

SOP: 303A MEETING AGENDA

1. POLICY

The IRB meeting agenda provides the framework for the IRB meeting. It is used as a critical tool to facilitate management of the IRB meeting as it provides the meeting content and establishes a sequence of review. It also provides, in advance of the IRB meeting, an overview for each IRB member of all items that have been previously reviewed and approved by the IRB Chairs as well as a list of items that are pending review by the convened IRB and assigned reviewers for each of those pending items.

Information documented in the meeting agenda provides the foundation for the IRB meeting minutes.

Specific Policies

1.1 Agenda Development

Each item submitted to the IRB for review is posted to the agenda of the appropriate Board. All items that receive approval by either the convened IRB or the IRB Chair are posted to the agenda reflecting the appropriate status (i.e., Approved by Board or Approved by Chair).

1.2 Information Documented

The agenda format is as follows:

- 1.2.1 Document Header: includes specific IRB Board (1-5) and meeting date
- 1.2.2 Board Members: names of IRB members listed on the meeting roster
- 1.2.3 Old & New Business: presentation of the previous meeting's minutes
- 1.2.4 Protocol Items: miscellaneous items such as protocol deviations, discussion items, Investigator correspondence, or Investigator question
- 1.2.5 Pending Board Review Items (items for discussion): new research projects, amendments, continuing reviews (both active & closed to enrollment), unanticipated problems involving risks to participants or others, and protocol deviations per SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations
- 1.2.6 Approved Items (items approved and listed for presentation to the IRB): includes Board requested revisions, new research projects, amendments, continuing reviews, and unanticipated problems involving risks to participants or others and protocol deviations per SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations
- 1.2.7 Other Items: includes inactivations and withdrawals of protocols or amendments
- 1.2.8 Other Information: items that involve radiation, the Veterans Affairs Medical Center, and names of IRB members assigned to review

1.3 Primary and Secondary Reviewer Model

The IRB utilizes the Primary Reviewer model for research proposals reviewed by the convened IRB. The IRB Chair is authorized to delegate the review to one Primary and one Secondary Reviewer with appropriate backgrounds and expertise. For protocols that are granted Expedited Review, the IRB Chair reviews or delegates review to an appropriate Vice Chair or designee.

2. SCOPE

These policies and procedures apply to all other SOPs.

3. RESPONSIBILITY

It is the responsibility of the IRB Administrator to consistently update the agenda applicable to her/his assigned Board, print the agenda, and include the agenda in the Board meeting packets.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 56

OHRP Guidance on Written IRB Procedures July 11, 2002

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations.

6. ATTACHMENTS

303A-A Agenda and Addendum to Agenda Template

303A-B IRB Database Manual

7. PROCESS OVERVIEW

All of the following processes involve the IRB database. For specific instructions, refer to the IRB Database Manual.

7.1 Items Requiring Convened IRB Review

7.1.1 The IRB Administrator posts all items that require convened Board review (new research projects, continuing reviews, amendments, unanticipated problems involving risks to participants or others and protocol deviations per SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations, and miscellaneous items) to the appropriate meeting agenda. These items are assigned a status of 'pending' or, if deferred at a previous meeting, of 'resubmission.'

7.1.2 Once an item has been reviewed by the convened Board, the IRB Administrator updates the appropriate status to the database, to either 'approved,' 'contingently-approved,' 'deferred,' or 'disapproved.'

7.2 Items Reviewed by the IRB Chair or Designee

7.2.1 The IRB Administrator posts all items that are reviewed by the IRB Chair or designee to the meeting agenda and assigns the appropriate status as described in 7.1.2 above.

7.3 Agenda Preparation for IRB Meeting

- 7.3.1 Following consultation with the IRB Chair or designee, the IRB Administrator posts the appropriate reviewers to each item pending Board review.
- 7.3.2 The IRB Administrator closes the agenda by sending the IRB staff an email indicating that the agenda is closed and that no additional items may be posted.

The agenda should be completed and closed 7-10 calendar days prior to the IRB meeting date.
- 7.3.3 The IRB staff copies the completed meeting agenda and includes it in the Board meeting packets for distribution.

7.4 Agenda Addendum

- 7.4.1 Once the agenda has closed, if additional items need to be added to the meeting, the IRB Administrator will create an agenda addendum.
- 7.4.2 The IRB Administrator consults with the IRB Chair or designee regarding reviewer assignments, posts the reviewers to the agenda addendum, and forwards the agenda addendum and necessary documents for distribution.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012