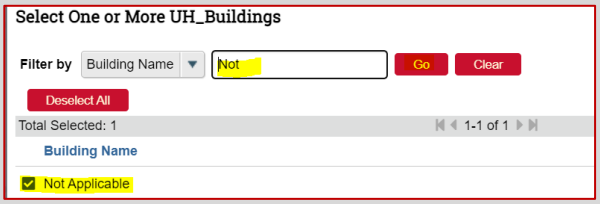
Exercise #8: External Study Submission

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-

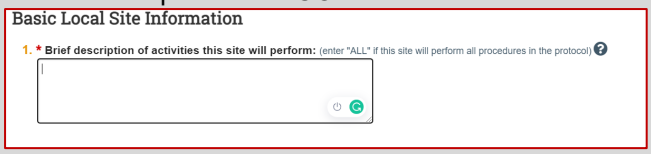
- **7. Will an external IRB act as the IRB of record for this study:** Relevant if you are doing a reliance agreement in which the other IRB is already has granted approval to the main study. This must indicate "yes." A screenshot is provided below to help you find this question.

- **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

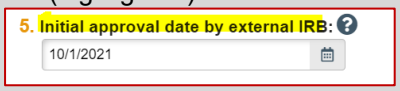
the research, type “ALL.” If your site will be conducting only certain portions or the research, include a summary.

- 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:

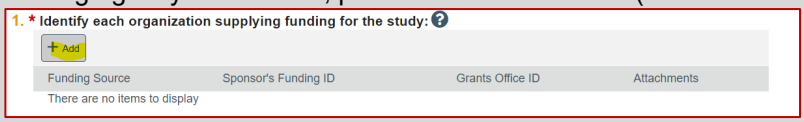
  - **5. Initial approval date by external IRB:** Enter the date the external IRB issued its very first approval of the study. Do **not** update this date when the external IRB approves an extension of the approval period. Only change it if necessary, to correct an error. Below, is a screenshot of the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



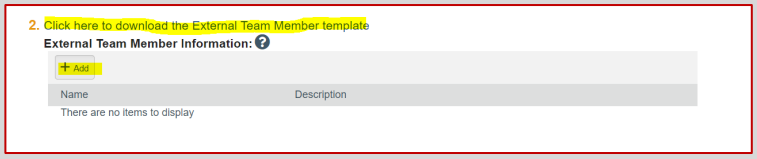
  - **6. Last day of approval period:** Record the last day of the approval period for the study communicated to you by the external IRB.
    - For a study:
    - This date will be used to send out Continuing Review reminder notifications. If the date is not populated, Continuing Review reminder notifications 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.