INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

Board Member Guidance Series

WRITING A REVIEW SUMMARY

Background

The board reviewer checklist asks specific questions about the requirements that need to be satisfied for approval. The criteria for IRB approval of research includes ensuring: risks are minimized; risks are reasonable in relation to anticipated benefits; ~~, such as risks and benefits,~~ equitable selection of subjects; informed consent will be sought; provisions are made for safety monitoring; and provisions are made to protect privacy and confidentiality ~~, and vulnerable populations.~~ The Reviewer Description, or review summary, acts as a written summary of your review and should include relevant, study-specific statements regarding these topics ~~as well~~. For example, the checklist will specifically ask you if the risk:benefit ratio is appropriate, but the review summary allows you to describe why the risk:benefit ratio is appropriate.

Description

This document ~~includes descriptions~~describes ~~of~~ the information that should be included in a review summary. ~~Board members should use this guidance and their reviewer checklists as a guide when preparing their review summaries. This document addresses the following types of reviews:~~

- ~~New studies~~
- ~~Continuing reviews~~
- ~~Reports~~
- ~~Amendments~~

Many board reviewers will read directly from the review summary when giving their review at the board meeting. Depending on the type of review, ~~A~~a review summary should take 1 – ~~2~~ 5 minutes to present to the Board. Additional discussion from board members may occur after the summary is presented. At the end of each review presented to the Board, the board reviewer must make a recommendation regarding approval or other determination for the study.

New Studies

Main Summary:

- Summarize the purpose, design, and procedures of the study (typically 1 – 3 paragraphs).
- Summarize any significant risks.
- Summarize recruitment procedures and the study population (typically 1 – 3 sentences).
- Summarize consent process and documentation (typically 1 – 3 sentences).
  - Discuss unique consent processes.
  - Always state how consent will be obtained and documented.
- Mention plans for data and safety monitoring, when applicable.
- Mention extra precautions to protect privacy and confidentiality.
  - Mention when there is an increased risk to privacy and confidentiality compared to a normal study.
- Summarize any investigator conflict of interest management plans and state whether all IRB requirements are met.
- Summarize any concerns about the study or topics that need board discussion and provide specific revisions needed~~that are necessary~~.

Vulnerable Populations:

Describe any vulnerable populations which are involved. Additional points that may need to be mentioned include:

- Children:

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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- What ages are included?
- What is the assent process?

- ~~Cognitively Impaired Adults~~Individuals with Impaired Decision-Making Capacity:
  - What are the circumstances or nature of the impairment (e.g. coma, permanent mental impairment, sedation, etc.)?
  - What is the consent/assent process?
  - Will ~~Is~~ a Legally Authorized Representative be used to obtain consent~~involved~~?~~)~~
- 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?

Investigational Drugs or Devices: ~~:~~ If there are investigational drugs or devices included in the research, the board reviewer should include:

- A description of the investigational agent
- A description of the regulatory status of the drug or device.

Waivers of Consent or Authorization: While the board reviewer checklist will direct board reviewers to the criteria for approving the waivers, some studies may include multiple waivers that apply to different components of the study. In these cases, the board member should:

- Address each waiver ~~should be addressed~~ individually within the review summary.

~~**Investigational Drugs or Devices:** If there are investigational drugs or devices included in the research, the board reviewer should include:~~

- ~~A description of the investigational agent~~
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- ~~Address each waiver should be addressed individually within the review summary.~~

Continuing Reviews

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Main Summary:

- Summarize the purpose of the study (1 – 3 sentences). This should provide a layperson explanation of difficult procedures and/or scientific terms.
- Summarize the study's enrollment status.~~:~~
  - ~~O~~Is the study open, closed, suspended, over- or under-accrued?
- Summarize the event/problem reports.
  - Have any of these events/problems been significant?
  - State whether or not these events/problems have been reviewed by the IRB.
- Mention any ~~DSMB~~ data and safety monitoring findings in the last year, if applicable.
- Amendments with the continuing review.~~:~~
  - Give a *short* summary of the amendment and if the change is appropriate.
  - State whether or not the risk:benefit ratio has changed.
- If there has been a conflict of interest management plan modified or added since the last review, please summarize."
- ~~o~~ Summarize any concerns about the study or topics that need board discussion and provide specific revisions needed.
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Reports

Main Summary:

- Summarize the purpose of the study (1 – 3 sentences).
- Describe the problem or event.
- Mention if an amendment has been submitted in conjunction with the report.
- Describe any corrective actions the investigator has implemented in response to the problem.
  - Describe how the problem or even affects local participants (e.g. how many enrolled, how many will be informed, etc.)
- State if any corrective actions need to be requested.
- Give the problem assessment, based on the checklist:
  - Does this problem or event represent an unanticipated problem involving risks to participants or others?
  - Does this problem represent serious or continuing non-compliance?

Note: Board reviewers are not required to complete both the unanticipated problem *and* the non-compliance checklists for each report form. Reviewers should complete the checklist(s) as applicable to the report circumstances.

Amendments

Main Summary:

- Summarize the purpose of the study (1 – 3 sentences). The summary is meant to reorient the board to the study so that ~~further~~ discussion of the amendment can occur.
- Describe the changes that are being made.
- State whether or not the risk:benefit ratio has changed.
- Indicate if there are new determinations that need to be made.
- State whether or not the changes are acceptable to allow the study to continue.
- Summarize any concerns about the study or topics that need board discussion and provide specific revisions

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needed.

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Helpful Tips for Writing Your Review

Review summaries should be written in a way that is understandable. Some things to consider include:

- Summaries should provide a layperson explanation of difficult procedures and/or scientific terms.
- Spell out acronyms at least once in your written review to ensure the clarity of the written reviews.
- Try to use complete sentences when drafting your review summary.
- Write any revisions requests clearly and with as much specificity as possible.
- If during your completion of the board checklist you find that some of the checkboxes don't seem to apply to the review, or that clarification may be needed regarding your selection(s), include an explanation in your review summary.
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Additional Considerations: Review summaries should be written in a way that is understandable. Some things to consider include:
Spell out acronyms at least once in your written review to ensure the clarity of the written reviews.
Try to use complete sentences when drafting your review summary.
Write any revisions requests clearly and with as much specificity as possible.
If during your completion of the board checklist you find that some of the checkboxes don't seem to apply to the review, or that clarification may be needed regarding your selection(s), include an explanation in your review summary.

References & Links

How to Write a Review" Board Member Training Video located in Canvas: https://irb.utah.edu/board-members/new-board-member-trainings.php*For more information regarding reviewer presentations, please refer to the* ***Institutional Review Board Member Handbook*** *by Robert Amdur, MD.*

References & Links

"How to Write a Review" Board Member Training Video	*https://irb.utah.edu/board-members/new-board-member-trainings.php*

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