Reviewers Guide on Expedited Studies

Office of Research Integrity & Compliance | Version 2
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There is a guidance on the Expedited Categories of research. Remember any expedited protocol must be no more than minimal risk AND fit one of the categories in order for it to be expedited review.

CITI ethics training will be checked by the ORIC staff; no protocol will be approved until the training requirements are met.

If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at IRB@mail.wvu.edu.

Contents

Personnel

The PI must address these two points in their qualifications summary:

1. The PI's role/affiliation with WVU (i.e. professor of Biology, or clinician at Ruby Memorial, etc.)
2. Research experience (i.e. 10 years of experience conducting research)

A student may never be the PI on a study. If the PI is not the person qualified to perform all the procedures in the protocol (i.e. PI is an engineer but surgery is required), the reviewer/board may require that a person with the correct qualifications be added to the research team.

Notes & Attachments

The intent of the 'Notes' section is for PI's to respond to revisions requests. Sometimes, investigators respond by attaching a supporting document. If a protocol is resubmitted, it is recommended that the reviewer check for a note before proceeding with the review.

All file attachments can be accessed from either the Notes & Attachments tab, as well as the Protocol Summary tab.

Protocol Summary

All information, excluding 'Notes from the investigator', can be found in this section of the protocol. This section of the guidance will go through each area of the protocol submission and what appears in the summary.

Personnel

This section gives a quick overlook of the PI and research team. Specifics can be found under the Personnel tab.

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 selected. If the study is conducted at an off-site facility (non-WVU), a letter of permission from that location needs to be in the *Attachments* section.

If the location of research is international, 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.

Note: The two letters may be combined in one document and signed by one person.

Design

Lay Summary: Should not contain jargon or technical terms. It must be written at a sixth grade language and comprehendible by someone without any experience in the research area.

Procedures: It helps if the PI gives the procedure in 1, 2, 3 format; however, they may need to elaborate on the points. 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.

Investigational and Standard of Care Procedures: A common issue for researchers is answering the investigational procedures question. Since this is a research study there are procedures that are being conducted to answer the purpose of the research. This response needs to be answered with all the procedures that are being conducted for the sake of the research that would not be done otherwise.

- Examples for a biomedical study could be taking an extra blood draw or MRI scan for participants who would be having procedures done for standard care.
- For social behavioral studies this could be a survey that is being done for research.

On the other hand, Standard of Care procedures are those that would be done even if the research was not conducted. Often, the appropriate response is 'not applicable.'

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.

Sensitive Questions: If the researcher states that there are stressful questions, then there needs to be a referral list in the 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 a plan for data analysis. If appropriate, a power analysis should be described.

Expedited Review

The first question in this section asks if the proposed research is only minimal risk; if the response is 'no', the submission cannot be reviewed as expedited.

If 'yes' is select – a corresponding expedited category needs to be indicated.

Note: More than one expedited category of review can be selected.

Note: If more information about expedited protocols and the review categories, please see either:

1. The Reviewer Feedback form (on the Online Review tab)
2. The Expedited Categories document, on the ORIC website.

A textbox will appear towards the bottom of the section so that the researcher can address how the study fits the selected category (i.e. 'Survey of faculty regarding teaching practices' if category 7 was selected).

Researchers are asked to indicate whether an intervention is involved.

Interventions can be either a medical procedure (biomedical) or an educational/training session (social science).

1. Is 'yes' is selected, the next question asks about medical research procedures and will ask specifics on those procedures.
2. If answered No, the explanation of the intervention is requested.

Should the researchers indicate that subjects will be deceived, 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 them the option to withdraw any data associated with their participation from 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. Please refer to the HIPAA Identifiers Guidance. Anytime medical charts are involved there is HIPAA.

Surveys can also be covered by HIPAA if they ask questions such as 'do you see a doctor for your illness?' 'Do you take medication when you have a cold? What type of medicine?' This information must also be identifiable in order to be covered under HIPAA.

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 the Forms Page of the ORIC website. Applicable forms must be attached in the submitted protocol.

- 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 below should not be used in most cases. 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 this option 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 with a limited data set.

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 identifiable data or samples are received or shared with another entity, a Data Use Agreement should be signed by both entities. If WVU is sharing, the PI should contact Legal Counsel for review before submitting.

Subjects

Researchers are required to specify the maximum number of subjects to be enrolled by the WVU research team. Enrollment can occur locally, nationally, or internationally. A justification for the sample size is also required; it may be applicable to say a convenience sample or a power analysis may need to be included.

Note: It is a violation to go over that number, but enrolling less than the goal number is not an IRB violation.

Inclusion and exclusion criteria need to be clearly explained and outlined. A justification that equitable selection of subjects is needed as well (i.e. explain why only males are invited to 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.

If the researcher says that minors (< 18 years old) they will be asked for exact ages. Any minor between the ages of 7 and 17 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. All children between the ages of 7 and 17 must sign an assent form, unless a waiver is granted.

The vulnerable population question is only applicable if they (children, pregnant women, mentally handicapped, prisoners, WVU students/employees) are targeted for the study.

Note: 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 normally means if an employer uses their own employees or a WVU faculty member uses their own 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.

- 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.

If cancer patients are being targeted, a letter from the PRMC must be attached in the submission.

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 for Advertisements and must not be coercive in formatting or wording. The checklist for advertisements in the Online Review tab should help with this determination. Any payment amount may not stand out in the text, either by size, color or formatting.

Sample Collection

The type of collection 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.

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.

Biological Safety

If IBC approval is determined to be needed, then the approval letter must be attached to the submission.

Data Protection

If there are any questions regarding the security of the data collected in this study, this should be marked with a 'yes.' If the researcher is planning to share or transfer data between institutions, it is recommended that the researcher select 'yes.'

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. We cannot approve if not a PDF.

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

Note: 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 but rather under Personnel.

Responses to the IRB should not be in this section. They should be in the Notes section of the Questionnaire tab.

Correspondence

If the submission is a revisions request, the request can be found in the Correspondence section. 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 the current amendment/renewal.

Protocol History

If the submission is a revisions request, the request can be found in the Correspondence section under History on this page. 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 the current submission.

Protocol Actions

The **Route Log** will show when the submission was created and when it arrived in the ORIC.

Online Review

Determination Recommendation

Something must be selected by the reviewer. The reviewers of an Expedited study should only use:

- Defer - Specific Minor Revisions: this will indicate that the protocol must be sent back to the researcher for revisions, before being approved
- Approved

Note: Defer - Substantive Revisions should only be used for Full Board/Clinical Trial studies, unless the reviewer would like to refer the protocol for full board review.

Note: No expedited reviewer may disapprove a study, only the full board can take that action. If the reviewer feels a study should be disapproved, it must be referred for full board review

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 have information on the 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.

The Unanticipated Event form is the RFF for all deviations, violations, UPIRTSOs, AEs and SAEs.

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). If you do not click this button, the comment will not save to the protocol.

If this is the final review and you are ready to approve either an initial protocol review or a continuing review of an expedited study, please remember to put the expedited category in the comments.

- When complete, please click the button labeled “Approve Review.”

Note: No expedited reviewer may disapprove any study. It must be referred to full board for disapproval.