UNIVERSITY OF CENTRAL FLORIDA

Institutional Review Board
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Institutional Review Board, Office of Research

External IRB Study Application Instructions

This guidance document provides a step-by-step look at the application process for using an external IRB. Researchers must request that the University of Central Florida (UCF) IRB cede review to an external IRB (allow for another IRB to be the IRB of record). Researchers must also create a "shadow file" with the UCF IRB and submit copies of all research and IRB documents to the UCF IRB for its records.

Before the UCF IRB reviews your request for use of an external IRB, you must follow these steps to meet pre-review requirements. Once pre-review requirements are met, the IRB Office will assign your external IRB application to a staff member for administrative review. If you do not meet the requirements from the pre-review, the IRB Office will withdraw your study application, taking it back to pre-review status. We will ask you to correct the application before you re-submit to the IRB Office.

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1. External IRB Overview

Institutions such as UCF may agree to use an IRB external to their institution to oversee a research study or studies. This is called ceding IRB review.

A written agreement (usually an IRB Authorization Agreement or IAA) between the institutions must be executed for an institution to rely on an external IRB and for the external IRB to serve as the IRB of record. The agreement spells out the responsibilities of the institution providing IRB review (the external IRB), as well as the responsibilities of the institution relying on the external IRB (the UCF IRB).

In general, the IRB offices at the reviewing and ceding institutions will negotiate the agreement and obtain authorized signatures for the agreement. These agreements, called authorization agreements or reciprocity agreements, vary among institutions and the complexity of the study.

It is important for the UCF research community to understand that not all studies are eligible for UCF to cede review to an external IRB. Additionally, UCF still has obligations for administrative review of ceded. research.

UCF has a responsibility under both federal human subject research regulations and AAHRPP accreditation standards to perform administrative review of the research prior to agreeing to cede review. This review involves:

- assessing local context issues;
- assessing UCF investigator qualifications, training, and conflict of interest; and
- ensuring that required ancillary reviews by other UCF departments are completed (e.g., Institutional Biosafety, General Counsel, Privacy Office, etc.).

In addition to following any requirements for conducting research approved by the external IRB, UCF researchers are responsible:

- to communicate with the UCF IRB office about the plan to use an external IRB,
- to apply for UCF administrative review through Huron IRB to provide documentation of the study documents approved by the external IRB, and
- to provide updates/communications from the external IRB via Huron IRB.

2. What types of studies are eligible for external IRB review?

Typically, only non-exempt (i.e., studies reviewed via an expedited or convened board process) are eligible for external IRB approval. UCF researchers proposing Not Human Subject Research (NHSR) or Exempt research activities should plan to apply to UCF for a study determination regardless of a previous external IRB determination.

In other words, UCF typically does not cede review for NHSR and exempt determinations. If you are working with one of the three hospital systems listed below, UCF generally will accept that hospital system's exempt determination.

3. When are new agreements needed?

UCF currently has pre-negotiated agreements with the following institutions and a new agreement is not needed:

- Advent Health- for Exempt and Non-Exempt Human Subject Research regardless of funding.
- Naval Air Warfare Center Training Systems Division- for NAWCTSD supported human subjects research in training and human performance improvement.
- Nemours Children's Health- for Exempt and Non-Exempt Human Subject Research regardless of funding.
- Orlando Health— for Exempt and Non-Exempt Human Subject Research regardless of funding.

In all other cases, a new agreement is needed specific to a study or associated group of studies.

4. What are the steps for starting a new external IRB agreement?

- First, work with the lead PI at the external institution or lead site, or with the study sponsor, to ensure that the external IRB agrees to serve as the IRB of record. If yes,
- Contact irb@ucf.edu with the following information:
  - Name of the external IRB and IRB reliance coordinator information
  - Study title, Lead External PI name, and external IRB protocol number
  - Funding source(s)
  - Brief description of the research (study population, interventions, etc.) along with a list of the specific Human Subject Research activities that will be conducted at UCF
  - If available, include a copy of the external IRB review outcome letter.
- If UCF determines the proposed external IRB is eligible to serve as the reviewing IRB for your study, you will receive a confirmation email and will be asked to start an external IRB application in Huron.

5. Creating an External IRB Study Application in Huron IRB

UCF uses electronic research administration software called Huron Research Suite. Anyone with current single sign-on credentials can create a study application in the Huron IRB module. If you have sign-on credentials but have trouble logging in to Huron, contact Graduate and Research IT Service Desk GRITservicedesk@ucf.edu for assistance. The IRB office does not manage the sign-on process.

A. You can access Huron IRB by clicking on the Huron icon at the top of the IRB website, https://www.research.ucf.edu/Compliance/irb.html or by visiting https://apps.research.ucf.edu/

B. After you sign into Huron, select the IRB tab and then **Create New Study**. This will open the **Basic Study Information** page of the application. Note the question mark icon ? next to the

different sections. Clicking this icon will pop-up instructions about completing that section. Complete items 1 - 7.

- The study title listed needs to be identical to the study title as reviewed by the external IRB
- In the Brief Description section, give an overview of the research and detail what study activities will be performed by UCF study team members
- When asked **What Kind of Study is This?** Only select Multi-Site/Collaborative if there will be UCF specific local study documents such as a protocol or consent addendum or UCF specific recruitment or other study materials OR if the UCF is part of a multi-site trial where each PI conducts the entire protocol. Otherwise, select Single-Site. Note, the following directions may vary if you select Multi-Site/Collaborative.
- Select Yes for External IRB
- Include the name of the UCF PI. If you are not the PI of the study, click on the ellipsis icon  in item 6 to search for the name of the PI. This list will only contain persons with active UCF sign-in credentials.

C. Item 8, click add and upload a clean copy of the protocol which is already approved by the external IRB **Do not attach any other documents in this section.**

To upload the document, once you have selected the file and given it a Version number, click "OK." Then click Save, and then click Continue. Use this same process (or a similar process) for uploading other documents as you go through the submission. Always remember to hit "Save" then "Continue" when you finish each section of the submission form.

NOTE: If the proposed study is still pending approval by the external IRB, you can upload a draft version of the protocol and the other study documents requested below. You will be asked for the final version once external IRB review is complete.

D. The next page is **External IRB.** Use the ellipsis icon to search for the name of the external IRB. If it is not found, select **TBD customer** instead. Add the IRB protocol number assigned by the external IRB, if known

E. The next page in the application is **Study Funding Sources.** Complete this section if an external sponsor is funding your study. You do not need to list UCF internal funding. You can search for the name of the funding source using a wildcard search. For example, to search for NIH use %NIH. If the funding source is not available, you can contact GRITServiceDesk@ucf.edu. The IRB office does not manage the funding source list. Click Save and Continue.

F. The next page is **Local Study Team Members** which includes a section for internal study team members and external study team members.

- Under Item 1, add all persons other than the PI who are involved in the design, conduct, or reporting of the research at UCF. Use the ellipsis icon to search for the person. If the search does not list the person, you can add them under item 2. Answer the three questions for each person.

- If you are a graduate student, be sure to add your faculty advisor's name with the role of faculty advisor.
- Leave Item 2 External Team Member Information blank. You do not need to add external team members already approved by the external IRB.

  Note, see **Required Training** below. All study team members engaged in the human subject research must complete UCF affiliated CITI training prior to UCF IRB ceding review.

G. The next page is **Study Scope** regarding use of drugs or devices. Complete the section, if applicable, and contact irb@ucf.edu with any questions. Click Save and Continue

H. The next page is **Local Research Locations**. If you are conducting only online research, you can leave this blank. If your research includes in-person activities, either select the location from the drop-down or type in the locations. Click Save and Continue

I. The next page is **Local Site Documents**. This page is where you will attach most of your study documents to the application starting with the Consent document(s).

J. Under item 1, if applicable, click add and upload a clean copy of the consent form(s) approved by the external IRB.

K. Under item 2, click add and upload recruitment materials including email, social media posts, phone scripts, etc. as approved by the external IRB.

L. Under item 3, click add and upload all other study documents approved by the external IRB. Include a copy of the external IRB approval letter. Be sure that the approval letter includes the most current approval and, if applicable, expiration date.

M. The final page is **UCF Additional Information.** Depending on the selections you make, the application will include additional fields.

N. Item 1, description of the PI. Select the applicable description. If the PI is a graduate student, the application will prompt you to attach a faculty advisor checklist. **The Faculty Advisor listed in the Local Study Team page of the application must complete and sign this checklist.** The faculty advisor you list must be a core UCF faculty member and the person who is overseeing your human subject research as a UCF graduate student. This person is likely different from the external lead PI

O. The application will ask if the study involves accessing student, employee, or medical records or accessing a non-UCF population. Plan to get documentation from the official responsible for these records or populations to indicate that you have research access to those resources. Even if you are an instructor or a physician who has access to records professionally, you will need additional permissions to access the records for research purposes.

6. Required Training

CITI Human Subjects Research is the basic training requirement for all members of the study team who will:

- Have contact, communication or interactions with study participants and/or
- Be involved in the consent process or listed as a study contact and/or
- Have access to identifiable information and/or
- Serve as a faculty advisor

See Guidance-IRB G4-CITI Training for details about how study team members can access this training. This training is free of charge to the study team members.

Additional training may be required, and this depends on the scope of the study. For example, FDA regulated, or NIH funded studies may require Good Clinical Practices.

All study team members required to complete UCF affiliated CITI training must have completed the training prior to the next step.

7. **Finalizing and Submitting the Application**

After you have saved the last page of the study application and click continue, finalize the application. To finalize, you will click "Save" and then "Finish." IMPORTANT, finalizing the application does not submit it to the IRB.

The person listed as PI on the Basic Study Information page will need to click "SUBMIT" to move the study from Pre-Submission, which indicates the application is still with the research team, to Pre-Review, which indicates the IRB Office has received the study.

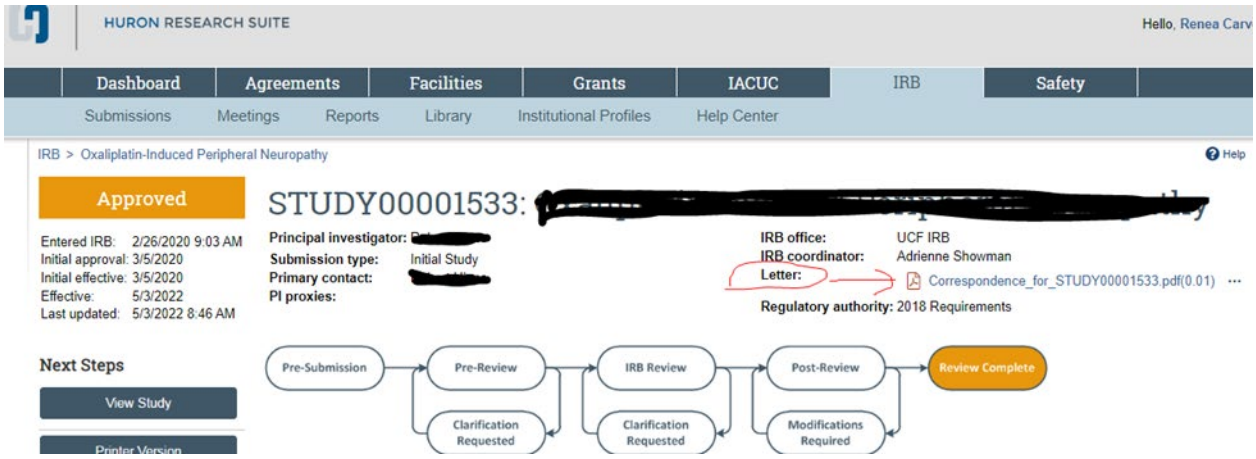
8. **Responding to reviewer request for more information**

During the review process, your reviewer will ask for changes to your study documents. It is important that when you revise a document for you to upload the revision correctly:

Go to the page of the application where you attached the current version of the document and click UPDATE to upload the revision. DO NOT delete the current version and DO NOT click ADD.

9. **Receiving an IRB outcome letter indicating that UCF agrees to cede review indicating your study activities can begin.**

After the administrative review process is complete, you will be issued an outcome letter. The link to the letter will be located on the top right side of your study dashboard. This letter indicates that UCF IRB cedes review to an external IRB. You may need to provide this letter to the lead PI and/or the external IRB.



10. **During and at the end of research**

Provide ALL updates/communications from the external IRB via Huron IRB, including but not limited to:

- Modifications to the application information, including UCF study team member updates
- Continuing review/annual reports
- Any modifications to the protocol and the external IRB's approval or acknowledgment of that modified protocol.
- Any modifications to the consent and the external IRB's approval of that modified consent form.
- Any modifications to investigator brochures, instructions for use, or other documents related to study conduct and participant safety
- Protocol deviations and unanticipated problems and, if applicable, the external IRB's response to these.
- Closure of the external IRB study in Huron. If there is a closure document for the study or a closure document for the UCF site from the external IRB, include that in your closure submission to UCF IRB.
- Any other information from the external IRB about study oversight, study conduct, or participant safety. This includes audit reports, notice of upcoming study termination, notice of recruitment/enrollment closure for the study or for an arm of the study, and any warning notices or product safety notices.