ICON
Integrated Compliance Oversight Network

UNIVERSITY of HOUSTON

DIVISION OF RESEARCH
Institutional Review Boards

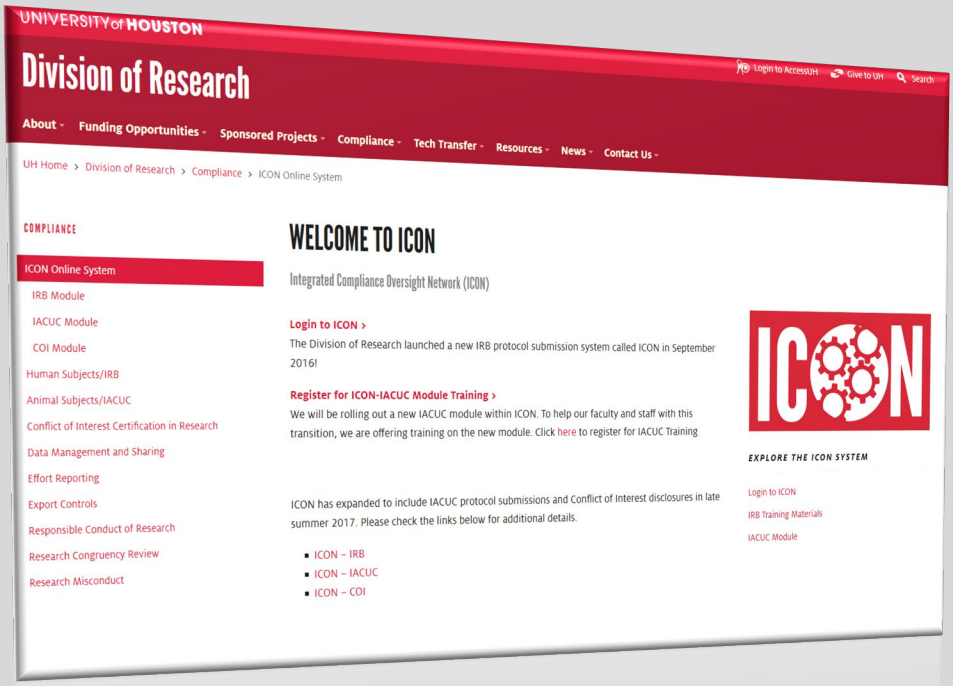
ICON User Guide

Research Teams and Ancillary Reviewers

Contents

Accessing the ICON System

- To access the ICON System, click the following link:
- http://icon.research.uh.edu/
- Access the ICON system using your UH CougarNet ID and password. Links to ICON are also located on the AccessUH Website and the Division of Research Website.



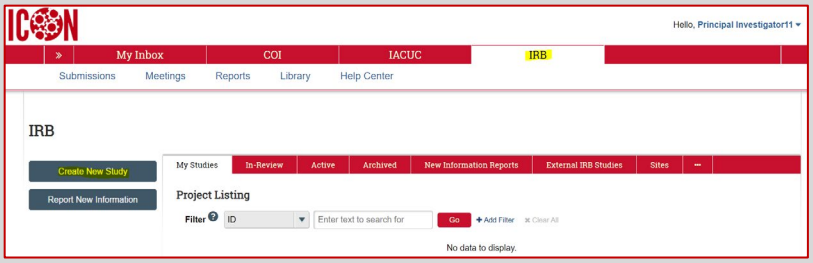
Exercise Instructions

- This document contains exercises for the IRB software training course.
- The exercises don't list every single step that you must perform in the system to accomplish a given exercise. Refer to the Division of Research Website for IRB Training Materials.
  - http://www.uh.edu/research/compliance/icon/

Exercise #1: Create a Study

Steps

- **To create a study:**
  - Log in as PI.
  - The system will automatically direct you to the "From My Inbox."
    - Please navigate to the header titled "IRB."
    - Then click "**Create New Study"** and complete the study pages as follows. Answer all other required fields as you like.
    - Below the buttons you will use are highlighted to help guide you:

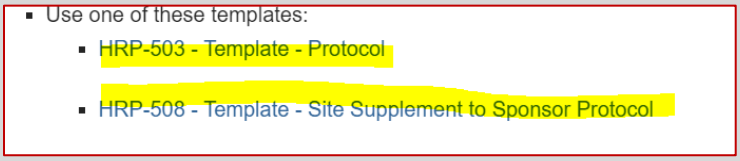


- **Basic Information page:**
  - **Complete questions 1 through 8. Below are tips to assist you in completing these questions:**
- **2. Short title:** This title appears in the inbox or the search pages. Can be the same as the actual title or an abbreviated version of the title
- **3. Brief Description:** Please provide a general summary of your study within this section.
- **4. Principal Investigator:** Your name defaults as PI. Do not change if you are completing the application as the PI.
- **5. If subjects will take part research procedures on the UH campus…:** if no subjects are taking part in research procedures on campus please type "Not Applicable" in this section.
- Below, is a screenshot on how to select the "not applicable" option.

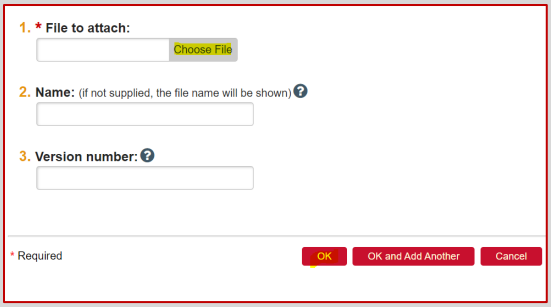
- **6. Does the investigator have a financial interest related to this research?** If an individual has a financial interest, a review by the UH COI office is required. If a plan to manage the conflict has already been approved by the institution, provide a copy of the signed management plan using the Supporting Documents Page, which appears later in the submission process.
- **7. Will an external IRB act as the IRB of record for this study:** Relevant if you are doing a reliance agreement in which the other IRB is already has granted approval to the main study.
- **8. What kind of study is this?** This question is based upon the institution in which the PI(s) are located. If you are the only PI, then UH is the single site. If you are collaborating with other institutions that are engaged in research, then the other responses may be relevant

- Multi-site study (More than one site will conduct the entire study)
- Collaborative study (each site will conduct a portion of the study)

- **9. Attach the protocol:** Add a document. Protocol templates are available below to serve as a reference. The two possible protocol templates are provided below:

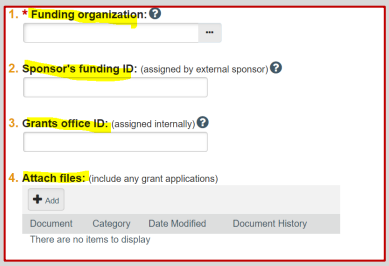


- Below the buttons that are used to upload the protocol are highlight. **Please note** if you do not type anything in the name or version sections the system will default to the name of the file you are uploading.

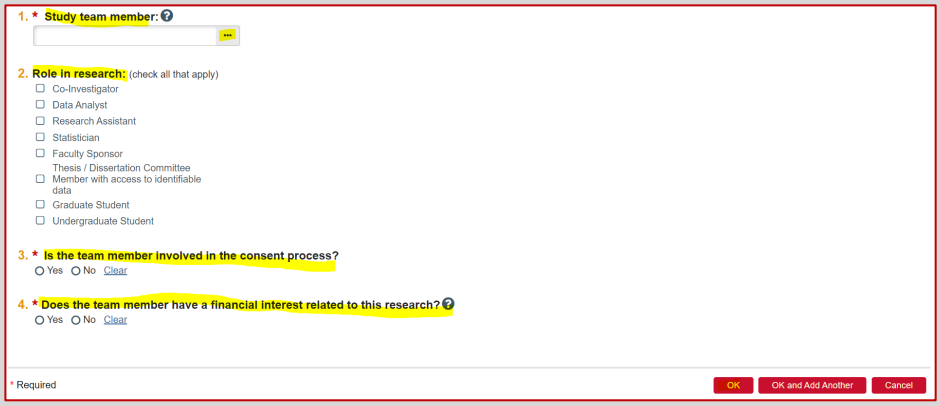


- **Funding Sources page:**

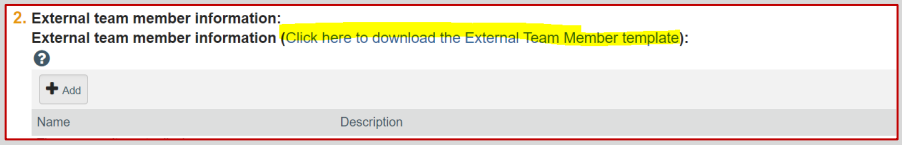
- Identify each organization supplying funding for the study:
- If your study is funded, please list the name in the section “Funding Organization.”
- If you have a grant ID number, please provide it in the section labeled “Grant Office ID.”
- If your study is utilizing a sponsor and you have a sponsor funding number, please provide the number in the section titled “Sponsor’s Funding ID.”
- If you have a copy of the grant or any supporting documents related to funding, please provide the documents in the sections titled “Attach Files”.
- If your funding agency is not listed, please contact our office.
- If you **do not** have a sponsor, grant, or other external funding, click “Add” and search for “Unfunded”. If your funding agency is not listed, please contact our office.
- Below are the buttons (highlighted) you will use in this section to help guide you:



- **Study Team Members page:**
  - **1. Identify each additional person involved in the design, conduct, or reporting of the research:** Section 1 is for all study team affiliated with the University of Houston. Only list people that are engaged in the research conduct. Below, the buttons you will use and the sections you need to complete are highlighted to help guide you.

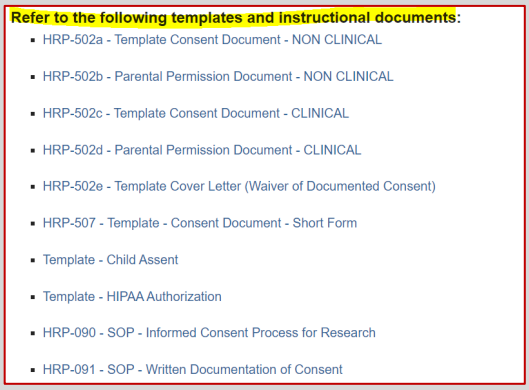


  - **2. External Team:** Download the template to add any non-UH team to the protocol.
  - Below, the UH External Team template is highlighted to help guide you.



- **Study Scope page:**
  - **1-4. Smart Form questions:** If your response is a “yes” to any of the questions on this page, new questions may appear or additional pages in the application will be added.
  - **1. Are there other research sites where the investigator will conduct or oversee the research?** Research sites are sites outside of UH that are collaboratively engaged in the research. For example: colleges/universities, clinical practices, hospitals, schools, or other entities that may receive federal funding for research - either directly or through a subaward. Members of the study team conducting research at these sites must be included on the external team member document on the "Study Team Members" page.
  - **2-3: Investigational Drugs or Devices:** Does the protocol require one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care; or evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

- **Local Site Documents page:**
  - **1. Consent forms:** Add only consent related documents to this section.
  - Below, the consent templates are highlighted to help guide you:



  - **2. Recruitment Materials:** Add only recruitment related materials (such as social media recruitment scripts, flyers, SONA Scripts, audio or video recordings, etc.) to this section.
  - **3. Other Attachments:** Any study related documents that have not been uploaded at this point should be added here.
  - On the last page, click Finish to exit the study.
  - Confirm you met the success criterion below.

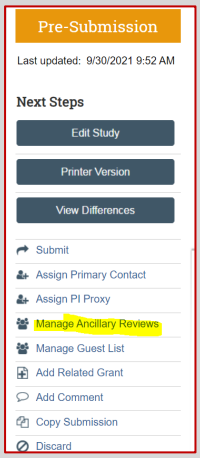
Success Criterion

- No errors displayed when the “Finish” button was clicked.
- The study is still in Pre-Submission State.
- The submission you just created appears in the PI’s Inbox.

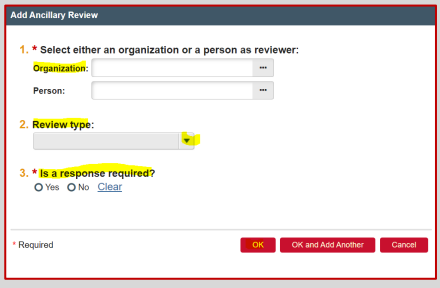
Exercise #2: Obtain Department Chair and/or Dean Sign Off and Submit a Study

Steps

- **To submit the study:**
  - **Please Note:** Before the study can be submitted, the PI needs Department Chair or Dean sign off. If PI is a student, the Faculty Sponsor is required to submit an ancillary review in addition to the Department Chair or Dean.
  - Click **Manage Ancillary Reviews** under My Current Actions.
  - Below, the button you will use is highlighted to guide you.



  - Click the **Add** button. Enter the name of the Dean or Department Chair in the "Person" field. Organization is only required if needing Biosafety, Radiation Safety, or Optometry review.
  - Indicate the Review Type as **Department** for the Department or College Approval and **Faculty Sponsor** for Faculty Sponsor Approval (if applicable).
  - Indicate that the Review is required and click OK.
  - Once reviews are accepted, click **Submit** under My Current Actions. The system checks for missing information and errors.
  - Click **OK** to verify your intent to conduct the research appropriately.
  - Confirm you met the success criteria below.
  - Log off the ICON system.
  - All the buttons you will use in this process is highlighted below to help guide you:



Note: The PI can assign a PI Proxy to submit the study on his/her behalf. The PI is the only member of the study team that can assign a proxy. Please refer to the reference guide on instructions on how to do that.

Once Department Chair / Dean or Faculty Sponsor approval has been received, the study is ready to submit to the IRB for review. Only the PI can submit the study. Other study team members can create and edit the study, but the PI must sign off each time the study is submitted to the IRB.

Note: PIs can keep track of approval from Department Chair and/or Dean, or Faculty Sponsor under the Reviews tab of the protocol workspace. No automated alerts will be sent to the PI.

Success Criteria

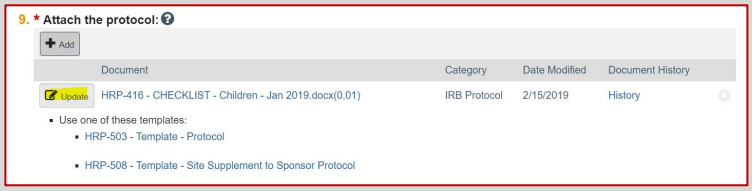
- The study has moved to the **Pre-Review** state.
- The study's History tab shows the Submitted activity. Notice also:
  - The list of activities has changed and Submit is no longer available.
  - The edit study button has changed to View Study.
  - The study no longer appears in your ICON inbox.

Exercise #3: Respond to Clarification

Steps

- **To respond to a clarification request:**
  - Please Note: This guide provides an overview of how to respond to stipulations/modifications in the new IRB system ICON, for stipulations / modifications requested in ICON.
- Click the **IRB** dropdown menu on the left navigation bar.
- Under the "In Review" tab, you will find protocols in Modifications Required state. Click on the protocol name. The protocol workspace will open.
- Below, is a screenshot of the buttons you will use to guide you:

- Once the workspace opens, you will be on the "History" tab. Locate the clarification request listed in the history or a PDF document letter with a list of changes.
- Once you have reviewed the IRB letter you can make edits to the study and related documents.
- Click the Edit Study button to open the SmartForm.
- Go through each page editing the SmartForm or uploading new or revised documents clicking Continue to move through the submission form.
- When revising a document, make the changes to the current version of the document. Locate the document in ICON. Click the **Update** button next to the most recently reviewed version in ICON. Search your computer for the revised version. Click **OK** to replace the previous version of the document. Click **Continue** to save.
- Below, I've provided a screenshot of the button you will utilize to upload a document:



- On the last page, click **Finish** to exit the study.
- Return to the workspace and click the **Submit Response** button to re-submit your protocol for IRB review.
- Click **OK** to verify your intent to conduct the research appropriately.
- Confirm you met the success criteria below.
- Log off the IRB system.

Note: There can be multiple clarification requests and responses to IRB review prior to final approval. Please allow 7 – 10 business days from each time you submit to receive a response from the IRB or final approval.

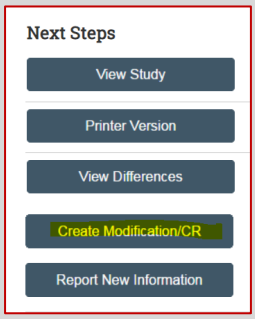
Success Criteria

- The study has moved back to the **Pre-Review, IRB Review, or Post Review** state.
- The study's History tab shows the Submitted activity. Notice also:
  - The list of activities has changed and Submit is no longer available.
  - The Edit Study button has changed to View Study.
- The study no longer appears in your ICON inbox.

Exercise #4: Submit a Continuing Review or Study Closure Report

Steps

- To submit a continuing review:
  - **Please Note:** Now, you will start a continuing review for the same study.
- Log in as PI.
- First you need to return to your approved study. From your inbox, click **Submissions** and then the **Active** tab. Open the study you wish to submit a Continuing Review or Closure.
- Click **Create Modification / CR**.
- Below, I have provided a screenshot with the button you will use highlighted to help guide you:



- Select **Continuing Review** and click **Continue**.
- Complete the Continuing Review/Study Closure page as follows:
  - **Specify Enrollment Totals:** Type numbers for all the spaces for the enrollment totals questions.
  - **2. Research milestones:** Select several answers based on the status of your study. If you are closing the study, be sure to select all of the first four answers. You will be prompted to confirm that you are closing the study.
  - **3. Do any investigators or research staff have a financial interest related to the research that was not described in a previous application or continuing review?** Select an answer.
  - **4. Check the items that are true since the last IRB approval (initial review or last continuing review) for all sites involved in the study:** Select the appropriate answers for question 4. (This question requires you to read carefully and select a check box for everything that does not apply. Explain anything left unchecked in an attached document.)
  - **5. Attach supporting documents:** Attach files to explain any boxes that were unmarked in section 4. See the help text (by clicking) for a list of all documents that should be attached.
  - **6.** Additional Comments: provide any additional details to clarify enrollment numbers, why the study is closing, or additional responses for unmarked items in section 4.
  - Click **Continue** and then **Finish**.

- Notice that a new study workspace and submission number was created specifically for this submission. All activities related to this submission will be done under this new submission number.
- Ancillary reviews are not required for CR or Closure submission. Click **Submit** then agree to the terms listed. Notice the breadcrumb at the top left that gives a link to the study before the name of the CR.
- Click the study link (in the breadcrumb trail at the top) to return to the study workspace.
- Click the **Follow-on Submissions** tab.

Note: Continuing Reviews, Modifications, and Reportable New Information are listed under the Follow-on Submissions tab. This is another way the study workspace is collecting all the information related to the study.

New information reports, CRs, and modifications all use a review process similar to the process for initial submissions. RNI has some other differences that will be mentioned later.

- Confirm you met the success criteria below.
- Log off the IRB system.

Success Criteria

- Open the CR you just created. The CR is in the **Pre-Review** state.
- The CR appears on the Follow-on Submissions tab of the original study. (From the breadcrumb trail, open the original study and then click the **Follow-on Submissions** tab.)
- The CR is no longer in your inbox.

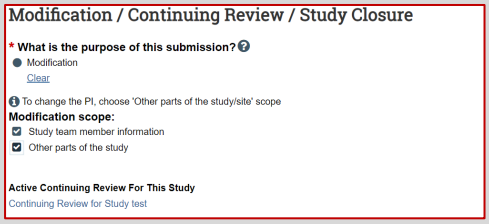
Exercise #5: Submit a Modification

Steps

- **To create a modification to the study:**
- Log in as PI.
- Open the original study from the Active tab on the IRB Submissions page (submissions shortcut).
- Click **Create Modification / CR**. If a CR already exists for this study, the system gives you a link to the CR and prevents you from creating another one.
- Select **Modification**.

Note: You can create a modification that changes only the study team, a modification that changes the rest of the study, or both. Since study team changes are quick to review and are reviewed administratively by IRB coordinators, these can be separated so their approvals are not slowed down by more complex modifications. Please make sure to mark the correct submission type, otherwise you will be required to discard the submission and start over.

- Select both **Study team member information** and **Other parts of the study**. Then, click **Continue** (screenshot below).

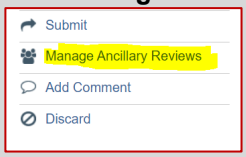


- Summarize the modifications by filling out the Modification Information page. Please provide specific details regarding what is changing, indicate what documents are new or revised, and provide a rationale for why the change is required.

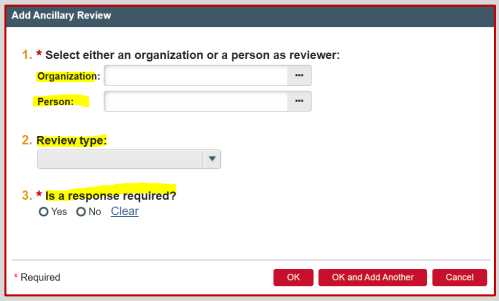
Note: In the summary, please do not make simple statement such as “We revised the Protocol.” Pleas describe what specific aspect of the protocol was revised; or say, “we added study team member.” Who specifically is being added and what it their role? Also provide a rationale for why the change is required.

- Click **Continue**. (Now you are placed into an independent, unlocked version of the study that is separate from the approved study. Your changes will appear on the approved study if the IRB approves the modification.)
- Attach new or updated documents in fields of your choice.
- If you are updating a document within the study, use the **Update** button to update the document rather than uploading a new one. By updating the document, you will retain a version history.
- Click **Continue** to move through each page of the form. On the last page, click **Finish** to exit the study.

- Click **Manage Ancillary Reviews** under My Current Actions (screenshot below).



- Click the **Add** button. Enter the name of the Dean or Department Chair in the "Person" field.
- Indicate the Review Type as **Department** for the Department Approval and **Faculty Sponsor** for Faculty Sponsor Approval (if applicable).
- Indicate that the Review is required and click **Ok** or **Ok and Add Another** if adding additional reviewers or organizations (screenshot below).



- Click **Submit** and agree to the terms listed. Type your PI username and password again. (Your modification summary information, along with the draft modified study, is submitted to the IRB for review.)
- Confirm you met the success criteria below.
- Log off the IRB system.

Success Criteria

- The modification is in the **Pre-Review** state.
- The modification appears on the Follow-on Submissions tab of the original study. (From the breadcrumb trail, open the original study and then click the **Follow-on Submissions** tab.)

Exercise #6: Submit Reportable New Information

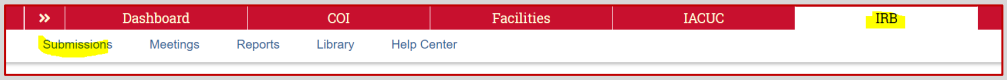
Steps

- **To submit a new information report:**
  - **Please Note:** You may have new information to submit about your study, about a group of studies, or about research in general at your institution. Any adverse event or reports of potential non-compliance need to be reported promptly, so it is important to know how to submit Reportable New Information.

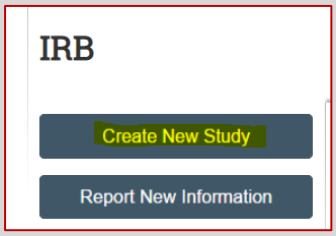
- Log in to ICON and click the IRB drop down menu.

Note: Notice the Report New Information button here. You can submit a report from My Inbox without relating it to a study or using the options within the report form to relate it to one or more studies or follow-on submissions. Because the new information is specifically related to your study, you'll submit the new information report from the study itself. Notice that the study is not in your inbox. It doesn't currently require any action from you, so you will have to locate it in a list of active studies.

- Click the Submissions shortcut, and then click the Active tab to find research that is approved.
- Below I've provided you a screenshot of the buttons you will use:



- Open the study.
- On the left, click **Report New Information** (screenshot below).



- **1. RNI short title:** Fill in a title for your RNI to be used to identify the RNI.
- **2. Date you became aware of the information:** Fill in appropriate date.
- **3. Identify the categories that represent the new information:** more than one box could apply.
- **4. Briefly describe the new information:** Type a brief description of what occurred and the likely relationship to the research and if any actions are proposed to correct or follow-up on the problem.
- **5. In the submitter's opinion:**
  - Does this information indicate a new or increased risk, or a safety issue? Select Yes or No.
  - Does the study need revision? Select Yes or No.
  - Does the consent document need revision? Select Yes or No.
- 6. Related studies and modifications: You have an opportunity to add other studies that may have similar issues (screenshot below). Your study is already included in the list because you created the report from its workspace.

Note: If you are creating an RNI for a study that you are not listed as PI or as Study Team, you will not be able to link the RNI to another submission. Anyone who has access to ICON can submit an RNI.

- **7. Attach files containing supporting information:** You can attach a file to explain the situation more thoroughly or as supporting documentation.
  - **Click Continue on the right. You are taken to the RNI workspace. (As usual, the information is not sent to the IRB until you submit it. Ancillary reviews are not required for an RNI submission.**
  - Click **Submit RNI**.
- Confirm you met the success criterion below.
- Log off the IRB system.

Success Criterion

- The RNI is in the **Pre-Review** state.
- The RNI appears on the New Information Reports tab of the IRB Submissions page (submission's shortcut).

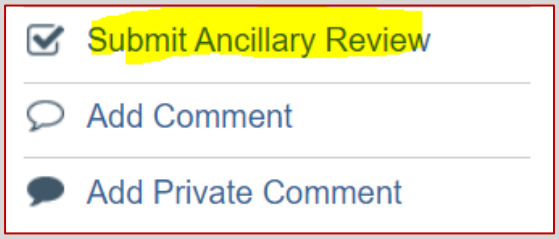
Exercise #7: Submit your Ancillary Review

Steps

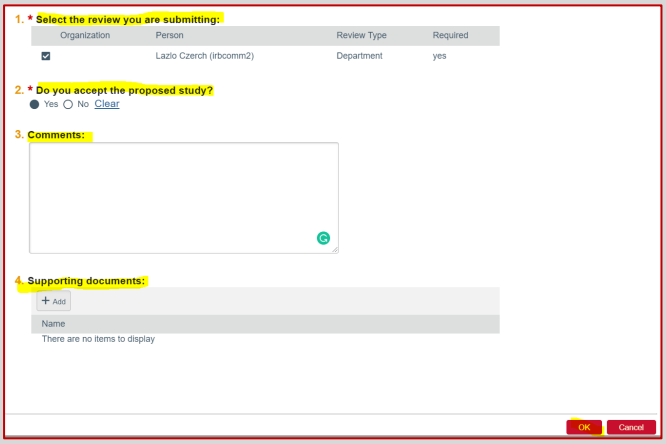
- **To submit an ancillary review:**
  - Now that the review has been requested, we will login as the ancillary reviewer and complete the review
- Log in to ICON.
- The protocol waiting for review should appear in your inbox.
- Click on the protocol name to access the workspace.
- You can use the **View Study** button to browse through the protocol.
- On the protocol workspace, review the **Funding** tab which will provide sponsor information.
- The **Projects Contacts** tab will display all the research staff.
- The **Documents** tab will contain all the documents that have been uploaded by the research staff as part of protocol build.

Note: Document's tab will contain the Protocol document, consent forms etc.

- The **Training** tab will display CITI training information of study team members listed on the protocol.
- Once you have reviewed the protocol, click the **Submit Ancillary Review** activity (screenshot below).



- Click **Yes** or **No** whether or not you approve the study submission.
- Provide **Comments** supporting your decision.
- Complete the activity form and **Approve** the protocol.
  - Below, is a screenshot of all the button you will utilize in this process to help guide you:

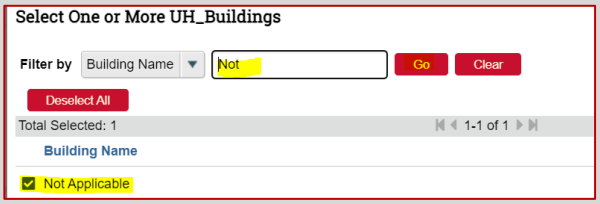


Success Criterion
▪ The protocol is in **Pre-Submission** state. ▪ The **Reviews** tab is populated with your review. ▪ The **History** tab is updated. ▪ The study will no longer be in your ICON Inbox.

Exercise #8: External Study Submission

Steps

- **To create the external IRB steps just as creating a regular study:**
  - Log in as PI.
  - From My Inbox, click **Create New Study** and complete the study pages as follows. Answer all other required fields as you like.
  - **Basic Information page:**
    - **Short title:** This title appears in the inbox or the search pages. Can be the same as the actual title or an abbreviated version of the title
    - **Principal Investigator:** Your name defaults as PI. Do not change if you are completing the application as the PI.
    - *** If subjects will take part in research procedures on the University of Houston campus, specify applicable building(s). If not, please select "Not Applicable."** Below, is a screenshot of the button you will use to indicate "Not Applicable."



    - **Does the investigator have a financial interest related to this research?** If an individual has a financial interest, a review by the UH COI office is required. If a plan to manage the conflict has already been approved by the institution, provide a copy of the signed management plan using the Supporting Documents Page, which appears later in the submission process.

Note: The following questions makes the difference: External IRB/Single IRB-

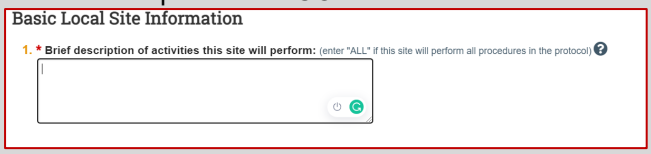
- **7. Will an external IRB act as the IRB of record for this study:** Relevant if you are doing a reliance agreement in which the other IRB is already has granted approval to the main study. This must indicate "yes." A screenshot is provided below to help you find this question.

- **8. What kind of study is this?** This question is based on both institutions. If you are collaborating with other institutions that are engaged in research, then the other responses may be
  - Multi-site study (More than one site will conduct the entire study)
  - Collaborative study (each site will conduct a portion of the study)
- **9. Attach the protocol:** Add a document (The protocol that you upload should be the protocol approved by the other institution).

- **Basic Site Information:**
  - ***Brief description of activities this site will perform:** (enter "ALL" study activities the UH site will perform) In a few words, summarize your activities as a participating site in this multi-site or collaborative research study. If your site will be conducting all portions of

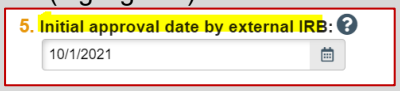
the research, type “ALL.” If your site will be conducting only certain portions or the research, include a summary.

- Below is a screenshot of this question in ICON:



- **External IRB**
  - **External IRB:** Select the IRB outside your institution that will act as the IRB of record for this study. If you cannot find the external IRB in the list, contact your institution's IRB for assistance.
  - **External study ID:** The external study ID is the ID number assigned to this study in the system of the institution responsible for its IRB review.
    - You can use the external study ID as a reference when you correspond with the external IRB review institution.
    - If the study has the same ID in your local system and in the external IRB system, you can leave this field blank.
    - **For a multi-site study:**
    - The external study ID is the ID assigned to this study by the sIRB.
  - **3.* Specify the reason the study should be reviewed by an external IRB:** Clearly discuss all aspects of UH’s role in the research. *If funding is involved for your portion of the study, please explain who primary and secondary recipients is.
  - **4. Approval letter from external IRB:** Upload the approval letter from the external IRB.
  - Below the button you will use (highlighted) to upload the document:

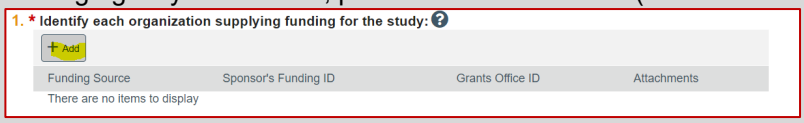
  - **5. Initial approval date by external IRB:** Enter the date the external IRB issued its very first approval of the study. Do **not** update this date when the external IRB approves an extension of the approval period. Only change it if necessary, to correct an error. Below, is a screenshot of the question (highlighted) that need to be completed:



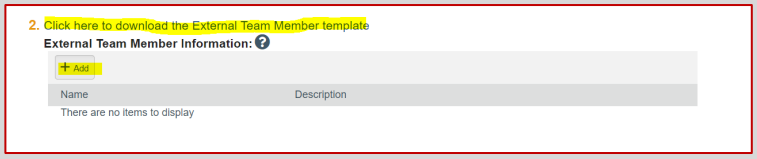
  - **6. Last day of approval period:** Record the last day of the approval period for the study communicated to you by the external IRB.
    - For a study:
    - This date will be used to send out Continuing Review reminder notifications. If the date is not populated, Continuing Review reminder notifications will not be sent.
    - For a participating site in a multi-site or collaborative study:
    - This date will be used to send out Continuing Review reminder notifications if Last Day of Local Site Approval Period is not populated. If neither Last Day of Local Site Approval Period nor Last Day of Study Approval Period is populated, Continuing Review reminder notifications will not be sent.
    - Below the button you will use (highlighted) to upload the document:

- **Funding Sources page:**

- **1. Identify each organization supplying funding for the study**: If you do not have a sponsor, grant, or other external funding, click "Add" and search for "Unfunded". If your funding agency is not listed, please contact our office (screenshot below):



- **Study Team Members page:**
  - **1.** Identify each additional person involved in the design, conduct, or reporting of the research**: Section 1 is for all study team affiliated with the University of Houston. Only list people that are engaged in the research conduct.**
  - **2. External Team:** Download the template to add any non-UH team to the protocol.
  - Below, the template up upload button are highlighted:



- **Study Scope page:**
  - **1-3. Smart Form questions:** If your response is a "yes" to any of the questions on this page, new questions may appear or additional pages in the application will be added.
  - **1-2: Investigational Drugs or Devices:** Does the protocol require one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care; or evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?
  - **1. *Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?** "Specify the evaluation of" means the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of the overall study design/hypothesis/evaluation, regardless of whether its use is considered standard of care.
  - **2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
  - **3. * Does the research require access to/use of Protected Health Information from a HIPAA-covered entity?**
- **Study-Related Documents page:**
  - **1. Consent forms:** Add only consent related documents already approved by the institution
  - **2. Recruitment Materials:** Add only recruitment related materials already approved by the institution.
  - **3. Other Attachments:** Any study related documents that have not been uploaded at this point already approved by the institution.
  - **Local Site Documents page:** Relevant only if your site institution has developed documentation related to Consent forms, Recruitment Material, and Other attachments.
  - On the last page, click **Finish** to exit the study.
  - Confirm you met the success criterion below.

Success Criterion

- No errors displayed when the "Finish" button was clicked
- The study is still in Pre-Submission State
- The submission you just created appears in the PI's Inbox.

- Add ancillary reviewers, wait for at least one faculty sponsor (if you are student) and one departmental chair/dean.
- After you click submit the study will no longer be in your ICON Inbox.