

Register a Clinical Trial

Clinical Trials Center of Excellence

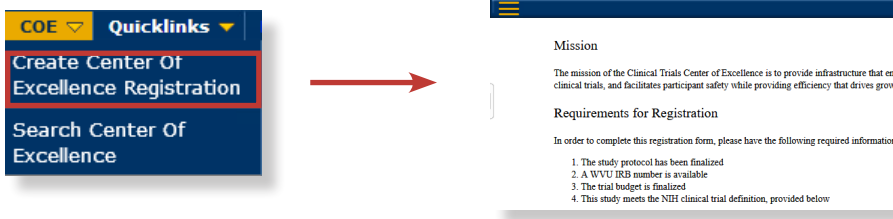
Registration with the Center of Excellence is required for all clinical trials on the Morgantown campus that meet the [NIH clinical trial definition](#).

1. From your WVU+kc dashboard, click on **CoE** in the menu at the top.



2. Choose **Create Center of Excellence Registration** from the menu options.

- A page displaying the mission of the CoE and the requirements for registration, as well as CoE contact information will appear.



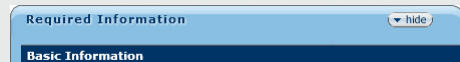
3. Read through the information, including:

- Mission statement,
- Requirements for Registration,
- NIH Clinical Trial Definition, and
- Key Contacts at the CoE.

4. Click **Continue** at the bottom of the page to proceed.



Note: The Clinical Trial Registration form will display, showing the Center of Excellence Registration tab. Complete the **Required Information** section first.




5. In the Basic Information sub-section, you are asked to verify that the study meets the NIH definition of a clinical trial based on four criteria. You can only submit the registration for studies that meet the definition. Review the four questions and answer **Yes** or **No**.

- If you select *No*, the form will close.
- Click *Yes* to continue.

A screenshot of the 'Basic Information' section of the registration form. It has a dark blue header with the text 'Basic Information'. Below the header, there is a paragraph: 'Please Review the four questions to determine if this study meets the NIH definition of a clinical trial'. This is followed by four numbered questions: 1. Does the study involve human participants? 2. Are the participants prospectively assigned to an intervention? 3. Is the study designed to evaluate the effect of the intervention on the participants? 4. Is the effect being evaluated a health-related biomedical or behavioral outcome? At the bottom of the section, there is a question: 'Does this study meet all four of the above criteria?:' followed by two radio buttons labeled 'Yes' and 'No'. The 'No' radio button is highlighted with a red box.

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6. Click the **search icon** in the **WVU IRB Lookup** field to locate your IRB protocol.

WVU IRB Lookup:		Click here to create a new Protocol	<input type="button" value="create"/>
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Note: If this study does not yet have a protocol, you can quickly start one by clicking the **Create** button to [start a new protocol document](#) in WVU+kc. On the new page, just supply the:

- Description (a short title)
- Protocol Type
- Title
- Principal Investigator
- Department or Lead Unit

After you **save** the protocol, it will be assigned a *Protocol Number* (in the header area), which can be used to search for the protocol in the **WVU IRB Lookup** on this registration.

Protocol #:	2002886374
* Principal Investigator:	Jodie T Trainer


7. Complete one or more fields on the search page to identify the protocol. For example, enter text for the *Protocol #*, *Title*, or *Investigator* fields.

8. Click the **Search** button at the bottom of the page.

9. Locate the correct IRB Protocol in the search results. Click the **Return Value** link in that row to populate the protocol information.

- The WVU IRB Lookup info, Title, PI info, and Department will appear on the form.

10. You can also link the WVU+kc Proposal document to this clinical trial. Click the **search icon** to look for your proposal.

Click here to find your WVU Proposal →	
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Note: You must have permission to view or edit the Proposal in WVU+kc to see it on the Proposal Lookup page.

10-1. On the Proposal Lookup page, click the drop-down in the **Proposal Category Type** field to select the proposal type. (required)

* Proposal Category Type:	Full Proposal <input type="button" value="v"/>
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10-2. Complete one or more fields on the search page to locate your proposal. For example, enter text for the *Proposal #*, *Project Title*, or *Principal Investigator* fields.

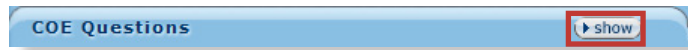
10-3. Click the **Search** button at the bottom of the page.

10-4. In the search results, locate the correct Proposal Development document, and click the **Return Value** link to fill in the field.


- The WVU Proposal Lookup and Title info will populate.

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11. Click the **Show** button to display the *COE Questions* section of the registration form.



12. Answer each of the questions in the COE questionnaire to the best of your abilities. You can hold your mouse over the help icons (question marks) if you need clarification.

5. Is this an NIH-funded trial? 

13. Click the **Save** button at the bottom of the page. This will enable the *COE Attachments* section.



Note: After saving, you will see a confirmation message at the top of the page, indicating that the 'Document was successfully saved'.

14. Click the **Show** button in the COE Attachments section, where you will upload the Protocol document and Clinical Trials Agreement.



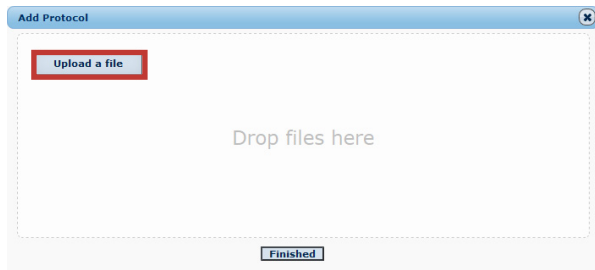
15. In the *Upload Protocol* field, click the **Upload** button.

- The Protocol document is a *required* attachment.

Upload Protocol: 

16. On the *Add Protocol* screen, you may either click the **Upload a file** button to browse your computer for the protocol document, or you can *drag-and-drop* the file into the area with the dotted line.


- You will see the file name appear below the drag-and-drop area.



17. After you have selected the file, click the **Finished** button to attach it to the COE registration.

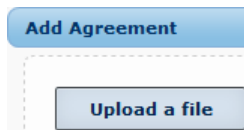
Finished

18. Next, upload the Clinical Trials Agreement for this study. Click the **Upload** button in the second attachments field.

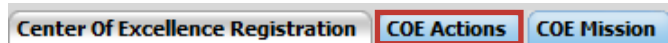
Upload clinical trials agreement: 

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19. On the *Add Agreement* screen, attach the agreement by clicking the **Upload a file** button, or drag the file into the dotted line - then click **Finished** to attach the file.

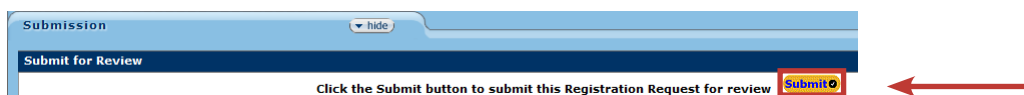


20. You are now ready to submit the registration. Click the **COE Actions** tab at the top of the screen.

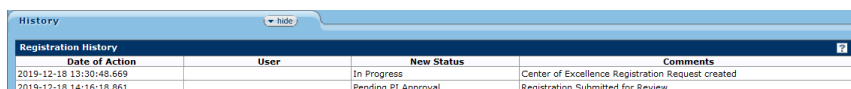


Note: In the *Personnel* section, you will see the Requestor for this registration and the PI already have viewing access to the COE registration in WVU+kc. You can add other viewers if desired.

21. In the *Submission* section, click the **Submit** button to send this clinical trials registration to the Principal Investigator for approval, which will forward it to the Center of Excellence for review. If you are the PI, the registration will go directly to the Center of Excellence.



Note: You can see each step of creation, submission, and approval by viewing the *History* section on the **COE Actions** page.



Registration History			
Date of Action	User	New Status	Comments
2019-12-18 13:30:48.669		In Progress	Center of Excellence Registration Request created
2019-12-18 14:16:18.861		Pending PI Approval	Registration Submitted for Review