

<b>SOP Title</b>	<b>NMREB Meeting Administration</b>
<b>Number.Version</b>	N302.001
<b>Effective Date</b>	07/05/2018

## Approvals

<b>Name and Title of Signatories</b>	<b>Signature</b>	<b>Date mm/dd/yyyy</b>
Erika Basile Director, Research Ethics		2019-02-26
Dr. Randal Graham Chair, Non-Medical Research Ethics Board		2019-03-06

## 1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the required activities for the preparation, management and documentation of convened Non-Medical Research Ethics Board (NMREB) meetings.

## 2. GENERAL POLICY STATEMENT

Except when a delegated review procedure is used, the NMREB will review proposed research at convened meetings at which a Quorum is present. The NMREB will meet one a month, or at the call of the Chair.

The NMREB meeting agenda provides the meeting content and provides the foundation for the NMREB meeting minutes. It also includes an attachment of all items (initial approvals for Delegated studies, amendments, etc.) that have been reviewed and approved by delegated review procedures since the last convened meeting, a list of items that are pending review by the convened NMREB and a list of expired studies for closure by the NMREB.

The NMREB meeting minutes document the actions that occur during an NMREB meeting and should provide the NMREB with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

## 3. RESPONSIBILITY

This SOP applies to the NMREB Chair, Vice Chair(s), all NMREB Members, NMREB consultants, NMREB meeting guests and Office of Human Research Ethics (OHRE) staff involved in NMREB Meeting Administration.

## 4. DEFINITIONS

See Glossary of Terms

## 5. SPECIFIC POLICIES AND PROCEDURES.

### 5.1. Agenda and Meeting Preparation

5.1.1. The Ethics Officer (EO), in consultation with the NMREB Chair as necessary, drafts the meeting agenda according to the *NMREB Agenda Template*, and posts all items that require full NMREB review to the agenda (e.g. previous meeting's minutes, business carried, new

business, Amendments, new protocol submissions, new approvals by delegated review, educational items and other pertinent items);

5.1.2. The EO, in consultation with the NMREB Chair as necessary, reviews the agenda to ensure that quorum will be met with those who have indicated they will be in attendance.;

5.1.3. The EO includes the completed meeting agenda in the NMREB meeting packages for distribution to the NMREB members;

5.1.4. The OHRE staff distributes the meeting packages to the NMREB members, electronically, 7 days prior to the NMREB meeting;

## **5.2. Prior to the NMREB Meeting**

5.2.1. All NMREB members will review the materials provided prior to the meeting and will be prepared to participate in the discussion at the convened meeting.

5.2.2. Prior to the NMREB meeting, NMREB members are expected to log their individual comments online for each submission;

5.2.3. All reviewer comments are accessible in the online system to all NMREB members and OHRE staff;

5.2.4. If changes need to be made to the agenda, the EO will modify the agenda, notify the NMREB Chair and NMREB members, and circulate the revised agenda;

## **5.3. During the REB Meeting**

5.3.1. A Quorum must be present to conduct a convened meeting, the meeting will not begin until Quorum is met;

5.3.2. Attendance is recorded by the EO. Time of arrival, recusal, return to meeting and departure will be noted for each member as applicable;

5.3.3. Should Quorum fail during a meeting (e.g., through recusal of members with conflicts of interest or early departures), the NMREB may not make further decisions until Quorum can be restored;

5.3.4. An alternate member may attend in the place of a regular member to meet quorum requirements.

5.3.5. Should a member not be physically present during a convened meeting, he/she may participate via videoconference or teleconference. Members participating by videoconference or teleconference count towards quorum;

5.3.6. Ad hoc advisors will not be used to establish a quorum;

5.3.7. Members recusing themselves due to conflicts of interest are not counted toward quorum;

5.3.8. Under unusual circumstances (e.g., public health alerts and quarantines) the NMREB Chair may, at his/her discretion, conduct an NMREB meeting with all members attending via

simultaneous videoconference or teleconference, provided everyone has received the review materials and quorum is met;

5.3.9. Only those NMREB members present (i.e., in person or via videoconference or teleconference) at the convened meeting may participate in the deliberation and final decision regarding approval;

5.3.10. Guests may be invited or permitted to attend NMREB meetings, subject to the agreement of the NMREB Chair and execution of a *Confidentiality and Conflict of Interest Agreement*. Guests must disclose any vested interest in, or scientific or management responsibility for any applications being considered at the meeting;

5.3.11. If requested, Investigators, or their designate, may attend the NMREB meeting to present their project and respond directly to any comments or questions raised by the NMREB, subject to the agreement of the NMREB. Investigators may not be present for NMREB discussions, deliberations and decisions;

5.3.12. Any individual not listed on the current NMREB membership list may not participate in the decisions of the NMREB.

#### 5.4. Meeting Minute Preparation

5.4.1. The EO creates the outline of the meeting minutes according to the *NMREB Meeting Minutes Template* and incorporates the meeting agenda;

5.4.2. The EO records the key NMREB discussions, the Board's motion and votes within the minutes document;

5.4.3. The NMREB concerns, clarifications and recommendations to the Investigator as discussed at the meeting are included in the minutes. An additional separate document encompassing the clarifications and concerns discussed by the board is developed and sent to the investigator as the *NMREB Recommendations*;

5.4.4. The draft minutes should be completed prior to the next meeting.

#### 5.5. Meeting Minute Approval

5.5.1. The designated EO includes the minutes from the previous NMREB meeting in the upcoming NMREB meeting packages for distribution to the NMREB members;

5.5.2. It is the responsibility of the NMREB members to review and recommend changes (as necessary) to the meeting minutes;

5.5.3. The NMREB Chair requests a motion to approve the minutes at the next convened NMREB meeting noting any required revisions;

5.5.4. If modifications to the minutes are required, this will be done by the EO and presented to the NMREB Chair or designee for final approval. Any modifications to the minutes will be noted in the succeeding meeting minutes.

5.5.5. The final version of the minutes is available to all NMREB members should they request it.

#### 5.6. Recommendations

5.6.1. The EO compiles all NMREB recommendations from the online system and from the meeting notes. The recommendations are then entered into the *NMREB Recommendations Form*;

5.6.2. The *NMREB Recommendations Form* is sent to the Investigator via the online system within 3 business days of the NMREB meeting.

### 5.7. Documentation

5.7.1. The meeting minutes and/or attendance record include the following items:

- Time meeting commenced and adjourned;
- Names of NMREB members and OHRE staff in attendance (present, teleconference, videoconference);
- Names of NMREB members absent;
- Presence of guests and ex-officio members;
- Use of expert consultants and their specialty as applicable;
- Declaration of any real, potential or perceived NMREB Member conflicts of interest;
- A summary of key issues including the basis for requiring changes in or for rejecting research;
- The decisions taken by the NMREB regarding approval;
- Members recused related to conflicts of interest for each project;
- Number voting for, against or abstaining in the event of a vote.

5.7.2. Reviewer comments entered in the online system are kept on file in the online system. Reviewer comments discussed at the NMREB meeting are compiled and kept on file with the study.

5.7.3. Meeting agendas and minutes and completed reviews are stored.

5.7.4. The agendas, meeting minutes and reviews are confidential documents not released outside the Office of Human Research Ethics unless required by law. They may be inspected by authorized regulatory personnel.

## 6. REFERENCES

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2) Article 6.10; 7.4;
- 6.2. U.S. Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103;
- 6.3. OHRP Guidance on Written IRB Procedures.

## 7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N302.001	Original	07/07/2016
N302.002	Update to NMREB Chair and NMREB processes	11/05/2018