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.

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) for HSC; IRB Board (1-2) for NC 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, discussion items, Investigator correspondence, or Investigator question

1.2.5 Pending Board Review Items (items for discussion): new human research projects, continuing reviews (both active and closed to enrollment), modifications, protocol deviations, and unanticipated problems

1.2.6 Approved Items (items approved and listed for presentation to the IRB): includes Board requested revisions for new research submissions, modifications, continuing reviews, and protocol deviations and unanticipated problems, and items approved by expedited procedures.

1.2.7 Other Items: includes inactivations and withdrawals of protocols or modifications

1.2.8 Other Information: items that involve 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 IRB designee.
2. SCOPE

This SOP applies to all policies and procedures.

3. RESPONSIBILITY

It is the responsibility of the IRB Administrator to consistently update the agenda applicable to her/his assigned Board.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 56
OHRP Guidance on Written IRB Procedures (July 1, 2011)

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

303A-A Agenda Template

7. PROCESS OVERVIEW

All of the following processes involve the IRB electronic information system. For specific instructions, refer to the Operating Procedures of the electronic information system.

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, modifications, protocol deviations, and unanticipated problems and miscellaneous items) to the appropriate meeting agenda.

7.1.2 Once an item has been reviewed by the convened Board, the IRB Administrator updates the review outcome and research project status in the IRB’s electronic information system.

7.2 Items Reviewed by the IRB Chair or IRB Designee

7.2.1 The IRB Administrator posts all items that are reviewed by the IRB Chair or IRB designee to the meeting agenda and assigns the review outcome and research project 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 IRB designee, the IRB Administrator assigns the appropriate reviewers to each item pending Board review.

7.3.2 The agenda should generally be finalized 7-10 calendar days prior to the IRB meeting date.

7.3.3 If additional items need to be added to the meeting agenda after the agenda has been finalized, the IRB Administrator will update the agenda.
APPROVED BY:________________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016