



Researcher Guide for Full Board: Clinical Trials

Office of Research Integrity & Compliance

Version 2

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This document is intended for investigators and administrators who are creating a Full Board: Clinical Trial protocol to the WVU IRB for review. This guidance document will summarize the expectations of each section of the IRB application. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at IRB@mail.wvu.edu.

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Requesting WVU+kc Access

Anyone who needs to create or edit an IRB protocol needs to request access from ITS. To submit the request, please follow the steps under the *Training* section of the [WVU+kc page](#) of the ORIC website. There will be a short tutorial video on how to use and navigate the electronic submission system. **It is highly recommended that new users watch this video.**

This guidance document is intended to assist faculty and students in developing a Full Board (non-clinical trial) protocol. This sequence follows the protocol in the order it appears in WVU+kc system.

CITI Training Requirements

Anyone listed on the study, regardless of his/her assigned role, must complete one of the following courses in Human Subjects Research:

1. Biomedical Research Investigators (Human Subjects Research)
2. Social and Behavioral Research Investigators (Human Subjects Research)

Note: Abbreviated or Responsible Conduct of Research (RCR) versions of the biomedical or social and behavioral courses cannot be accepted.

Only Primary and Co-Investigators are required to complete the following course, in addition to the training listed above:

3. Conflict of Interest

Creating a Full Board: Clinical Trial Protocol

When you log into the system, you will be taken to the Dashboard page. This page is pictured below. Click on the IRB menu (outlined in red below) at the top of the Dashboard. Select the option to 'Create Protocol.'

The screenshot shows the WVU + KC Dashboard. At the top, there is a navigation bar with the following items: Dashboard, Proposals, Awards, IRB (highlighted with a red box), Internal Grants, Admin, Quicklinks, System Admins, and News Feed (none). Below the navigation bar, there is a 'News Feed' section with the message 'No news feed items found.' and a 'Last Activity' section with a list of activities: 'Open IRB Protocol null', 'IRB Action List', 'Open IRB Protocol null', and 'IRB Action List'. On the left side, there is a sidebar with icons for Proposals, Award, IRB (highlighted with a yellow bar), and Internal Grants. On the right side, there is a main content area with a dark blue header containing tabs: 'Not Submitted', 'Submitted to IRB', 'Active Protocols', 'Amend or Renew', and 'All My IRB Protocols'. Below the tabs, there is a message: 'No results found.'

A blank protocol will open. Only fields with an asterisk are required; all other fields are optional and/or specific to certain studies. A series of tabs are at the top of the page. Use these tabs to navigate throughout the sections of the protocol.



This guide will go through each of the above protocol sections and explain the information that is needed in each.

Protocol Tab:

Description: This section has a 40 character limit. Choose wording that will identify the protocol to you and your research team.

Protocol Type: Choose from the drop down list. The type you select determines the questions you will be asked later, based on the level of risk to the subjects. If you require additional assistance in determining your protocol type, please contact the ORIC at 304-293-7073 or at IRB@mail.wvu.edu. The ORIC provides multiple [Checklist and Guidance](#) documents to help investigators make this determination. If a study does not fit in any of these categories it is full board. Full Board studies are divided into two types: Clinical Trials and Non-Clinical Trials.

- /// **Full board (non-clinical trial)** studies are considered more than minimal risk or do not fit any Exempt or Expedited category (please see the checklist on the ORIC website under checklist and guidance). The Non-Clinical Trial option is generally for those studies that are more than minimal risk but may not involve the use of drugs or devices.
- /// If the study is a clinical trial please choose **Full Board (Clinical Trial)** – these are mainly drug and/or device studies).

Please note that all studies involving drugs (even if it is FDA approved and/or commercially available) will require full board review.

Note: Studies involving children are not automatically full board. This is only true if the study is more than minimal risk or does not fit in an expedited category.

Title: The official title of your study.

Principle Investigator: Only faculty or permanent staff may be the PI. If a student is entering the protocol, please add the PI name using search (magnifying glass icon). Type in the last name of the PI and click Return Value.

- /// If a student is creating the protocol, the student's name needs to be included as a co- investigator under the Personnel tab. That is the only way to be able to access the study after logging out. At least these two personnel need to be added before you submit.

Lead Unit/Department: Use search to find your department. If you know the department number (WVUXXX) you may enter the value without using the search. If searching by name, use a keyword (i.e. Psychology). Click Return Value to enter the department on the protocol page.

Keyword: Click search (magnifying glass icon) for a keyword that best matches your study design.

Note: The additional information section on the protocol tab is only for Full Board (Non Clinical-Trial) and Full Board (Clinical Trial) studies. If the study is a co-op oncology group, please select the group in this section.

Personnel Tab:

Principle Investigator: Open the tab and click “Show” beside Person Details. Add the qualifications of the PI; this can be one sentence containing the PI’s affiliation/position with WVU and the number of years that he/she has conducting research. Be sure that the PI’s contact information is accurate.

Note: A student, PhD student, resident, or non-affiliated person may not be the PI for a protocol.

Co-Investigators: Any student project should have the student listed as the Co-I. If collaborating with other institutions, investigators not affiliated with WVU may be added as Co-I’s.

Study Personnel: If the PI is not qualified to perform a procedure that is part of the research, the IRB may require that a person with the correct qualifications be added to the research team. Study personnel also includes any regulatory workers, as well as student assistants or statisticians working on data analyses.

- /// If you have persons from another institution collaborating with you, they can be listed as non-affiliated co-investigators on the study. Or you can indicate that this is a non-WVU employee who is an affiliated site’s Principal Investigator.

Research Team: Primary assignments must be selected for personnel on Full Board protocols indicating one or more activities the person will be conducting: recruiting, consenting, data collection/analysis, procedures, regulatory personnel, and/or study coordinator. The WVU+kc system will show each person’s CITI Ethics training once they are added to a protocol. Be sure that the necessary training is completed and up-to-date.

- /// If CITI training is not showing in the electronic system, but the team member has complete the required course(s), please upload their completion certificate provided by the CITI system.

///

Permissions Tab:

This section is where you will grant each person listed on the Personnel tab their rights to access the protocol. To provide someone with the ability to edit and submit the protocol, mark them as an ‘Aggregator.’ If someone only needs to be able to view information in the protocol, mark them as a ‘Viewer.’

The PI is provided ‘Aggregator’ rights automatically and they should always be able to access, edit, and submit the protocol.

Questionnaire Tab:

Human Subject Research: There is a possibility of 3 questions for this section of the Questionnaire. Each of these must be responded with yes. If you answer no, that would indicate that the study is Not Human Subjects research and the wrong protocol type was chosen on the first page of the application.

Funding: Provide a yes or no response. The IRB is interested in knowing who is paying for the study, if anyone. If the PI is receiving external funding, it needs to be mentioned in the consent form. Delete: If the funding is private or industrial, the billing contact is needed. The next upgrade will give you an option to add the billing contact in this section, for now please add the billing contact to the Design section.

/// If the funding is external, the billing contact is needed.

Location: There may be more than one location, please enter each appropriate option. If you are conducting the study in various locations (homes, courthouses), state that in the text line.

HIPAA: To determine If PHI is being used, it must include both health information and an identifier. A list of the [18 HIPAA Identifiers](#) is provided on the ORIC website.

In most cases the HIPAA form must be included in the consent form. Consent form templates can be found on the [IRB Forms](#) page of the ORIC website.

/// A separate HIPAA form is only used if the HIPAA information is not part of the consent form. In that case, it is a separate form and must be used in conjunction with the consent form.

A [HIPAA Waiver](#) must be requested to review PHI information without first receiving the patient's permission (with signature) to do so.

A Data Use Agreement is only used if WVU is sharing identifiable HIPAA data with another institution or entity. A limited data use agreement can be signed in the ORIC and must be attached in the attachments.

/// If identifiable data/samples are received from another entity, a Data Use Agreement should be attached from the other site.

Consent Procedures: Will signed informed consent be obtained? If this is a prospective study the answer is usually yes. All studies involving drugs and or investigational devices must include a consent form. For full board non-clinical trial studies the answer can only be no if the researcher can justify a waiver. Mere convenience is not justification.

The federal guidance states that the researcher must make an effort to obtain consent and prove that the research could not be carried out. At that point an amendment may be submitted to request consent form waiver or consent form documentation waiver. Or this could be a records review where consent is not necessary, in which case it would not be a full board study.

/// A waiver of informed consent means that no consenting will be done.

/// If you request a waiver of documentation of consent, the consent form document will be used but will not be signed by the participant. It may or may not be signed (like a cover letter) by the investigator. (This is often case with internet studies. WVU has a template for this type of consent form on the website under forms.)

- /// The consent process question is to address how and where the consent is obtained. Does the participant take the consent home to discuss with family and friends? Is the study explained by a student, nurse, or coordinator? When does the person obtaining consent interact with the participant?

The last question is to indicate who will obtain consent, and how they will be trained to obtain consent.

Note: If consenters are not listed on the consent form, the consent should state, “This study has been explained to me by _____” leaving a blank where the consentor can print in their name and sign their name at the end of the form.

Advertisements: Please see the checklist for [Advertisement Requirements](#). Some of the criteria are that the ad must include the word research must be stated near the top, the compensation cannot stand out by font-size or color, and the PI and the PI’s department must be named.

Radiation Safety: This only applies to studies where radiation is given as part of the research protocol, not if the radiation is being administered as part of the participants standard of care.

Biological Safety: If you are not using a hospital lab and are working with infectious agents, you will need to apply for approval by the Institutional Biohazard Committee (IBC). The approval letter must be attached before IRB approval can be given.

Subjects: You will first be asked to state the maximum number of subjects to be enrolled in the research. Any subjects that are enrolled (or any charts/records that are reviewed) by the WVU or VAMC research team should be included.

- /// We encourage the PI to put a value higher than what is estimated. **It is a violation to go over that number, but enrolling less than the goal number is not an IRB violation.**
- /// The total number nationwide may be the same number as above if this is physician created study.
- /// The next set of questions concern any drugs that are being used. The IND number must be listed for all investigational drugs. Please be aware that this number must be verified in one of the attachments (for example: the sponsor protocol or an FDA letter).
- /// Any devices being used must be listed with the corresponding information.
- /// Any samples collected need to be described.
- /// Will this study involve cancer patients or staff at the Mary Babb Randolph Cancer Center (MBRCC)? If yes, the study must be approved by the PRMIC (cancer studies review committee) before it is submitted to the IRB. The approval letter from this committee can be attached to the IRB submission.
- /// If the study is funded by the Clinical and Translational Science Institute (CTSI), a review letter from the Clinical Trials Working Group (CTWG) needs to be attached to the IRB submission.

The lay summary must be in lay language without jargon and must be at the 6th grade level. There are lay persons on the Board and they must be able to understand the lay summary.

Data Protections: If there are any questions regarding the security of the data collected in this study, answer with a yes. You will be contacted by a WVU data security specialist. If you are planning to share or transfer data between institutions, it is recommended that you select yes.

Notes & Attachments Tab:

Attachments: Any attachment noted on the Questionnaire page must be included here: Consent forms, advertisements, recruitment scripts, letters, surveys, variable lists, HIPAA forms, etc. Name each document, so that it is clear delete: as to which document is being referenced.

- ✓ Any assent, consent, or parental consent must be in .pdf format in order to be watermarked with an approval and expiration date. We cannot approve if not a .pdf. Please remember ONLY watermarked consents / assent may be signed by participants.
- ✓ All old amendments and continuing reviews should be removed from this section, since the newest one is now in the Questionnaire section. Only valid documents that are presently being used or will be used should be in this section.

Notes Section: Study team members are able to write notes and comments regarding revisions requested, or particular sections of their IRB application. These notes are read by the reviewers.

Protocol Summary Tab:

All information entered into the protocol, including attachments, will be viewable from this page. Correspondence between the IRB and the investigators can be viewed from this page.

Note: This page cannot be edited.

Protocol Actions Tab:

Request an Action: This is where you are able to submit your protocol for review, close your protocol, or notify the IRB of any issues or enrollment closure. The following options are available under this section of the Protocol Actions tab.

- ✓ **Submit for Review** – If you are a Co-Investigator/student, once you have completed creating the study, the protocol is then ready to be submitted. You should keep the 10 digit protocol number for referencing the protocol at a later time.
 - **Submission Type:** The type of submission for the protocol will depend on the actions already taken on it. This section will automatically populate with the correct response.
 - **Initial Submission** – This is the option you will choose when you are submitting your protocol for the first time.
 - **Response to Revisions** – This is the option you will choose when you are submitting your protocol after revisions have been requested by the IRB office and completed by the research team.
 - **Submission Review Type** – The selection here should match the first tab (Protocol) selection.

Submit: After the above determinations are made, the Submit button is ready to be pushed. If the protocol is submitted by the PI, the protocol will come directly to the IRB office for review. If submitted by the Co-Investigator, the PI will have to approve the submission after being notified by the KC system. The PI needs to open the Protocol Actions page and scroll to the bottom of the page, click the Approve button, and then the Close button.

Route Log: The route log will show when the submission was created and where it is in the system. If it shows 'Multiple Users' you will know it arrived in the ORIC. You can track where the protocol is in the system by viewing the route log.

Specific Minor Revisions: Once review is complete, you will receive a correspondence from the WVU+kc system notifying you of either revisions required or that the protocol was approved.

Upon review, the study may be sent back to the PI for specific minor revisions. The revisions request letter can be found in both the Correspondence section of the Protocol Summary tab and the Protocol History section under the Protocol Actions page. Go to History. In the tab for Correspondence click on show.

- Upon completion, the investigator must submit the protocol again using:
 - Response to Revisions: This is the option you will choose when you are submitting your protocol after revisions have been requested by the IRB office and completed by the research team.

Approval Letters: Acknowledgement and approval letters can be found either in the correspondence section of the Protocol Summary tab, or in the Protocol History tab. Both locations can be used to open, view, and download any correspondence.

Note: An email notification is sent to the PI for any correspondence via the WVU+kc system on behalf of the IRB office.