Guidance on Clinical Trial Studies for Reviewers

All the questions under the other Questionnaires are not listed in the clinical trial questionnaire since these should all be answered in the external sponsored protocol.

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

- Only the fields with an asterisk are required. Any other field is not necessary.
- The additional information section is usually only for oncology group clinical trials.

**Protocol**

- PI needs two things in textbox:
  - Role at WVU (i.e. professor of Biology at WVU, clinician at Ruby Memorial, etc.)
  - Research Experience (i.e. 10 years of experience)

**Research Team:**

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 surgery is required.) the reviewer may require that a person with the correct qualifications be added to the research team.

**Permissions**

- This section may be skipped.

**Questionnaire**

**Human Subject Research**

- All three answers should be yes. If not, it may not be human subject research, needs to be flagged and sent back.

**Funding Source**
• There needs to be a yes or no response. We are 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 sponsor is external, expect to find a sponsored protocol in the Notes and Attachments.

**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:
  1) Whether the questions and consents require translation in another language, if so, there must be a letter verifying that the translation is accurate. The letter must be from an expert who is not involved in the study.
  2) A 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.
• Collaborating institution question. WVU needs to be aware if a WVU person is collaborating with another institution. For example, this can be in the form of a project both are working on, shared data, or data analysis. This should be explained in the design or summary.
• If the PI answers yes, then collaboration can be an IAA (Inter-institutional Authorization Agreement, which should be in the attachments).
• The last question will be changed to Multi-Center study rather than multi-site. The intent is to find out if there are more than one institutions who are conducting the very same protocol as in commercially sponsored research. We are not asking if the WVU PI is recruiting or conducting procedures at more than one site.

**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. Anytime medical charts are involved there is 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 can be found [here](#). 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 HIPAA is yes then the PI must choose which HIPAA form will be used.
  o (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, i.e. More than Minimal Risk with HIPAA consent. The consent form will state this in header. 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 form 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 send it back to request these be removed or justify why one of these options was chosen.
• The option for authorization from the subject is ONLY for those few cases where the consent is not merged with the HIPAA. This is generally only used if the sponsor requires a separate HIPAA form and does not want the HIPAA merged to the consent. This separate HIPAA form needs 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. It can only be No if 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.
• The description of the consent process should be detailed and 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.
• Note: Any study involving an IND or IDE must have signed consent.
• 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 research team.
• The additional pertinent information 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 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.

Advertisements

• If an advertisement is used, the PI must explain what type of ad and where it will be used. It must conform to our guidelines on advertisements (see oric.research.wvu.edu) and must not be coercive in formatting or wording. The checklist for advertisements in the On-Line review section should help with this determination.

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, 3) Examples include:
  - Medical records in a clinic are reviewed to find patients with a certain disease or condition.
  - At the patient’s next clinic visit the physician asks if the individual is interested in participating in a study.
  - If the person says yes, the research team is contacted. The team member discusses the study with the patient in a private room. If the patient is interested, the consent form is discussed. The patient is given the opportunity to take the consent form home and discuss with their family/friends.
  - At the next visit, the patient and the PI discuss any additional questions and sign the form. Upon signing, the patient is given a copy of the consent form.
• Any subjects less than 18? If the researcher says yes further question will ask for exact ages. Any minor between the ages of 7 and 18 must sign an assent form. 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.

If the applicant enters yes to the question regarding drugs/substances/nutrients/biologics, then a list of questions appear. If the study involves an IND there must be an IND number – in that case there must
be attachment in the Notes and Attachments page that verifies this. It can be in the sponsor protocol or a separate FDA letter.

Off-label use of drugs needs to be discussed at the full board meeting and may require that an IND be obtained.

If this is an IND and an external sponsor, the sponsored protocol and the investigator’s brochure need to be attached.

WVU Pharmacy must be involved if the drug is stored here.

All drugs that will be used and are not INDs need to be named.

If a device is investigational, there should be an IDE number, which needs to be verified similar to an IND.

The protocol can be reviewed, but not approved if the IDE is pending.

If the device has HUD status, the study is not considered research, but 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 is in the SOPs and the website under HUD. The PI should not use this Questionnaire but should use the HUD Questionnaire. It should be sent back to the PI with the request to use the HUD questionnaire.

For all clinical trials that are sponsored externally a sponsored protocol and investigator brochure are required. For WVU physician initiated studies a protocol should be attached.

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**Notes & Attachments**

- 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 an approval and expiration date. 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 be watermarked.
- 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.
All IND or IDE studies require sponsored protocols and investigator brochures.

Notes Section:

- The main thing that reviewers should look for in the Notes section is the PI’s response to any revisions request should be loaded here. Sometimes PIs either do not respond or place their response in Attachments.
- 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

- If there was a revisions request, it can be found under Summary and History -> History -> Correspondence
- This allows you to look up what was requested before and the dates of actions. If this is an amendment or renewal, the History will show only the history of that action.
- The route log will show when the submission was created and when it arrived in the ORIC.

Online Review

- **Determination Recommendation**
  
  This should be determined. The reviewers of a Clinical Trial study should only use:
  
  - **Defers** – Specific Minor Revisions
  - **Defers** – Substantive Major Revisions
  - **Approved**
  - **Disapproved**
  - **Tabled**

- **Reviewer Feedback Forms (RFF)**
  
  - Each of the reviewer feedback form asks questions which should help with the reviews, and serve as a guidance to what reviewers should look for when reviewing the study. The Initial Review and the CR checklists include information on expedited categories.
  - When reviewing an initial review use the Initial Protocol Checklist.
  - The CR checklist is for all renewals.
The other RFFs should be self-explanatory. (Please contact the office if further guidance is necessary)
Remember if you have already seen the protocol and it is returned for revisions review, please use the Contingent Review RFF, which is very short.

Note: The Conflict of Interest RFF is mandatory for all reviews.

- **Comments**
  - Each comment should be placed separately (the reason is that despite the formatting and space, when incorporated into a letter for the PI, it all comes together into one paragraph – which is very hard for the PI to read and may lead to missing some of the comments).
  - After writing in the comment, **ALWAYS** click add (button on the right).
- When complete, please click the button labeled “Approve Review.”