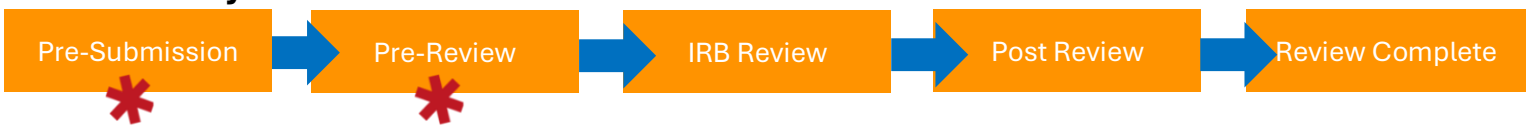
New Study Submission Workflow



At minimum, there are four (4) parts to complete to Submit a New Study to the VU HRPP Office:

1. Complete all six (6) SmartForms (File in state: **Pre-Submission***)
2. **Manage Ancillary Review** to Department Chair or Department Chair Proxy for Approval
3. If the PI is a student, **Assign PI Proxy** (this will be the student's faculty advisor)
4. Click on the activity: **Submit** to officially send the submission to the IRB Office for review (state changes to: **Pre-Review***)

Back to Guide List

GUIDE

Step 1 – Getting Started

↓

Step 2 - SmartForms

- Basic Study Information SmartForm
- Study Funding Sources SmartForm
- Local Study Team Members SmartForm
- Study Scope SmartForm
- Local Research Locations SmartForm
- Local Site Documents SmartForm

↓

Step 3 – Manage Ancillary Review to Department Chair

↓

Step 4 – Assign PI Proxy (if applicable)

↓

Step 5 – Submit to VU IRB/HRPP office

↓

New Study Submitted

Miscellaneous Activities available on the Main Workspace of the New Study

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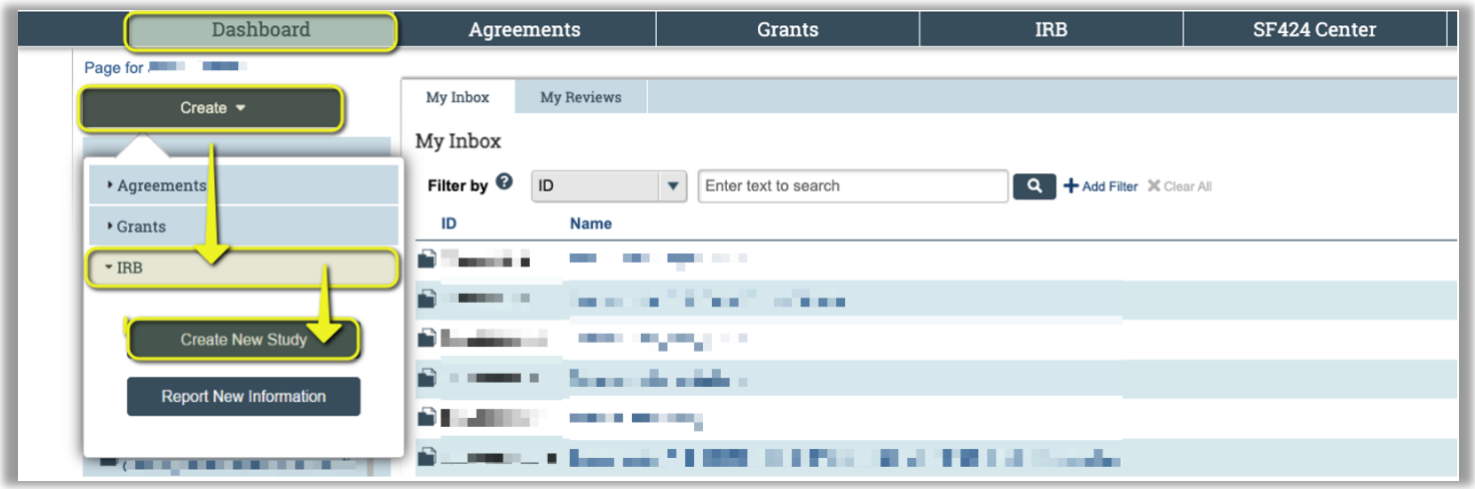
Back to Guide List

STEP 1

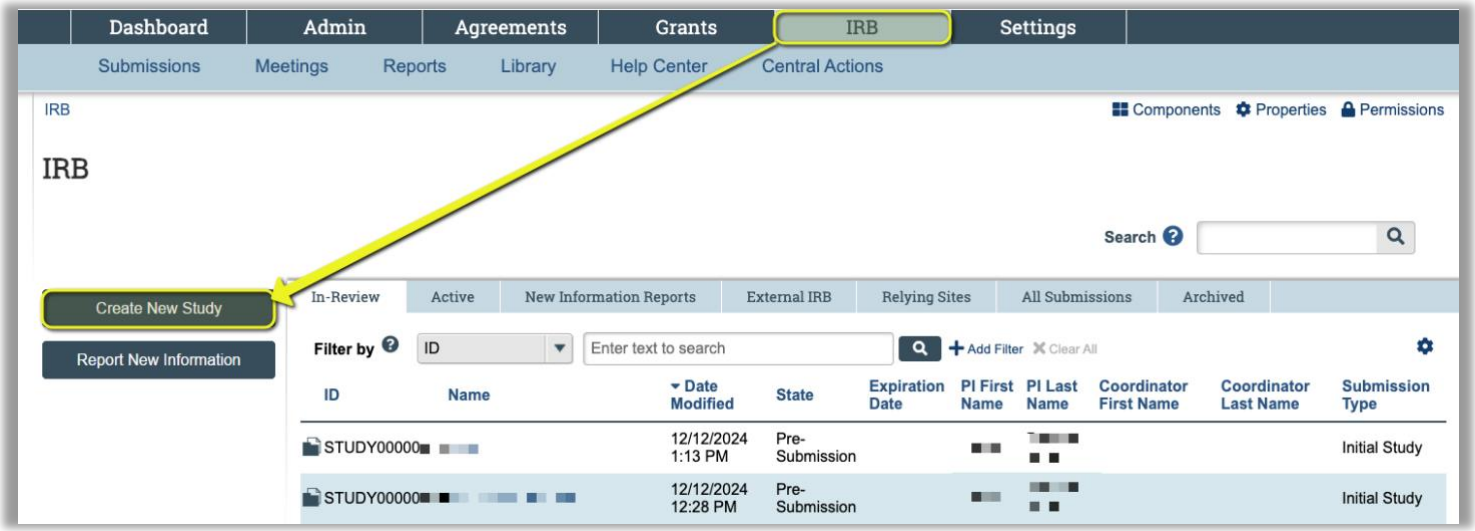
Log into **VERA** (https://vera.vanderbilt.edu/)

There are two (2) places from which to **Create a NEW Study**:

1) From the **Dashboard**, click on the blue action button (drop-down options): **Create** > **IRB** > **Create New Study**



2) From the **IRB Main Workspace**, click on blue action button: **Create New Study**

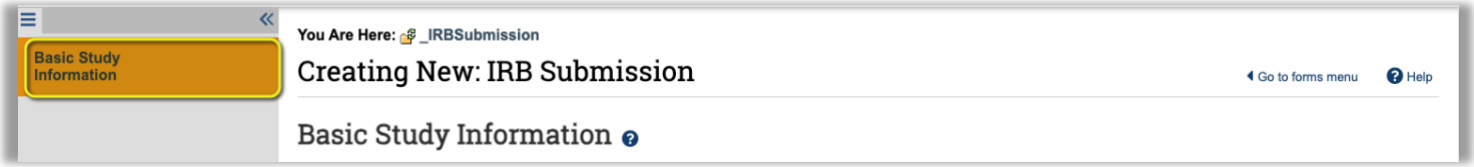


Back to Guide List

STEP 2 - SmartForms

From here, you begin entering the New Study information into VERA IRB. Make sure you have all necessary materials regarding the study available.

The first SmartForm for a New Study opens: **Basic Study Information SmartForm,** complete all items available.



Please note that * indicates a response is required and you cannot continue to the next SmartForm without providing a response. All items are required in this SmartForm.

Item 1. * Title of study: Enter the Title of the Research Study. For federally funded studies, the study title should match the sponsor award title.

Item 2. * Short title: Enter a shortened study title. It must not exceed 50 characters. The short title should reflect the following format: "PI Last Name_Department_Shortened Study Title"

Example: "Smith_SON_Cognitive Identity"
Note: the short title identifies the study throughout the VERA IRB system, such as in your VERA Inbox and in the IRB's list of submissions to review.

Item 3. *Brief description: Provide a brief summary of the research study in lay language. This should be no longer than a few sentences.

Summarize:

- The central question the research is intended to answer
- The primary objectives
- The methods used

Example:
"This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine..."

Item 4. * What kind of study is this?: Choose either: 1) Multi-site or collaborative study, **or** 2) Single-site study

A **multi-site or collaborative research** study is one where two or more institutions collaborate to complete the research outlined in a specific protocol. Note that a study that utilizes one or more research locations at your institution would likely not be considered a multi-site or collaborative research study in this system. For example, conducting research at a VU residence hall and a VU dining hall would be considered a single-site study where all research activities occur at this one institution (VU). Please contact the VU HRPP office at irb@vanderbilt.edu for any questions about single site and multi-site/collaborative research.

Item 5. * Will an external IRB act as the IRB of record for this study?: Choose 1) YES or 2) NO

For a multi-site study (MSS):

- Select Yes if an IRB outside your institution will review this study and decide whether to approve it—with permission from the local (your institution's) IRB. For example, if you are a participating site in an MSS, select Yes.
- If you are the sIRB of record for a multi-site or collaborative study, select No.

Back to Guide List

Item 6. * Local principal investigator: Manually select the PI for this research study. The PI is responsible for the compliant and ethical conduct of the research study.

Note:

- The Local PI field defaults to whomever is logged in and completing this SmartForm. It is editable for you to change the PI to anyone who is listed in the VU Oracle HR feed.
- Select the local principal investigator for this study or participating site. If this is a multi-site or collaborative research study for which your IRB will be serving as the IRB of record, then select the name of the principal investigator responsible for the entire conduct of the study. You will enter individual site principal investigators on the site records.

To Edit the Local PI Field:

- Click on the (blue circle with white x), which clears the textbox.
- Enter percent sign (**%**) then the last name of the person who is the PI (example: "%mckay").
  The **%** is the "**wildcard**" for searching in VERA when there is a text box with a data feed populating the responses.

Item 7. * Does the local principal investigator have a financial interest related to this research?: Choose YES or NO

For more guidance on financial interest, refer to *the* VU Office of Conflict of Interest and Commitment Management website for more information related to Financial Conflict of Interest (FCOI).

Important! If an individual has a financial interest, provide a copy of the Conflict of Interest Committee's determination regarding the interest. Attach a copy of the COI Committee's determination and/or COI management plan (if applicable) using the **Local Site Documents SmartForm**, which appears later in the submission forms.

Item 8. * Attach the protocol: Researchers are required to attach a research protocol in Word format here. The Protocol Templates can be found on the VU HRPP's website.

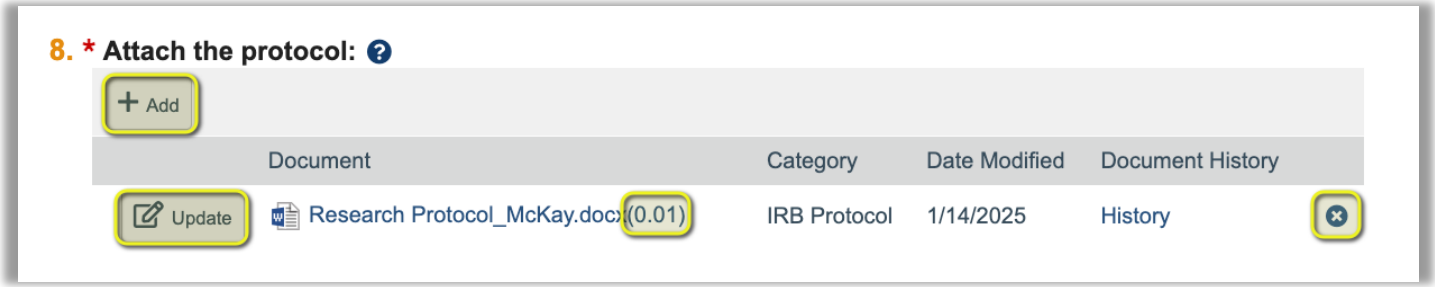
- Please do not attach your grant proposal here.
- 118 Determination Requests: Complete the *HRP-902-118 Determination Request Form* found on the VU HRPP's website and attach it here.
- Note: For industry-sponsored or multi-site research, attach the sponsor's protocol and a site supplement. A site supplement usually describes any local variations to the protocol being performed at this institution.

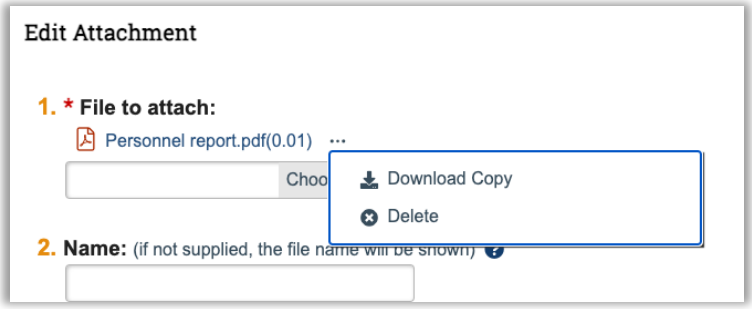
1. Click on the "**+Add**" gray button to attach the Protocol.
   a. An "Add Attachment" pop-up window opens:
      i. **Item 1. * File to attach**: Click on "Choose File" to search for and attach the research protocol in Word format.
      ii. **Item 2. Name** (if not supplied, the file name will be shown) Be sure the document is clearly labeled as a research protocol. Example: "Research Protocol_PI Last Name".
      iii. **Item 3. Version number is optional.**

Back to Guide List

Once you attach a document, it is visible under **Item 8.** Each attached document will have an "**Update**" button and a "Delete" button.

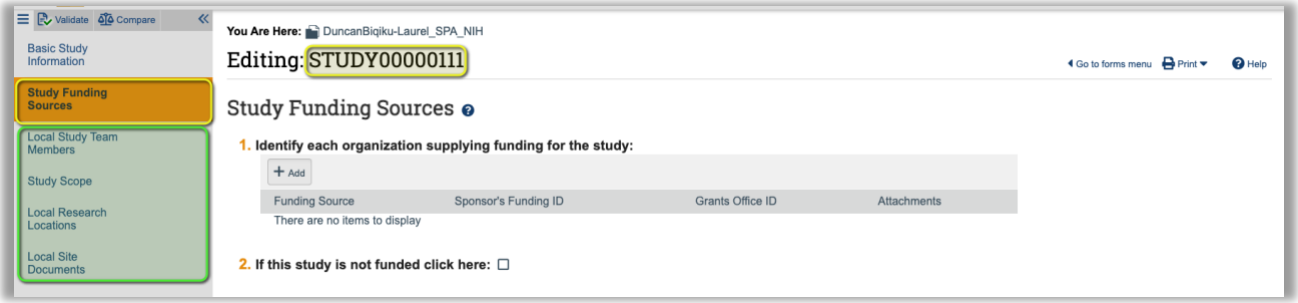
- You are able to "**Delete**" an attachment.
- When you click on "**Update**" – an "**Edit Attachment**" pop-up window opens.
  - Clicking on the "**...**" next to the file's name, gives you two (2) options: (1) Download Copy or 2) Delete.





Click CONTINUE. Be sure to have provided an answer to all eight (8) items.

- This saves the SmartForm information, moves you to the next SmartForm, and assigns the New Study an ID (e.g., **STUDY00000111**).
- SmartForms are listed on the left side.



Back to Guide List

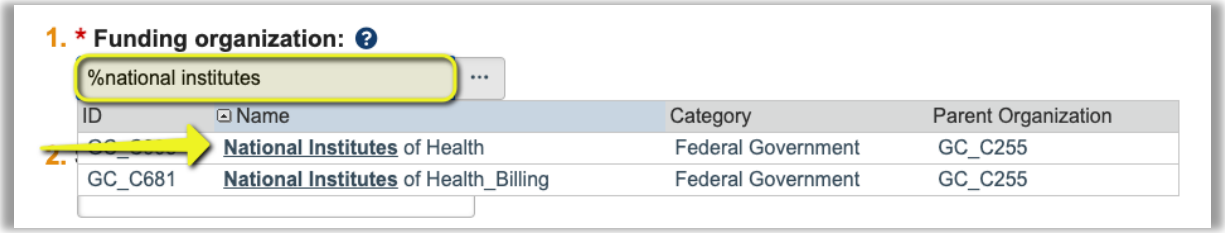
The second SmartForm for a New Study opens: **Study Funding Sources SmartForm,** complete all items available.

Item 1. Identify each organization supplying funding for the study:

- Click on the "**+Add**" gray button to add each funding source.
  - Complete the four (4) questions for each funding source in the pop-up window.
  - Identify all external and internal funding sources.
    - 118 Determination Requests: Funding information and a grant proposal is required to be included here. See *118 Determination / Just in Time (JIT) Guidance* Document found on VU HRPP's website.
- Once all funding sources are listed, you will see them listed under the "**+Add**" button.

Question 1. * Funding organization: This item is a text box field.

- Search through all the organizations available through Oracle.
  - Enter "**%**" plus the beginning of the organization's name to search for and choose each individual funder.
- If your funding source is new and does not appear on the list, **contact the VU HRPP** at irb@vanderbilt.edu.



Question 2. Sponsor's funding ID: (assigned by external sponsor) – enter the Sponsor's ID/Award #.

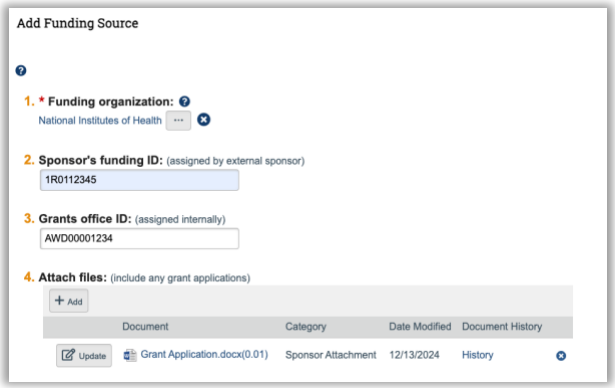
Question 3. Grants office ID: (assigned internally) – enter the VERA Award ID #. For example: AWD00001234.

Question 4. Attach files: (include any grant applications)

- Click on "**+Add**" button.
- Complete the three (3) items for each attachment added in the pop-up window.

Item 1. * Files to attach: Click on "Choose File" to search for and attach relevant documents.
Item 2. Name (if not supplied, the file name will be shown)**:** Optional.
Item 3. Version number: Optional.

- Click on **OK** or **OK and Add Another**. Using **OK and Add Another** saves you a few clicks when adding multiple attachments.



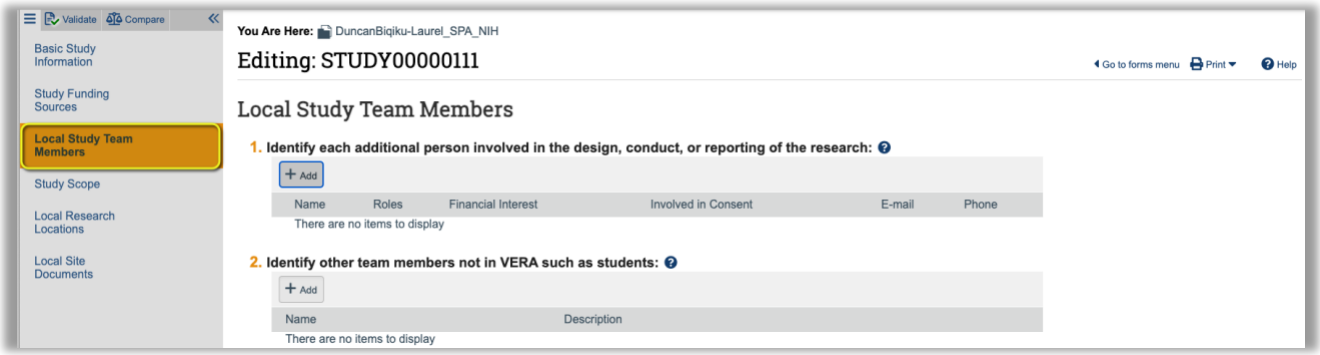
Item 2. If this study is not funded, click here: ☐

- ☐ Check the box if the study is not receiving any funding.

Click CONTINUE to move to the next SmartForm.

Back to Guide List

The third SmartForm for a New Study opens: **Local Study Team Members SmartForm.** Complete all items.



Item 1. Identify each additional person involved in the design, conduct, or reporting of the research:

- Click on the gray "**+Add**" button.
  - Complete four (4) questions about each person added in the "**Add Study Team Member**" pop-up window.
  - Do not add the PI here.
- **Note:**
  - Multi-Site Study: Both sIRB and participating site institutions should only include information about team members at your local institution. Other sites involved in the multi-site study will add their own information about local study team members.
  - Do not add the study's primary contact person for IRB communications here unless the person is also engaged in human research. The person who creates the study in the IRB system is assigned as the primary contact by default, and can be changed later using the **Assign Primary Contact** activity.
  - If you have difficulty finding the person on the list, type the beginning of the first or last name. Contact the VU HRPP staff for assistance at irb@vanderbilt.edu if a person is not listed in the system.

Item 1. * Study team member:

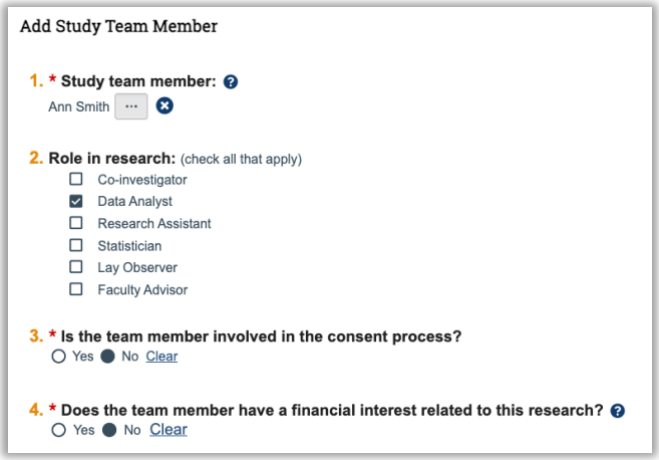
- Enter "**%**" and the **Last Name** for the study team member you are adding

Item 2. Role in research: (check all that apply)

- Check this study team member's role(s):

OPTIONS:

- Co-investigator
- Data Analyst
- Research Assistant
- Statistician
- Lay Observer
- Faculty Advisor



Item 3. * Is the team member involved in the consent process: Choose YES or NO

Item 4. * Does the team member have a financial interest related to this research: Choose YES or NO

- For more guidance on financial interest, refer to *the* VU Office of Conflict of Interest and Commitment Management website for more information related to Financial Conflict of Interest (FCOI).

- Click on **OK** or **OK and Add Another**. Using **OK and Add Another** saves you a few clicks when adding multiple study team members.

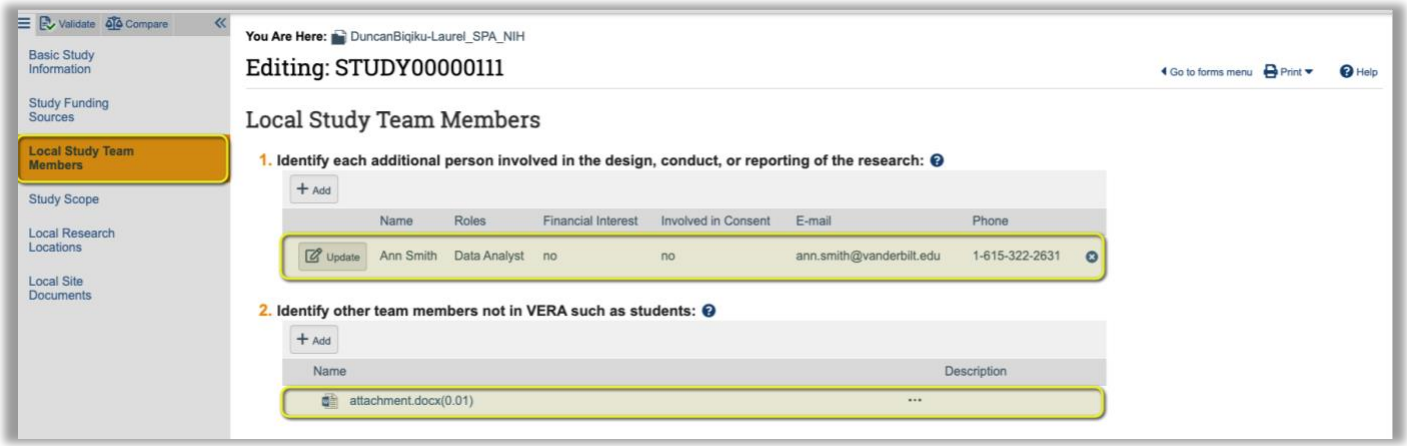
Back to Guide List

Item 2. Identify other team members not in VERA such as students:

- Click on the gray "**+Add**" button.
  - "**Submit a Document**" pop-up window will open.
  - Click on "**Choose File**" to search for and attach the individual's *CITI Training Certificate of Completion*.

- **Note**:
  - Add study team members who are engaged in human subjects research activities and who are not listed in Oracle at Vanderbilt University here. Example: Students or other individuals VU does not include in Oracle.
  - Do not add individuals who were added in the previous question.
  - If VUMC study team members are engaged in human subjects research activities do not add them here.
  - Multi-Site Research Study: If VU acts as a single IRB (IRB of Record) do not include information about participating site study team members here.
  - If you have questions, contact the VU HRPP at irb@vanderbilt.edu.

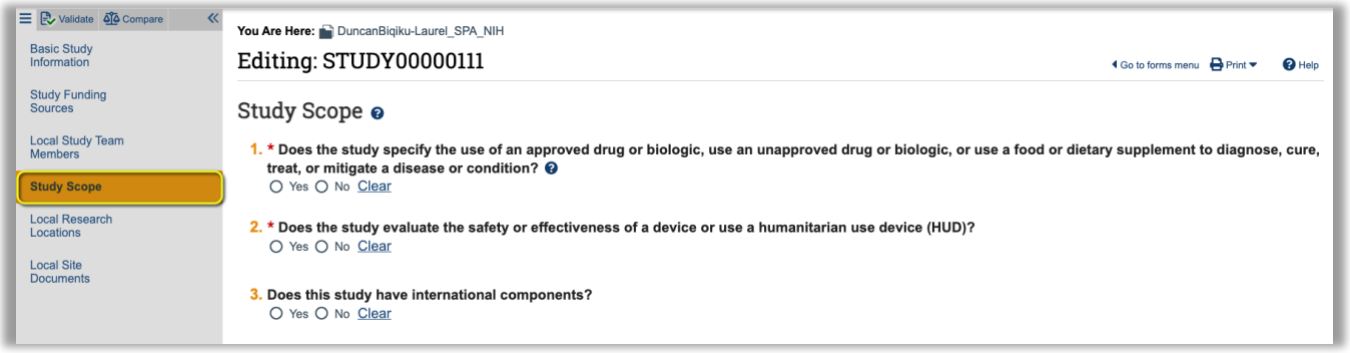
- Click on **OK** or **OK and Add Another**. Using **OK and Add Another** saves you a few clicks when adding multiple documents.



Click CONTINUE to move to the next SmartForm.

Back to Guide List

The fourth SmartForm for a New Study opens: **Study Scope SmartForm.** Complete all items.



Item 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: Choose YES or NO

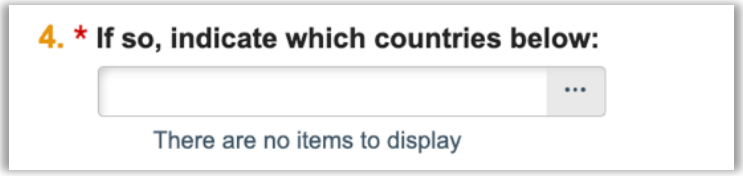
- **Note**:
  - If your study involves use of an unapproved/investigational drug of biologic, **then stop here**. The study must be submitted to the VUMC IRB.
  - If your study involves an IND Exempt Drug, then please complete the **IND Exempt Form** found on VU HRPP's website and attach it to the IRB submission.
  - The phrase "specify the use of" means the protocol requires 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.

Item 2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?: Choose YES or NO

- **Note**:
  - If your study involves use of an unapproved/investigational device, **then stop here**. The study must be submitted to the VUMC IRB.
  - If your study involves an IDE Exempt Device, then please complete the **IDE Exempt Form** found on VU HRPP's website and attach it to the IRB submission.

Item 3. Does this study have international components?: Choose YES or NO

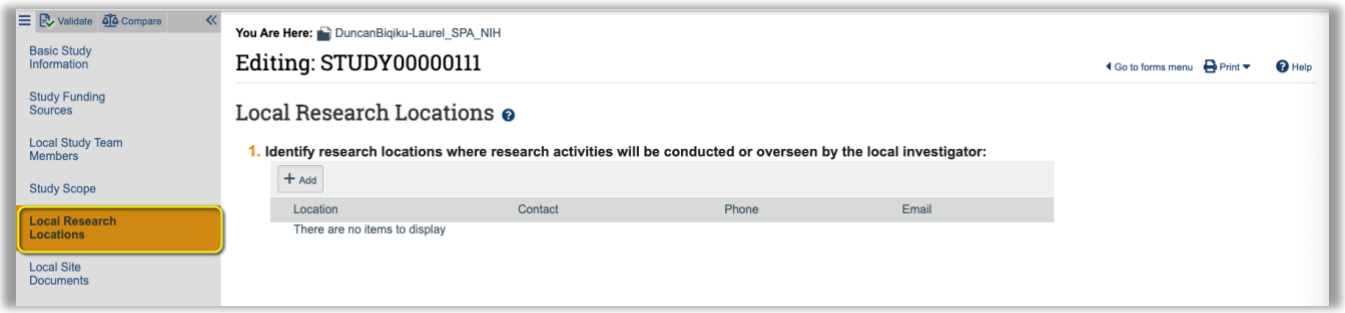
- **Note**:
  - International research involves data and/or study populations located outside of the United States.
  - For more information, refer to the *International Research Guidance* on the VU HRPP's website.
  - If you selected YES, then indicate the specific country(ies).



Click CONTINUE to move to the next SmartForm.

Back to Guide List

The fifth SmartForm for a New Study opens: **Local Research Locations SmartForm.** Complete **Item 1**.



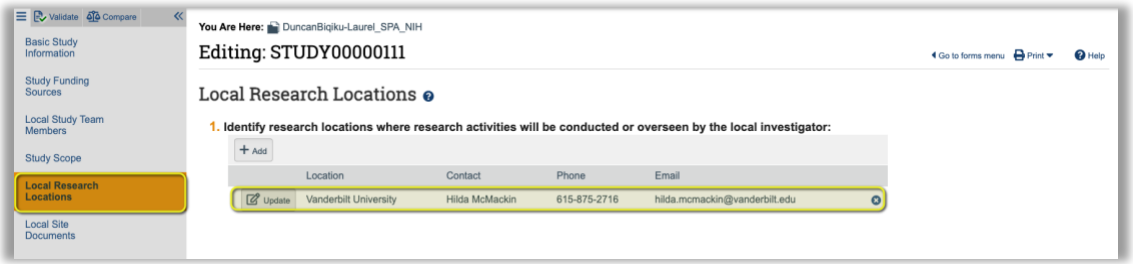
Item 1. Identify research locations where research activities will be conducted or overseen by the local investigator:

- Click on the gray "**+Add**" button
  - "**Add Research Location**" pop-up window will open.

Item 1. Select the research location:

- If your research is occurring at Vanderbilt University, then type "**%Vanderbilt"** and select Vanderbilt University.
- For other research location(s), enter the specific name of the research location(s), city, state, and country where the human research activities will occur.

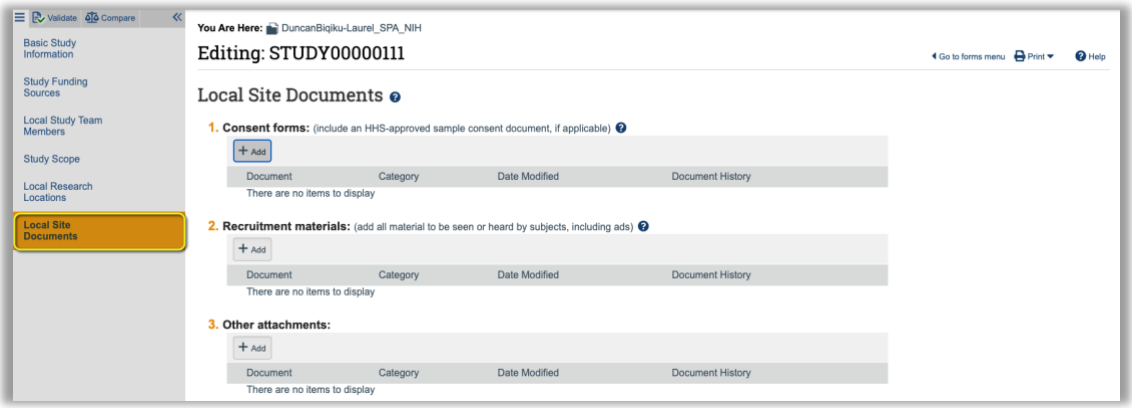
- Click on **OK** or **OK and Add Another**. Using **OK and Add Another** saves you a few clicks when adding multiple research locations.



Click CONTINUE to move to the next SmartForm.

Back to Guide List

The sixth SmartForm for a New Study opens: **Local Site Documents SmartForm.** Complete all items.



Item 1. Consent forms:

- Click on the gray "**+Add**" button.
  - "**Add Attachment**" pop-up window will open.

    - **Item 1. * File to attach:** Click on "Choose File" to search for and attach consent forms, assent forms, parental permission forms, and/or a research information sheet in Word format. Translated versions can be attached here as well.
      - Find templates for consent/assents/parental permission forms and the research information sheet on VU HRPP's website.
      - Label each document clearly. Example: "Consent Form for Adult Teachers"; "Assent Form for 13-15 Year Old Students"; "Research Information Sheet for Adults"

    - Click on **OK** or **OK and Add Another**. Using **OK and Add Another** saves you a few clicks when adding multiple attachments.

Item 2. Recruitment materials:

- Click on the "**+Add**" button.
  - "**Add Attachment**" pop-up window will open.

    - **Item 1. * File to attach:** Click on "Choose File" to search for and attach all recruitment documents. Translated versions can be included here as well.
      - Label each document clearly. Example: "Social Media Recruitment Posting"; "Recruitment Email for Surveys"; "Recruitment Flyer for Community Member Interviews"
      - Recruitment materials include specific information about the study to invite potential participants to participate in the research study.

    - Click on **OK** or **OK and Add Another**. Using **OK and Add Another** saves you a few clicks when adding multiple recruitment material attachments.

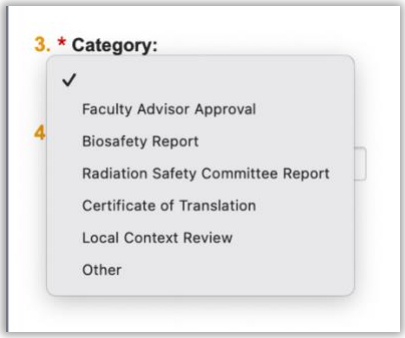
Item 3. Other attachments:

- Click on the gray "**+Add**" button.
  - "**Add Attachment**" pop-up window will open.

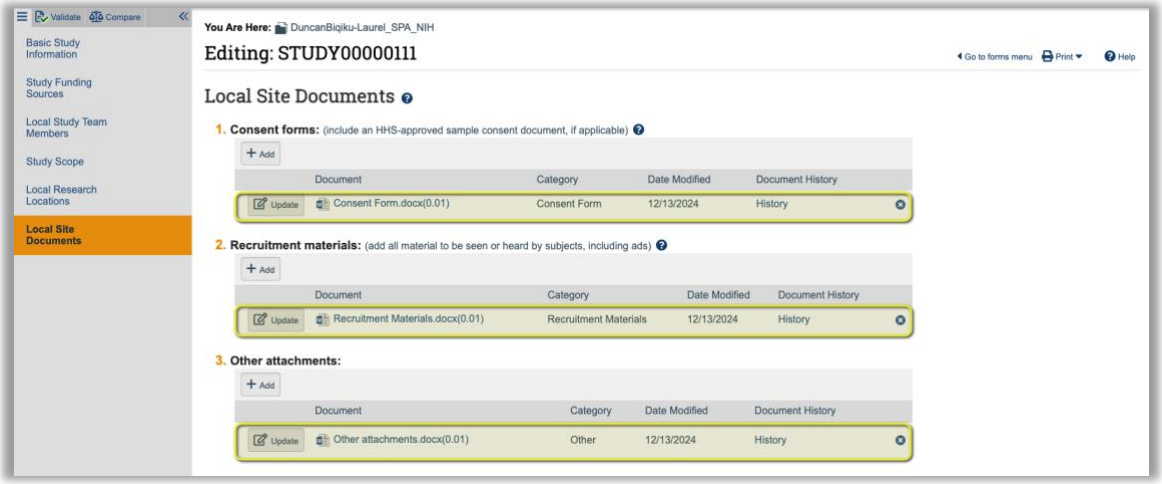
    - **Item 1. * File to attach:** - click on "Choose File" to search for and attach additional relevant research study related documents.
      - Examples: data collection tools, faculty advisor approval, certificate of translation, additional study supporting supplements (e.g., participating site documents, IND Exempt Form, IDE Exempt Form), site permissions/letters of support, handouts, ancillary review approvals (e.g., Radiation Safety Committee approval), etc.

Back to Guide List

- **Item 2. Name:** (if not supplied, the file name will be shown). Label each document clearly.
- **Item 3. * Category:** Click on the drop-down menu and choose one option.



- **Item 4. Version number:** Optional.
- Click on **OK** or **OK and Add Another**. Using **OK and Add Another** saves you a few clicks when adding multiple attachments.



You completed all the SmartForms.

Click Finish to exit and return to the Main Workspace.

- Other selection options: **"Save Changes"** or **"Exit"**

Returning to the Main Workspace for the New Study:

- The study status is now currently in the **Pre-Submission** state.
- The ID # can be found to the right of where it states: "**Pre-Submission**".

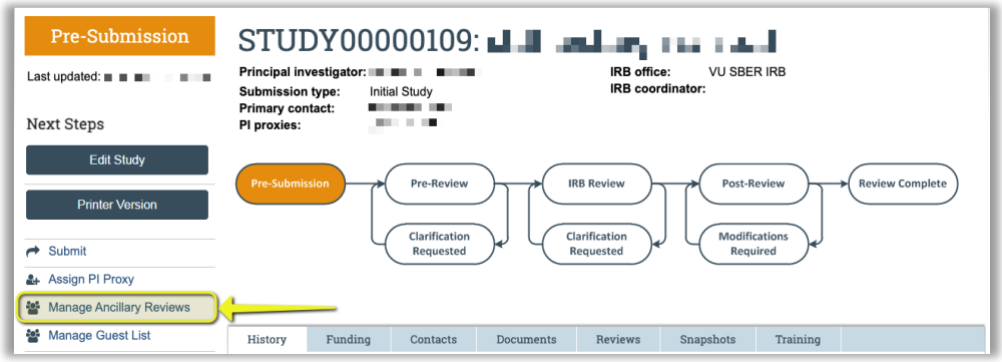
Back to Guide List

STEP 3 – Manage Ancillary Review to Department Chair (or, Department Chair Designee)

REQUIRED: Department Chair/Designee Approval is required for all new studies being submitted to the VU IRB.

From the New Study's Main Workspace:

- **Click** on the activity: **Manage Ancillary Review** (left side of the Main Workspace, located below the blue action buttons: **Edit Study**, **Printer Version**)



- A "**Manage Ancillary Reviews**" pop-up window opens:
  - Click on the gray button "**+Add**" to setup each Ancillary Review needed.
  - **Note**: * (a red asterisk) means it is required to complete the item. You cannot complete setup and send the Ancillary Review without completing the required item.

    - Item 1. ***Select either an organization or a person as review:**
      - Enter "%DEPTNAME" in the textbox next to Organization or enter the 5-digit department number "%DEPTNUMBER".
        - Example: "%Psychology and Human Development" or enter the 5-digit Department Number "%21240"
    - Item 2. **Review type:** Select the type of Ancillary Review:
      - **Select "Departmental Approval"**
    - Item 3. ***Is a response required?** – Choose YES
      - This means that the Department Chair Approval must be submitted before the Study can move past the **Pre-Review** state.
    - Item 4. **Comments**
      - Optional. You can write a message to the Ancillary Reviewer here.
    - Item 5. **Supporting documents**
      - Optional.
    - **Click OK.**

You are now redirected back to the "Manage Ancillary Review" pop-up window:

- Item 1. "**Identify each organization or person that should provide additional review:**" now you will see a list of the Ancillary Review(s) you created.
- **Click** on **OK.**
  - This sends the Ancillary Review through VERA Notifications to the recipient's Vanderbilt email address.
  - The recipient will receive a notification from VERA called: "*Ancillary review notification*".
  - The VERA notification is sent once you "**Submit**" the VERA Study to the IRB Office.

You can verify the **Ancillary Review** that you set up in the **Reviews** tab on the Main Workspace.

Note: If a change needs to be made to the Ancillary Review, this can be edited.

Back to Guide List

STEP 4 – Assign PI Proxy (if applicable)

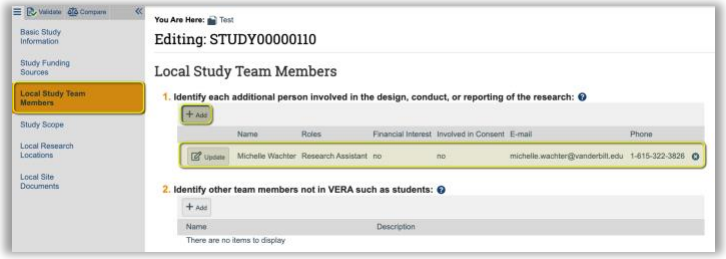
REQUIRED: For student principal investigators, their faculty advisors are required to be added as a PI Proxy.

Note: The PI Proxy performs the same activities as the PI.

STEP 1

The **PI Proxy** must be entered in the **Local Study Team Members** **SmartForm** before assigning the PI Proxy on the Main Workspace.

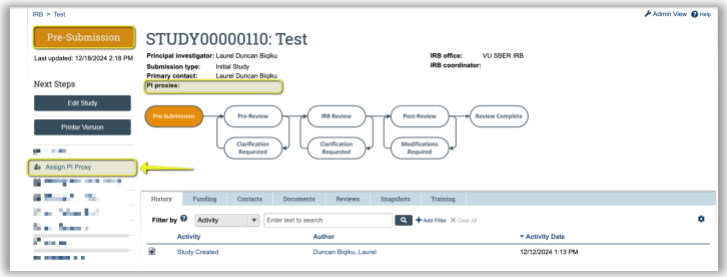
- **Click** the "**+Add**" button.

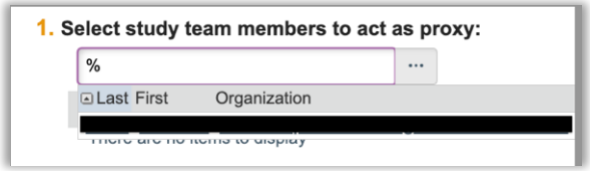


Once you enter the person that you want as your PI Proxy in the **Local Study Team Members** **SmartForm**, move to Step 2.

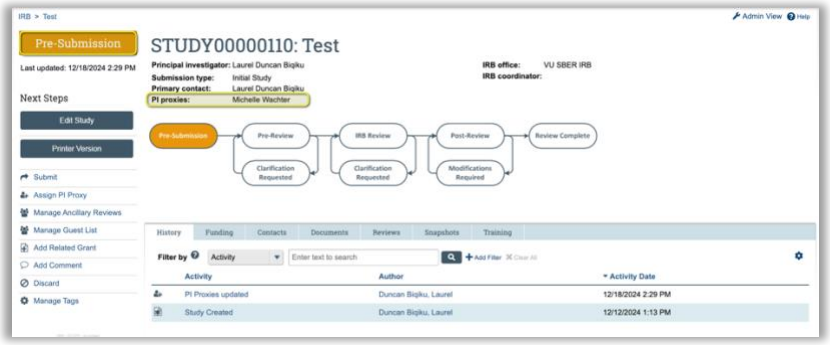
STEP 2

On the **Main Workspace** of the **New Study Submission**, **click** **Assign PI Proxy.**





- An "**Assign PI Proxy"** pop-up window will open:
  - **Item 1. Select study team members to act as proxy:**
    - Enter "**%**FirstName LastName" or "%Last Name"
    - **Note**: The person you added on the **Local Study Team Members** **SmartForm** will show up here to select.
    - **Click** on **OK**
    - Back on the Main Workspace, you will see a status update of the **PI Proxy** you assigned



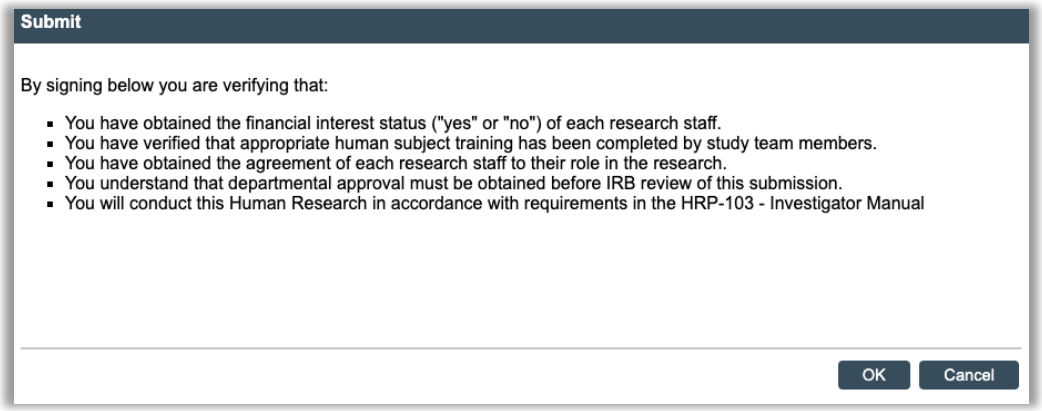
Note:
If you do not find who the person you want to list as your PI Proxy, then **return to Step 1 and follow the instructions.**

Back to Guide List

STEP 5 – Submit to the VU HRPP Office for Review

Click on activity: **Submit**

- A "**Submit**" pop-up window will open.
  - Review the attestation statement.



  - **Click OK.**

The state of the submission changes to **Pre-Review** in the workflow. Your study is now submitted to the VU HRPP.

The VU HRPP staff are notified of the submission to review.

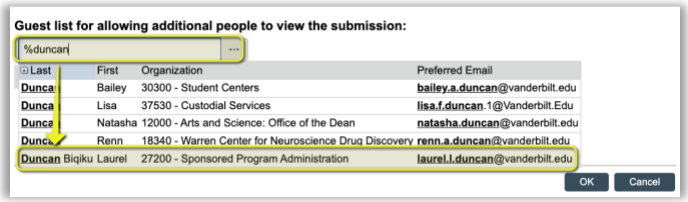
Back to Guide List

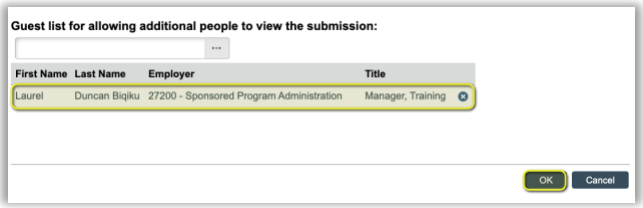
Miscellaneous Activities available on the Main Workspace of the New Study:

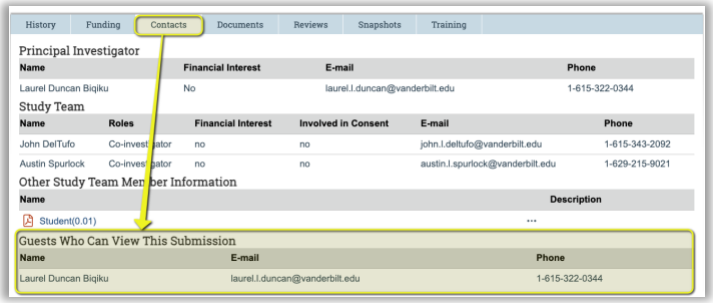
Manage Guest List:

This activity allows you to add "viewers" to the study. For example, the Department Grants Managers who manage the proposals and awards, would be able to verify protocol #s and dates, if they are given access to view the VERA IRB file.

1. Click on **Manage Guest List**, a "**Manage Guest List**" pop-up window opens
2. "**Guest list for allowing additional people to view the submission**:"
   - In this HR feed textbox, search for and select anyone you would like to add to have "viewing" access only to the study.
   - Begin your search with "%" before the Last Name or First Name you want to select.
3. Once selected, the individual selected will show up in the list below the searchable textbox.
4. If everyone you would like added is listed, then click on **OK**.
   - Clicking on **OK** closes the pop-up window.
5. You can double-check the list of viewers by clicking on the blue tab: **Contacts**.
   - Look for row: **Guests Who Can View This Submission**







Copy Submission:

If you want to re-use an IRB Study File, you can "copy" the file and make changes to the new submission.

1. Click on **Copy Submission**, a "**Copy Submission**" pop-up window opens
2. Provide a "**New submission name**"
3. Click on **OK**
4. Look under the tab: **History**. You will see a line item called: Copied Submission
   - Once the submission is copied, you will see the note: "New Copy: STUDY00000000 NAME"
   - Click on the link (STUDY00000000) to access the new Workspace
5. You can access the new submission by going to the "Submissions" menu option, then look for the name of the copied submission.

Add Comment:

You can add comments or notes to the History tab of the VERA IRB file, by using activity: **Add Comment**.

1. Click on **Add Comment**, an "**Add Comment**" pop-up window opens
2. Provide comments or notes in **Item 1. Comment**.
3. Attach any document that you'd like to include in **Item 2. Supporting documents**.
4. Check one of the three (3) options to the question: **Item 3. Who should receive an e-mail notification?**:
   a. PI/PI Proxy/Primary Contact
   b. Study Team
   c. IRB Coordinator
5. Click on **OK**
6. Go to the tab: **History** to view the saved comments

Discard:

If you created a study in error or you no longer need IRB Approval:

1. Click on **Discard**, a "**Discard**" pop-up window opens
2. Click on **OK** to officially discard the submission
3. You will be returned to the Main Workspace, and the state changes to: **Discarded**
4. The submission is no longer usable

Back to Guide List