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Office of Research
3100 Technology Parkway, Suite 201
Orlando, FL 32826-3246

UCF

UNIVERSITY OF CENTRAL FLORIDA

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 who wish to use an external IRB 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 an external IRB application in Huron IRB and submit copies of all research and IRB documents to the UCF IRB for its records. **Ensure that the other IRB will agree to let UCF rely on their oversight BEFORE you begin your external IRB submission or start your reliance process.** IRB staff may be able to assist with this.

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-Submission status. We will ask you to correct the application before you re-submit to the IRB Office.

Table of Contents

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). See below for a list of local hospital systems we have standing agreements with.

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 may also vary based on the complexity of the study.

Institutional Review Board
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Many institutions, including UCF, are part of a reliance platform called SMART IRB, which helps to streamline the reliance agreement process. If UCF is using SMART IRB for the reliance agreement process, this will be done by UCF IRB staff of the reviewing site is not handling this. Please notify the IRB office at IRB@ucf.edu if you wish to set up a reliance agreement using SMART IRB. **Do not start the SMART IRB process yourself.**

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 administrative review involves:

- assessing local context issues;
- assessing UCF investigator qualifications, training, and conflicts 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 **BEFORE starting the reliance process or the submission process**,
- 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?

In most cases, only non-exempt (i.e., studies reviewed via an expedited or convened board process) are eligible for external IRB approval. Contact the UCF IRB if the sponsor/funding agency requires single IRB review for an exempt study.

UCF researchers proposing any Not Human Subject Research (NHSR) should plan to apply to UCF for a study determination regardless of any previous external IRB determination. We do not do reliance agreement for NHSR studies

UCF researchers proposing Exempt research should plan to apply to UCF IRB for a study determination regardless of a previous external IRB determination, *unless you are working with certain Department of Defense (DOD) IRBs OR one of the three hospital systems listed below under "3. When are new agreements needed?"* UCF generally will accept that hospital system's Exempt determination.

To summarize, UCF IRB does not cede review for NHSR and only in certain cases for exempt determinations.

3.   When are new agreements needed?

UCF IRB currently has pre-negotiated agreements with the following institutions and a new agreement is not needed. This includes three local hospital systems:

- **Advent Health**- for Exempt and Non-Exempt Human Subject Research regardless of funding.

Institutional Review Board
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- **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.

NOTE that these agreements do not extend to Not Human Subjects Research projects.

FOR FIRE STUDENTS: If you are being added to a study at Advent Health, Nemours Children's Health, or Orlando Health, we need the following included in your submission:

- The approved protocol approved by the reviewing IRB
- Initial approval letter from the reviewing IRB.
- If the study has had a continuing review, we also need the most recent continuing review study to determine when the next report is due, if applicable
- Documentation that the reviewing IRB has approved your work on the study. This documentation can be your name on the approved protocol, or your name on an amendment submission, your name on an approval letter from the reviewing IRB, correspondence or other certification from the reviewing IRB, or a screen shot of the IRBNet study page with your name (Orlando Health)

We also have pre-negotiated agreements for some Department of Defense studies. Contact the IRB at irb@ucf.edu for more information.

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

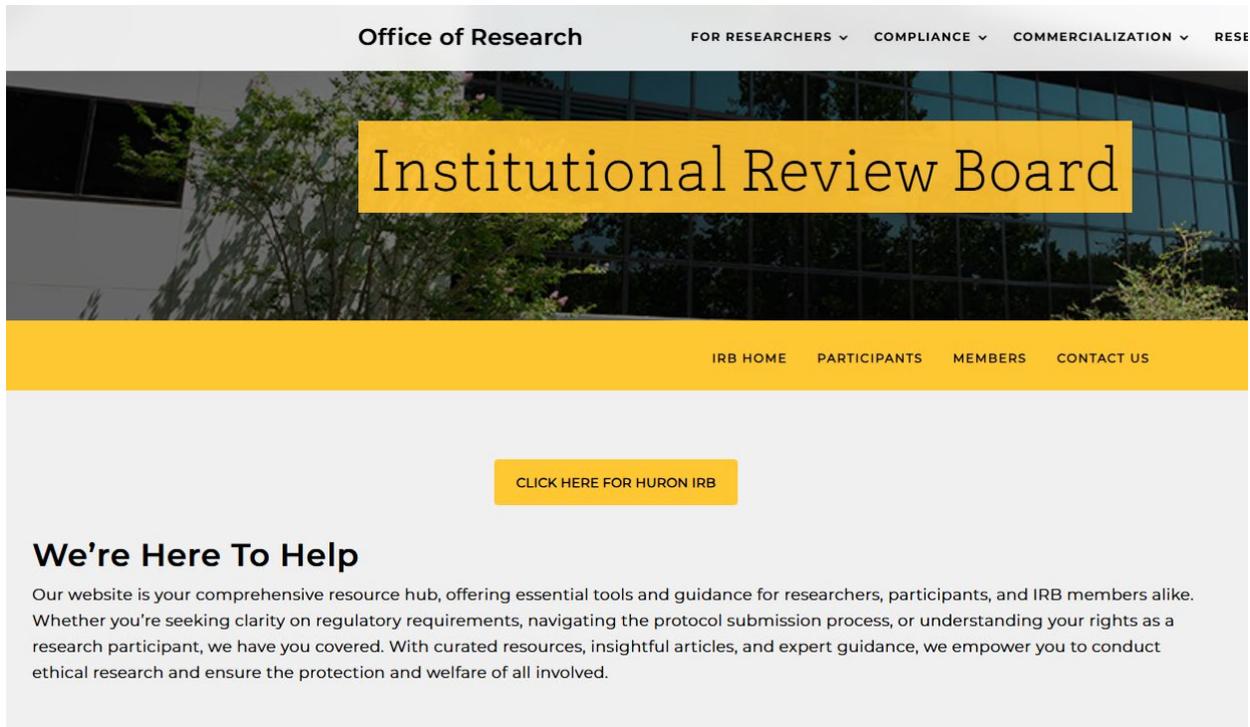4. **What are the steps for starting a new external IRB agreement?**

- **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:
    o Name of the external IRB and the IRB reliance coordinator's contact information
    o Study title, Lead External PI name, and external IRB protocol number
    o Funding source(s)
    o 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
    o 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.
- If the external IRB will accept reliance through the SMART IRB platform, the UCF IRB staff will handle the SMART IRB process. They may ask you for information when completing the SMART IRB request.

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.

Institutional Review Board
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A. You can access Huron IRB by clicking on the "Click here for HURON IRB" link just below the page header at the top of the IRB website, https://www.research.ucf.edu/for-researchers/compliance/irb/ or by visiting https://apps.research.ucf.edu/ and scrolling down to select the tab for HURON IRB.

B. After you sign into Huron, select the IRB tab and then select **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?"**
    o Select Multi-Site/Collaborative if there will be implementation of the same protocol at two or more independent investigational sites where participants are seen for an intervention and/or outcomes assessment. For Multi-site, UCF will have a study team that is conducting the same protocol as the lead site.
    o Select Single Site if UCF researchers are **contributing** to the other site's study **without conducting the entire protocol.** This includes UCF Fire student projects where the main research is conducted elsewhere under an external PI.
- Select Yes for **External IRB**
- Include the name of the UCF PI (the person overseeing the **UCF** conduct of the study or study activities.) If you are not the UCF PI of the study, click on the ellipsis icon (three dots)

Institutional Review Board
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in item 6 to search for the name of the PI. This list will only contain persons who have active UCF sign-in credentials. The local PI must have active UCF sign-in credentials. NOTE that for FIRE student projects conducted at other sites, the FIRE student is the UCF PI for the purposes of the UCF IRB submission.

C. Item 8, click add and upload a <u>clean copy of the protocol which is already approved by the external IRB*.</u> If UCF has a protocol addendum to the lead site/external IRB protocol, click "add" and upload a clean copy of that document. **For item 8 "Attach the protocol," ONLY attach the protocol that UCF will be using**. **If UCF is using the other site's protocol, upload that prototol**. **If a protocol addendum is required, you can attach it as well.** **<u>Do not attach any other documents in this section.</u>** If your submission requires a protocol addendum for UCF-specific protocol information, use HRP-508, Template Site Supplement to Sponsor Protocol, for your template. You can find it in the Huron IRB Library under the Templates tab.irb@ucf.edu

To upload the document, select the file and indicate the version number. If the external IRB or lead site has given it a version number, use the same version number. For a UCF-specific protocol addendum, you will assign it a version number. Once you have done this, 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.

D. **Study-related documents and Local Site documents (Multi-site studies only):** If you selected "Multi-site" you will have a choice of uploading documents into Study Related Documents or into Local Site Documents. Most of these documents will be <u>uploaded under the appropriate sections of Study-Related Documents.</u> For Multi-site studies, the Local Site Documents section should be limited to **documents that are ONLY being used at UCF.**

*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.

E. The next page is **External IRB.**   Use the ellipsis icon (three dots) 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.

F. 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.

When you enter your funding information, you must enter the UCF Grants Office ID number. **The number will start with FP or AWD.** FP is for Funding Proposal and AWD is for Awarded Funding. If you don't have access to the number(s), ask the pre-award support person for your department or ask the person who works with the grants office for your submission. This information must be entered in order to link the research to the funding. You can also find the grants office ID for your study by accessing your PI Dashboard in Workday--Go to Grant Budget Summary.

Institutional Review Board
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G. 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 (three dots) to search for the person. If the search does not list the person, you can add them under item 2. Answer the three questions in the form for each person.
- If you are a graduate student, be sure to add your faculty advisor's name with the role of faculty advisor.
- Do NOT list the PI again under Local Study Team members. The PI should only be listed once, where the PI name is requested.
- 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 UCF study team members engaged in human subjects research must complete UCF affiliated CITI training before UCF IRB can agree to cede review.

    If the UCF team wants to add someone who is not affiliated with UCF or the reviewing IRB site, the reviewing site's IRB must approve that. Since UCF IRB is relying on the reviewing IRB, we have no authority to extend our approval to other external investigators.

H. 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

I. 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

J. The next page for multi-site studies is **Study-Related Documents**. This page is where you will attach most of your study documents to the application starting with the Consent document(s). For multi-site studies, documents that ONLY apply to UCF will be entered in **Local Site Documents.** If you are submitting your research as a single-site study, most of your study documents will be entered into **Local Site Documents.**

K. Under item 1, if applicable, click add and upload a clean copy of the consent form(s) <u>approved by the external IRB</u>. Make sure the file you upload does not have any comments, track changes, or the IRB stamp from the other institution's IRB. If UCF will use an addendum consent along with the consent form(s) approved by the external IRB, upload it here.

L. Under item 2, click add and upload recruitment materials including email, social media posts, phone scripts, etc. as approved by the external IRB. Any UCF-specific recruitment materials should also be uploaded here.

M. 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.

Institutional Review Board
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N. The final page is **UCF Additional Information.** Depending on the selections you make, the application will include additional fields, which may include information about online research, international research, and other information.

O. Item 1, description of the PI. Select the applicable description for the PI listed on the application. For example, if the graduate student is the PI but is working with a faculty advisor, select Graduate Student and not Core Faculty. The local PI in Huron IRB is likely different from the external lead PI or faculty advisor.

P. 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 Practice training.

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**

A. 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 for review.

B. Ancillary Reviews:

- Graduate and Medical Students must contact the faculty advisor listed on the application and study documents to have them review the application and study documents. The advisor can sign-off by selecting "Add Comment" and then indicating that "I have reviewed the study documents and approve this application and research plan."

- If your department requires an Ancillary Review, select "Manage Ancillary Reviews" and add your departmental reviewer. Contact irb@ucf.edu if you need assistance.

Institutional Review Board
FWA00000351
IRB00001138, IRB00012110
Office of Research
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C. 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.
   IMPORTANT: When you revise a document you must upload the revision correctly, using the UPDATE process:

   The UPDATE process for revised documents: 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 through UCF Huron IRB. 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 in your External IRB submission. This includes but is not limited to:

    - Modifications to the application information, including UCF study team member updates.
    - Continuing review/annual reports. You can report these by clicking on "Update Study Details" or by clicking "Report Continuing Review Data." Your submission **MUST include the APPROVAL letter from the external IRB for the continuing review,** with the next review due date.

Institutional Review Board
FWA00000351
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- 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 "**Report Continuing Review Data**" to UCF IRB. This can be found under "Next Steps" on the left-hand side of the study submission.

    NOTE: Only the PI of the submission will have access to the "**Report Continuing Review Data**" function.

    FOR FIRE STUDENTS: If you are leaving an external study that is not closing, email IRB@ucf.edu and let us know so that we can close out your Huron submission if applicable.

- 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.

11. Commercial IRBs - Additional Instructions and Guidance

A. Give us a heads up. **Contact the UCF IRB at irb@ucf.edu FIRST before agreeing to any IRB arrangements with the external IRB or the sponsor.** Provide details of the study to the UCF IRB.
B. External IRB agreements must be made by IRB staff, who will then request sign-off by the institutional official. External IRB agreements will not be finalized until the following steps are completed.
C. The IRB manager or designee must be listed as the point of contact for the IRB reliance agreement process.
D. We will not allow sponsors to submit to an external IRB on behalf of the UCF study team.
E. Review Process:
    a. Commercial IRBs will usually review the protocol first, before they approve any local sites. For most external IRBs this is done by the sponsor and/or the lead site, using a longer form. This is when the protocol is approved. This is standard for commercial IRBs.
    b. Once the protocol is approved, the external IRB will begin reviewing site applications. This is when the sponsor can get individual sites approved to conduct the study. There is a shorter submission form for the site approval that is part of a site application packet. Since the protocol is already approved, the external IRB only needs to confirm that all the paperwork from the site is in place to approve the site and the local principal investigator and sub-investigators. They may ask for information like credentials and certifications/licensing, CVs, financial disclosure forms, number of active studies the PI is overseeing, number of FTEs on the study team, appropriate facilities and equipment on site, storage facilities for investigational products etc.

Institutional Review Board
FWA00000351
IRB00001138, IRB00012110
Office of Research
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Orlando, FL 32826-3246

    i.   The local site application will also include, if the commercial IRB does not already have it on file, local context information like contact information for the study team and contact information for the IRB for the consent form, any required research related injury language for the consent form, DSMB and safety information if applicable, and if there are any procedures the site will do that differ from the procedures in the approved protocol (usually in recruitment, types of scans that might be done, or state/local requirements about parental consent for minors [required in Florida], age of consent [in some states it is 19], reporting requirements for signs of abuse or testing positive for reportable diseases, etc.) **This is a major part of what the UCF IRB will review before we confirm the reliance submission. The UCF IRB must see the local site application to the external IRB BEFORE it is sent to the external IRB. This way, errors and incompletions can be corrected in advance.**

F.   Studies requiring an Authorization to Use or Disclose PHI usually need a separate Authorization form. This form needs to be based on the UCF Health form and will require ancillary review from the privacy officer. The local site team must obtain an ancillary review of the Authorization form and post it in your Huron file prior to submitting the local documents to the reviewing IRB.

G.   The external IRB often relies on the local IRB to verify investigator credentials, study team member training, local facility appropriateness, etc.

H.   The external IRB will require that the local IRB provide written verification that all local requirements have been met. This is why the UCF IRB needs the team to upload into Huron everything you are submitting for your local site submission to the external IRB. We have to review your external IRB submission for completeness and accuracy before we can issue our verification. Some commercial IRBs will have their own form that the UCF IRB will sign. Other commercial IRBs may ask us to generate our own document but will tell us what information needs to be in the form we sign.

I.   We may already have a reliance agreement in place, but the above process is required before the external IRB will begin their review of this site. Doing this in advance will speed up the approval process.

J.   Only in rare circumstances should there be direct communication between the sponsor and the UCF IRB. NONE of these circumstances relate to the IRB approval process or IRB approval timeline. The rare circumstances are limited to times where there are issues with study procedures, consent language, disagreements in device risk determinations, unanticipated serious device effects, withdrawn IRB approval, withdrawn FDA approval, etc.

K.   For IDE studies, the sponsor is required to send their sponsor annual progress reports and their sponsor study closure report directly to the designated commercial IRB. They will also send these to the site, so we will ask the site to upload them into Huron for UCF IRB record keeping.

L.   For Investigational New Drug (IND) studies, the sponsor will require the local team to complete an FDA form 1572, signed by the local PI, which the sponsor collects and sends to the FDA. Device studies may use a similar form, but it is for sponsor use only and does not need to be reported to the FDA. Both the external IRB and the UCF IRB should have a copy of the signed form and any subsequent updates, but this is not a requirement. We use this for record keeping, audit preparation, and to verify that information provided to the sponsor and the FDA matches the information in our study files. If we don't have one on file, we may ask for one if needed.

M.   We recommend that only ONE person in the study team, other than the principal investigator, be allowed to upload documents into the Huron submission.

N.   We need the external IRB submission documents FIRST. From these, we can determine if we need a supplemental protocol document (HRP 508), if UCF COI needs to provide an ancillary

Institutional Review Board
FWA00000351
IRB00001138, IRB00012110
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review on any investigator financial conflicts, if other departments or individuals need an ancillary review, or any other local issues need to be resolved. The external IRB site submission form, even though they may call it the "short form", is lengthy and comprehensive. If we have it early in the review process, we can avoid asking for items that may not be needed and can get started on processes that may take time. **The HRP 508 should focus on anything that is different than the sponsor protocol.** You do not need to repeat information that is already in the sponsor protocol.

O. <u>The Huron file for UCF must contain everything sent to the external IRB for site approval.   After the site is approved, the Huron file must be updated with the site approval document, and amendment approvals, continuing review approvals if required, and any other communication between the site and the external IRB relevant to study conduct. Exceptions may be made for studies reviewed by Advarra IRB or WCG IRB, since the UCF IRB team has access to their study files.</u>

P. **Following these procedures should significantly reduce the turnaround time for the local site to be approved by the external IRB.**

Q. To help streamline your communications with the IRB staff, we ask that you use irb@ucf.edu for your primary communication with the IRB office outside of Huron IRB.   It is not necessary to copy Renea and Harry on all communications sent to irb@ucf.edu.   If you have a specific question to just one person, you can still use that person's direct contact information or you can send it to irb@ucf.edu and address the email to that specific person. **Do not include sponsor representatives in group emails that include the IRB.**