Clinical Trial Studies Tips for PI/Submitters

This tip sheet is intended to assist faculty and students in developing a Clinical Trial 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.

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

- **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. A Clinical Trial is considered any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. 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 coordinator is entering the protocol, please add the PI name using search (magnifying glass) and then add the coordinator’s name as a Primary Study Contact or Study Personnel under the Personnel tab.
  - 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 to search the department (i.e. Oncology). Indicate the oncology group in the additional information section

- **Personnel**
  - Principal Investigator
    - Open the folder 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. clinician in Oncology) and years of experience conducting research (e.g. with 10 years of experience conducting research in this area).
    - Check Contact Information to ensure correctness.
Co-Investigators: If the study is performed by the student, then the student will need to add themselves as Co-Investigators on this page. All other KEY Personnel (For more information, refer to the HRPP FAQs) may be added in this section.

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 Physical Therapist but the protocol requires surgery, the IRB reviewer may require that a person with the appropriate qualifications be added to the research team.

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 to designate the person as a viewer or aggregator.

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.

PLEASE REMEMBER TO SAVE AS YOU GO. You should do this often, since the system times out.

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. 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.

**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 study, you must consider:
  - Whether the questions and consent documents or cover letters 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.
  - An IAA should be used when researchers are collaborating with another institution. If WVU is the lead institution, the protocol in its entirety must be reviewed at WVU and the appropriate IAA form attached in the *Notes and Attachment* section.
  - If WVU is not the lead institution, the IAA form must be submitted to IRB staff signed by the other institution, accompanied by a summary of the study and the other institute’s IRB approval letter. Please contact the IRB office at (304) 293-7073 for further information.
  - A multi-site study refers to multi-center studies, usually under one external sponsor where each center goes through their own IRB review. Most clinical trials are multi-center trials.

**HIPAA**

- To be covered by HIPAA, a study must ask for medical information such as blood pressure, diagnosis, etc. and have an identifier. If a researcher is reviewing medical charts HIPAA information is involved. If the medical information is recorded without one of the 18 HIPAA identifiers it may be medical, but it is anonymous and cannot be linked to any individual, so only a HIPAA waiver to review the medical charts is required. If the response to HIPAA 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 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, for clinical trials the most commonly used is the More than Minimal Risk with HIPAA consent. The consent form will state this in the upper right corner. This is the first option after the question “is this PHI?”

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 below are usually not used. This is confusing to both reviewers and researchers, but the other options are very rare. Please reevaluate if the other options are needed for your study.

- 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.
- One that may occur occasionally is: The Data Use Agreement is only for sharing HIPAA data with another institution or entity. The Data Use Agreement should go through Legal Counsel before submission.
- The option for HIPAA De-Identification Certification is only for non-human research subject protocols (NHSR).
- The decedent HIPAA form is also usually used only for NHSR protocols.
- If the data/sample is received from another entity, a Data Use Agreement should accompany this if HIPAA is involved. The PI should contact Legal Counsel before submitting.

Consent Procedures

- Will informed consent be obtained? If this is a prospective study the answer is usually yes. The FDA requires a consent for all drug and device studies. It can only be No if the study is not for a drug or device and the researcher can justify a waiver. Mere convenience is not justification. The federal guidance says that the researcher must make an effort to obtain consent and prove that it could not be done. Or this could be a records review where consent is not necessary.
- If you request a consent waiver, you do not intend to either give the individual a document with the elements of the consent form or a verbal narrative of those elements.
- 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.
- 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 person(s) not on the study.

- The additional pertinent information provided to the subject question, when answered Yes, must be responded by stating a letter will be sent, a subject may be re-consented, or informed at the next procedure.

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

- PI or Co-I consent subjects. If someone other than the PI or Co-Is 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 their name at the end of the form.

Advertisements

- If an advertisement is used, you must explain what type of ad will be used and where it will be used. Please make sure it conforms to our guidelines on advertisements and must not be coercive in formatting or wording.

Radiation Safety

- If yes is indicated, the Radiation Safety Officer at WVU will be sent the study for sign off automatically.

Biological Safety

- If IBC approval is required, an IBC approval letter must be in the attachments.

Subjects

- The “identify and recruit” response should give details in chronological order (1, 2, or 3). Examples include:
  - A physician identifies a patient with a certain disease or condition. At the patient’s next visit the physician asks the patient if they are interested in participating in a research study. Upon the affirmative, a coordinator goes over the consent form with the patient. The patient takes the consent form home to discuss with family and friends. At the next visit the physician discusses any questions the patient may have and both sign the consent form.
  - The study coordinator records the date of the first visit and the date when the patient signs the consent.

Drug/Substance/Nutrient/Biologic

- If you enter yes to the first question, then a list of questions appear. If the study involves an IND there must be an IND number, you will need to attach a document in the Notes and Attachments section that verifies this number. It can be in the sponsor protocol or a separate FDA letter.
- Off-label: A drug may be used off-label if it is changing the marketability of the drug. Please refer to Chapter 7.4.1 in our SOPs.

**Device Information**  7.4.1. IND/IDE Requirements

- If a device is investigational, there should be an IDE number, which needs to be verified similar to an IND.
- The protocol can be submitted, but it cannot be approved if the IDE is pending.
- If the device has HUD status, please be aware that a different questionnaire must be completed. The study will still require full board review. No consent form is required, but a cover letter is needed explaining the device and its use. Further information on the contents of the letter can be found under the HUD Guidelines.
- For all of these studies a sponsored protocol and investigator brochure are required.

**Notes & Attachments**

- Any attachment noted on the Questionnaire page must be included here: Consent forms, advertisements, CFRs, letters, surveys, HIPAA forms, patient cards, diaries 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 in order to be watermarked with an approval and expiration date. We cannot approve if not a .pdf.
- If you are adding a password protected sponsor protocol, please include the password in the Notes section and describe it clearly.
- 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.
- 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.

**Notes Section:**

- The main thing that reviewers will look for in the Notes section is your response to any revisions request the reviewer may make. Do not place your responses in Attachments section.
- Staff may place notes here that the CITI training is complete.
- IT staff may place notes here that this is a copy of another protocol (which froze in the system and had to be copied). Please note this, since background and original approvals
that you may be looking for are in the frozen protocol. If you need information on a copied protocol, please ask staff for assistance at 293-7073.

- IT staff may state that an amendment or renewal has been successfully merged.

### Protocol Actions

#### Request an Action

- **Submit for Review**
  - If you are a Co-Investigator/administrator, once you have completed creating the study, the protocol is then ready to be submitted. You should record 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 clicked. If the protocol is submitted by the PI, the protocol will go directly to the Chair for sign off. If radiation or biohazards are involved, the protocol will be routed to those offices before coming 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.

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### 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.

Approval Letters

- The 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.