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IRB and HRPP Information and Updates

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Human Research Protection Program (HRPP) Quality Improvement

A key element of all Human Research Protection Programs (HRPPs) is a continuous quality improvement (QI) program. At UCF, the IRB office conducts QI reviews of IRB meeting minutes, reviews efficiencies, and assesses general compliance with IRB operating procedures. In addition, the Office of Research Compliance Office reviews the conduct of approved studies. These reviews are called Investigator Quality Improvement Assessments (QIA).

Currently, only non-exempt (expedited and convened board) studies are included in the QIA program. Here is what you should know about the QIA process:

- All studies approved by the convened board are reviewed on an annual basis and a small number of expedited or Food and Drug Administration-regulated studies are randomly selected each month. All studies with an active status in Huron IRB are eligible for selection.
 - Selection procedures for the QIA process have recently been updated. Researchers with multiple expedited studies who were reviewed in the previous 12 months and had no major findings (low risk) will not be selected again.
- If your study is selected for QIA review, you will be contacted by a member of the QIA team to schedule an on-site or virtual visit, a new option in 2023, to review your research records. Checklists can be found in the Huron Library Checklists tab to help you prepare and understand what is included in the assessment. Use checklist HRP-430 Investigator QIA to conduct a self-assessment. The HRP-430b Investigator QIA checklist is completed by the QIA team during the assessment process.
- The QIA process is meant to help investigators identify potential study compliance issues and provide on-site investigator training when needed. Take advantage of the QIA team's expertise during the assessment and ask questions. The goal of these assessments to help you improve your human subjects research through early identification of issues and education.
- Should study issues be identified, you will be asked to create a Reportable New Information (RNI) application in Huron IRB to describe the issues and steps you and your study team will take to correct and try to prevent the issues from reoccurring.
- The IRB office reviews these issues and tracks trends to identify training and outreach needs.

Study issues identified to date mostly involve the following minor non-compliance items:

- Not using the most recent version of the informed consent document that includes the timestamp issued at approval. To find this version of the consent form, go to the **Documents** tab of your approved study and click on the version under the **Final** column.
- Not providing participants with all pages of the signed consent form. A copy of the full version of the signed consent form needs to be offered to the participant and a full signed version needs to be maintained as part of the study records for the retention period.
- Missing signatures and dates on the consent form. Signatures from both the participant and the person obtaining consent are needed unless your study has a waiver of written documentation of consent. Some studies will additionally require a witness. Note: best practice is to use blue or black ink for signatures on hard copies of the consent form.
- Data storage that is not consistent with the study protocol.

If you have any questions about the QIA process, contact HRPPQIA@ucf.edu or irb@ucf.edu

AAHRPP Accreditation

The UCF HRPP is fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). This accreditation “offers assurance...that an Organization’s HRPP is focused first and foremost on excellence” (<https://www.aahrpp.org/>). After initial accreditation, HRPPs submit annual reports and go through re-accreditation every 5 years. UCF is currently in our 3rd re-accreditation cycle.

What do I need to know about re-accreditation?

The first step of the accreditation process is focused on completeness and quality of the written HRPP documents, including policies, procedures, templates, and checklists. After this step is completed, AAHRPP will schedule a site visit where the focus is on compliance of both committee and non-committee operations, study reviews, and interviews of selected research teams.

UCF expects an AAHRPP site visit in late spring/early summer 2023. The site visitors will provide a list of study teams to be interviewed as part of the visit. If your team is selected by AAHRPP, the IRB office will contact you to schedule your interview and to provide more information about what to expect during the process.

New Toolkit and Guidance Documents

As part of the AAHRPP accreditation process, a new version of the UCF toolkit has been released and is available in the Huron Library. Visit the **Huron Library Templates** tab for current versions of protocol, consent form, and other forms that may be needed as part of your study applications. The Huron Library also contains investigator standard operating procedures (SOPs) along with worksheets and checklists that are used in the review process.

The **Huron Library General** tab contains several guidance documents along with a copy of the written HRPP program and Investigator Manual. Several new guidance documents were released in the past year including:

- Study Application Instructions
- Advertisements and Recruitment
- Payments
- Study Application Instructions for External IRB Studies

Did you know? Most of the tabs in the Huron Library contain multiple pages. If you cannot find what you are looking for, use the arrow at the bottom of the document list to select the next page.

IMPORTANT: You do not need to change template versions for modifications of currently approved studies or initial studies in the Pre-Review or Non-Committee Review process on or before 3/20/2023.

Studies in Pre-Submission at the time of this notice can use the previous versions of templates until 3/20/2023. After that, the 1/31/2023 version of the templates will be required for ALL initial study applications. If you have a study in Pre-Submission that is ready for review, ensure that the study PI completes the “SUBMIT” process to move the study to Pre-Review prior to 3/20/2023. After that date, all applications in Pre-Submission will be discarded from the system.

When preparing for a new study application, you are encouraged to always start with a blank version of the most currently dated template instead of ‘recycling’ already written protocols. Re-using protocols and consent forms from previously approved studies often results in the research team missing important study elements or providing incorrect information resulting in a longer review process.

Working with External IRBs

The UCF HRPP allows the use of external IRBs (IRBs other than the UCF IRB). If UCF agrees to allow an external IRB to review a research study or studies, this is called ceding IRB review. Requests to use an external IRB MUST be reviewed by the UCF IRB, and the UCF Institutional Official (IO) must agree to sign an IRB Authorization Agreement (IAA) with the external IRB, if there is not already an agreement in place. This has to happen before the UCF IRB can cede review to the external IRB. Research teams must also create a “shadow file” with the UCF IRB. Research teams must submit copies of all research and IRB documents to this shadow file. The UCF IRB needs a record of these documents.

Not all studies are eligible for UCF to cede review. The UCF IRB office, in conjunction with the IO, must make the determination to allow ceded review. Research teams cannot make this determination. In addition to its work in allowing ceded review, the UCF IRB also has obligations for administrative review of the ceded projects, including ensuring that UCF policies are followed and that the consent forms contain required UCF information. This review process includes:

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

UCF researchers must follow any requirements the external IRB has for conducting research. In addition, UCF researchers are responsible for:

- letting the UCF IRB know you plan to use an external IRB.
- applying for UCF administrative review through Huron IRB and using Huron IRB to provide copies of approval letters and approved study documents to the UCF IRB
- using Huron IRB to provide updates and communications from the external IRB

In most cases, only non-exempt studies (studies requiring expedited review or convened board review) are eligible for external IRB approval. ALL research designated as NHSR (Not Human Subjects Research) must go through the UCF IRB for a determination. Most exempt review research will also have to go through the UCF IRB for a determination. However, if the researcher is working with one of the hospital systems that we have an agreement with (listed below), UCF will generally accept the Exempt determination from the hospital system's IRB.

Even though UCF currently has pre-negotiated agreements with the following institutions, the researcher must still go through the steps described above to register the study with the UCF IRB, set up a shadow file, and receive an agreement from the UCF IRB to cede review to the institution's IRB.

We have pre-negotiated agreements with the following:

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

NOTE that these agreements are subject to change.

These are the steps for starting a new external IRB agreement:

1. Work with the lead PI at the external institution or lead site — or work with the study sponsor — to ensure that the external IRB agrees to be the “relied upon” (reviewing) IRB. If they agree, then:
2. Contact irb@ucf.edu with the following information:
 - Name of the external IRB and the contact information for their IRB reliance coordinator
 - Study title, Lead External PI name, and the protocol number being used for the external IRB
 - Funding source(s)
 - Brief description of the research (study population, interventions, etc.) along with a detailed list of the specific Human Subjects Research activities that will be conducted at UCF or by UCF researchers
 - If available, include a copy of the external IRB review determination letter or approval letter for the research
3. 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.

There detailed instructions for starting an external IRB application in IRB Guidance 10 – External Study Application Instructions.pdf, which can be found in the Huron IRB library under the “General” tab.

<https://ucf1.huronresearchsuite.com/IRB/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5B OID%5BE258B74E9300D14F8F4F7410463EB60D%5D%5D&tab2=14773F5B21DBD429EC0FB75662BD9BC>

Updates to Study Reporting Requirements — Continuing Review and Administrative Check-in

Prior to the Common Rule revision in 2018, all non-exempt human subjects research studies were subject to an annual continuing review. As part of the continuing review, investigators reported study progress information through the Huron IRB study portal and received a year extension on the approved protocol.

With the Common Rule change, many expedited studies no longer require a formal continuing review. You may have received an automated notice that one or more of your studies does not require continuing review.

This spring, UCF will adopt the best practice implemented by many other HRPPs and begin requiring an annual administrative check-in for active expedited studies that are not currently under a continuing review requirement. Exempt studies will now require an administrative check-in every three years.

UCF is adopting this practice to ensure our human subjects research portfolio is current. The check-in process will consist of researchers communicating that an active study is still ongoing, study team members are current, and all protocol revisions or study issues have been reported to the IRB.

What do I need to do?

When you receive a comment that an administrative check-in is requested for your study, respond to the comment:

1. Is the study ongoing or can it be closed? Use the comment box to indicate if the study will remain active or will be closed. Studies can be closed when all the following 4 milestones are met:
 - Study is permanently closed to enrollment OR was never open for enrollment.
 - All subjects have completed all study-related interventions OR this is not applicable (e.g., study did not include interventions; no subjects were enrolled)
 - Collection of private identifiable information is complete OR this is not applicable (e.g., no subjects were enrolled; no private, identifiable data was collected)
 - Analysis of private identifiable information is complete OR this is not applicable (e.g., no subjects were enrolled; no private identifiable data was collected).

NOTE: Guidance on creating a study closure request can be found at the bottom left side of the main IRB website at <https://www.research.ucf.edu/Compliance/irb.html>

If the study is ongoing:

2. Have there been any protocol, funding, or study team changes that have not been already reported to the IRB? If yes, describe the changes in the comment box and submit a study modification request to include the changes. If no, state that the study application information is current.

3. Have there been any adverse events, protocol deviations, or study issues that have not been reported to the IRB? If yes, describe the issues in the comment box and wait for additional information from the IRB office. If no, state that there have not been any study issues.

Additional information on other post-approval requirements can be found in the Investigator Manual, located in the Huron IRB Library General tab:

<https://ucf1.huronresearchsuite.com/IRB/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5B OID%5BE258B74E9300D14F8F4F7410463EB60D%5D%5D&tab2=147773F5B21DBD429EC0FB75662BD9BC>

If you have any questions, please contact irb@ucf.edu