

SOP 302.003

Title



review. It also provides an overview of all items that have been previously (i.e., during the preceding time between REB meetings) reviewed and approved by delegated review procedures, a list of items that are pending review by the Full Board, and assigned reviewer(s) for each of those items. Information documented in the REB meeting agenda provides the foundation for the REB meeting minutes.

The REB meeting minutes document the actions that occur during an REB meeting. The minutes should enable a reader who was not present at the REB meeting to determine how and with what justification the REB arrived at its decisions. They should also provide the REB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

5.1 Agenda Preparation

- 5.1.1 Following an administrative review of the submission (e.g., new studies, amendments, continuing review applications, reportable events) by the REB Office Personnel and the determination of the review type by the REB Chair or designee, the responsible REB Office Personnel adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;
- 5.1.2 For submissions that were reviewed and approved via delegated review procedures, the REB will be made aware of these approvals in a timely manner;
- 5.1.3 The REB Office Personnel attaches to the agenda any previous REB meeting minutes for Full Board review and approval, and adds any other items for information or discussion at the REB meeting (e.g., SOPs, educational articles, presentations, reports, etc.);
- 5.1.4 The REB Office Personnel, in consultation with the REB Chair or designee as necessary, reviews the agenda, confirms REB meeting attendance and assigns the reviewers;
- 5.1.5 The REB Chair or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend;
- 5.1.6 The reviewer assignment and the agenda are issued in a timely manner prior to the REB meeting date. The REB members attending the REB meeting will receive a copy of the REB meeting agenda;
- 5.1.7 Ad hoc advisors will receive copies of relevant submissions;
- 5.1.8 Any changes to the agenda are communicated to all REB members and REB Office Personnel. The REB Office Personnel or designee also may issue an updated agenda notice depending on the nature of the changes.



Secondary Reviewers

Following the meeting, the REB Office Personnel, in consultation with the REB Chair, will assign a primary reviewer as necessary, will assign one or more secondary reviewers for each new research project and at least one reviewer for each amendment;

No REB member will be assigned as a reviewer on a submission in which they are a researcher or co-Researcher or in which there is a declared conflict of interest;

5.2.3 The REB Office Personnel will issue the reviewer assignment. The assigned reviewers will receive notification with a copy of the meeting agenda;

5.2.4 If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.

5.7 Prior to the REB



SOP 302.003

applicable,
The basis for requiring changes or for disapproving submissions,
Number of REB members in attendance for the review of each submission requiring a decision,
REB member(s) recused related to conflicts of interest for each submission requiring a decision,
Number(s) voting for, against or abstaining in the event of a vote for each submission requiring a decision,
Reference to any attachments to the agenda;

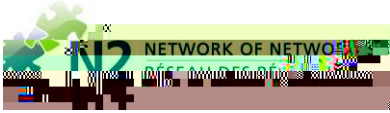
- 5.7.2 All REB meeting agendas and minutes are retained in the REB records;
- 5.7.3 The agendas, REB meeting minutes and review documents are confidential and will not be released or made available unless required for inspection or auditing purposes.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP302.001	15-Sept-2014	Original version
SOP302.002	08	



SOP 302.003

biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body),

At least one member who is primarily experienced in non-scientific disciplines,

At least one member who is knowledgeable in ethics,

At least one member who is knowledgeable in the relevant law,

At least one community member who has no