



WRITING A REVIEW SUMMARY

Description

This document includes descriptions 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

A review summary should take 1 – 2 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). Provide a layperson explanation of difficult procedures and/or scientific terms.
- Summarize any significant risks.
- Summarize recruitment procedures (typically 1 – 3 sentences).
- Summarize consent process and documentation (typically 1 – 3 sentences).
 - Discuss unique consent processes.
 - Always state how consent will be obtained.
- 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 concerns about the study or topics that need board discussion and provide specific revisions that are necessary.

Vulnerable Populations:

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

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

Continuing Reviews

Main Summary:

- Summarize the purpose of the study (1 – 3 sentences).
- Summarize the study's enrollment status:

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- 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 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.

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.
- 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?

Amendments

Main Summary:

- Summarize the purpose of the study (1 – 3 sentences).
- Describe the changes that are being made.
- State whether or not the risk:benefit ratio has changed.
- State whether or not the changes are acceptable.

References & Links

*For more information regarding reviewer presentations, please refer to the **Institutional Review Board Member Handbook** by Robert Amdur, MD.*

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