Guidance on Expedited 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 expedited 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.

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.

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

When you open the protocol for review, you will see a series of tabs:

- Protocol
- Personnel
- Permissions
- Questionnaire
- Notes & Attachments
- Protocol Actions
- Online Review
- Medusa

- **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, 304-293-7073.

- **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. 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 without using search. If searching by name, use a keyword (i.e. Psychology).

- The additional information section on the protocol tab is only for full boards and clinical trials.
**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 subject 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: If this is a student project, the student 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.
- Research Team
  - Be aware that if the PI is not the person qualified to do all the procedures in the protocol (i.e. the PI is a mechanical engineer but the protocol requires surgery, the IRB reviewer may require that a person with the correct qualifications be added to the research team.

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. Be sure to 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.
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 subject 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

- There needs to be 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.

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.

Design

- **Question 1**: Used for the lay summary – should be in 6th grade language
- **Question 2**: The procedures need to be detailed. It helps if you give the procedures in 1, 2, 3 format. Be sure to be very clear as to where the participants are recruited, how they are approached, when consent is obtained or a cover letter is given, what the participant is asked to do and how long that will take. How many times will the participant be asked to do something? Will there be reminder letters, follow-up, etc.? After reading this section, the IRB reviewer should know exactly how the subject will be approached, where and when consent (if appropriate) takes place and what participants are being asked to do.
Participants will be students enrolled in, etc.
- Participants will be invited to be part of the study via, etc.
- Participants will be given a survey with a cover letter, duration of time, etc.
- Surveys will be placed in an envelope and, etc.
- I will pick up envelopes from the box.
- Data will be analyzed.
- Intent to publish. Is this a thesis/dissertation?

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.

- Group Assignment Question: If there is more than one group, if subjects are being used in a matched group design, if a control group is used, if randomization is involved, this should be explained here.
- Survey Question: Surveys and Questionnaires include demographic forms. Any surveys or questionnaires that will be used must be attached in the Notes and Attachments section.
- If you state that there are stressful questions such as suicide ideation, abuse, relationship conflicts, illegal behavior, there needs to be a counseling referral list in the Notes and Attachment page.
- In the Description of Procedures section of the consent form, cover letter or at the end of the survey. There should be a statement regarding the referral list.
- Scientific Rationale and Literature Review Question: Remember to add some literary references. At least a few citations are required. These should be summarized, just giving the references with no comments is not sufficient.
- Data Analysis Question: Describe how the data will be analyzed. If appropriate, and this is a quantitative study, a power analysis should be included.

**Expedited Review**

- Question 1: Is there more than minimal risk involved in this research? Minimal risk studies would include non-sensitive surveys, focus groups, giving classes on how to brush teeth correctly, ultrasounds, blood draws, and registry studies. More than minimal risk studies are asking sensitive questions, X-rays, trying a new method of extracting teeth, and drug or device studies.
  - If answered No, this cannot be an expedited. Go to the Protocol page and change to the appropriate review level.
If answered Yes, then the categories of expedited are named. One or more categories must be selected. Please check all categories that apply, i.e. survey and video and blood sample.

- If you need more information on the expedited categories please go to our Expedited Review Determination Checklist on the oric website and review the checklist section for expedited. You must answer yes or no for all categories in order to complete this section.

- The textbox should only address how the study fits the category(ies) chosen above (i.e. Survey of faculty regarding teaching practices if category 7 was chosen.)

- Intervention Question: An intervention can be a physical or medical procedure, but it may also be a classroom or training session, or other manipulations of the subject performed for research i.e. a video game or a computer program.
  - If answered Yes, the next question asks about medical research procedures and will ask specifics on those procedures.
  - If answered No, the explanation of the intervention is requested.

- Deception Question: If this is marked yes, then a debriefing letter informing the participant at least by the end of the study about the deception, and giving the participant the option to withdraw their data from the study. The debriefing letter needs to be attached in the Notes and Attachments section.

- Cancer Question: If your study targets the Mary Babb Randolph Cancer Center faculty or patients, then there needs to be letter from the Protocol Review and Monitoring Committee (PRMC) in the Notes & Attachments section approving the study.

**HIPAA**

- To be covered by HIPAA, a study must ask for medical information such as blood pressure, diagnosis, etc. and have an identifier. All medical record/chart reviews involve HIPAA. But also if it is a survey that asks do you see a doctor for your illness? Do you take medication when you have a cold? What type do you take? - IF there is an identifier. The list of 18 identifiers is on our website at: http://oric.reserach.wvu.edu/r/download/134087. Remember exact dates are identifiers, such as date of birth, date of hospital admission or release, etc. If there is no identifier the data may be medical but it is anonymous and cannot be linked to any individual so HIPAA is not required.
  If the response to the PHI question is yes then the PI must choose which HIPAA form will be used.
  - All HIPAA forms and consent forms with HIPAA language are on our [website](http://oric.reserach.wvu.edu/r/download/134087) and need to be attached in the Notes and Attachment page.
• For any study with a consent form, HIPAA information should be part of the consent form, i.e. Only Minimal Risk with HIPAA consent. The consent form will state this in the upper right corner. This is the first option after the “is this PHI” question.
• For studies without a consent form, or if records are reviewed before approaching subject for consent then the HIPAA waiver form should be chosen and the HIPAA waiver attached. Any retrospective medical chart study must use the HIPAA waiver form.
• The other options listed on the Questionnaire should not be used in most cases.
• The option for authorization from the subject is ONLY for those few cases where the consent is not merged with the HIPAA. This is a separate HIPAA form to be signed by the patient.
• The Data Use Agreement is only for sharing HIPAA data with another institution or entity. The Data Use Agreement must go through Legal Counsel before submission to the IRB.
• The option for HIPAA De-Identification Certification is only for non-human research subject protocols (NHSR).
• The decedent HIPAA form is usually used for NHSR protocols.
• If the data/sample is received from another entity, a Data Use Agreement should accompany this if HIPAA is involved.

Subjects

• Maximum number: Any subjects that are enrolled (or any charts/records that are reviewed) by the WVU research team. This can be anywhere nationally or internationally. We encourage you to estimate this number high. **It is a violation to go over that number, but enrolling less than the goal number is not an IRB violation.**
• Worldwide numbers are usually for a study conducted by different investigators at different centers (institutions), of which we are just one. These are usually clinical trials and do not apply to expedited studies, so the number should be n/a or the same as the first number.
• Sample Size Choice: Is the number you chose based on calculations? In some cases it could be sufficient to say you are using a convenience sample. For example saying there are 100 student in Soc/Anthro 101 could be sufficient. The IRB reviewer needs to determine if the numbers seem to be sufficient to answer the research question.
• Eligibility Criteria: There needs to be something in here: such as over the age of 18, not in school, students in Biography 101, working at the newspaper, has a certain disease, etc.
• Equitable: Explain for example why only males are invited to participate, or state that anyone who responds to the ad can participate.
• The “identify and recruit” response should give specific details in chronological order (1, 2, or 3) whereas the Description of Procedures in Design should be more general concerning how subjects are identified and recruited. Examples include:
  o A list is obtained from HR and every freshman student in General Studies will be chosen. They will receive an email asking if they would like to be in a research study (see attached script), a cover letter and survey will be sent electronically to that person (all of which are attached), etc.
  o A poster is placed in the receptionist area. If someone is interested they will call me and I will go to the clinic and accompany the person in a private room and discuss the protocol with them. Then I will obtain consent after going through it carefully with the participant, etc.
• Any subjects less than 18? If the researcher says yes further questions will ask for exact ages. Any minor between the ages of 7 and 18 must sign an assent form, unless a waiver is granted. A parent must sign a parental consent form for any child under 18 years of age. Children cannot give permission for HIPAA, so that must be in the parental consent form if HIPAA collection is involved.
• Vulnerable Population: This refers only to the population that is targeted for the study.
  o If the target is the general population, there may be students, employees, pregnant women etc. but they are not the target population i.e. it is not a study to specifically look at those groups. Researchers often misunderstand and say yes in error.
• Coercion: Coercion normally means if an employer uses their own employees or a WVU faculty member uses their own current students. Note: One way of handling this is to be sure the responses are anonymous and to ask that someone other than the PI recruit and administer the procedures.
  o The textbox should explain that the subjects are told that the research is completely voluntary, employee or student status will not be affected. In addition efforts should be made to have someone other than the employee or professor enroll the participant.

Consent Procedures

• Will a signed informed consent be obtained? If this is a prospective study the answer is usually yes. It 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 it could not be obtained.
• The description of the consent process should be detailed in chronological order (1, 2, 3): At what point in the process is consent obtained, who will do this, and where, i.e. The physician will ask the patient if they would like to be in a research study and contact the researcher. The researcher will go to the clinic and sit with the participant in a private room and discuss the consent form with the patient.
• If the consent needs to be translated, an expert in the language must write a letter verifying that this is a true translation of the English copy. Also an expert in the social culture of that country must write a letter that the social norms of that culture are not violated by the consent or the procedures of the study. The letters must come from an expert not on the study.

• The additional pertinent information provided to the subjects question when answered Yes, must be responded by stating how this information will be given to the participant.

• The Waiver of Documentation of Consent is so that the requirement of a signature is not necessary during the consent process. A normal consent document is created, but the signatures are not included – such as may be needed for on line consents.

• Sometimes the study risk is “identification of participants” (e.g. cases where there is suspected abuse or where employability is in jeopardy) and in that case it should mean that this study is more than minimal risk and should be submitted as a full board study. The protocol type needs to be changed to Full Board. Some of this questionnaire will disappear and new questions may appear. Please note not all of the section will be removed, only those directly related to expedited studies.

• PI or Co-I consent subjects. If someone other than the PI or Co-Is listed in the personnel page will obtain consent, then the PI needs to explain who that person(s) would be and how they will be trained to obtain consent. If they are not listed on the consent form, the consent should state, “This study has been explained to me by ______” leaving a blank where the consenter can print in their name and sign in the investigator signature section.

**Potential Benefits:**

• Individual Subject: This is usually “no benefits to the individual”. Remember this is from the present research, not from the long term goals.

• Society Benefits and/or scientific/medical knowledge: There has to be some benefit to society and/or scientific knowledge or medical knowledge to make this study approvable.

**Confidentiality**

• Identifiable Data:
  o The only time this can be answered No is if this is an anonymous survey. If the data is received de-identified, then it is not Expedited but an NHSR (Not Human Subjects Research level review).
  o If answered yes, then the data should be secure, for example it could be located on a password locked computer. Paper files should in a locked file cabinet in a locked room.
Data must be kept for a minimum of three years after study completion. Sponsors, the FDA, or the researchers themselves may wish to keep the data longer.

Describe the steps that will be taken to maintain confidentiality and the privacy of subjects.

- Most researchers answer the first part, but not the second concerning privacy. Privacy concerns the interaction between researcher and participant. Where is the subject approached? Where does consenting take place? Where do the procedures occur? If in the privacy of their own environment (such as online) then it should say so. If in a private patient room then, then this should be described. If procedures occur in a classroom (such as taking a survey) then the survey probably is innocuous and privacy is not applicable. Sometimes the research is innocuous and privacy is not a concern, but then this should be stated as such. Please remember privacy mainly refers to the interaction between the researcher and the participant (where and how does the interaction take place). Confidentiality mainly refers to how the data is being kept.

**Financial Considerations**

- Incur costs: Are there any costs to the subject incurred due to their participation in the research? Such as travel, specific research procedures, parking?
- Paying Subjects: What is the total payment and the payment schedule? The important thing to add is how they will be paid and if the participant receives payment at the end of each procedure or at the end of the study.
- Extra credit: Only certain WVU Colleges/Departments are approved to offer extra credit to students. Please contact your department or school to determine if there is an approved extra credit policy.

**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*
- If an advertisement is used, the PI must explain what type of ad and where it will be used. It should conform to WVU guidelines on advertisements (see http://oric.research.wvu.edu/human-research-protectations-program-and-the-irb/irb_checklist) and must not be coercive in formatting or wording. Any payments must not stand out by being in different ink or larger type.

**Sample Collection**
The type of sample collected must be stated. The collection must be non-invasive to be expedited. Biopsies would be full board review. Bone marrow and genetic testing are full board collections.  

The Institutional Biohazard Committee (IBC) review may be needed. This is needed for all sample collection that is not for diagnostic purposes. For instance blood, saliva, tissue collection would require IBC approval.

**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.

**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 such as consent form for control group adults, state if this is a revision and the version such as Investigator Brochure version 3, dated October 20, 2016.
  - File Name: Browse and attach.
  - Make sure to push the add button to save.

- 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.

- Any attachment noted on the Questionnaire page must be included here: Consent forms, advertisements, recruitment scripts, letters, surveys, variable lists, HIPAA forms, etc.

- Any assent, consent, or parental consent must be in .pdf format in order to be watermarked with IRB approval dates. We cannot approve if not a .pdf.

- Other .pdf attachments will be watermarked, but this is not required by the IRB, and is up to the PI if they want attachments to have the watermark.

- All amendments and continuing reviews should be removed from this section, since the newest one is now in the Questionnaire section.

- Any non-valid attachments should be removed: such as replaced investigator brochures, questionnaires, or sponsored protocol. If the study is a migration from BRAAN, the BRAAN protocol should be left in the attachments as a reference, but not the latest BRAAN approval letter since that has been superseded by the newest KC approval.
• COI forms and CITI training should also not be in this section. Responses to the IRB should not be in this section. They should be in the Notes section.
• If you are replacing one document with an updated document, please use the replace option.

• Notes Section:
  o If a revision request is made, please respond in the Notes Section.
  o Staff may place notes here that the CITI training is complete.
  o IT staff may place notes here that this is a copy of another protocol (which froze in the system and had to be copied).
  o IT staff may state that an amendment or renewal has been successfully merged.

Protocol Actions

Request an Action

• Submit for Review
  o 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.

  o Submission Type
    o Initial Submission: This is the option you will choose when you are submitting your protocol for the first time.
    o 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.

  o Submission Review Type
    o The selection here should match the first tab (Protocol) selection.

• Submit
  o 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.

Route Log
The route log will show when the submission was created and when it arrived in the ORIC. You can track where the protocol is in the system by viewing the route log.

**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.
- Upon completion, the investigator must submit the protocol again.
- 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.

**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.