Institutional Review Board, Office of Research and Graduate Studies

Huron IRB – Proposal Frequently Asked Questions

Below find answers to frequently asked questions about the Huron IRB system and related business processes.

Table of Contents:

Institutional Review Board
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IRB00001138, IRB00012110
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12201 Research Parkway
Orlando, FL 32826-3246

How do I know if my study has an approval end date or not?

I am done with my research. Is there anything else I need to do?

How do I close a study? I do not see a Study Closure option.

Huron IRB Office of Research Ancillary Review Contacts

Where do I access the Huron IRB site?

All solutions in the Huron Research Suite can be accessed from: https://apps.research.ucf.edu/. You can also access Huron from the IRB homepage by selecting the Huron icon on https://www.research.ucf.edu/Compliance/irb.html.

How does a new employee get access to the system?

UCF Employees will be able to access the system once their NID has been created. All users can create studies and be listed on studies.

If additional access is needed for an employee or you are not in the system, create a GRIT help desk ticket (GRITservicedesk@ucf.edu) with your name, employee ID, and title. The ticket will be routed to the GRIT BA team to have the appropriate user roles/offices assigned.

What if I have an external team member that is not listed in the Huron system?

Only UCF faculty, staff, and students have access to the Huron system. If you need to add an external team member, please follow the "Help" box guidance in the smart form in the Huron system for attaching the **HRP-253 External Members** and additional documents as needed. The help box can be found by clicking on the question mark at the end of "External team member information."
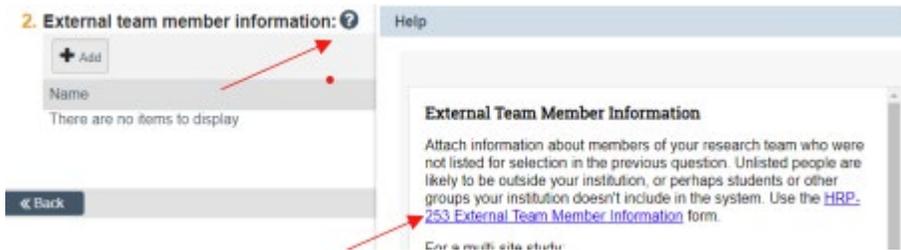
Where can I find Huron IRB training resources?

Within the Huron IRB system, the "**Help Center**" contains quick reference guides and videos. You can access the Help Center by clicking the IRB tab in the top navigation then clicking the Help Center tab.

How do I know which templates to use?

The below table references the types of submissions and reviews and which documents are required. All documents can be accessed from the Huron IRB Library under **IRB**> **Library**> **Templates**.

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📝 *Note: The IRB may request different documents depending on the research being conducted.*

CATEGORY (links contain guidance on determining research category)	PROTOCOL (links contain the templates)	CONSENT DOCUMENT (links contain templates)
Not Human Subjects Research	HRP-250	N/A
Exempt	HRP-255	HRP-254, HRP-509 (if applicable)
Exempt #4 - Secondary Research Only	HRP-255SR	N/A
Expedited	HRP-503	HRP-502, HRP-502b (if applicable), HRP-509 (if applicable)
Full Board Review	HRP-503	HRP-502, HRP-502b (if applicable), HRP-509 (if applicable)

Where can I find IRB templates?

Within the Huron IRB system, the "**Library**" tab contains the templates. You can access the Library by clicking the IRB tab in the top navigation then clicking the Library tab and finally the Templates tab. Additional guidance documents can be found in the **"Library"** as well.

📝 *Note: Templates are updated frequently in the Huron IRB system and the most up-to-date templates must be used.*

How do I know if my study is an external IRB?

If the study was reviewed and approved by an outside IRB, you first should ensure the UCF IRB has an agreement with the external institution by contacting the UCF IRB. After this is confirmed, you would check "Yes" to the question "Will an External IRB act as the IRB of record?"

If you are working with collaborators outside of UCF or if your study involves the use of study populations or facilities outside of UCF, it is important to determine when UCF will serve as the IRB of record or when UCF will cede review to an external IRB.

It is common for different IRBs to handle the external IRB process in different ways. Because of this difference, it important for UCF researchers to ask the external IRB about the external requirements when proposing to conduct or collaborate in non-exempt studies (i.e. studies that require expedited or convened board review) involving study populations or facilities outside of UCF. In some cases, it is appropriate for the external IRB to review the study and for UCF to cede review of the study. In some cases, the external IRB will not need to review the study and refer you back to the UCF IRB.

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Orlando, FL 32826-3246

When IRBs cede review to another IRB, an agreement between the two IRBs needs to be in place before the study can begin. Some of these agreements are specific to individual studies—these are called Institutional Authorization Agreements (IAA) and need to be negotiated and put in place by the IRBs before the study begins. However, some agreements that cover multiple studies are already in place. Currently, UCF has pre-existing agreements with Nemours, Orlando Health and Advent Health.

In the event that UCF does cede review to another IRB, it is still necessary for UCF to have a complete study record in Huron IRB.

For studies falling under Advent Health, Nemours, and Orlando Health IRB jurisdiction:
1. Check with the External IRB first and go through their review process.
2. When you have your outcome letter from the external IRB, create an External IRB application in Huron IRB and upload ALL study documents reviewed by the external IRB along with the approval letter.
3. The UCF IRB will issue an additional outcome letter through Huron IRB and at that point you can start your study.
4. Note that the agreements with the three hospital IRB's include ceding review of both exempt and non-exempt studies.

For non-exempt studies falling under any other external IRB jurisdiction:
1. Check with the External IRB first. If they agree to review the study, contact irb@ucf.edu with the following:
    • Name and contact information for the External IRB.
    • External IRB Study Number, Study Title, and External PI (or note that you are serving as the PI at the external site)
    • A description of the study activities you will perform.
2. The UCF IRB will initiate the IAA or let you know that dual review* is required.
3. Once the agreement is in place and you have the outcome letter, create an External IRB application in Huron IRB and upload ALL study documents reviewed by the external IRB along with the approval letter. Note that the external IRB may not be listed in Huron IRB if there have not been previous IAAs in place with that external IRB.
4. The UCF IRB will issue an additional outcome letter through Huron IRB and at that point you can start your study.

When I create an application in Huron IRB for a study approved by an external IRB, what documents should I include?
While the IRB of Record (the external IRB) is responsible for the full review of the study, the ceding IRB (in this case UCF) is still responsible for an administrative review of the study for local context issues and maintaining study documents. Because of this, you should upload all the study documents that were reviewed by the external IRB along with the external IRB approval letter in your application to the ceding IRB.

When I create an application in Huron IRB for a study approved by an external IRB, what study team personnel do I need to list?

Only include individuals from UCF who are doing work on the study as part of their UCF affiliation. You would not need to add external personnel or vendors that are already approved through the external IRB.

> *Dual review means that both IRBs will need to review the study. This is the case with most studies that qualify for a not research/not human subjects research or exempt determination or when the two IRBs are unable to execute an IAA. A current example is when UCF researchers are conducting studies with VA populations or facilities, the VA is unable to serve as the IRB of record. In this case, both the VA and UCF IRBs must review the study.

My study is funded but when I search for my funding source, it does not show up. What should I do?

First try searching by adding "%" in front of and after the first few letters of the funding source. For example, if searching for NSF, type "%National%." If you are still unable to find the funding source, you will need to email Graduate and Research Information Technology (GRIT) help desk at GRITServiceDesk@ucf.edu so that the funding source can be added to the Huron IRB system.

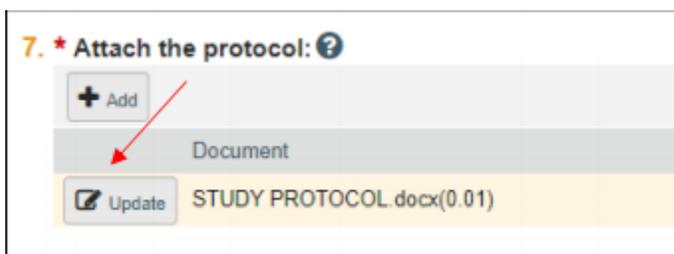## Who can edit a study in the Huron IRB system?

The Principal Investigator (PI), Co-Investigators (Co-PI's), and the Primary Contact. If it is a Modification, only the PI and Primary Contact can make changes to the study and study documents in the system.

Note: Only the PI is able to submit modifications or changes to any submission.

The IRB asked for changes to my documents, should I add or update these in Huron IRB?

When making changes to an existing document, always use the update function that is located next to the previously uploaded document. You will need to select "Edit" to open the smart form and to the left of the document you plan to change, use the "Update" button. The "Add" button is only for new documents that are not yet uploaded in the system.

Who can submit a Huron IRB study?

Any researcher can create a study, however only the PI can submit or resubmit a study in the Huron IRB system. Only the PI has access to the final "submit" button in Huron IRB.

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IRB00001138, IRB00012110
Office of Research & Graduate Studies
12201 Research Parkway
Orlando, FL 32826-3246

Who can be a Principal Investigator (PI)?

A faculty member, graduate student, or FIRE student can be a PI on a study. An undergraduate student cannot be a PI of a study. The undergraduate must be listed as the Co-PI, and their Faculty Advisor must be listed as the PI.

**Who should I list as my Faculty Advisor?**

Your Faculty Advisor is the person overseeing your research. Your thesis chair, dissertation chair, or faculty mentor are all examples of appropriate Faculty Advisors. The Faculty Advisor has the responsibility of guiding the PI through your Human Subjects Research. They will also need to complete the **HRP-251 Faculty Advisor Review** form for your research study and have it uploaded into the Huron IRB application.

Can anyone submit on behalf of the PI?

No, only the PI can submit and resubmit a study.

I need to add my department chair/director/dean to review my study. Where do I do this?

You can add your department chair by selecting the "**Manage Ancillary Reviews**" on the workspace screen and type in the department chair/director/dean's name and select "Department" under "Review Type."
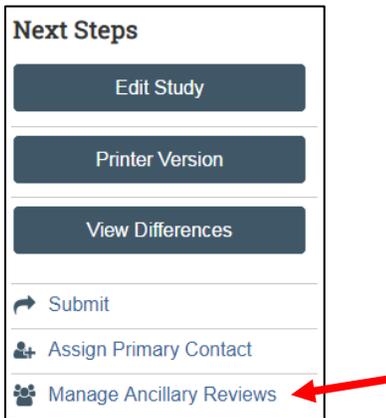

How do I know if the IRB has received my study or clarification responses?

The study is submitted and on the IRB's side when it is in **Pre-review, IRB Review, or Post Review** in the workflow. It is on your side when it is in **Pre-Submission, Clarifications Requested, or Modifications Required**. See the below workflow:

Institutional Review Board
FWA00000351
IRB00001138, IRB00012110
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📝 *Note: Be sure to hit **Submit** or **Submit Response** when the study is in Pre-Submission, Clarifications Requested, or Modifications Required to move the study back to the IRB's side.*
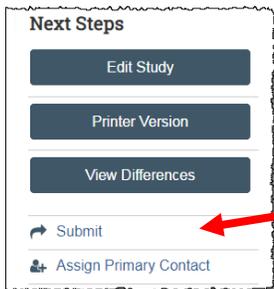
How long does it take for my study to be approved?

The usual turnaround time for studies is 2-6 weeks from **Pre-Review** state to **Review Complete** State. It is dependent on the current queue as well as the amount of time it takes the you to make the requested revisions and resubmit.

Where is my study?

See "How do I know if the IRB has received my study or clarification responses?"

When a study gets sent back with Clarification Requested, Modifications Required, or Review Complete, who will be notified and how will I be notified?

The PI and Primary Contact will receive an email notification when changes are needed or when the approval is granted. The "**My Inbox**" tab on the dashboard will also contain all studies where action is needed from the study team.

Is there any training needed prior to approval?

CITI Training, Group 1 or 2 is required prior to approval of a study. There are also additional modules required for NIH funded clinical trials and FDA clinical trials. See additional information about CITI in the Huron IRB Library under **IRB**> **Library**> **General**> **Guidance - IRB G4 - CITI Training**.

📝 *Note: The IRB will review a study if key personnel do not have completed CITI training. However, approval will not be granted until training has been completed.*

How long can my study stay in Pre-Submission or Clarification Requested/Modification Requested states before it is Withdrawn and/or Discarded?

Studies in the Clarification Requested state have 30 days to be returned to the IRB before they are Withdrawn. Studies in the Pre-Submission state have 90 days to be submitted before they are Discarded.

If my study is Discarded, am I still able to access it?

Yes, you are able to make a copy of a study by selecting "**Copy Submission**" on the bottom left side of the study workspace.

Institutional Review Board
FWA00000351
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Once my study is approved, where can I find a copy of the approval letter?

You can find a copy of the letter by opening your study and at the top right corner there will be a PDF document next to "Letter."

Where can I find my finalized documents?

You can locate your finalized forms under the "Final" column of the "**Documents**" tab of the study workspace.

🗒 *Note: Only the consent form and debriefing forms will have approval stamps at the bottom of the finalized document.*

How do I know if my study has an approval end date or not?

If a study has an approval end date, it will be listed in the approval letter as well as on the study workspace at the top left corner and will be listed as "Approval End."

I am done with my research. Is there anything else I need to do?

If the four research milestones below apply to your study, please submit a study closure. If not, please keep the study open until all four milestones below are met.

- Study is permanently closed to enrollment **OR** was never open for enrollment
- All subjects have completed all study-related interventions **OR** not applicable (e.g. study did not include interventions, no subjects were enrolled)

Institutional Review Board
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- Collection of private identifiable information is complete **OR** not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete **OR** not applicable (no subjects were enrolled)

How do I close a study? I do not see a Study Closure option.

To close a study, a Continuing Review submission must be made. There is no study closure button. You can find a guide on how to submit a study closure in the Huron IRB system under **IRB**> **Help Center**> **Guides**> **UCF Huron IRB Quick Reference Guide - How to Submit a Study Closure**.

Huron IRB Office of Research Ancillary Review Contacts

ORC Department	Ancillary Review Type	Primary Ancillary Reviewer	Backup Ancillary Reviewer(s)	Conditions Requiring Ancillary Review	Required Review?
Contracts Office	Contracts Office	Peggy Allen		Negotiable Terms and Conditions.	Yes
IACUC	Other	Cristina Calcano		Follow currently defined business processes for IACUC reviews.	Per Business Process
IRB	Other	Renea Carver		Follow currently defined business processes for IRB reviews.	Per Business Process
COI	Other	Mary Stanley		An institutional key, non-key or significant contributor has disclosed financial interest in the research on the proposal (Answered "yes" to Personnel Conflict of Interest Financial or contractual interest question on the Proposal UCF Financial Interest Disclosure SmartForm.	Yes
eCRT	Other	Daniel Sierra		Follow currently defined business processes for eCRT reviews.	Per Business Process
Export Control	Export Control	Ashley Guritza	Mike Miller Nino Frederico	Documents containing Export Control Red Flags. For guidance on Export Control Red Flags, please see the Office of Export Controls Compliance Protocol ECO-1.	Yes
VPR Cost Share	VPR Cost Share	Chris Hale		The sponsor requires cost share. **NOTE:** The cost share request should go to departments first	Yes

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IRB00001138, IRB00012110
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				to ask for coverage. If denied, they can seek VPR Cost Share.	
Pre-Award Proposal Support Office	IDC/F&A Cost Reduction	Celeste Rivera-Nunez	Jennifer Shambrook	The research rate is outside of the standard 49%.	Yes
Compliance	Credit Split	Mary Stanley		Another PI or Department will share credit with the primary PI and the supporting documentation is complete.	No