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. Addressing the criteria for approval is particularly important in both the written review and the presentation of the review during the board meeting.

The criteria for IRB approval of research (45 CFR 46.111) includes ensuring:

- risks are minimized;
- risks are reasonable in relation to anticipated benefits;
- equitable selection of subjects;
- informed consent will be sought;
- provisions are made for safety monitoring (when applicable);
- and provisions are made to protect privacy and confidentiality.

The Reviewer Description, or review summary, acts as a written summary of your review and should include relevant, study-specific statements regarding these topics. 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 describes the information that should be included in a review summary.

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 review summary should take 1 – 5 minutes to present to the Board and should focus on how the application meets the criteria for approval of research. 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 and comment on how the study is minimizing risks, as well as the overall risk:benefit ratio.
- Summarize recruitment procedures and the study population and indicate if subject selection is equitable (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.

☐ **Vulnerable Populations:** Describe any vulnerable populations which are involved, the justification for involvement, and the protections in place. Additional points that may need to be mentioned include:

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

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- What are the risks associated with the research?
- Is there prospect of direct benefit?

- 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 participants' ability to consent/assent improve, decline, or remain unchanged over the course of the study?
  - Will surrogate consent/a Legally Authorized Representative be used to obtain consent?
  - Is there prospect of direct benefit?
- 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/product
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- A description of the regulatory status of the drug or device.
- If the study is asking for an IND/IDE exemption, or an NSR device determination, what is the basis for granting the determination? How does the investigational product meet the exemption criteria or NSR device definition?

Waivers or Alterations 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 individually within the review summary.
- Consider which protections are in place for participants.

Investigator Conflict of Interest Management Plans: If an investigator has a conflict of interest on a study and has accepted a management plan, board reviewers should review the information regarding the nature and extent of the conflict in conjunction with the management plan and evaluate whether the interest and its management plan allow the research to be approved. Board reviewers should consider the following and confirm in their Reviewer Description and during the meeting discussion that the management plan is adequate and appropriate.

- Are the investigator's potential biases minimized by the study design (blinding, objective endpoints, measurements of endpoints by someone other than the investigator)? Should they be recused from data collection, data analysis, safety monitoring, obtaining consent, etc.? Is the integrity of the data appropriately protected?
- The board should consider whether additional clauses should be added to the current management plan to minimize the potential for bias or harm associated due to the nature and extent of the conflict.

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Continuing Reviews

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.
  - 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 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 and any effect on the criteria for approval for the study.
  - State whether ~~or not~~ the risk:benefit ratio has changed including your basis for that assessment~~d~~.
- If there has been a conflict of interest management plan modified or added since the last review, please summarize.~~"~~
- Summarize any concerns about the study or topics that need board discussion and provide specific revisions needed.

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 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 needed.

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.

References & Links

"How to Write a Review" Board Member Training Video	*https://irb.utah.edu/board-members/new-board-member-trainings.php*
Criteria for IRB approval of research	*https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.111*