

Presenting a Review Summary

Description

This document includes descriptions of what information should be included in a review summary. Primary reviewers should use this and their reviewer checklists as a guide when preparing their review summaries. This document addresses the following types of reviews:

- Initial Reviews (New studies)
- Continuing Reviews
- Reportable New Information Items
- Modifications

Additional discussion from board members may occur after the summary is presented.

Initial Reviews (New Studies)

Summary Presentation should include:

- The purpose, design, inclusion/exclusion criteria and procedures of the study.
- The risks and benefits to study participants.
- Recruitment procedures/materials to be used and whether payments are available to participants.
- Is a partial HIPAA waiver for recruitment needed? (A partial waiver is needed when PI's need to do broad searching for recruitment and they do not have a treatment relationship with their patients).
- Consent process; include if there are unique consent processes for the board to consider or discuss (such as documentation alternatives, e-consent, delayed consent, etc.)
- The plans for data and safety monitoring, including any notable stopping rules or safety review triggers, when applicable.
- The measures to protect privacy and confidentiality; include if there are any sensitive data points collected (HIV, abuse, drug/alcohol use, etc.).

Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary.

Informed Consent Form review should include:

- Is the consent form presented in a way that facilitates understanding of the proposed research, the procedures and the risks/benefits related to participation?
- Is the Key Summary complete and includes the main information that is most likely to assist in understanding the research and the reasons why one might or might not want to participate in the research?
- Are any informed consent elements missing? The reviewer checklist in iRIS contains a element review. If you find missing elements state at the meeting which element is missing.
- Does the consent form explain the study well?
- Are the procedures and expectations clear and organized for understanding?
- Are the relevant risks included (risks related to standard of care procedures may not be needed in the form).
- Provide the specific wording for the changes including page numbers and paragraphs in the ICF. This will help the Analyst to provide the directed edits to the study team.
- Should the ICF include any additional information related to participation in the study?

- If yes, provide exact wording for the change including page numbers and paragraphs in the ICF.
- Are any required elements of HIPAA Authorization missing?
 - If yes, state which element is missing
 - Ask for additional input from the board or privacy representative.
 - Provide the exact wording for revision including specific page numbers and paragraphs.
- Ask for additional input from the board.

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? Is the assent process adequate? If not, provide recommended changes for discussion.
 - Is there a direct benefit to the children in this study? If there is no direct benefit, then is the risk only a minor increase over minimal?
- 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? Is the consent/assent process adequate? If not, provide recommended changes for discussion.
- Pregnant Women

What are the research procedures that are happening on the pregnant individual and/or their fetus?

 - How long will they be enrolled (e.g. the entire pregnancy, portion of the pregnancy, after the birth, etc)? Does the study include pregnant minors?
 - Is the research studying the woman or the fetus, or both?
 - Is there a direct benefit to the pregnant women or the fetus? Or both?
 - If there is no prospect of benefit to the woman nor the fetus, is the risk to the fetus not greater than minimal?
 - If the benefits of the research can only be accrued to the fetus, does the consent process describe obtaining consent from the mother and the father (unless he is unable to consent)?
 - Does the study include research procedures on a non-viable neonate or a neonate of uncertain viability?
- Describe any additional vulnerable populations included in the study:
 - Examples include: HIV positive, economically disadvantaged, non-English speakers, Non-Readers/Visually Impaired, employees, at-risk youth, etc.
 - For each of the identified vulnerable populations, describe the measures taken to protect their rights and welfare. Specifically:
 - Are the plans to include these populations adequate?
 - Does the study include, non-readers/visually impaired or limited English proficient participants? If so, are there plans to include the appropriate witness, interpreter, etc. in the consent process? Will documents require translation (e.g. surveys, recruitment, consents, etc.)

End your presentation with a recommendation for the vote. At the end of each review presented to the Board, the primary reviewer makes a recommendation regarding approval, approval with modifications, deferral, or disapproval.

Things to Consider When Conducting Reviews

Requesting Modifications/Revisions

- Will a change in the application, consent, or protocol be likely to improve the welfare of research subjects to a meaningful degree?
 - If not, approve the study without the change.
 - If so, require the change be made prior to approval.
- **Are my revisions clear?**
 - The IRB staff will be communicating your requests to the PI, make sure it is clear what you are asking for and why.
 - Provide the exact wording for the change including page numbers and paragraphs in the ICF and Protocol.
- **Don't sweat the small stuff – but let the IRB Analyst know.**
 - If you find errors in consent forms or recruitment forms, etc. (e.g., typos, grammar, formatting, etc.) - inform the assigned IRB analyst. The study may still be approved with Modifications to correct these errors after the meeting. The IRB Analyst will inform the study team of the errors in the forms that need to be corrected.
 - Discuss at the meetings the revisions that are substantive and meaningful to enhancing the understanding of the consent form.
 - In general, the consent forms should be written at a 6-8th grade level, and complex scientific concepts should be explained in lay-terms. Complicated instructions or schedules can be explained with bullet points.
 - Passive, long sentences should be avoided. Active language is preferred.
- **IRB Analysts are available to assist. By sending meeting agendas out a week in advance it allows time:**
 - To have questions that you would like sent to a Principal Investigator or study team in advance (reserved for major issues that may be deferrable).
 - Have a discussion about major concerns about a study and that may not meet the criteria for approval and may need to be deferred.
 - For the Analyst to help or assist you with finding submissions, checklists, or navigating iRIS.
 - To request a Principal Investigator to attend the meeting to explain a study or answer questions.

Continuing Reviews

Main Summary should include:

- The purpose of the study
- The study's enrollment status:
 - # of local participants enrolled in the last year and overall.
 - Open, closed, or suspended
 - Have any subjects withdrawn?
- Any event/problem reports since the last review (sponsor/regulatory body reports, safety reviews, reportable new information, etc.)
 - Have any of these events/problems been significant?
 - State whether or not these events/problems have been reviewed by the convened IRB
- Any DSMB findings in the last year, if applicable.
- Any protocol deviations that raise concern.
- Modifications 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.

State any concerns about the study or topics that need board discussion, or if there is a specific approval criteria that is no longer met, and provide specific revisions that are necessary.

Informed Consent Form

Are any required informed consent elements missing? The reviewer checklist in iRIS contains a element review. If you find missing elements state at the meeting which element is missing.

- Ask for additional input from the board.
- Provide the exact wording for the change including page numbers and paragraphs in the ICF.

End your presentation with a recommendation for the vote. At the end of each review presented to the Board, the primary reviewer makes a recommendation regarding approval, approval with modifications, deferral, or disapproval.

Modifications

Main Summary should include:

- The purpose of the study.
- Describe the changes that are being made.
- If, as a result of the modifications, the risk/benefit ratio has changed explain how.
- Whether or not the changes are acceptable in relation to the justification/rationale provided.
- If, as a result of the modifications, there is a change in the inclusion of vulnerable populations and if the study documents have been adequately updated.
- Describe if the modification should include patient notification or re-consent.
 - If re-consent is necessary include the reason for the re-consent or verbal patient notification
 - If re-consent is necessary , is it required for subjects on active treatment or all subjects?

Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary.

End your presentation with a recommendation for the vote. At the end of each review presented to the Board, the primary reviewer makes a recommendation regarding approval, approval with modifications, deferral, or disapproval.

Reportable New Information

Main Summary should include:

- The purpose of the study.
- Describe the problem/event/information item.
- Mention if a modification has been submitted in conjunction with the report, or if there are indicated plans to make changes to the study.
- Describe the corrective action plan the investigator has (or will) implement in response to the problem (if applicable).
- State if the corrective action plan needs to be modified.
- Present your assessment:
 - Does this problem or event represent an unanticipated problem involving risks to participants or others??
 - Does this problem represent serious or continuing non-compliance?
 - Neither? (motion to acknowledge acceptance of the reportable new information)
 - Does the board need more information? The board can defer the submission and request specific information.

Initial

Purpose:

Design:

Procedures:

Summarize Significant Risks:

Recruitment Procedures:

Summarize Consent Process & Documentation (*Discuss unique consent processes & how consent will be obtained*):

Discuss data and safety monitoring plans (if applicable):

Mention extra precautions to protect privacy and confidentiality (If applicable)

Mention when there is an increased risk to privacy and confidentiality compared to a normal study

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Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary: (Are any Required Informed Consent Elements Missing)

Vulnerable Populations:

Describe any vulnerable populations which are involved.

Recommended vote (choose one of the following)

Approve; Approve with Modifications; Deferred; Disapprove

Continuing Review

Purpose:

Summarize enrollment status (# of local participants, open, closed, or suspended)

Summarize event/problem reports

Summarize DSMB finding (if applicable)

Are there Modifications with the continuing review? (give a short summary of the modification & if the change is appropriate; State whether or not the risk/benefit ratio has changed)

Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary: (Are any Required Informed Consent Elements Missing)

Recommended vote (choose one of the following)

Approve; Approve with Modifications; Deferred; Disapprove

***NOTE-** When suggesting to approve the Continuing Review identify the length of time for the approval period (i.e. standard 12 month approval period or shorter length of time for study check in {3 months, 6 months})

Modification

Purpose:

Summarize Changes

State whether or not the risk/benefit ratio has changed?

State whether or not the changes are appropriate

Determine if re-consent is necessary

Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary: *(Are any Required Informed Consent Elements Missing)*

Recommended vote (choose one of the following)

Approve; Approve with Modifications; Deferred; Disapprove

Reportable New Information

Purpose of Study:

Summarize Problem or Event

Mention if a modification has been submitted in conjunction with the report.

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?)*

*The Office of Human Research Protections (OHRP) defines unanticipated problems involving risks to study participants and others as an event that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

Definitions - CHW Research Policy: Reportable New Information to the IRB for Previously Approved Research	
Non-Compliance	Failure to follow the research regulations, CHW Policy or the requirements or determinations of the IRB.
Continuing Non-Compliance	A pattern of non-compliance (serious or non-serious) that suggests a potential for future non-compliance without intervention; a repeated unwillingness to comply with applicable research standards, regulations or determinations of the IRB; or a persistent lack of knowledge of how to comply on the part of the investigator or a willful lack of commitment by the investigator and study team to protect human participants.
Serious Non-Compliance	Non-Compliance that has, or could, reasonably be anticipated to have the potential to increase a physical, psychological, safety, or privacy risk to, or impair the rights of, local subjects.
Unanticipated Problem (UAP) Involving Risks to Subjects or Others	Any information or event that is (1) unanticipated or unexpected in nature, severity or frequency; (2) indicates that subjects or others are at increased risk of harm than was previously known or recognized; and (3) related to the research. Harm can be physical, emotional/psychological, social, or economic, and can include privacy harms.