Guidance on Exempt Protocols for Researchers

To access the KC system you will need to attend training, which may be by signing up for a training session or if you cannot attend in-person training, watch this video which will explain how to submit a protocol, create and submit amendments/renewals, search for protocols, and other various functions of the WVU+kc IRB Protocol module. After watching the video, you will need to complete a short test in order to submit your request for access to create protocols. http://kuali.wvu.edu/training/protocol-training.

This tip sheet is intended to assist faculty and students in developing an exemption protocol. This sequence follows the protocol in the order it appears in KC.

Only fields with an asterisk are required, all other fields are optional and specific study related.

Please be sure to save often, since the system may time out.

When you begin a protocol, you will see a series of tabs at the top of the page. Use these tabs to navigate throughout the sections of the protocol.

- **Protocol**
  - Description: This section has a 40 character limit. Choose wording that will identify the protocol to you.
  - Protocol Type: Choose from the drop down list - the type you choose determines the questions you will be asked later based on the level of risk of your research. For more information, please refer here to the protocol type criteria. If not certain, please call the ORIC office for assistance.
  - Title: The official title of the 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) and the student’s name as a co-investigator under the Personnel tab. Both need to be added before you submit.
  - Lead Unit/Department: Use search to find your department. If you know the department number (WVUXXXX) you may enter without using search. If searching by name, use a keyword to search the department (i.e. Psychology).

- **Personnel**
  - Principal Investigator
    - Open the tab and click on show Person Details. Add qualifications of PI to conduct research. This can be one sentence stating the PI’s role at University
(e.g. adjunct professor teaching forensics) and years of experience conducting research (e.g. with 10 years of experience conducting human research in this area).

- Check Contact Information to ensure correctness.
- A non-affiliated person may not be the principal investigator on a protocol, except in certain cases. Please contact the ORIC office for more information (304) 293-7073.

- Co-Investigators: Students will need to add themselves as Co-Investigators on this page.
- If you have persons from another institution collaborating with you, they can be listed as non-affiliated co-investigators on the study.

Please be aware that KC now shows training under each person, so this is an opportunity to take or update training if necessary.

Permissions

- This section will be where you edit your viewer/editing rights for the protocol. The PI will automatically receive editing rights (aggregator) and as you add more personnel, you may choose whether they are a viewer or aggregator. Once you choose, please click the Add button.
- Note: It is important that everyone who should be able to edit the protocol needs to have 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

Human Subject Research

- All three questions must be answered with a yes. If you answer any of the three with a no, it is not human subjects research. Please be aware that collecting individual information is considered human subjects research even when you are looking at charts or records, or an anonymous survey.

Funding Source

- Please enter if there is a funding source and then select the type of funding.
**Exemption Category**

- Choose all exemption category(s) that best suits the research you will be conducting. Answer all others with no.
- Describe how your research meets the requirements of the exemption category.
  
  *Response:* 1-3 sentences, state that this is an anonymous on-line survey, a mail survey, interviews conducted at the school, records review, etc.

**Design**

- In outline format, fully describe all procedures to be performed with human subjects; e.g. how recruited, what they will be asked to do, how long it will take, etc.
  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.

  - If you are recruiting for surveys, interviews, or focus groups in person, per telephone or per email you must attach a recruitment script in the Notes and Attachments. The script should state that you are recruiting for a research study, a short description of requested involvement (e.g. this is a questionnaire regarding your understanding of friendship, which will take approximately 10 minutes), that participation is voluntary and confidential or anonymous. The procedures section should also explain when and how the script is used and when and how the questionnaire will be distributed.
  - Answering the above Design section when using existing data (Category 4), you will need to explain what records (i.e., medical, public) are being reviewed, what data will be retrieved and if any identifiers will be recorded. The list of variables needs to be attached in the Notes and Attachments section.
  - Note: If procedures exceed the character limit, you may continue the descriptions via an attachment in Notes and Attachments and note in this section the title of the attached document.
- Will the cover letter be used as a recruitment script?
  - Attach the cover letter in the Notes and Attachments. There is a sample cover letter that can be found [here](#) for reference.
- Does the research involve surveys/interviews/questionnaires/focus groups?
  - If no, be sure that the correct category is chosen under Exemption Category.
- Will you be asking any questions that might distress your subjects?
  - If so, you will need to attach a counseling referral list under Notes and
Attachments.

- Will you be audio recording?
  - If so, you need to mention it to your subjects in the cover letter.
- Does this study involve anyone in the Mary Babb Randolph Cancer Center? If yes, a PRMC letter needs to be attached under Notes and Attachments. For more information, please call our office at 293-7073.

Locations of Research

- A location needs to be named.
- If the study is conducted at an off-site facility, a letter of permission from that facility needs to be attached in the Notes and Attachments.
- If this is an international studies, you must consider:
  - Whether the questions and consents require translation in another language, if so, there must be a signed letter verifying that the translation is accurate. The letter must be from an expert who is not involved in the study.
  - A signed letter is needed from an expert that the questions and methods will not violate any cultural norms of that culture. The letter must come from an expert who is not part of the study.
  - The two letters may be combined in one document.

Subjects

- Indicate the maximum number of subjects.
  - The number is an estimate. Please estimate high. It is a violation of the protocol if you enroll more than the number given here. Once approved, if you think you may need more, an amendment needs to be submitted. Please do not leave this blank or say that there is an unknown number of participants expected.
- Are the subjects less than 18 years old?
  - If you answer yes and the study is not simply observation or records review it cannot be exempt.
- Will the subjects include any of the vulnerable groups?
  - The question refers to specifically targeted vulnerable groups, not incidental individuals.
- Does the research involve participants who could be unduly influenced?
  - The question refers to an employer who targets employees, or a faculty member who targets their own students.
- Describe how and where researchers will interact with participants. How will these interactions be kept private?
- Describe where the participant will be when recruited. Describe where the participant will be when completing the study. If the recruitment is on-line and surveys are taken
on-line then the answer would be that there are no issues with privacy, since the subject participates in their own environment. Privacy is in regards to your interaction with the subject.

- Describe and assess potential possibilities for risk or harm to the subjects.
- Describe any potential risks of physical, social or behavioral harm.

**HIPAA**

- If this is a Category 4 Exemption using retrospective medical data, you must answer Yes to the first question (Does the research involve PHI?) under this section. If you answer yes, you must go to the next question.
  - The only HIPAA form that applies to an exemption is the HIPAA waiver form: If the study looks at medical records and no identifiers or links will be recorded, pick waiver request form. You can find this form [here](#). Then upload on the Notes and Attachments page.

**Advertisements**

- Will there be advertisements? If the answer is yes:
  - Select the advertisement method.
  - Describe the advertisement methods.
  - Attach all advertisements in the Notes and Attachments

**Biological Safety**

- If you are collecting any bodily fluids or tissues the answer should be yes. In that case, an Institutional Biohazard Committee approval needs to be attached to the Notes and Attachments.

**Confidentiality**

- Is there any way the PI or the research team can identify subjects using the data?
  - This should be answered Yes, unless the study is totally anonymous. Interviews CANNOT be anonymous. Recording without identifiers is not anonymous. This answer can only be no if you are conducting a totally anonymous survey with no identifiers.
  - 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.
  - Describe the steps that will be taken to maintain the confidentiality of the data and privacy of subjects.
    - If a Master Code will be used to link subjects to a set of data, please discuss here.
    - You can discuss how you will be taking steps to keep data secure and removing
Financial Considerations

- Will subjects be paid or reimbursed? If yes:
  - Indicate the total dollar amount.
  - If a gift card will be used, state the dollar amount value.
- Will students receive extra credit for participating?
  - Extra credit can only be given by those departments that have an IRB approved policy for extra credit.

Notes & Attachments

- Add Protocol Attachment
  - Attachment Type: Select the type of attachment, if the appropriate one is not found select Other (course syllabus, etc.)
  - Status: Select Complete unless the document is a draft.
  - Description: Be specific describing the type of attachment, state if this is a revision and the version.
  - File Name: Browse and attach.
- The box will repeat until no more attachments are added. Please delete any attachments which are no longer being used. If a revisions request to an attachment is made, delete the old attachment.
- Notes
  - If a revision request is made, please respond in the Notes Section.

Protocol Actions

Request an Action

- 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
    - 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. Directions for approving the submission can be found in the email you will receive.

Correspondence from the IRB office post-submission:

Once the review is complete, you will receive a correspondence from the KC system noting that the protocol is approved or if there are revisions needed:

Specific Minor Revisions

- Upon review, the study may be sent back to the PI for specific minor revisions. The revisions request letter will be found in the Summary and History section under the Protocol Actions page. Go to History. In the tab for Correspondence click on show.
- Respond in the Notes section of Notes and Attachments, refer to each item under the same number.
- Revise as requested.
- The responses to the revisions request should be in the Notes section of Notes and Attachments tab, each answer should correspond in the order that the questions were posed. The response needs to state which section of the protocol or attachment has been changed. The changes need to be made in the protocol and/or attachments as appropriate.
- Upon completion, the investigator must submit the protocol again.

Acknowledgement/Approval Letters

- The acknowledgement and approval letters are under Summary and History in the Protocol Actions Page. Go to the correspondence in the History section.

Note: An email notification is sent to the PI for any correspondence via the Kuali Coeus system for the IRB office. To find the correspondence, go to the Protocol Actions page, then to Summary and History, then History, and then to correspondence and view. The correspondence can be uploaded to your desktop or printed as needed.