## 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\***)

## **GUIDE**

Step 1 – Getting Started

## Ŧ

## Step 2 - SmartForms

- Basic Study Information SmartForm
- <u>Study Funding Sources SmartForm</u>
- Local Study Team Members SmartForm
- <u>Study Scope SmartForm</u>
- Local Research Locations SmartForm
- Local Site Documents SmartForm

# Ŧ

## Step 3 – Manage Ancillary Review to Department Chair

Ť

Step 4 – Assign PI Proxy (if applicable)

Ť

Step 5 – Submit to VU IRB/HRPP office

Ť

## **New Study Submitted**

Miscellaneous Activities available on the Main Workspace of the New Study

## STEP 1

Log into VERA (<u>https://vera.vanderbilt.edu/</u>)

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

Dashboard	Agreements	Grants	IRB	SF424 Center
Page for				
Create 👻	My Inbox My Reviews			
	My Inbox			
• Agreements	Filter by 🚱 ID	Enter text to search	Add Filter 💥 Cle	ar All
• Grants	ID Name			
• IRB	e			
	2	CARDING STREET		
Create New Study	8	english and		
Report New Information	Street Second	in a finite of		
	81			
	States and States and	<ul> <li>CONTRACTOR</li> </ul>	TRUE Resolution	

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

Dashboard	Admin	Agreements	Grants		RB	Settings			
Submissions	Meetings Rep	oorts Library	Help Center	Central Actio	ons				
IRB							Components	Properties	Permissions
IRB									
						S	earch ?		Q
Consta Maria Chada	In-Review	Active New Inf	ormation Reports	External IRB	Relying Sites	All Submissio	ns Archiv	ved	
Create New Study	Fillers by 2	ID =	Enter text to coore	h		Mar Mariana			~
Report New Information	Filter by U		Enter text to searc	an	T Add F	itter A Clear All			*
	ID	Name	✓ Date Modifi	ed State	Expiration PI Fir Date Name	st PI Last Co Name Fin	oordinator ( rst Name I	Coordinator Last Name	Submission Type
	STUDY0000	C	12/12/ 1:13 P	2024 Pre- M Submission		1000			Initial Study
	STUDY0000		12/12/2 12:28	2024 Pre- PM Submission		100			Initial Study

## 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.

	Basic Study Information	You Are Here: 📽 _IRBSubmission Creating New: IRB Submission	Go to forms menu	😮 Help
l		Basic Study Information 🥑		

**Please note** that **\*** indicates a response is required and you cannot continue to the next SmartForm without providing a response. <u>All</u> 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 <u>not</u> exceed 50 characters. The short title should reflect the following format: "PI Last Name\_Department\_Shortened Study Title"

Example: "Smith\_SON\_Cognitive Identity"

<u>Note</u>: 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):

- <u>Select Yes</u> 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. <u>For example</u>, if you are a participating site in an MSS, <u>select Yes</u>.
- If you are the sIRB of record for a multi-site or collaborative study, select No.

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 (<u>example</u>: "%mckay"). The % is the "**wildcard**" for searching in VERA when there is a text box with a data feed populating the responses.

7.	* Local J	principal i	nvestigator: 😮		
	%mckay			•••	
	■ Last	First	Organization		
8.	<u>McKay</u>				

#### 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* <u>VU Office of Conflict of Interest and Commitment</u> <u>Management</u> 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 <u>in Word format</u> here. The Protocol Templates can be found on the <u>VU HRPP's website</u>.

- Please do <u>not</u> attach your grant proposal here.
- <u>118 Determination Requests</u>: Complete the *HRP*-902-118 Determination Request Form found on the <u>VU HRPP's</u> <u>website</u> and attach it here.
- <u>Note</u>: 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. <u>Example</u>: "Research Protocol\_PI Last Name".
    - iii. Item 3. Version number is optional.

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.

8. *	Attach the p	protocol: 😧				
		Document	Category	Date Modified	Document History	
	Update	Research Protocol_McKay.doc>(0.01)	IRB Protocol	1/14/2025	History	8

1. * File	to attach:			
P 月 P	ersonnel report.	pdf(0.01) ····		
_		Ohar		
		Choo	E Download Copy	
			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.

Basic Study	You Are Here: DuncanBiqiku-Lau Editing: STUDY000	rrel_SPA_NIH			4 Go to forms menu 🛛 🖨 Print 🔻	Help
Study Funding Sources	Study Funding Sou	rces 🛛				
Local Study Team Members	1. Identify each organizatio	n supplying funding for the stud	y:			
Study Scope	+ Add					
Local Research	Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments		
Locations	There are no items to displa	y .				
Local Site Documents	2. If this study is not funde	d click here: 🗌				

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.
    - <u>118 Determination Requests</u>: 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.

. * Funding	organization: 😮		
%national in	istitutes		
ID	Name	Category	Parent Organization
	National Institutes of Health	Federal Government	GC_C255
GC_C681	National Institutes of Health_Billing	Federal Government	GC_C255

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.

• <b>Funding</b> National Instit	organization: 🛿			
2. Sponsor's	funding ID: (assigned by external sp	onsor)		
1R0112345				
1R0112345 . Grants offi AWD000012	ce ID: (assigned internally)			
Attach files	ce ID: (assigned internally) 334 5: (include any grant applications)			
AWD000012	ce ID: (assigned internally) 334 5: (include any grant applications)			

#### Item 2. If this study is <u>not funded</u>, click here: $\Box$

• Check the box if the study is not receiving any funding.

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

E Compare Basic Study Information	You Are Here: DuncanBigiku-Lau Editing: STUDY000	urel_SPA_NIH 0001111				4 Go to forms menu  🔒 Print 🔻	🕜 Help
Study Funding Sources	Local Study Team I	Members					
Local Study Team Members	1. Identify each additional	person involved in the des	ign, conduct, or reporting of the	research: 😮			
Study Scope	+ Add						
Local Research Locations	Name Roles There are no items to disp	Financial Interest	Involved in Consent	E-mail	Phone		
Local Site	2. Identify other team mem	bers not in VERA such as	students: 😮				
Documents	+ Add						
	Name	Descri	ption				
	There are no items to displa	ау					

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

- Click on the gray "+Add" button.
  - o Complete four (4) questions about each person added in the "Add Study Team Member" pop-up window.
  - Do <u>not</u> add the PI here.
- Note:
  - <u>Multi-Site Study</u>: Both sIRB and participating site institutions should only include information about team members <u>at</u> <u>your local institution</u>. Other sites involved in the multi-site study will add their own information about local study team members.
  - Do <u>not</u> 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 <u>irb@vanderbilt.edu</u> 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:

- o Co-investigator
- o Data Analyst
- Research Assistant
- Statistician
- o 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* <u>VU Office of Conflict of Interest and Commitment</u> <u>Management</u> 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.

#### 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 <u>are</u> engaged in human subjects research activities and who <u>are not</u> listed in Oracle at Vanderbilt University here. <u>Example</u>: Students or other individuals VU does not include in Oracle.
  - $\circ\quad$  Do  $\underline{not}$  add individuals who were added in the previous question.
  - o If VUMC study team members are engaged in human subjects research activities do <u>not</u> add them here.
  - <u>Multi-Site Research Study</u>: If VU acts as a single IRB (IRB of Record) do not include information about participating site study team members here.
  - o 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.

Basic Study	✓ You Are Here:  ☐ DuncanBi Editing: STUDY	iqiku-Laurel_SPA_NIH						Go to forms manue Print	O Help
Study Funding Sources	Local Study Te	am Members	5					0	
Members Study Scope	+ Add Nam	ne Roles	Financial Interest	Involved in Consent	E-mail	Phone			
Local Site	Update Ann	Smith Data Analyst	no	no	ann.smith@vanderbilt.edu	1-615-322-2631	0		
Documents	2. Identify other team + Add	n members not in V	/ERA such as stu	udents: 😧					
	Name attachmer	nt.docx(0.01)				escription			

E Validate Compare You Are Here: PuncanBigiku-Laurel SPA NIH Basic Study Information Editing: STUDY00000111 🕻 Go to forms menu 🛛 🖨 Print 🔫 C Help Study Funding Study Scope @ Local Study Team 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? O Yes O No Clear Study Scope Local Research 2. \* Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)? O Yes O No Clea Local Site Documents 3. Does this study have international components? O Yes O No Clear

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

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

- Note:
  - o 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.
  - o <u>If you selected YES</u>, then indicate the specific country(ies).

4. *	f so, indicate which countries be	low:
	There are no items to display	

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

E CValidate Compare 《	You Are Here: PuncanBigiku-La	urel_SPA_NIH 000111			4 Go to forms menu 🛛 🖨 Print 🔻	Help
Study Funding Sources	Local Research Loc	cations 🛛				
Local Study Team Members Study Scope	1. Identify research location	ns where research activities wil	l be conducted or overseen b	by the local investigator:		
Local Research Locations Local Site Documents	Location There are no items to dis	Contact play	Phone	Email		

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.

E Study Information	You Are Here: 🕋 Du Editing: ST	uncanBiqiku-Laurel_SPA_NIH UDY00000111					4 Go to forms menu 🛛 🔒 Print 🔻	🕜 Help
Study Funding Sources	Local Resea	arch Locations	0					
Local Study Team Members	1. Identify rese	earch locations where re	esearch activities will	be conducted or	overseen by the local investigator:			
Study Scope	1 700	Location	Contact	Phone	Email			
Local Research Locations	Update	Vanderbilt University	Hilda McMackin	615-875-2716	hilda.mcmackin@vanderbilt.edu	0		
Local Site Documents								

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

😑 🕞 Validate 🏘 Compare 🛛 ≪	You Are Here: 🚔 DuncanBigiku-L	aurel SPA NIH			
Basic Study Information	Editing: STUDY00	000111			4 Go to forms menu 🔒 Print 🔻 🕜 H
Study Funding Sources	Local Site Docume	ents 👔			
Local Study Team Members	1. Consent forms: (include a	an HHS-approved sam	ple consent document, if applicable)	9	
Study Scope	+ Add				
Local Research Locations	Document There are no items to di	Category splay	Date Modified	Document History	
Local Site	2. Recruitment materials:	(add all material to be	seen or heard by subjects, including a	ds) 🚱	
bocumenta	+ Add				
	Document	Category	Date Modified	Document History	
	There are no items to di	splay			
	3. Other attachments:				
	+ Add				
	Document	Category	Date Modified	Document History	
	There are no items to di	splay			

#### 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 <u>VU HRPP's website</u>.
      - Label each document clearly. <u>Example</u>: "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.
  - o "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. <u>Example</u>: "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.

- 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.

,	/
	Faculty Advisor Approval
	Biosafety Report
	Radiation Safety Committee Report
	Certificate of Translation
	Local Context Review
	Other

- 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.

Basic Study								
nformation	Editing: ST	JDY00000111					4 Go to forms menu 🛛 🖨 Print 💌	Help
Study Funding Sources	Local Site D	ocuments o						
.ocal Study Team Members	1. Consent form	s: (include an HHS-approved sample conse	ent document, if applicable) 😧					
Study Scope	+ Add							
ocal Research		Document	Category	Date Modified	Document History			
ocations	Update	Consent Form.docx(0.01)	Consent Form	12/13/2024	History	0		
ocal Site locuments	2. Recruitment + Add	Consent Form.docx(0.01) materials: (add all material to be seen or h	Consent Form neard by subjects, including ad-	12/13/2024 s) 😧	History	0		
ocal Site occuments	2. Recruitment + Add	Consent Form.docx(0.01) materials: (add all material to be seen or h Document	Consent Form neard by subjects, including ad	12/13/2024 s) 🕑 Date Modified	History Document History	0		
ocal Site ocuments	2. Recruitment + Ad	Consent Form.docx(0.01)      materials: (add all material to be seen or h      Document      @ Recruitment Materials.docx(0.01)	Consent Form heard by subjects, including ad Category Recruitment Materials	12/13/2024 s) Date Modified s 12/13/2024	History Document History History	0		
ocal Site ocuments	2. Recruitment + Add Update 3. Other attacht	Consent Form.docx(0.01)      materials: (add all material to be seen or h      Document      Recruitment Materials.docx(0.01)  nents:	Consent Form Heard by subjects, including add Category Recruitment Materials	12/13/2024 Date Modified 12/13/2024	History Document History History	0		
ocalions ocal Site ocuments	2. Recruitment + Ads C Update 3. Other attacht + Ads	Consent Form.docx(0.01)  materials: (add all material to be seen or h Document  Recruitment Materials.docx(0.01)  nents:	Consent Form eard by subjects, including ad Category Recruitment Materials	12/13/2024 ) Date Modified 3 12/13/2024	History Document History History	0		
ocalions ocal Site ocuments	2. Recruitment + Ads C Update 3. Other attacht + Ads	Consent Form.docx(0.01)  atterials: (add all material to be seen or h Document  Recruitment Materials.docx(0.01)  nents:  Document	Consent Form leard by subjects, including add Category Recruitment Materials Category	12/13/2024 s) Date Modified Date Modified	History Document History History Document History	0		

#### You completed all the SmartForms.

**Click Finish** to exit and return to the Main Workspace.

o 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".

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

#### <u>REQUIRED</u>: 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".
        - <u>Example</u>: "%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.
  - o 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.

Basic Study Information	Editing: STU	JDY00000	110				
Study Funding Sources	Local Study	Team Me	mbers				
Local Study Team Members	1. Identify each	additional pers	on involved in th	e design, cond	luct, or reporting	of the research: 📀	
Study Scope	+ Add	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
Study Scope Local Research Locations	(+ Add	Name Michelle Wachter	Roles Research Assistant	Financial Interest	Involved in Consent	E-mail michelie.wachter@vanderbill.edu	Phone 1-615-322-3826
Study Scope Local Research Locations Local Site Documents	2. Identify other	Name Michelle Wachter team members	Roles Research Assistant not in VERA suc	Financial Interest	Involved in Consent	E-mail michelle wachter@vanderbilt.edu	Phone 1-615-322-3826
Study Scope .ocal Research .ocal Site Jocuments	2. Identify other + Add	Name Michelle Wachter team members	Roles Research Assistant not in VERA suc	Financial Interest	Involved in Consent	E-mail michelle.wachter@vanderbilt.edu	Phone 1-615-322-3828

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.

IRB > Test	₽ M	imin View 🔞 Help	
Pre-Submission	STUDY00000110: Test		
Last updated: 12/18/2024 2:18 PM	Principal investigator: Laurel Duncen Bigliou IRB effice: VU SBER IRB Submission type: Initial Study IRB coordinator:		
Next Steps	Primary contact: Laurel Duncan Bigitu Pi proxies:		
Edit Study	Pre-Submision		
Printer Version			1. Select study team members to act as proxy:
procession and the second s	Connection (Connection ) (Conn		
4. Assign PI Proxy			%
a management	History Funding Contacts Documents Reviews Stapshots Training		I ast First Organization
Res. March 4	Filter by 😢 Activity 💌 Enter text to search Q + Add Filter X Clear Al	•	C Luot 1 list Organization
Contraction of Contraction	Activity Author * Activity Date		
	Study Created Duncan Bigiku, Laurel 12/12/2024 1:13 PM		There are no terns to display

- 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

RB > Test				F Admin View OH
Pre-Submission	STUDY00000110: 7	Test		
Last updated: 12/18/2024 2:29 PM	Principal investigator: Laurel Duncan Biqiku Submission type: Initial Study	IRB office: IRB coordinat	VU SBER IRB	
Next Steps	Primary contact: Laurel Duncan Bigiku PI proxies: Michelle Wachter			
Edit Study	Contraction of the American		Remission Computer	
Printer Version			neview comparts	
r Submit	Clarification Requested	A Clarification Requested A Modifications		
Assign PI Proxy				
Manage Ancillary Reviews				
Manage Guest List	History Funding Contacts	Documenta Beviewa Snapshota Training		
Add Related Grant	Eller to Q Annual - Colo	- In the second se		*
<ul> <li>Add Related Grant</li> <li>Add Comment</li> </ul>	Filter by 🛛 Activity 💌 Ente	r text to search Add Filter X Cross	48	٥
Add Related Grant  Add Comment  O Discard	Filter by O Activity  Contemporate  Enter Activity	r text to search Author Action	* Activity Date	٥
Add Related Grant  Add Comment  Obscard  Manage Tags	Filter by  Activity  Activity  Activity  Enter  Activity  PI Proxies updated	r text to search Q + Add Filler 'X Cross Author Duncan Bigliku, Laurel	* Activity Date 12/18/2024 2:29 PM	۰

Note:

If you do not find who the person you want to list as your PI Proxy, then return to <u>Step 1</u> and follow the instructions.

## STEP 5 – Submit to the VU HRPP Office for Review

Click on activity: Submit

0

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

By signing below	you are verifying that:	
<ul> <li>You have c</li> <li>You have v</li> <li>You have c</li> <li>You unders</li> <li>You will control</li> </ul>	btained the financial interest status ("yes" or "no") of each research staff. erified that appropriate human subject training has been completed by study team merr btained the agreement of each research staff to their role in the research. tand that departmental approval must be obtained before IRB review of this submissior iduct this Human Research in accordance with requirements in the HRP-103 - Investiga	ıbers. ı. ator Manual

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.

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

#### **Manage Guest List:**

٠

1. 2.

3.

4.

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.

- Click on Manage Guest List, a "Manage Guest List" pop-up window opens
- "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.
- Once selected, the individual selected will show up in the list below the searchable textbox.
- 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 (STUDY0000000) 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