the Designated Review has been completed, and the letter is ready to be sent
- When a submission is in this state, the IRB coordinators will send the letters ASAP

# Modifications Required

- When a submission goes to a meeting for IRB review, the IRB may request additional revisions. If they happen to have additional revisions, the submission will go into this state after the letter is sent.
- It is important to review the letter and ensure all of the requests/requirements have been addressed before submitting back to the IRB coordinator – this will prevent multiple back and forth and faster approval
- Also, just because a submission goes to board, it does not mean that approval will automatically be granted

# Review Complete

- When all clarifications have been addressed and the submission is ready for approval, the IRB coordinator will send the approval letter and the process of the submission is complete

# Tips to streamline approval

- *Save the last changes* of the revised documents before you add any new changes. This allows only new changes appear as “tracked.”
- It is unnecessary to provide a clean version of the revised documents AND a word track changes version.
- For pdf protocols, please save the clean final version under the Protocol section using the update button to replace the old version and add a tracked changes version to the Other attachments section.
- For updated Drug/Device documents, please upload the clean final version to the Drug/Device section and add a tracked changes version and summary of changes document to the Other attachments section.
- All team members must complete their Conflict of Interest disclosure in the UDisclose system, follow up with individuals who have not completed their disclosure to complete during the HSRO/IRB review process
- Reach out to the pending ancillary committees to obtain approval in parallel with HSRO/IRB review
- Ensure that the study documents are uploaded into the appropriate categories

# Tips to streamline approval

- When using our template language, view the document in the “Simple Markup” and ensure the highlight and red texts are formatted to black text
- When the IRB coordinator has a comment in the study document, please do not respond with a comment, we are asking for the change to be made within the document
- If a sponsor has their own consent, it is best to use their version and just incorporate the applicable information from our template
- It is NOT necessary to use our template consent when a sponsor has their own, it creates too much extra work for all parties involved in the review
- When a submission is in “Modifications Required” or “Deferred”, please ensure you address all required points outlined in the letter
    - Just because we post a revised a consent document as a comment, does not mean that the revised cosent is the only requirement.

# HSRO Website

- https://hsro.uresearch.miami.edu/
- Our website has a lot of useful information as well as access to various templates

# Questions?