Tips for Preparing an IRB Member review

Initial Reviews (IR)

Review of the protocol

In general, for a straightforward study, a review presentation should take **3 to 5 minutes**. Studies with more complex or challenging issues, or multiple vulnerable populations, may require more time for presentation. Additional discussion from board members may occur after the reviewers present. At the end of each review presented to the Board, the board member must make a recommendation regarding approval or other determination(s) for the study.

- Summarize the purpose, design, and primary procedures of the study (typically 3-5 sentences).
- Summarize any significant risks and how those will be mitigated.
- Summarize recruitment procedures (**typically 1 – 3 sentences**).
- Summarize consent process and documentation (**typically 1 – 3 sentences**).
    - Always state how consent will be obtained.
    - Discuss unique consent processes.
    - Is the PI requesting a waiver or alteration of consent or waiver of documentation of consent? If yes, did they provide an adequate justification in the protocol?
- Mention plans for data and safety monitoring, when applicable.
- Mention when there is an increased risk to privacy and confidentiality compared to a normal study.
- If there is an investigational device being used in the study, is it significant risk, non-significant risk or IDE exempt?
- Are there other materials (e.g. recruitment materials) that require discussion?
- State if you think the protocol meets the criteria for approval as submitted.
- If you think the protocol does not meet the criteria for approval: Summarize any concerns about the study or topics that need board discussion (which criterion is not met?) and provide specific revisions that are necessary.

Vulnerable Populations

Describe any vulnerable populations which are involved, and address if the PI provided adequate justification in the protocol to include the population(s). Additional points that may need to be mentioned include:

- Children:
    - What ages are included?
    - What is the assent process?
- Individuals with Impaired Decision Making:
    - What are the circumstances or nature of the impairment (e.g. coma, permanent mental impairment, sedation, etc.)?
    - What is the consent/assent process?
- Pregnant Women:
    - How long will they be enrolled (e.g. the entire pregnancy, portion of the pregnancy, after the birth, etc.)?
    - Is the research studying the woman or the pregnancy?

Review of the Informed Consent Form

- Is it written such that it is likely to be understood by prospective participants.
    - Consider the population being approached for enrollment.
- Are any Required Informed Consent Elements Missing?
    - If yes, please state which element is missing.
- If you have proposed changes to the consent/assent form(s), use the "Tracked Changes" feature found in Microsoft Word and provide the exact wording for the change and attach your tracked document(s) to your review summary in PROTECT.
- Ask for additional input from the committee.

End your presentation with a recommendation for the vote.

Continuing Reviews (CR)

The purpose of the CR is to determine if there is any new information that would alter the approvability of the study. Always start with the presumption that the initial approval was

appropriate. The CR review can be very brief (**about 3 minutes**) if there are no issues with the study since the past review.

- Summarize the purpose of the study (**typically 1 – 3 sentences**).
- Summarize the study's enrollment status:
    - Enrolling, long term follow up, data analysis, suspended
    - # of local participants, # of participants enrolled at other sites (if we are the reviewing IRB for any pSites)
- Summarize any reported events in the past year (include if these occurred at other sites if we are the reviewing IRB for any pSites), if any.
    - Have any of these been significant events/problems?
    - State whether or not these events/problems have been reviewed by the IRB
- Mention any DSMB reviews during the last continuing review reporting period and if there were any significant findings, if applicable.

Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary to meet the criteria for approval (very rare for this to occur at CR).

End your presentation with a recommendation for the vote.

Modifications (MOD)

A MOD review should be limited to discussion of the changes being made; this is not a complete re-review of the protocol. In a MOD review, the board should determine if the proposed changes alter the approvability of the study in any way. New determinations may need to be made, and the board should consider if re-consent of existing participants is needed.

Review of the protocol

- Summarize the purpose of the study (**typically 1 – 3 sentences**).
- Describe the changes that are being made.
- State whether the risk/benefit ratio has changed or if any new determinations are needed (e.g. adding a pediatric population with the MOD)
- State whether the changes are acceptable

- Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary
- Are there other modified materials (e.g. recruitment materials) that require discussion?
- Determine if re-consent is necessary
    - If reconsent is required be specific about who needs to sign the revised consent, and how and when the study team should be providing reconsent. For example, at the next study visit for all subjects in follow-up.

Review of the Informed Consent Form

- Are any Required Informed Consent Elements Missing?
    - If yes, please state which element is missing.
- If you have proposed changes to the consent/assent form(s), use the "Tracked Changes" feature found in Microsoft Word and provide the exact wording for the change and attach your tracked document(s) to your review summary in PROTECT.
- Ask for additional input from the board.

End your presentation with a recommendation for the vote.

Reportable New Information

Review of the event

- Summarize the purpose of the study (1 – 3 sentences).
- Describe the problem or event.
- Mention if any modifications to the study have been submitted in conjunction with the reported event
- Describe any corrective actions the investigator has proposed or implemented in response to the problem, and if the corrective action is adequate.
- Assess if the problem or event represents an unanticipated problem (UP) involving risks to subjects or others.
- State if any corrective actions need to be requested. This may include:
    1. A notification to be sent to currently enrolled subjects
    2. A letter to be sent to subjects previously enrolled regarding the additional information

3. Modifications to the current research protocol
4. Changes in consent process or documents
5. Suspension or termination of the protocol (very rare)

End your presentation with a recommendation for the vote.

Things to consider for all submissions

If you have questions about the submission, ask ahead of time (as far ahead of time as possible---but give the study team at least 2 business days to answer)! The meeting is the place to make decisions, not to ask questions.

When requesting revisions to a submission:

- Will a change in the application, consent, or protocol be likely to improve the welfare of research subjects to a meaningful degree and/or is this change related to the criteria for approval?
    - If not, approve the study without the change
    - If so, require the change be made prior to approval
    - Remember that the consent template has language that cannot be changed (e.g. confidentiality and privacy)
- Are my revisions clear?
    - The IRB staff will be communicating your requests to the PI via PROTECT. Make sure it is clear what you are asking for and why. Any stipulations must be very specific.
    - Whenever possible, if you must make changes to a consent form, use the "Tracked Changes" feature found in Microsoft Word and provide the exact wording for the change. The tracked consent document(s) should be uploaded in PROTECT into your review summary. For changes to other documents, clearly spell out in which section of the document you think a change is needed and what specifically should be changed.
- Don't sweat the small stuff
    - Don't worry too much about correcting typos, formatting, etc., unless the correction will significantly improve the document or change the meaning of the document.

- Requested revisions should be substantive and meaningful—avoid personal preferences.