Human Subjects Protection Office
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http://pennstatehershey.org/irb.

GUIDELINES FOR IRB REVIEW

IRB REVIEW RESOURCES

- Worksheet HRP-314: Criteria for Approval
- Guide to Assessing IRB Requirements –A reference to help assess criteria and requirements for review
- Chapter 2, IRB Member Handbook - Discusses IRB committee review functions
- IRB Operations page at www.pennstatehershey.org/irb - board member resources and links

IRB MEMBER REVIEW

- Review the IRB materials several days before the meeting.
  - Everyone is expected to be familiar with the proposals in order to participate in the discussion.
  - If you identify significant questions or issues, communicate these to the Primary Reviewer (or IRB Chair or HSPO) in advance of the IRB meeting. If needed, the primary reviewer will contact the investigator to obtain additional information or clarifications before the board meets.
  - Consider IRB meetings primarily a place to make decisions, not to gather information.

- All materials for an IRB meeting are posted for online access in the *IRB Monthly Review Docs* folder. Details access instructions are provided in the document, *Access to Online IRB Materials.*
  - The IRB minutes, Executive Committee minutes, and addenda reports are also provided online.

- Review the research according to the type of submission provided (i.e., New research or Ongoing study):
  - For new research, evaluate whether the proposal meets the criteria for approval. (The IRB Member Handbook, chapters 2.2 & 2.3, discussed new research and informed consent review.)
  - For review of ongoing research, such as a modification, continuation review or reportable new information, focus on the current issue(s) undergoing review and what is new or different since the last review occurred. Edits should not be made to previously approved documents unless revisions are needed to address the current issues. (Ch. 2.4 - 2.6 cover these types of reviews.)

- If you make recommendations for a submission keep these points in mind:
  - For design or procedural recommendations ask yourself: Is a change likely to improve the welfare of subjects to a meaningful degree?
  - The consent form should be considered as a reference and documentation of the informed consent process. Any edits should be limited to essential revisions. If suggesting specific wording, come to the meeting with it rewritten as you recommend. (Do not edit previously approved consent forms unless needed to address the current issues undergoing review.)
  - Major changes require IRB discussion and consensus.
  - IRB discussion should focus on substantive issues.
  - Changes to risks and discomforts must be supported by written documentation of references relevant to the study, provided to the HSPO staff, and IRB consensus will be needed.

IRB COMMUNCIATION POLICY

Board members should not discuss the proceedings and decisions of an IRB meeting with investigators or others, and if approached should explain that the HSPO is responsible for communicating the IRB decisions on the behalf of the board. In addition, informal consultations with researchers about human subject research issues are discouraged in order to avoid misinformation or misinterpretation that does not reflect current IRB policies and procedures. Board members and IRB Chairs are asked to refer inquiries to the HSPO or IRB Executive Chair, or to e-mail the investigator a summary of any discussion and advice given and copy the HSPO Associate Director (khay@hmc.psu.edu), so that communication to the investigator is clear and the HSPO remains informed.

Any board member with concerns about IRB communications, or any sense of coercion or undue influence related to a study or other IRB issues should report the situation to the Associate Director or IRB Chair.

PRIMARY AND SECONDARY REVIEW RESPONSIBILITIES

A primary and secondary reviewer system is used in order to identify and resolve issues for each proposal. Primary and secondary reviewers should read the entire submission to assess whether the approval criteria are met, referring to the *Worksheet HRP 314 - Criteria for Approval*, and the applicable *Checklist(s)* provided with the submission.

- For new research - Evaluate the overall submission for adherence to the IRB approval criteria. Document any issues that need to be addressed to meet a specific requirement.
- For ongoing research - Focus on the new information submitted for review. Do not edit previously approved documents unless needed to address the current issues undergoing review.

- Resolve questions before the IRB meeting
  - If significant issues are identified, the primary reviewer should contact the principal investigator (PI) or study coordinator in advance to obtain additional information or clarifications needed in order to facilitate IRB review at the meeting. The HSPO may serve as an intermediary if the primary reviewer does not have time to make this inquiry.
  - It is preferable to engage the principal investigators regarding issues of substance.
  - The focus of these communications is to get information, not to give advice about the study.
  - Primary reviewers should be transparent as they represent the IRB.

- Inform the IRB chair or the HSPO of any major issues in advance of the meeting
  - Or if you believe a consultant is needed or the PI's attendance at the meeting will facilitate the review (i.e., to discuss an important issue that cannot be resolved in advance.)

- Making IRB Reviewer Presentations
  - The suggested outlines below may be useful to guide presentations.
  - At an IRB meeting the chair will call on the primary reviewer to present the review, or if absent the secondary reviewer will be expected to assume this role and present the review.
  - Briefly summarize the proposed protocol or issue under review (remembering that board members have reviewed it). Try to limit your explanations to 2 or 3 sentences, where possible.
  - Refer to the Worksheet HRP-314: Criteria for Approval and explain any criteria that are not met and the issues identified. It is unnecessary to discuss sections where criteria *are* met.
  - Secondary reviewers should focus on any issues/interpretations that differ from the primary reviewer.
  - If the discussion reaches a point where unexpected or unresolved issues might cause a tabled/disapproved decision, a reviewer should suggest calling the investigator (if not present).
  - After the board discussion the primary reviewer should tender a motion, including any IRB determinations (e.g., children's category, parent signatures, and assent) and specific stipulations.

Suggested Presentation Outlines

New Research Review Presentations

- Explain the type of study (e.g., clinical trial, placebo controlled and purpose *(2-3 sentences)*
- Summarize basic study procedures (2-3 sentences)
- State if all the approval criteria are met, or identify the specific criteria not met and explain issues
- Explain if PI responded to any issues, where things stand, and possible solutions
- Note if the consent form needs to be revised and if so how, and justify requiring changes
- Indicate if vulnerable populations are proposed, justification and if the criteria are met
- After discussion make a motion, and include the categories and stipulations, if applicable

Ongoing Review Presentations – Modifications, Continuation Review, Reportable New Info.

Focus on the current issue(s) undergoing review, what is new since the since the last review and approval. Edits should not be made to previously approved documents unless needed to address the current issues.

- Explain the type of study and purpose briefly *(2 or 3 sentences)*
- Indicate the enrollment status and total enrolled to date, if applicable
- Explain the current issue submitted for review:
  - For modifications, summarize the changes being made
  - For continuation review, indicate if the research is proceeding in accord with the protocol, and indicate if the research appears to continue to satisfy all criteria for approval
  - For problem reports, summarize the event. Is it expected or unanticipated?
- Is there new information that would alter the IRB's prior determination?
- Is there anything that affects the risk-to-benefit ration? Are there safety monitoring issues?
- Are there new findings? If so, who needs notice (i.e., prior subjects, current, future enrollees)?
- After board discussion make a motion and include any IRB stipulations to be met
  - Include the approval period for renewals, and if any contingencies apply