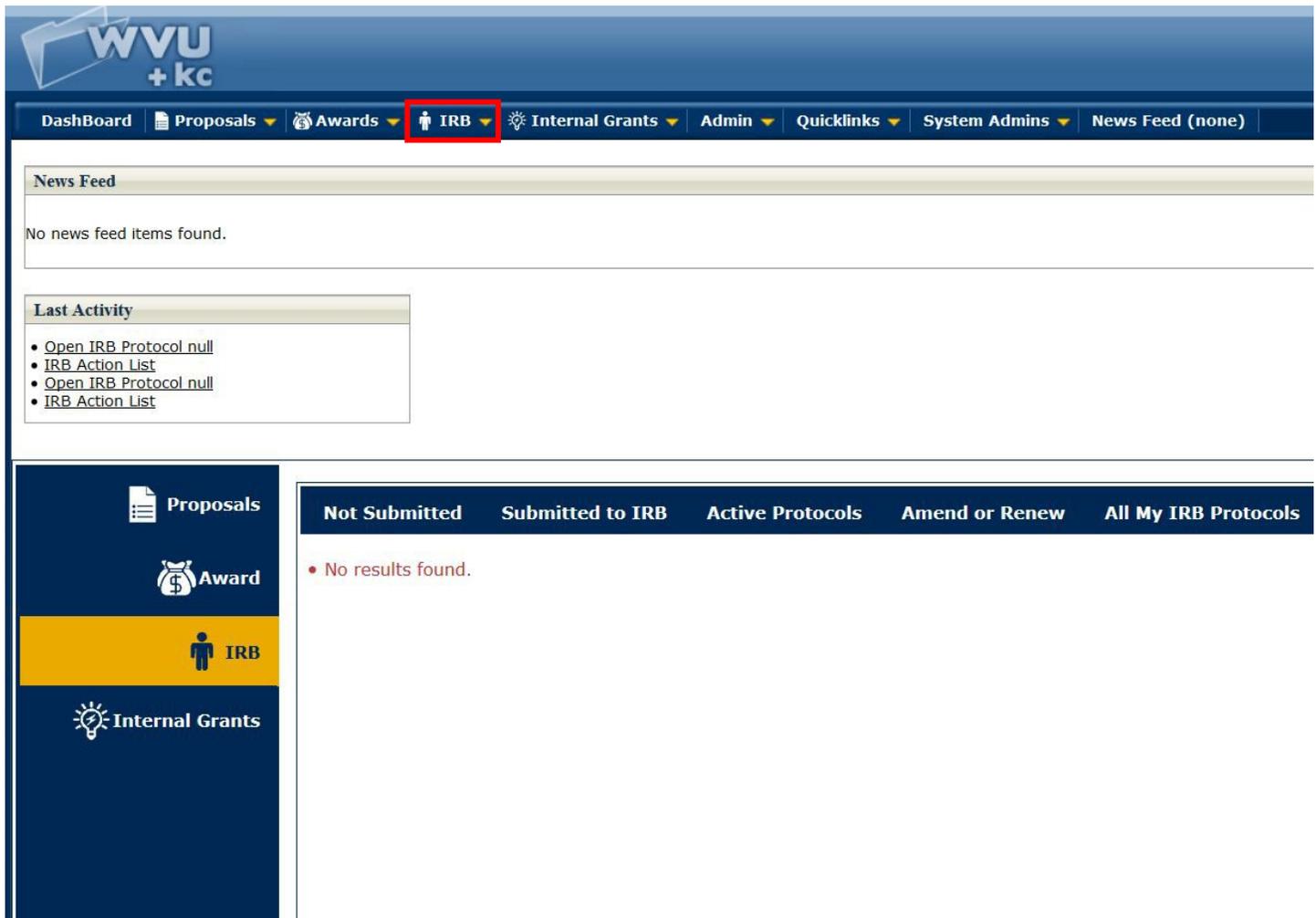


This document is intended for researchers who are creating an Exempt Protocol submission. This guidance document will summarize the requirements for each section of the protocol application. Creating an Exempt Protocol

1. Log into the WVU+kc system and begin on the Dashboard page. This page is pictured below.
2. Click on the IRB menu (outlined in red below) at the top of the Dashboard.
3. Select ‘Create Protocol.’



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.



Protocol Type

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

The OHRP 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.

Principal 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 needs to have aggregator rights under the Permissions tab. That is the only way to be able to access the study after logging out.

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

Principal 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 conducted research. Be sure that the PI’s contact information is accurate.

Note: A student, Ph.D. 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 and 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 Principle 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 view the information in the protocol, select 'Viewer.'

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

Note: It is essential 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 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 email address 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 in 1-3 sentences, how your research meets the requirements of the exemption category. An example is:

- ✓ The research will include an online survey conducted with adults regarding their impressions of political debates.
- ✓ The research will include a retrospective chart review for 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 in an eighth-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. Your response should include all procedures that will be conducted related to the research that would not be done otherwise.

- Examples for a biomedical study could be 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.

Standard of Care procedures are procedures 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 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 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 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. If the response is YES, attach a letter from PRMC indicating approval.

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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 enrolled in the research. Any subjects that are enrolled (or any charts/records reviewed) by the WVU 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 as above if this is a 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) must be attached to the IRB submission.

HIPAA: To determine if PHI is being used, it must include health information and an identifier. A list of the 18 HIPAA Identifiers is provided on the OHRP 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, state that the consenting or procedures will occur in a private room. If the interaction occurs 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 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 on file with WVU OHRP. Schools and Departments with an approved extra credit policy are listed on the WVU OHRP website.

Data Protection: If there are any questions regarding the security of the data collected in this study, answer with a yes. If you are planning to share or transfer data between institutions, select yes. Refer to the WVU OHRP website for more information regarding Data Protection and WVU institutional requirements as soon as possible to avoid delays with protocol approval.

Notes and 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 as to which document is being referenced.

- ✓ Any assent, consent, or parental consent must be in .pdf format for the system to insert the IRB approval watermark with the approval and expiration date. Participants may sign ONLY watermarked consent and assent forms. If using e-consent materials, refer to the WVU OHRP Guidance section for more information.
- ✓ 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 can write notes and comments regarding revisions requested or sections of the IRB application. The reviewers read the notes.

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 the protocol is submitted for review, close the 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 ten-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 submitting your protocol for the first time.

- ✓ **Response to Revisions** – This is the option you will choose when 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, click on the SUBMIT button. If the PI submits the protocol, the protocol will come directly to the WVU OHRP office for review. If submitted by the Co-Investigator, the PI must approve the submission upon system notification.

PI Approval: To approve the protocol, the PI should open the Protocol Actions page and scroll to the bottom of the page, click Approve, and then Close.

Route Log: The route log indicates when the submission was created and where it is in the system. If it shows ‘Multiple Users,’ the application has arrived in the WVU OHRP office. Use this log to track where the protocol is in the system.

Specific Minor Revisions: Once the review is complete, the system will send notifications for revisions requests or protocol approval.

Upon review, the study may be sent back to the PI for 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, resubmit the protocol:

- Select, Response to Revisions

Acknowledgment/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 all Correspondence send via the WVU+kc system.