



This document is intended for investigators who are creating an Exempt protocol for submission 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 an Exempt 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 background), and Internal Grants. On the right side, there is a main content area with a 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 'Exempt' 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.

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.

Note: It is important that everyone who should be able to edit the protocol has aggregator rights. Remember only aggregators can make changes to the protocol. If personnel are added after the protocol is approved, they will only receive viewer rights automatically. The person making the changes must decide at that time, if aggregator rights should be given. Viewers may only view the protocol, but cannot make any changes. Anyone on the study team who may now or in the future need to type or edit information should be given editing (aggregator) rights.

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.

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

Exemption Category: Choose all categories that best suit the research that will be conducted. All others can be answered with a 'no'. You will also be required to describe, 1-3 sentences, how your research meets the requirements of the exemption category. An example is:

- /// This is an online survey conducted with adults regarding their impressions of political debates.
- /// This is a retrospective chart review from year 2014 - 2016 of all patients seen in the Family Medicine clinic with diabetes who have high blood pressure.

Design: The lay summary should not contain jargon or technical terms. It must be written at a sixth grade language and comprehensible by someone without any experience in the research area.

In outline form, full describe:

1. Participants will be students enrolled in, etc.
2. Participants will be invited to be part of the study via, etc.
3. Participants will be given a survey with a cover letter, duration of time, etc.
4. Participants will place in an envelope and, etc.
5. I will pick up envelopes from the box.
6. Data will be analyzed.
7. I intend to publish or this is a thesis/dissertation.

A common issue for researchers is answering the investigational procedures question. Since this is a research study there are procedures that are being conducted to answer the purpose of the research. This response needs to be answered with all the procedures that are being conducted for the sake of the research that would not be done otherwise.

▮ Examples for a biomedical study could be taking an extra blood draw or MRI scan for participants who would be having procedures done for standard care.

▮ For social behavioral studies this could be a survey that is being done for research.

On the other hand, Standard of Care procedures are those that would be done even if the research was not conducted. Often, the appropriate response is 'not applicable.'

If you are recruiting for surveys, interviews, or focus groups per telephone or per email you must attach a recruitment script in the Notes and Attachments. The script should

1. State that you are recruiting for a research study,
2. Give a short description of requested involvement (e.g. this is a questionnaire regarding your understanding of friendship, which will take approximately 10 minutes),
3. State that participation is voluntary and confidential or anonymous.
 - a. The procedures section should also explain when and how the script is used and when and how the questionnaire will be distributed.

If any questions are asked that may distress the subjects – a counseling referral list must be attached.

A question asks for the investigator to describe how privacy will be addressed. A description of where the interaction between the researcher and the participant will take place should be provided. Indicate if audio recording will occur and, if it does, you must include this in the Cover Letter.

If participants are being deceived, or there is an element of deception to the research, there must be a debriefing letter which must be used to inform the participant, at least by the end of the study, about the deception and give them the option to withdraw their data from the study.

One of the final questions is meant to ascertain if the Mary Babb Randolph Cancer Center (MBRCC) staff or patients are involved in the study. All studies that are done with this targeted population must go through the PRMC Committee. So if the response is yes, then there needs to be letter from PRMC approving the study.

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.

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.

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. No identifiable information can be recorded from medical records in exempt protocols.

A [HIPAA Waiver](#) must be requested to review PHI information without first receiving the patient's permission (with signature) to do so (typically done in a Category 4 Exemption).

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.

Confidentiality: The only time collected data is not identifiable is when an anonymous survey is conducted. Otherwise, this answer should always be yes.

The question regarding privacy and confidentiality needs to be answered in two parts:

1. Where does the interaction take place with the participant? If it is online or in an environment of the subject's choosing this should be stated since there are no privacy issues. If in a clinic or hospital it should state that the consenting or procedures are in a private room. If interaction takes place somewhere else, the PI must confirm that there are no privacy issues with the processes.
2. The second part regards how the data is stored and maintained.

Note: For a Category 4 Exemption, you will have access to identifiable data in the medical charts, so the answer to this question would be 'Yes.' It is your responsibility as the research team to ensure that all identifiers are removed before analyzing data in order for it to remain Exempt. If you prefer to keep identifiers when gathering data, the protocol will need to be submitted as an Expedited protocol.

Financial Considerations: A common incentive, when recruiting students, is to offer extra credit. To do this, the College or School of the PI must have an IRB approved extra credit policy filed with the IRB. Schools and Departments that have an approved extra credit policy are listed on the [IRB Policies](#) page of the ORIC website.

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** – Once you have completed creating the study, the protocol is ready to be submitted. You should note 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.

Acknowledgement/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.