

IRB SOP 401 IRB Meeting Agenda

Purpose

This Standard Operating Procedure (SOP) describes the procedures used to prepare for an IRB meeting. This occurs after the agenda items, order, attendees, and primary reviewers have been assigned.

Policy

The meeting agenda document is used to communicate pertinent information about upcoming IRB meetings to members of the IRB. The meeting agenda outlines human subject research activities subject to review by a convened meeting of board members under the jurisdiction of the IRB. Submission of a research protocol will satisfy all of the procedural requirements necessary for the comprehensive review of all of the relevant materials prior to the convened meeting. Additionally, the agenda provides a listing of any discussion items relevant to the operations of the human subject protection program.

Procedures

1.0 Meeting Agenda

The IRB Compliance Specialist prepares the meeting agenda. Additionally, relevant materials for review are distributed via IRBNet to all board members a week in advance of the scheduled meeting.

The agenda shall include the following items:

- Date of meeting
- Minutes from previous meeting (approved at convened meeting)

- Adverse Events
- Protocol Deviations
- Closed/expired protocols
- Protocol Reviews (noted for informational purposes)
 - Exempt protocols
 - Expedited protocols
- Quality Improvement College of Nursing*
- Administrative Reviews
- New Protocol Reviews
 - New Submissions
 - Amendments
 - Continuing Reviews
- Information/Education
- Research Compliance
- Quality Assurance and Quality Improvement
- Old/New Business
- WIRB*
- NCI IRB*
- External IRBs*

*Sections of minutes do <u>not</u> apply to Educational Behavioral Research –IRB agenda.

- 2.0 An abbreviated agenda listing the assignments is prepared separately from the generated IRBNet management system. The list is distributed by email to IRB committee members and posted in IRBNet for access.
- 3.0 Maintenance and revision of meeting agenda templates

The IRB Office utilizes a meeting agenda template to prepare the meeting agenda for each IRB meeting. The agenda template is created in IRBNet online management system and includes items listed in section 1.0 above.

HISTORY:

Effective Date: Revisions: October, 2019

Responsible Party:

Office of Research Compliance and Assurance