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**1 PURPOSE**

This standard operating procedure (SOP) describes the required activities for the preparation, management and documentation of Full Board meetings of the Research Ethics Board (REB).

## 2 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

## 3 RESPONSIBILITIES

All REB members and REB Support Staff are responsible for ensuring that the requirements of this SOP are met.

## 4 DEFINITIONS

See Glossary of Terms.

## 5 PROCEDURES

Except when a delegated review procedure is used, the REB must review proposed research at Full Board meetings at which a quorum is present, in accordance with basic REB composition criteria.<sup>1</sup>

Unless they do not involve confidential or prescriptive information, in which case they may be open to the public, REB meetings are held behind closed doors.<sup>2</sup>

The REB meeting agenda provides the meeting content. 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 Support Staff and the determination of the

<sup>1</sup> ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter “ICH GCP”, s. 3.2.3; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter “Modèle”, s. 10.6; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 6.9; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter “TDR” s. 4.5.2.

<sup>2</sup> *Modèle*, s. 8.4.

review type by the REB Chair or designee, the responsible REB Support Staff adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;

- 5.1.2 Submissions that were reviewed and approved via delegated review procedures, will be added to the agenda of the next REB Full Board meeting;
- 5.1.3 The REB Support Staff attaches to the agenda any previous REB meeting minutes for review and for approval by the Full Board as well as for approval by REB members present at that meeting. The REB Support Staff then adds the other items for information or discussion at the REB meeting (e.g. SOPs, educational articles, presentations, reports, etc.);
- 5.1.4 The REB Support Staff, 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 persons called to the meeting.

## **5.2 Reviewers**

- 5.2.1 Prior to the meeting, the REB Support Staff, in consultation with the REB Chair or designee as necessary, may assign reviewers to each research project, whether for initial or subsequent review;
- 5.2.2 No REB member will be assigned as a reviewer on a submission in which he or she is a Researcher or co-Researcher or in which there is a declared conflict of interest.

## **5.3 Prior to the REB Meeting**

- 5.3.1 The reviewers will conduct in-depth reviews of their assigned submissions and may submit reviewer comments prior to the REB meeting. The primary reviewer should be prepared to lead the discussion at the Full Board meeting;
- 5.3.2 All REB members examine each agenda item prior to the Full Board meeting.

## 5.4 During the REB Meeting

5.4.1 In accordance with basic REB composition criteria,<sup>3</sup> a quorum is present when at least five REB members<sup>4</sup> are present and represented by the following categories:

- At least two members who have expertise in relevant research disciplines, field and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who is a physician, dentist, or pharmacist and who is in good standing with the Council of Physicians, Dentists and Pharmacists (CPDP)<sup>5</sup>),
- At least one member who is primarily experienced in non-scientific disciplines,<sup>6</sup>
- At least one member who is knowledgeable in ethics,<sup>7</sup>
- At least one member with legal expertise, knowledgeable in laws relevant to the types of research being reviewed,<sup>8</sup>
- At least one community member or representative of an organization interested in the areas of research being reviewed who has no affiliation with the institution or the sponsor,<sup>9</sup> and who is not part of the immediate family of a person who is affiliated with the institution;

5.4.2 Should quorum fail during a Full Board meeting (e.g. through recusal of REB members with conflicts of interest or early departures), the REB may not make further decisions<sup>10</sup> unless quorum can be restored;

5.4.3 Should a REB member not be physically present during a Full Board meeting, he/she may participate via videoconference or teleconference. REB members participating by videoconference or teleconference count towards quorum<sup>11</sup>;

<sup>3</sup> *Modèle*, s. 10.6 and 11; TCPS2, art. 6.9; ICH GCP, s. 3.2.3; TDR, s. 4.5.2.

<sup>4</sup> *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec*, Part I, vol. 35, 1998, hereafter "Avis", p. 1039; Food and Drug Regulations, C.R.C., c. 870, art. C.05.001, Definition of research ethics board; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Ministère de la Santé et des Services sociaux du Québec* (PAM), 1998, p. 21; ICH GCP, s. 3.2.1 (a); Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 6.4.

<sup>5</sup> *Avis*, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (i); PAM, p. 21; *Modèle*, s. 6.1; TCPS2, art. 6.4 (a).

<sup>6</sup> Food and Drug Regulations, art. C.05.001 (b) (iv); ICH GCP, s. 3.2.1 (b); *Modèle*, s. 6.1.

<sup>7</sup> *Avis*, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (ii); PAM, p. 21; *Modèle*, s. 6.1; TCPS2, art. 6.4 (b).

<sup>8</sup> *Avis*, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (iii); PAM, p. 21; *Modèle*, s. 6.1; TCPS2, art. 6.4 (c).

<sup>9</sup> *Avis*, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (v); *Modèle*, s. 6.1; ICH GCP, s. 3.2.1 (c); TCPS2, art. 6.4 (d) and p. 74. N.B.: According to PAM, this person must use the services of the institution, p. 21.

<sup>10</sup> TDR, s. 7.3.

<sup>11</sup> TCPS2, art. 6.9 and 6.10.

- 5.4.4 A member who cannot attend the meeting can exceptionally send in his comments in advance, to be read by the REB members present at the meeting. This member would count toward quorum. The REB decision will be sent back to him for approval;
- 5.4.5 Ad hoc advisors will not be used to establish a quorum<sup>12</sup>;
- 5.4.6 REB members recusing themselves due to a conflict of interest are not counted toward quorum;
- 5.4.7 Under unusual circumstances (e.g. public health alerts and quarantines), the REB Chair or designee may, at his/her discretion, conduct an REB meeting by collecting written comments from the REB members constituting a quorum, provided everyone has access to the review materials;
- 5.4.8 Only those REB members present at the Full Board meeting may participate in the deliberation and final decision regarding approval;
- 5.4.9 Observers may be invited or permitted to attend REB meetings, subject to the agreement of the REB and execution of a *Confidentiality Agreement*. Rules and regulations regarding conflict of interest apply;
- 5.4.10 If requested, Researchers may attend the REB meeting to present their research and respond directly to any comments or questions raised by the REB;
- 5.4.11 Any individual not listed on the official REB membership roster may not participate in the decisions of the REB.
- 5.5 Meeting Minutes Preparation**
- 5.5.1 The REB Chair or designee or REB Support Staff will draft the REB meeting minutes;
- 5.5.2 The key REB discussions and decisions, abstentions and dissensions, for submissions are recorded in the minutes<sup>13</sup>;
- 5.5.3 The REB's concerns, clarifications and recommendations to the Researcher as discussed at the REB meeting are included in the REB review letter that is sent to the Researcher. The information documented in the letter is included in the REB meeting minutes;
- 5.5.4 The meeting may be audio recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft of the minutes;
- 5.5.5 The draft minutes should be completed within 10 working days.
- 5.6 Meeting Minutes Approval**

<sup>12</sup> TCPS2, art. 6.9.

<sup>13</sup> TDR, s. 6.1.3.

5.6.1 The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval.<sup>14</sup>

## 5.7 Documentation

5.7.1 The REB meeting minutes include the following items:

- Date, place, and time the REB meeting commenced and adjourned,
- Names of REB members in attendance (present, teleconference, videoconference), and names of REB members absent,<sup>15</sup>
- Names of REB Support Staff present at the meeting,<sup>16</sup>
- Presence of observers, use of ad hoc advisors and their specialty,<sup>17</sup>
- Exact title of each research project reviewed or submitted, along with the name of the applicant,<sup>18</sup>
- A summary of key discussions and controverted issues and their resolution for each submission, as applicable,<sup>19</sup>
- The basis for requiring changes or for disapproving submissions,<sup>20</sup>
- REB member(s) recused related to conflicts of interest for each submission requiring a decision,
- The key REB discussions and decisions, abstentions and dissensions, for each submissions,<sup>21</sup>
- Reference to any attachments to the agenda;

5.7.2 All REB meeting agendas and minutes are retained in the REB records for at least three years,<sup>22</sup> or for at least 25 years in the case of clinical trials<sup>23</sup>;

5.7.3 The agendas, REB meeting minutes and review documents are confidential and will not be released or made available to anyone;

<sup>14</sup> TDR, s. 6.1.3.

<sup>15</sup> *Modèle*, s. 8.5.2.

<sup>16</sup> *Modèle*, s. 8.5.2.

<sup>17</sup> *Modèle*, s. 8.5.2.

<sup>18</sup> *Modèle*, s. 8.5.2.

<sup>19</sup> TCPS2, art. 6.17; *Modèle*, s. 8.5.2.

<sup>20</sup> TCPS2, art. 6.17; *Modèle*, s. 8.5.2.

<sup>21</sup> *Modèle*, s. 8.5.2.

<sup>22</sup> ICH GCP, s. 3.4; TDR, s. 10.5 and 10.6; *Modèle*, s. 14.1 and 14.4; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Ministère de la Santé et des Services sociaux du Québec (PAM)*, 1998, Mesure 5.

<sup>23</sup> Food and Drug Regulations, C.R.C., c. 870, art. C.05.012; Health Canada/Health Products and Food Branch Inspectorate, *Guidance for Records Related to Clinical Trials (Guide-0068)*, June 2006.

5.7.4 If required for inspection or auditing purposes in accordance with REB SOP 701.001, relevant parts of the minutes could be released. Individuals designated by the government are subject to due discretion and confidentiality.<sup>24</sup>

## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 302.001	2020-03-20	Original version

## 8 APPENDICES

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<sup>24</sup> *Ibid.*