Guidance on Full Board Studies for Reviewers

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

- **Protocol**
  - 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.

- **Personnel**
  - 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 the protocol requires surgery.) 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.
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.

Design

- **Question 1:** Used for the lay summary – should be in 6th grade language
- **Question 2:** The procedures need to be complete. It helps if the PI gives the procedure in 1, 2, 3 format. Usually these need to be expanded. You should know 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. The reviewer should know after reading this response exactly how the subject will be approached, where and when consent (if appropriate) takes place and what they are being asked to do.
- **Group Assignment Question:** If there is more than one group or randomization is involved, there should be an explanation here.
- **Survey Question:** Surveys and Questionnaires include demographic forms.
- **If the researcher states that there are stressful questions, then there needs to be a referral list in the Notes and Attachment page. The referral list needs to be mentioned in the consent form, cover letter or at the end of the survey.**
- **Scientific Rationale and Literature Review Question:** Often researchers do not 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:** There should always be a plan for data analysis. If appropriate, a power analysis should be described.

Risk Assessment

Question 1: An Intervention research can be medical, where something is done or given that is not standard of care such as a new procedure or drug. It can also be social behavioral where something is done or given that is fall under normal daily routine such as a class, training session, etc. that would not be done if it wasn’t for the research.
Deception Question: If this is marked yes, then there has to be a debriefing letter which must inform the participant at least by the end of the study about the deception, and give the participant the option to withdraw their data from the study.

Cancer Question: This question is meant 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. So if the response is yes, then there needs to be a letter from PRMC 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. 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 is on our website oric.research.wvu.edu. 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.
  - (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 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 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 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.
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 the PI 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 sites, of which we are just one. These are usually clinical trials.**
- **Sample Size Choice:** The PI needs to explain why they chose this number.
- **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:** The PI should explain why only a certain population is invited to participate, or make a statement such as “anyone who responds to the ad can participate.”
- The “identify and recruit” response should give details in chronological order (1, 2, or 3) whereas the Description of Procedures in Design should be more general. Examples include:
  - 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.
  - A poster is placed in the receptionist area. If someone is interested they will call me and I will go to the clinic and take 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.
- 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.
- **Vulnerable Population:** This is only if the population is the targeted one for the study.
  - 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 using one’s own employees or a WVU faculty member’s students.
  - 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 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 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-I 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.

**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: If there are none, then this shouldn’t be a study. There has to be some benefit to society and/or scientific knowledge or medical knowledge to make this study approvable.

**Confidentiality**

- Identifiable Data:
  - 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 an NHSR (Not Human Subjects Research level review). Other than at NHSR review, this question should be answered yes.
  - If answered yes, then the data should be located on a password locked computer. Paper files should be 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 mainly concerns the interaction between researcher and participant. Where is the subject approached? Where does the
consenting take place? Where do the procedures occur? If in the privacy of their own environment (such as on-line) 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. Confidentiality mainly refers to how the data is being kept.

Financial Considerations

- Incur costs: This is usually more applicable for full board studies and clinical trials. Will the subject have to pay for procedures or medication? Are there incidental costs, such as parking, babysitting, meals or travel?
- Paying Subjects: What is the total payment and the payment schedule? The important thing to find out is how they will be paid and if the participant receives payment at the end of each procedure. Is it too much money? This is a judgement call on the part of the reviewer.
- Extra credit: Only certain WVU Colleges/Departments are approved to offer extra credit to students. It is not available for other schools/colleges.

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.

Drug/Substance/Nutrient/Biologic 7.4.1. IND/IDE Requirements

If the applicant enters yes to the first question, 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, 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.

Again if they are used off-label an IND may be required.

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 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.

For all of these studies a sponsored protocol and investigator brochure are required.

**Sample Collection**

- The type of collection must be stated. All invasive collections require full board review, such as biopsies, and bone marrow collection. Genetic testing is usually full board.
- If tissue is banked at this institution an approved Tissue Banking Registration Form needs to be in the attachments.

Consider if Institutional Biohazard Committee (IBC) review is needed. This is needed for all sample collection that is not for diagnostic purposes. For instance for blood, saliva, tissue collection an IBC approval is needed.

**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.

**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 have the watermark.
- All old 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.

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 Full Board study should only use:

  - **Defer – Specific Minor Revisions**
  - **Defer – 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 protocol/application.
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.”