Institutional Review Board, Office of Research

Study Application Instructions

This guidance document provides a step-by-step look at the application process researchers use to submit proposed research to the UCF IRB. It is important to follow these steps to meet pre-review requirements before the IRB Office assigns your study to a reviewer. If you do not meet the requirements from these steps, the IRB Office will withdraw your study application, and will ask you to correct the application before you re-submit to the IRB Office.

The application process includes:

1. **Determining which protocol and consent form templates are needed for your proposed research.**
2. **Creating a study application in Huron IRB and attaching the completed protocol, consent form, and other study documents in the correct location of the application.**
3. **Ensuring that all members of the research team have completed required training.**
4. **Finalizing and submitting the application.**
5. **Responding to reviewer requests for clarification.**
6. **Receiving an IRB outcome letter and approved documents indicating your study activities can begin.**

1. **Types of Protocol and Consent Form Templates**

The below table references the types of human subject research categories and the corresponding protocol and consent form template version needed to accompany your study application. You can access these documents from the Huron IRB Library under IRB> Library> Templates. Be sure you are using most current template version as the IRB Office makes regular updates to these templates.

CATEGORY (Links contain guidance on determining research category)	PROTOCOL (Links contain the templates)	CONSENT FORM (Links contain templates)
Not Human Subjects Research **Use this template when requesting:** **Not Human Subjects Research Determination** Use of existing de-identified information or human biospecimens. Examples of providers of the information or biospecimens include, but are not limited to: other researchers; hospitals/medical	**HRP-250**	N/A

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records; public datasets/repositories; biobanks; commercial vendors **Not Research Determination-** Examples include: Case Studies; Quality Improvement Projects; Program Evaluation Activities; Oral Histories; Journalistic Activities See link above for details and limitations.		
Exempt **Use these templates when requesting an exempt determination for research that poses only informational risks.** Examples include: educational research; survey/interview research; brief behavioral interventions; taste and food quality evaluation. See link above for details and limitations	**HRP-255**	**HRP-254, HRP-509** (if applicable)
Exempt #4 - Secondary Research Only **Use this template when requesting an exempt determination for secondary use of identifiable private information or biospecimens that does not require consent.** See link above for details and limitations.	**HRP-255SR**	N/A
Expedited **Use these templates when requesting an expedited review for low-risk research.** Examples include: studies with vulnerable populations; low-risk clinical trials; small quantity blood collection; non-invasive collection of human biospecimens or health metrics (i.e., blood pressure, heart rate, etc.); research use of data requiring consent; Survey, interview, interventional research that may include health or psychological risks. See link above for details.	**HRP-503**	**HRP-502, HRP-502b** (if applicable), **HRP- 509** (if applicable)
Full Board Review **Use these templates when requesting review for greater than minimal risk research**	**HRP-503**	**HRP-502, HRP-502b** (if applicable), **HRP- 509** (if applicable)

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| External IRB **Upload these documents when you are participating in a study that an External IRB has reviewed. These require an agreement between UCF and the external IRB. UCF has a standing agreement with Nemours, Orlando Health, and Advent Health for all exempt, expedited, and full board studies. For all other external IRB's contact irb@ucf.edu with the study details to start the agreement process.**	The external IRB protocol	The external IRB consent form

2. Creating a Study Application in Huron IRB

UCF uses electronic research administration software call 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

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

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C. Complete items 1 - 7. 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

D. Item 8, click add and upload a completed copy of the protocol template you chose from the study category table above**.** Click on the box that says "Add" and then follow the instruction. You do not need to complete "Name." If you do not, the system will automatically give the file the same name you gave it when you completed the document and saved it in your computer for uploading. **Do not attach any other documents in this section.** The protocol must be
   a. Saved in MS Word format
   b. The current version from the IRB Template Library
   c. Completed. Do not delete sections, but instead mark any that do not apply as NA.
   d. Free of track changes, comments, typographical errors, template instruction language

E. 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: the following instructions will differ if you chose Yes for External IRB in item 5 of the Basic Study Information page.

F. The next page in the application is **Study Funding Sources.** Complete this section if an external sponsor is funding your study. 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.

G. The next page is **Local Study Team Members** which includes a section for internal study team members and external study team members.
   a. Under Item 1, add all persons other than the PI who are involved in the design, conduct, or reporting of the research. 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.
   b. If you are a graduate student, be sure to add your faculty advisor's name with the role of faculty advisor. If you are undergraduate, your faculty advisor must be listed as PI in step C above. You will add yourself here as a Co-Investigator.
   c. Under Item 2, click the question "?" icon to locate the External Team Member Information form used to add external members. If you answer "yes" to any of the questions in the form, attach the other documents requested in the External Team Member form. Click Save and Continue.

   Note, see section 3 **Required Training** below. All study team members engaged in the human subject research must complete CITI training prior to IRB review.

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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 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).

K. Under item 1, click add and upload a completed copy of the consent form template you chose from the study category table above. If you have other consent forms or a debriefing form, click add again to upload those files. The consent forms must be
    a. Saved in MS Word format
    b. The current version from the IRB Template Library
    c. Complete and written in simple language. You can delete sections that do not apply.
    d. Free of track changes, comments, typographical errors, template instruction language

L. Under item 2, click add and upload recruitment materials including email, social media posts, phone scripts, etc. Recruitment materials must:
    a. List the names and contact information of the investigator or research facility
    b. List the purpose of the research
    c. Summarize criteria used to determine eligibility for the study
    d. List the time commitment required of participants
    e. List the location of the research
    f. Not emphasize payments (example larger or bold type font, exclamation points)
    g. Not promise benefits or favorable outcomes other than what the protocol and consent list
    h. Not include exculpatory language that would indicate that the participant is waiving or appearing to waive rights or releasing the investigator from liability
    i. For email recruitment, include the subject line.
    j. Where possible, upload the document(s) in MS Word format

M. Under item 3, click add and upload all surveys, instruments, scales, measures, interview questions, other study items that the participant will view or hear, and letters of support. The following are general guidelines:
    a. If you are conducting online research and plan to present the consent form as question 1 of the survey instrument, leave a placeholder in the survey document "Q1 Contents of Consent form". Do not include the actual language from the consent form for the purpose of your IRB application but do include this language when you are conducting your study.
    b. If your study requires translation of documents into another language, do not attach the translated versions until your IRB reviewer requests them.
    c. Where possible, upload the document(s) in MS Word format
    d. Instruments need to be the version that the participants will view. If you are adapting an existing instrument, be sure to only include the information that you will present to participants.

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

O. 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.

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.

Q. The application will ask if you are including international participants and to provide the additional documentation needed for international research. Refer to [Guidance – IRB G1 – International Research Guidance Document.pdf](#)

3. **Required Training**

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

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

   See [Guidance-IRB G4-CITI Training](#) for details about how both internal and external 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 CITI training must have completed the training prior to the next step.

4. **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.**
   B. **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.

5. **Responding to reviewer requests for clarification**

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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:

A. 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.**
B. Prior to uploading the revised version, be sure you have saved the document in MS Word format and removed track changes and comments.
C. Finalize the application again and have the PI click the "**Submit Response**" link.

6. Accessing your IRB outcome letter and approved study documents

After the review process is complete, you will be issued an outcome letter which will be located on the top right side of your study dashboard. This letter indicates the review level of your study and signifies that you can begin human subject research activities.

You can find your study documents under the Documents tab on your study dashboard. Use only the **LAST FINALIZED** version of the documents. If your study includes a consent process, the finalized version of the consent form will contain a timestamp of the approval date.