Guidance on Full Board Studies for Researchers

This tip sheet is intended to assist faculty and students in developing a Full Board 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 the protocol is open for review, a series of tabs will appear. 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 that is chosen determines the questions that will be asked later based on the level of risk of your research. Full board studies are considered more than minimal risk or does not fit any Exempt or Expedited category. 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.
  - 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. Psychology).
  - The additional information section is usually only for oncology group clinical trials.

- **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. adjunct professor teaching forensics) and years of experience conducting research (e.g. with 10 years of experience conducting 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 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 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.

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.

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 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 studies, 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.

**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 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.
Participants will place surveys 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, then this should be explained here.
- **Survey Question:** Surveys and Questionnaires include demographic forms. Any questions that are asked 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 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 stating the references is insufficient.
- **Data Analysis Question:** Describe how the data will be analyzed. If appropriate, and this is a quantitative study, a power analysis should be included.

**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 a procedure is conducted that would not fall under normal daily routine, such as a class, training session, etc. that would not be done if it wasn’t for the research. In other words when a class or procedure is done ONLY for research and would not be performed if not for the research study.

Unexpected harms may be any side effects or adverse events that may occur, usually these are physical in nature, but it could also be related to suicide.

The PI may determine that the risks to the individual participant outweigh any benefits and may decide the participant should no longer continue in the research.

A date safety monitoring board would review any harms that occur and evaluate all submitted adverse event and determine if the study is safe to continue as is or needs to be amended as a result of harms.
The consenting process and any additional information should be given to the participant in privacy.

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. 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 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? This is only PHI, if identifiers are also collected. 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 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 full board studies 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.

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: You should explain how you are choosing your subjects. Examples may be, over the age of 18, not in school, students in Biography 101, working at the newspaper, has a certain disease, etc.

- Equitable: You should explain why only a certain population would be 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 you say yes further questions 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 group 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 denotes that there is perceived intimidation towards one’s 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.
- 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.

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. A study on mathematics teaching methods may help provide a better way to teach math to children, a study on engaging students in finding pulsars may map many more pulsars for astronomy, a study on using a new drug may help cure a disease.
Confidentiality

- Identifiable Data:
  - If at any point during this study, identifiable data will be seen or recorded then the answer should be yes. 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).
  - If answered yes, then the data should 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.
- Electronic data may be deleted in each place that it has been stored.
- 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: 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 include 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. The payment should not be in excess that would influence the subject to do something they would normally not agree to.
- Extra credit: Only certain WVU Colleges/Departments are approved to offer extra credit to students. Confirm to see if your department has an IRB approved policy.

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.
**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.

Please contact the WVU Pharmacy if any drugs will be dispense within WVU.

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

**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 you are using a HUD a separate 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 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.
- An IRB approval letter is needed from any off-site location providing samples.
- Explain if the samples were obtained through standard of care procedures or if they were obtained only for research and not as part of standard procedures.
- Samples may be saved for the purpose of this research and not for any future research. How long samples are being saved must be stated.
- More information can be found on genetic testing in the SOPs on our oricwebsite.

If Institutional Biohazard Committee (IBC) review is needed, please submit the appropriate form to the IBC committee. 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**

V.1 Last Updated 6/2015
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.

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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. 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.
- 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 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.

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**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 clicked. If the protocol is submitted by the PI, the protocol will go directly to the Chair for sign off 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.