

November 28, 2023

Institutional Review Board and Human Research Protection Program Information and Updates

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I. Upcoming IRB Office Closures

As we approach the upcoming holiday season, please plan your IRB application submissions and clarification responses with the following in mind:

- UCF will be closed November 22-24, 2023, and December 20, 2023 – January 1, 2024. The Huron IRB system will be open for researcher use, but review operations will be paused during those times.
- Additionally, IRB review staff are attending a conference on December 4 -7, 2023. There will be minimal staffing those days to respond to urgent requests. Normal IRB operations will resume on December 8.

II. Expedited and Convened Board Protocol Tips

The HRP-503 protocol template is to be used for non-exempt research that can either be reviewed via the expedited process (no greater than minimal risk, designated review) and the convened board process (greater than minimal risk, full board review). The template covers both social/behavior/educational (SBE) studies and biomedical (BIO)/clinical trials studies.

Pay attention to sections 4 Endpoints and 5 Intervention/Investigational Agents. The template language is drafted toward biomedical studies; however, some SBE studies involve interventions and have endpoints. Detailed information on completing these sections of the HRP-503 protocol template can be found in **Attachment 1-Endpoints and Interventions/Investigational Agents**.

III. Multisite/Collaborative Study Tips

Huron IRB asks two questions on the first page of the application that can sometimes be confusing to new applicants:

4. * What kind of study is this? ?

- Multi-site or Collaborative study
 Single-site study
[Clear](#)

5. * Will an external IRB act as the IRB of record for this study? ?

- Yes No [Clear](#)

For question 4, always select Single-site study when you are applying for a Not Human Subjects Research or an Exempt determination. For non-exempt research, only select Multi-site or Collaborative if individual sites will have protocol or consent information, recruitment materials or authorization forms that differ from the main study documents.

Multi-Site or Collaborative studies that are reviewed by the UCF IRB may need an agreement for external institutions to rely upon the UCF IRB review.

For question 5, only select Yes when:

1. This is an exempt or non-exempt study being reviewed by Advent Health, Nemours Children's Health, Orlando Health, Naval Air Warfare Center Training Systems Division (NAWCTSD) or
2. You have contacted the UCF IRB office to discuss whether your study is eligible to be reviewed by the proposed external IRB. See **Attachment 2 Studies Reviewed by an External IRB** for details.

IV. Ancillary Reviews/Guest Lists

Department administrators are reminded to inform their research faculty, staff, and students if departmental ancillary review or departmental guest lists are required for IRB applications. If so, the person preparing the IRB application should add the ancillary review or create the guest list prior to the principal investigator submitting the application to the IRB for review.

If you are a department administrator and would like more information on departmental ancillary reviews, please contact us at irb@ucf.edu

V. Studies Involving FERPA Protected Information

If your study involves accessing FERPA protected information belonging to anyone at UCF and your study

does not involve receiving a signature from the participant to access this information, you are required to receive a FERPA waiver from the UCF Registrar or College of Medicine Registrar. This is a separate process from IRB review. The IRB advises that you reach out to the Registrar prior to submitting to the UCF IRB to receive this waiver. Any studies submitted to the IRB needing a FERPA waiver will not be approved until the waiver is provided. This is necessary for studies that will be reviewed as exempt, expedited, and not human subjects research. Documentation from the Registrar can be in the form of an email and should be attached on the **Additional Information** page of the Huron IRB application.

VI. We Are Recruiting IRB Members!

The IRB Office is currently looking to add new Board Members to both Institutional Review Boards. We are looking for faculty, staff, students, and unaffiliated community members. Each Board meets once a month, either on the first or third Wednesday of each month. The meetings are from 3-5 p.m. and take place via Zoom. The total time commitment for joining a Board is about 5 hours a month, including the board meeting. The additional time is needed to review materials that will be discussed at the Board Meeting and to provide expert feedback to the IRB staff if they reach out with questions about a study being reviewed in office.

If you are interested in joining one of the Boards, please email irb@ucf.edu to request more information and an application.

VII. Upcoming IRB Office Hours

Starting mid-December, the IRB office will offer weekly office hours on Tuesday from 10 a.m. -12 p.m. and Thursdays from 2 p.m.-4 p.m. during normal campus operations.

To attend the office hours, make an appointment through Microsoft Bookings. These appointments will be to discuss questions about your application, questions about revisions you received, or questions about an application you are planning. Only persons with UCF email addresses will be able to make an appointment through Microsoft Bookings. If you have questions, please contact us at irb@ucf.edu. The link to create a bookings appointment can be found [here](#).

VIII. IRB Office Quality Improvement

The IRB office is conducting quality checks for a portion of IRB approved exempt and expedited submissions for internal quality improvement efforts. If while conducting the quality check it is determined that some elements of the IRB toolkit were not met in your study's approval, the IRB may contact you to submit a modification to update this information.

Attachment 1-Endpoints and Interventions/Investigational Agents

Section 4 – Study Endpoints only applies to clinical trials. An endpoint is NOT when you close the study to enrollment or finish the study.

- **Section 4.1** asks about endpoint(s)
- **Section 4.2** asks about safety endpoints.

DEFINITIONS

Clinical trial: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." Therefore, you need to provide endpoints here.

Endpoint is defined as "an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial."

A **safety endpoint** is similar to a primary endpoint and is defined as "an event or outcome that can be measured objectively to determine whether the intervention being studied is safe." The safety endpoint should include events (unexpected safety events) that would require a participant to be withdrawn as well as any criteria that, if met, will result in closing enrollment and/or stopping the study.

Note: for Section 5, "drug" refers to drugs, biologics, and vaccines.

Section 5 – Study Intervention/Investigational Agent – The information in this section must be consistent with the information in section 1 but should be expanded and clarified if applicable. Many protocols will add NA to section 5, as it does not apply.

- Section 5.1 asks for a (more detailed) description of the study intervention and/or the investigational agent. If there are no interventions, state that. (CFR 46.102 (2) defines intervention as both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes).

DEFINITIONS – Biologics (Biological Products)

<https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers>

What is a biological product?

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

How do biological products differ from conventional drugs?

In contrast to most drugs that are chemically synthesized and their structure is known, most biologics are complex mixtures that are not easily identified or characterized. Biological products, including those manufactured by biotechnology, tend to be heat sensitive and susceptible to microbial contamination. Therefore, it is necessary to use aseptic principles from initial manufacturing steps, which is also in contrast to most conventional drugs.

DEFINITION

(CFR 46.102 (2) defines intervention as both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes). This means that even if the study is SBE (Social, Behavioral, Educational), if there are physical procedures or manipulations of the subject's environment performed for research purposes, this is an intervention.

- INVESTIGATIONAL AGENT - List any investigational devices. If all the devices being used are approved and used per labeling, state that. You do not need to list approved devices here. We will ask you to list any approved devices, and provide information on them, in section 6.3. If there are investigational drugs, provide the generic name and the brand name (if applicable) and upload the investigator brochure for the drug into Local Site Documents – other attachments. We will ask you to list any approved drugs not being used in an investigational capacity in section 6.3.
- Section 5.2 asks you to tell how you will store, handle, and administer any investigational drugs or devices being used. Reference any applicable approved organizational SOP for handling these drugs and devices.
- Section 5.3 asks for information on investigational drugs that have an IND or investigational devices that have an IDE. Provide the IND or IDE number. Identify who “holds” the number. This is usually the manufacturer or sponsor, but it may be the local investigator. There is a chart in section 5.2 to identify the regulations that apply, so that you can describe how you will comply with the sponsor requirements for FDA regulated research.

DEFINITIONS – IND and IDE

An Investigational New Drug Application (IND) is a request from a clinical study sponsor to obtain authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.

An Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Attachment 2-Studies Reviewed by an External IRB

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 must 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 NHR (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=147773F5B21DBD429EC0FB75662BD9BC>