

<b>Title:</b>	<b>Standard Operating Procedures of the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal Research Ethics Board</b>
<b>SOP code:</b>	REB-SOP 101.001 to 702.001
<b>Responsible for application:</b>	<b>Academic Affairs and Research Ethics Directorate</b>
<b>Approved by:</b>	<b>Board of Directors (2021-09-30)</b>
<b>Procedure:</b>	<b>New</b> <input checked="" type="checkbox"/> <b>Revised</b> <input type="checkbox"/>
<b>Related policy:</b>	<b>Yes</b> <input checked="" type="checkbox"/> <b>No</b> <input type="checkbox"/> Research regulatory framework
<b>Recipient:</b>	<input type="checkbox"/> Intra-directorate: Specify the directorate <input type="checkbox"/> Inter-directorate: Specify directorates or departments concerned <input type="checkbox"/> Multidisciplinary: Specify disciplines (e.g., social workers, physicians, etc.) <input type="checkbox"/> Governance and senior management <input checked="" type="checkbox"/> Entire CIUSSS du Centre-Ouest-de-l'Île-de-Montréal
<b>Effective date:</b> <b>30-09-2021</b>	<b>Revision date:</b>

## 1. Scope

- 1) The Board of Directors' official representative(s)
- 2) REB Chairs, all REB members, and Research Review Office staff who support the REB
- 3) The entire research community

## 2. General framework

The Standard Operating Procedures (SOPs) are procedures pertaining to research ethics committees in the following fields: general administration; REB organization; REB functions and operations; review of research; reviews requiring special consideration; researcher qualification and responsibilities; quality control. CATALIS and

its collaborators revised N2 Canada’s SOPs for Research Ethics Boards (REBs) in order to adapt them to the Quebec policies. The CHUM, CHU Sainte-Justine, and MUHC have adopted these harmonized SOPs.<sup>1</sup>

Our institution has also chosen to refer to these SOPs. A revision committee was formed to validate consistency between the SOPs and the practices of our REB. Following working meetings and validation with the co-chairs of the REB, managers from the Academic Affairs and Research Ethics Directorate, as well as ethics specialists from the Research Review Office (RRO), the SOPs were adapted to reflect our organizational structure, the Nagano platform, and psychosocial research methods. We also based our revision work on the new *Cadre de référence ministériel pour la recherche avec des participants humains* (MSSS, 2020), with a few minor changes. A revision by CATALIS is ongoing, specifically to adopt these SOPs to this new *Cadre de référence ministériel*. As soon as this revision becomes available, we will review the SOPs to determine whether updates are needed.

CATALIS also specified on its website that new harmonized SOPs are expected soon:

204.001	REB support staff who serve as members of the REB	To come
405B.001	Active follow-up	To come
502.001	Biobanks	To come
503.001	Multicentre research	To come
504.001	Reproductive technologies research	To come

These new SOPs will also be considered during the update.

**3. Description of the procedure**

This document contains a description of each standard operating procedure.

**4. References**

Each standard operating procedure contains the appropriate references.

**5. Appendices**

The appendices, where applicable, are attached to each standard operating procedure. The glossary of CATALIS standardized operating procedures is included in the general appendix to the document.

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<sup>1</sup> [https://www.catalisquebec.com/en/about-catalis/resources/#standard\\_operating\\_procedures\\_\\_sops\\_](https://www.catalisquebec.com/en/about-catalis/resources/#standard_operating_procedures__sops_)

<b>Title:</b>	Authority and Purpose
<b>SOP code:</b>	REB-SOP 101.001
<b>N2/CAREB SOP code:</b>	SOP 101.002
<b>Effective date:</b>	2021-09-30

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## 1 PURPOSE

The purpose of this standard operating procedure (SOP) is to:

- State the organizational authority under which the Research Ethics Board (REB) is established and empowered;
- Define the purpose of the REB;
- State the principles governing the REB to ensure that the rights and welfare of participants are protected;
- State the authority of the REB.

## 2 SCOPE

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

## 3 RESPONSIBILITIES

The Board of Directors' official representative(s), all REB members, and designated RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

## 4 DEFINITIONS

See glossary.

## 5 PROCEDURES

The REB will maintain and follow all written policies and procedures consistent with federal and provincial regulations, good clinical practice, and ethics guidelines when reviewing proposed research.

### 5.1 Statement of organizational authority

- 5.1.1 The institution's Board of Directors has established and empowered the REB to review research involving human participants conducted under the auspices of the institution.<sup>2</sup>
- 5.1.2 All research involving human participants is to be reviewed and approved by an REB prior to the initiation of any research-related activities.
- 5.1.3 The institution is responsible for establishing the organizational conditions required to apply the standards set out in the *Cadre de référence ministériel pour la recherche avec des participants humains*.<sup>3</sup> As such, an institution whose activities include conducting research under its auspices must implement a research regulatory framework, adopted by the Board of Directors. The CIUSSS du Centre-Ouest-de-l'Île-de-Montréal Academic Affairs and Research Ethics Directorate is designated by the institution's President and CEO as the director it responsible for implementing, apply in, and regularly updating the regulatory framework adopted by the Board of Directors. To ensure the regulatory framework is adapted to the institution, the administration and all stakeholders concerned (e.g., researchers, REB, departments) rely on mechanisms to account for all relevant factors, including the volume and complexity of research activities, the issues likely to be involved in the research activities, and the profile of individuals authorized to conduct research activities at the institution.<sup>4</sup>
- 5.1.4 The REB is an independent body within the institution.<sup>5</sup> As such, it must have full independence in decision-making with respect to the projects it reviews, a condition necessary to fulfilling its purpose. The institution ensures that the REB is protected from undue influence.
- 5.1.5 The institution ensures that the REB fulfils its purpose in accordance with operational guidelines that guarantee the ethical nature of its decisions and the transparency of its activities.<sup>6</sup> The guidelines cover, in particular:
- the purpose and jurisdiction of the REB, as recognized by the Board of Directors;
  - the REB's attachment to the institution's Board of Directors;
  - the requirements regarding composition of the REB;
  - the roles and responsibilities of the REB support staff;

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<sup>2</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 6.2, hereafter TCPS2.

<sup>3</sup> *Cadre de référence ministériel pour la recherche avec des participants humains*, Direction de l'éthique et de la qualité, Direction de la recherche et de la coordination interne, Ministère de la Santé et des Services sociaux, October 2020. Hereafter *Cadre de référence ministériel*.

<sup>4</sup> *Cadre de référence ministériel*.

<sup>5</sup> *Cadre de référence ministériel*.

<sup>6</sup> *Cadre de référence ministériel*.

- the REB’s decision-making process and internal governance rules, including quorum requirements;
- the rules governing documentation and archiving of REB files;
- the REB’s reporting responsibility. The operational guidelines, which are openly available, must be adopted by the Board of Directors.

## 5.2 Purpose of the REB

- 5.2.1 The REB’s purpose is to protect the dignity, rights, and welfare of human participants in research.<sup>7</sup>
- 5.2.2 The REB’s purpose is also to sensitize the various stakeholders to the ethical principles applicable to research involving human beings.<sup>8</sup>
- 5.2.3 The REB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to the protection of human participants.<sup>9</sup>
- 5.2.4 These include, but are not limited to, the *Cadre de référence ministériel pour la recherche avec des participants humains*, the *Modèle de règles de fonctionnement d’un comité d’éthique de la recherche*, the Framework for Public Health and Social Services Institutions to Authorize Research Conducted at More Than One Institution, the Civil Code of Québec, Québec’s *Act respecting health services and social services*, Québec’s *Act respecting Access to documents held by public bodies and the Protection of personal information*; Canada’s *Food and Drugs Act* and *Food and Drug Regulations*; Health Canada’s *Good Clinical Practice: Consolidated Guideline*; the Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects; the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), Standard CAN/CGSB-191.1-2013 Research Ethics Oversight of Biomedical Clinical Trials; and, where applicable, U.S. federal regulations.

## 5.3 Governing principles

- 5.3.1 The REB’s work is guided by ethical principles<sup>10</sup> regarding all research involving human participants, including:
- Respect for persons:
    - (a) Recognize the intrinsic value of all human beings, and the respect and consideration they are due;
    - (b) Incorporate the moral obligations to respect autonomy and to protect those with developing, impaired, or diminished autonomy.

<sup>7</sup> *Good Clinical Practice: Consolidated Guideline*, 1997, s. 3.1.1, hereafter *GCP*; *Modèle de règles de fonctionnement d’un comité d’éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 4.1, hereafter *Modèle*; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 2, hereafter *OG*.

<sup>8</sup> *Modèle*, s. 4.1; *Cadre de référence ministériel*; *Plan d’action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 13, hereafter *PAM*.

<sup>9</sup> *Cadre de référence ministériel*. *PAM*, p. 13.

<sup>10</sup> TCPS2, art. 1.1; *OG*, s. 2.

- Concern for welfare:
  - (a) Aim to protect the welfare of participants, and, in some circumstances, to promote their welfare in view of any foreseeable risks;
  - (b) Provide participants with enough information to be able to adequately assess the risks and potential benefits associated with their participation;
  - (c) Ensure that participants are not exposed to unnecessary risks.
- Justice:
  - (a) Treat people fairly and equally;
  - (b) Potentially afford special attention to vulnerable or marginalized people.

## 5.4 REB authority

5.4.1 The REB has the authority to review, in an independent manner,<sup>11</sup> all research within its jurisdiction involving human participants.<sup>12</sup>

5.4.2 The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants.

5.4.3 Specifically, the REB has the authority to:<sup>13</sup>

- establish the ethics review processes and provide research ethics oversight to ensure the ethical conduct of the research;
- approve, require modifications to, or disapprove any research activity that falls within its jurisdiction;
- with active follow-up, ensure that the researcher follows policies and procedures aimed at protecting the rights, safety, and welfare of research participants;
- request, receive, and share any information involving research that the REB considers necessary to fulfill its purpose, while maintaining confidentiality and respecting privacy;
- conduct an ethical review to protect the rights, welfare, and privacy of research participants;
- suspend or terminate the ethics approval for the research;
- place restrictions on the research;
- take any actions considered reasonably necessary and consistent with policies and procedures, to protect the rights, safety, and welfare of participants in research conducted under the REB's jurisdiction.

## 5.5 Research subject to foreign regulations

The REB shall respect the regulations of foreign jurisdictions, where applicable.

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<sup>11</sup> OG, s. 2; *Modèle*, s. 5.1; TCPS2, p. 70 and 71.

<sup>12</sup> TCPS2, art. 2.1 to 2.6.

<sup>13</sup> *Modèle*, s. 4; *Cadre de référence ministériel*; PAM, p. 13-14; GCP, s. 3.1; TCPS2, art. 6.3.

## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

SOP code	Effective date	Summary of changes
REB-SOP 101.001		

<b>Title:</b>	Research Requiring REB Review
<b>SOP code:</b>	REB-SOP 102.001
<b>N2/CAREB SOP code:</b>	SOP 102.002
<b>Effective date</b>	2021-09-30

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**1 PURPOSE**

The purpose of this standard operating procedure (SOP) is to describe research activities that require Research Ethics Board (REB) review and research activities that do not.

**8 SCOPE**

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

**9 RESPONSIBILITIES**

All REB members and RRO staff designated to support the REB are responsible for ensuring that the requirements of this SOP are met.

**10 DEFINITIONS**

See glossary.



## 11 PROCEDURES

All research involving human participants must be reviewed and approved by an REB. No intervention or interaction with human research participants, including recruitment, may begin until an REB has reviewed and approved the research protocol, consent documents, and recruitment materials. Similarly, no research may begin until all other necessary approvals have been obtained by the RRO and authorization has been obtained from the institution.

### 11.1 Research that requires REB review

11.1.1 The following requires an ethics review and approval by an REB before the research commences:<sup>14</sup>

- Research involving human participants and/or personal data;
- Research involving human biological materials, embryos, fetuses, fetal tissue, reproductive materials, or stem cells. This applies to materials derived from living and deceased individuals.

### 11.2 Research exempt from REB review

11.2.1 Research that relies exclusively on publicly available information does not require REB review, where either of the following conditions applies:<sup>15</sup>

- The information is legally accessible to the public and adequately protected by law;
- The information is accessible to the public and there is no reasonable expectation of privacy.

11.2.2 REB review is not required for research involving the observation of people in public places, where all of the following conditions apply<sup>16</sup>:

- The research does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
- Individuals or groups targeted for observation have no reasonable expectation of privacy;
- Any dissemination of research results does not allow identification of specific individuals.

(c) REB review is not required for research that relies exclusively on secondary use of anonymous information or anonymous human biological materials, provided the data linkage, recording, or results dissemination processes do not generate identifying

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<sup>14</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 2.1, hereafter TCPS2. Also see: *Cadre de référence ministériel; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 11, hereafter PAM.

<sup>15</sup> TCPS2, art. 2.2.

<sup>16</sup> TCPS2, art. 2.3.

information.<sup>17</sup> Human biological materials collected as part of health care are never anonymous.

- (d) The researchers can consult the REB whenever there is any doubt about the applicability of this policy to a given research study.<sup>18</sup>

**11.3 Activities not requiring REB review**

11.3.1 Quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management, or improvement purposes, do not constitute research for the purposes of this SOP, and do not fall within the scope of REB review.<sup>19</sup>

11.3.2 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.<sup>20</sup>

11.3.3 The initial exploratory phase during which researchers may contact individuals or groups to develop research partnerships or to gather information for the development of a research project does not require REB review.<sup>21</sup>

**12 REFERENCES**

See footnotes.

**13 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 102.001		

<sup>17</sup> TCPS2, art. 2.4.

<sup>18</sup> TCPS2, p. 15.

<sup>19</sup> TCPS2, art. 2.5.

<sup>20</sup> TCPS2, art. 2.6.

<sup>21</sup> TCPS2, art. 6.11.

<b>Title:</b>	Training and Education
<b>SOP code:</b>	REB-SOP 103.001
<b>N2/CAREB SOP code:</b>	SOP 103.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the training and education requirements for Research Ethics Board (REB) members and RRO staff that supports the REB.

**14 SCOPE**

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

**15 RESPONSIBILITIES**

All REB members and RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

**16 DEFINITIONS**

See glossary.

## 17 PROCEDURES

REB members, RRO staff that supports the REB, and others charged with the responsibility of reviewing, approving, and overseeing human-participant research should be well-versed in the regulations, guidelines, policies, and ethical principles applicable to human-participant research. Training and education in these areas is critical for the REB to fulfill its purpose of protecting the rights and welfare of research participants in a consistent manner.<sup>22</sup> The Board of Directors is responsible for providing the financial support to ensure continuing professional development in ethics for REB members and support staff.<sup>23</sup>

### 17.1 Training and education – REB members

17.1.1 The REB Chair or designee will provide new REB members with a general overview of the policies and procedures relevant to REB meeting functions and REB member expectations, as well as an orientation on the principles and guidelines of research ethics;

17.1.2 REB members must have completed a recognized training program in research ethics.<sup>24</sup> New REB members will receive an orientation before officially commencing their duties. This orientation process includes:

- Background information on the Research Review Office and the REB (e.g., purpose, governance structure, flowchart);
- Policies and procedures (e.g., SOPs, consent form templates);
- Member information (e.g., meeting schedule, membership list, reviewer guide, letter of member designation, available training);
- Applicable regulatory texts;

17.1.3 New or future REB members will be offered the opportunity to observe at least one REB meeting prior to commencing their duties;

17.1.4 REB members are encouraged to attend conferences and professional development activities in research ethics.

17.1.5 New or revised policies and SOPs will be disseminated to the new REB members.

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<sup>22</sup> See: OG, s. 4.7.

<sup>23</sup> *Cadre de référence ministériel; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec, Ministère de la Santé et des Services sociaux, June 1998, p. 14, hereafter PAM; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 4.7, hereafter OG.

<sup>24</sup> Including the free online tutorials recognized by the MSSS and the Tri-Council: <https://ethique.msss.gouv.qc.ca/didacticiel/?lang=en> and <https://ciereh.uqam.ca/liens-utiles/formations-en-ligne/>

**17.2 Training and education – RRO staff that supports the REB**

- 17.2.1 The REB Chair and the RRO team leader will provide new RRO staff that supports the REB with an overall orientation on the REB, including a general overview of the policies and procedures relevant to their role in support of the REB;
- 17.2.2 New RRO staff that supports the REB will receive training on the REB SOPs and will be expected to be knowledgeable and compliant with the SOPs;
- 17.2.3 New RRO staff that supports the REB are required to complete a recognized training program in research ethics and are encouraged to complete additional and ongoing relevant education and training in research ethics and in the conduct of research, subject to available budget resources;
- 17.2.4 New or revised policies and SOPs will be disseminated to new RRO staff that supports the REB;

**17.3 Documentation of training and education**

- 17.3.1 The RRO, on the shared REB server, will retain copies of the CVs of all REB members and RRO staff that supports the REB;
- 17.3.2 REB members and RRO staff that supports the REB will record the relevant training and education they attend and provide copies of certificates of completion. Training records will be kept in Nagano and on the shared REB server;
- 17.3.3 REB members and RRO staff that supports the REB are encouraged to retain copies of the agendas of relevant workshops, seminars and conferences attended;
- 17.3.4 REB agendas and minutes will record the dissemination of relevant information and the distribution of any educational materials presented at the REB meetings.

**18 REFERENCES**

See footnotes.

**19 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 103.001		

<b>Title:</b>	Management of RRO staff that supports the REB
<b>SOP code:</b>	REB-SOP 104.001
<b>N2/CAREB SOP code:</b>	SOP 104.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the overall management of the RRO staff who support the Research Ethics Board (REB).

**20 SCOPE**

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

**21 RESPONSIBILITIES**

The Board of Directors' official representative(s), REB Chair or designee are responsible for ensuring that the requirements of this SOP are met. The institution's Board of Directors and its official representatives are responsible for providing sufficient resources to adequately support the functions of the REB.<sup>25</sup>

**22 DEFINITIONS**

See glossary.

**23 PROCEDURES**

RRO staff that supports the REB provide expertise and administrative support to the REB and serve as a daily link between the REB and the research community. RRO staff that supports the REB are vital to ensuring efficient and effective administration and enforcement of REB decisions. As such, the highest level of professionalism and integrity is expected.

**23.1 Job descriptions**

23.1.1 Job descriptions are developed by the Academic Affairs and Research Ethics Directorate to establish the role requirements for RRO staff that supports the REB.

23.1.2 Each member of the RRO staff who supports the REB will be provided, by the RRO team leader, with a copy of their job description, job expectations, and access to all policies and procedures that apply to the institution and their duties.

**23.2 Responsibilities**

23.2.1 The responsibilities of RRO staff that supports the REB include the following:

- The review of administrative requirements for requests to the REB;<sup>26</sup>
- The management of administrative issues involving REB research ethics oversight, as described by applicable REB policies;
- The implementation of REB directives;
- The provision of advice and information to the REB.

**23.3 Hiring and terminating REB support staff**

23.3.1 The Board of Directors of the institution will delegate to the Academic Affairs and Research Ethics Directorate the responsibility for the recruitment, hiring, and termination of RRO staff that supports the

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<sup>25</sup> *Cadre de référence ministériel; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec, Ministère de la Santé et des Services sociaux, June 1998, p. 13, hereafter PAM; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 2, hereafter OG.

<sup>26</sup> See REB-SOP 301.001.

REB, in accordance with the Board of Directors' policies and procedures and those of the institution's Human Resources, Communications, Legal Affairs and Global Security department.

#### **23.4 Delegation of authority or responsibility**

23.4.1 Appropriate tasks or responsibilities may be delegated to a member of the RRO staff that supports the REB, in accordance with the Board of Directors and/or REB policy, if the individual has the expertise to carry out the task(s), as per applicable guidelines. The delegation of responsibilities and signatures is formalized in a register at the RRO.

#### **23.5 RRO performance evaluations and documentation**

23.5.1 Performance feedback will be provided on an ongoing basis.

23.5.2 The institution's Board of Directors will delegate to the Academic Affairs and Research Ethics Directorate the responsibility for conducting formal performance

evaluations, in accordance with the Board of Directors' policies and procedures and those of the institution's Human Resources, Communications, Legal Affairs and Global Security department.

23.5.3 The institution's Board of Directors will delegate to the Academic Affairs and Research Ethics Directorate the responsibility for identifying, documenting, and recording formal interactions by RRO staff that supports the REB in relation to performance evaluations.

#### **23.6 Periodic evaluation of RRO human resources needs**

23.6.1 A periodic evaluation of the adequacy of resources will be conducted by the Academic Affairs and Research Ethics Directorate, in collaboration with the RRO team leader and the REB Chair.

23.6.2 The evaluation will assess whether the RRO support staff, equipment, and space are adequate to carry out its function in support of the REB.

23.6.3 The evaluation takes into consideration the volume, complexity, and types of research projects administered by the RRO staff, and whether activities in support of the REB can be completed in a timely manner.

23.6.4 If necessary, the need for additional resources will be discussed with the representative of the Academic Affairs and Research Ethics Directorate.

## **24 REFERENCES**

Note: References will reflect the policies and practices of the institution's Board of Directors.



**25 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 104.001		

<b>Title:</b>	Conflicts of interest – REB members and RRO staff that supports the REB
<b>SOP code:</b>	REB-SOP 105A.001
<b>N2/CAREB SOP code:</b>	SOP 105A.002
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**1 PURPOSE**

This standard operating procedure (SOP) describes potential conflicts of interest (COI) for Research Ethics Board (REB) members (including the REB Chair and any ad hoc advisors) and for RRO staff that supports the REB and describes the requirements and procedures for disclosure and management of COI.

**26 SCOPE**

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

**27 RESPONSIBILITIES**

All REB members and RRO staff that supports the REB are responsible for disclosing any real, potential, or perceived COI and for ensuring that the requirements of this SOP are met.

## 28 DEFINITIONS

See glossary.

## 29 PROCEDURES

COI may arise when activities or situations place an individual or an institution in a real, potential, or perceived conflict between the duties or responsibilities related to research, and personal, institutional, or other interests.<sup>27</sup> These interests include, but are not limited to, business, commercial, or financial interests pertaining to the institution and/or the individual(s) concerned, their family members, their friends, or their former, current, or prospective professional associates.<sup>28</sup> Such competing interests may influence their professional judgment, objectivity, and independence, as well as influence the outcome of a decision motivated by personal gain.

REBs should identify and manage COI in order to maintain public confidence, to protect the participants, and to maintain the independence and integrity of the ethics review.<sup>29</sup> All possible efforts should be made to avoid COI. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.<sup>30</sup>

The REB must be fair and impartial, immune from pressure either by the sponsor, affiliated organizations, the institution, or the researchers whose research project is being reviewed.

The standard that guides decisions about identifying COI is whether an independent observer could reasonably question whether an individual's actions or decisions are based on factors other than the rights, welfare, and safety of the participants.

### 29.1 REB reviewer assignment

29.1.1 The REB Chair or designee reviews the agenda prior to the REB meeting in order to identify potential conflicts of interest.

29.1.2 When the agenda is distributed, REB members are to disclose, as soon as possible, any COI for any of the projects on the agenda.<sup>31</sup>

29.1.3 If a member is unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether or not the circumstances correspond to a COI, and the member will respect the REB's decision regarding any actions required to mitigate the real or perceived COI.

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<sup>27</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, p. 101, hereafter TCPS2; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, glossary, hereafter OG.

<sup>28</sup> TCPS2, p. 101.

<sup>29</sup> TCPS2, p. 101.

<sup>30</sup> TCPS2, p. 101.

<sup>31</sup> TCPS2, art. 7.3.

29.1.4 If a COI is identified in the reviewer assignments, the project will be assigned to another REB member.<sup>32</sup>

## **29.2 REB meetings**

29.2.1 At the outset of the meeting, REB members are reminded of their obligation to verbally disclose/declare any real, potential, or perceived COI. All COI declared will be recorded in the REB meeting minutes.<sup>33</sup>

29.2.2 If a COI is declared and determined as such, the REB member must recuse themselves from the review, deliberations, and decision. However, they may be asked, in their capacity as researcher (where applicable), to provide the other REB members with information about the projected research.<sup>34</sup>

29.2.3 The REB member's recusal will be recorded in the minutes, and the REB member will not be counted toward the quorum in assessing the project.

## **29.3 REB Chair**

29.3.1 In the event the REB Chair declares a COI, the Vice-Chair or an REB member will assume the REB Chair's responsibilities for the project(s) in question.

## **29.4 RRO staff that supports the REB**

29.4.1 Any disclosure of a COI by RRO staff that supports the REB should be referred to the REB Chair or designee for the purposes of devising a management plan.

29.4.2 If the RRO staff that supports the REB are unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI.

## **29.5 External ad hoc advisors**

29.5.1 At their discretion, the REB Chair or designee may invite individuals with competence in specific areas to assist in reviewing issues that require expertise beyond or in addition to that available on the REB.<sup>35</sup> The REB Chair or designee will ensure that the ad hoc advisor has no COI.

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<sup>32</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. 1040.*

<sup>33</sup> TCPS2, art. 7.1.

<sup>34</sup> *Avis, p. 1040; TCPS2, art. 7.3; OG, s. 7.1; Cadre de référence ministériel; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 23, hereafter PAM.*

<sup>35</sup> *Avis, p. 1039; Good Clinical Practice: Consolidated Guideline, Health Canada, September 1997, s. 3.2.6, hereafter GCP; OG, s. 4.6; PAM, p. 22.*

29.5.2 If an ad hoc advisor becomes involved in a COI situation or is unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI.

**29.6 Documentation**

29.6.1 All REB members, guests, and ad hoc advisors agree to abide by the REB’s COI policies.

29.6.2 The REB members must sign a *Confidentiality of Information and Conflict of Interest Agreement* at the time of their nomination.

29.6.3 The signed *Confidentiality of Information and Conflict of Interest Agreement* is filed in the REB office.

29.6.4 The REB minutes will record any COI declared for any of the projects under review at the REB meeting, and the decision regarding management of the conflict.

29.6.5 At the time they are hired, all RRO staff that supports the REB must sign a *Confidentiality of Information and Conflict of Interest Agreement* and agree to abide by the COI policies of the REB and the institution.

29.6.6 The REB management plan for COI declarations related to research projects will be documented in the appropriate research files, namely, in the REB correspondence.

**30 REFERENCES**

See footnotes.

**31 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 105A.001		

<b>Title:</b>	Conflicts of Interest – Researchers
<b>SOP code:</b>	REB-SOP 105B.001
<b>N2/CAREB SOP code:</b>	SOP 105B.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes potential conflicts of interest (COI) for researchers and research staff engaged in human-participant research, as well as the requirements and procedures for disclosure and managing COI.

**32 SCOPE**

This SOP pertains to research ethics boards (REBs) that review human-participant research in compliance with applicable regulations and guidelines.

**33 RESPONSIBILITIES**

All REB members, RRO staff that supports the REB, and researchers are responsible for ensuring that the requirements of this SOP are met. Researchers are responsible for disclosing any real, potential, or perceived COI to the REB. The REB is responsible for determining whether the disclosed COI is likely to affect or appear to affect the conduct or reporting of the research.

**34 DEFINITIONS**

See glossary.

**35 PROCEDURES**

COI may arise when activities or situations place an individual or an institution in a real, potential, or perceived conflict between the duties or responsibilities related to research, and personal, institutional, or other interests.<sup>36</sup> These interests include, but are not limited to, business, commercial, or financial interests pertaining to the institution and/or the individual(s) concerned, their family members, their friends, or their former, current, or prospective professional associates.<sup>37</sup> Such competing interests may influence their professional judgment, objectivity, and independence, as well as influence the outcome of a decision motivated by personal gain.

REBs should identify and manage COI in order to maintain public confidence, to protect the participants, and to maintain the independence and integrity of the ethics review.<sup>38</sup> All possible efforts should be made to avoid COI. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.<sup>39</sup>

The REB must be fair and impartial, immune from pressure either by the sponsor, affiliated organizations, the institution, the researchers whose research projects are being reviewed, or by other professional and/or nonprofessional sources.

The standard that guides decisions about identifying COI is whether an independent observer could reasonably question whether an individual's actions or decisions are based on factors other than the rights, welfare, and safety of the participants.

This SOP is not intended to prohibit researcher relationships with companies; however, the REB should ensure that participant protection, the integrity of the ethics review, and the conduct of the research are not jeopardized by an unidentified and unmanaged COI.

**35.1 Researcher disclosure of conflicts of interest**

35.1.1 Researchers are required to disclose, in the research application they submit to the REB, any real, potential, or perceived personal or institutional COI that may affect their research.<sup>40</sup>

35.1.2 The researcher is additionally required to provide information on their research budget when submitting a research application.

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<sup>36</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* – Interagency Advisory Panel on Research Ethics, 2014, p. 101, hereafter TCPS2; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, glossary, hereafter OG.

<sup>37</sup> TCPS2, p. 101.

<sup>38</sup> TCPS2, p. 101.

<sup>39</sup> TCPS2, p. 101.

<sup>40</sup> TCPS2, art. 7.4.

35.1.3 COI disclosures shall be in writing and sufficiently detailed to allow an accurate and objective review of the conflict.

35.1.4 The researcher shall disclose any conflicts to the REB at the following times:

- With the initial REB application;
- At each continuing review of the project;
- Whenever a COI arises, such as changes in responsibilities or financial circumstances.

35.1.5 The researcher shall comply with all the requirements of the REB and with COI policies to eliminate and/or to manage the conflict.

35.1.6 The researcher shall declare any COI in the informed consent documents.

## **35.2 REB review of researcher conflict of interest**

35.2.1 The REB will review each application for disclosures of COI.

35.2.2 If the researcher indicates on the REB application that a conflict exists, the REB will determine whether the disclosed COI is likely to affect or appear to affect the conduct or reporting of the research.

35.2.3 The REB manages the aspects of the COI that may affect human-participant protection, and the steps taken should be context-based and commensurate with the risks.<sup>41</sup>

35.2.4 In determining the appropriate action, the REB may take into consideration information presented by the researcher, such as:

- The nature of the research;
- The magnitude of the interest or the degree to which the conflict is related to the research;
- The extent to which the interest could affect the research;
- Whether a specific individual is unique in their clinical and/or scientific qualifications to conduct the research;
- The degree of research-related risk to the human participants involved in the research;
- The management plan for the COI already developed by the researcher.

35.2.5 The REB may approve the research and may require a management plan, which may include, but is not limited to:

- Making changes to the researcher's or sponsor's expenses, including divestiture or termination of relevant economic interests;

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<sup>41</sup> TCPS2, p. 107.



- Requiring the researcher to recuse themselves from the research;
- Modifying or limiting the participation of the researcher in all or a portion of the research;
- Monitoring the research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of results reporting [to ensure there is no withholding of data]);
- Monitoring the consent process;
- Disclosing the conflict to the appropriate institutional bodies, research participants, journals, and data and safety monitoring boards.

35.2.6 The REB has the final authority to determine whether a COI has been eliminated or managed appropriately. The REB may reject a research project that involves a COI that has not been appropriately managed.<sup>42</sup>

35.2.7 Any COI management plan will be documented in the final project files. Any discussions at the REB meeting regarding COI and the management plan will be documented in the REB meeting minutes.<sup>43</sup>

## **36 REFERENCES**

See footnotes.

## **37 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 105B.001		

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<sup>42</sup> TCPS2, p. 107.

<sup>43</sup> TCPS2, p. 107.

<b>Title:</b>	Conflicts of Interest – Institution’s Board of Directors
<b>SOP code:</b>	REB-SOP 105C.001
<b>N2/CAREB SOP code:</b>	MON 105C.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) deals with potential conflicts of interest in the relationship between the institution and the Research Ethics Board (REB).

**38 SCOPE**

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

**39 RESPONSIBILITIES**

All REB members and RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

**40 DEFINITIONS**

See glossary.

**41 PROCEDURES**

Should a conflict of interest arise between the institution and the REB, the parties concerned must, in good faith, manage the situation with respect, collaboration, and transparency. The process implemented to manage the conflict of interest must comply with the institution's policies and applicable regulations.

**42 REFERENCES**

See footnotes, if any.

**43 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 105C.001		

# REB-SOP 106.001

Research Ethics Board  
Standard Operating Procedure

<b>Title:</b>	Signing Authority
<b>SOP code:</b>	REB-SOP 106.001
<b>N2/CAREB SOP code:</b>	SOP 106.002
<b>Effective date:</b>	2021-09-30

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## 1 PURPOSE

This standard operating procedure (SOP) specifies who has the authority to sign documents on behalf of the Research Ethics Board (REB) and describes the responsibilities of these individuals, and the circumstances under which signing authority may be delegated.

## 44 SCOPE

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

## 45 RESPONSIBILITIES

All REB members and RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for signing documents related to REB review and approval of research.<sup>44</sup> If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Chair.

## **46 DEFINITIONS**

See glossary.

## **47 PROCEDURES**

The REB is accountable for its activities and decisions, and appropriate controls must be applied to ensure that documentation related to REB review and approval of research is signed by a person or persons with the appropriate authority to do so.

### **47.1 Delegation of signing authority**

47.1.1 The REB Chair and Vice-Chair, where applicable, as part of their duties, have the authority to act as signing officers for the duration of their term.

47.1.2 The REB Chair and Vice-Chair, where applicable, may delegate signing authority for documents related to REB review and approval of research.

47.1.3 The REB Chair and Vice-Chair, where applicable, may only delegate signing authority to REB members or to RRO staff that supports the REB with the skill and knowledge necessary to effectively exercise the authority.

47.1.4 The REB Chair and Vice-Chair should clearly define the parameters of the delegated authority, including the scope of the signing authority and the duration of the delegation of signing authority.

47.1.5 Delegation of signing authority to other REB members or support staff must be documented and kept on file.

### **47.2 REB reviews, decisions, and other correspondence with the researcher**

47.2.1 For each submission reviewed at a full board meeting, the person responsible for the RRO staff that supports the REB records the decision made by the full board.

47.2.2 Communication of the REB decision made at a full board meeting or at a delegated review must be reviewed and authorized by the REB Chair or Vice-Chair, or as otherwise delegated by the REB Chair or Vice-Chair.

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<sup>44</sup> *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 8.14, hereafter OG.

- 47.2.3 For each submission that undergoes a delegated review, the reviewer’s decision is documented.
- 47.2.4 Once a final decision is documented by the REB Chair or Vice-Chair, where applicable, the person responsible for the RRO staff that supports the REB may issue the decision or send a letter via Nagano.
- 47.2.5 All activities are documented in the research file on Nagano.
- 47.2.6 Any letters, memos, or emails between the REB and the researchers that provide information concerning the research review (e.g., requests for consent form changes, requests for additional information) and that do not imply or appear to imply approval of the research, may be issued by the delegated signing authority.
- 47.2.7 All reviews, actions, decisions, and signatures are documented in the research file on Nagano.

**47.3 Correspondence with external agencies**

- 47.3.1 The REB Chair or designee signs all correspondence with federal government agencies (Health Canada, OHRP, FDA) and with all funding agencies and/or sponsors.

**48 REFERENCES**

See footnotes.

**49 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 106.001		

<b>Title:</b>	Use and Disclosure of Personal Information
<b>SOP code:</b>	REB-SOP 107.001
<b>N2/CAREB SOP code:</b>	SOP 107.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the duties of the Research Ethics Board (REB) and the REB office in the protection of research participants’ personal information.

**50 SCOPE**

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

**51 RESPONSIBILITIES**

All REB members, RRO staff that supports the REB, and researchers are responsible for ensuring that the requirements of this SOP are met.

The researcher is responsible for submitting information to the REB and to the participant regarding the nature of the personal information (including personal health information) that will be collected for the research. The REB

reviews the measures taken by the researcher to safeguard personal information for the full life cycle of the information, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of, and protected.<sup>45</sup> The REB verifies the measures taken by the researcher for meeting confidentiality obligations and any reasonably foreseeable disclosure requirements.<sup>46</sup>

The REB Chair, REB members, and RRO staff that supports the REB are responsible for maintaining the confidentiality of any personal information received by the REB office during the course of the research.

## **52 DEFINITIONS**

See glossary.

## **53 PROCEDURES**

Privacy is a fundamental value that is essential for the protection and promotion of human dignity. Breaches in privacy and confidentiality may cause harm to individuals or groups of individuals. Hence, personal information must be collected, used, and disclosed in a manner that respects a research participant's right to privacy, and in accordance with applicable privacy standards.<sup>47</sup>

Privacy regulations permit the use and the limited disclosure of personal information for research purposes, provided certain requirements are met. Privacy risks in research arise at all stages of the research life cycle and relate to the identifiability of participants and the potential harms that they, or groups to which they belong, may experience from the collection, use, and disclosure of personal information.<sup>48</sup> One of the key ethical challenges for the health and social services research community consists in the appropriate protection of the privacy and confidentiality of personal information used for research purposes.

The REB plays a role balancing the need for research against the risk of the infringement of privacy, in accordance with applicable standards. The REB supports the use of a proportionate approach.<sup>49</sup>

### **53.1 REB review of privacy concerns**

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<sup>45</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* – Interagency Advisory Panel on Research Ethics, 2014, art. 5.3, hereafter TCPS2.

<sup>46</sup> TCPS2, art. 5.2a).

<sup>47</sup> *Charter of Human Rights and Freedoms*, CQLR, c. C -12, art. 5; *Civil Code of Québec*, art. 35, 37; *Act respecting health services and social services*, CQLR, c. S-4.2, s. 19 and 19.2; *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR, c. A-2.1, s. 53, 59, 125.

<sup>48</sup> TCPS2, p. 61.

<sup>49</sup> TCPS2, p. 10.



53.1.1 In reviewing the research, the REB will consider a number of factors potentially affecting privacy protection,<sup>50</sup> such as:

- The type of personal information collected;
- The research objectives and justification of the need to obtain the requested personal data in order to fulfill these objectives;
- Respect for applicable privacy and confidentiality laws;<sup>51</sup>
- Intended uses of personal information derived from the research;
- How the personal data will be controlled, accessed, disclosed, and re-identified;
- Limits on the use, disclosure, and retention of personal data;
- Any anticipated secondary uses of identifying data issued from the research;
- Risks to participants in the case of a data security breach, including the risk of re-identification;
- Security measures appropriate to the life cycle of the information;
- Any anticipated linkage of personal data gathered during the research with other data about research participants, whether those data are contained in public or in personal records;
- Recordings used for research observations (e.g., photos, videos, and audio recordings) that may potentially identify individual participants;
- Whether consent is required for access to, or collection of, personal data from participants;<sup>52</sup>
- How consent is managed and documented;
- If and how prospective research participants will be informed of information about the research;
- How prospective research participants will be recruited;
- The administrative, technical, information technology, and physical safeguards and practices in place to protect the personal data, including de-identification strategies and the management of linkages to identifying data;
- How accountability and transparency in the management of personal data will be ensured.

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<sup>50</sup> TCPS2, p. 67. For further details on the secondary use of identifying information and on data linkage, see also art. 5.5A, 5.5B, and 5.7.

<sup>51</sup> *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 10.3; *Civil Code of Québec*, art. 35, 37; *Act respecting health services and social services*, CQLR, c. S-4.2, s. 19, 19.2; *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR, c. A-2.1, s. 53, 59, 125; *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, p. 1039, hereafter *Avis*; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 6.2.4 and 6.2.4.2, hereafter *OG*; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 13, hereafter *PAM*, p. 23; *Cadre de référence ministériel 2020*, p. 15.

<sup>52</sup> *Act respecting health services and social services*, CQLR, c. S-4.2, s. 19, 19.2; *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR, c. A-2.1, s. 53, 59, 125.

53.1.2 Before approving the research, the REB must ensure that there are adequate provisions in place to protect the privacy interests of participants.

### **53.2 Receipt, use, and disclosure of personal information**

53.2.1 The REB Chair, REB members, and RRO staff that supports the REB are bound by confidentiality agreements signed prior to commencement of their duties.<sup>53</sup>

53.2.2 If need be, the REB is permitted to access personal information for the purposes of the review, approval, ongoing monitoring, and/or auditing of the conduct of the research.

53.2.3 The RRO must adopt reasonable safeguards and ensure that the RRO staff that supports the REB receive training on the protection of personal information against unauthorized access.

53.2.4 REB members or RRO staff that supports the REB may consult with the REB Chair or designee if they are uncertain about the appropriate use or disclosure of personal information.

53.2.5 If any personal information is received inadvertently by the REB office (e.g., disclosed by a researcher), the facts surrounding the breach, the appropriate steps taken to manage the breach, the remedial activities to address the breach, and the outcome will be documented. The personal information will be destroyed in a secure manner, according to the institution's policies and procedures.

53.2.6 If there is a breach within the institution, involving the use or dissemination of personal information associated with research, the REB Chair or designee will be notified. If applicable, the REB will help develop a corrective action plan in a timely manner. This process may include notification, containment, investigation, and remediation, as well as prevention strategies. The facts surrounding the breach, the appropriate steps taken to manage the breach, and the outcome will be documented.

53.2.7 If there is a breach within the REB, involving the use or dissemination of personal information, the REB Chair or designee will be notified, and, where applicable, notification will be sent to the appropriate official(s) of the institution; a determination will be made in a timely manner regarding a corrective action plan. This process may include notification, containment, investigation, and remediation, as well as prevention strategies. The facts surrounding the breach, the appropriate steps taken to manage the breach, and the outcome will be documented. If applicable, the personal information will be destroyed in a secure manner, according to the institution's policies and procedures.

53.2.8 At the discretion of the REB Chair or designee, in consultation with the institution, the provincial privacy office (or equivalent) may be notified.

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<sup>53</sup> OG, s. 4.3.3.

# REB-SOP 107.001

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## 54 REFERENCES

See footnotes.

## 55 REVISION HISTORY

SOP code	Effective date	Summary of changes
REB-SOP 107.001		

<b>Title:</b>	Standard Operating Procedures Maintenance
<b>SOP code:</b>	REB-SOP 108.001
<b>N2/CAREB SOP code:</b>	SOP 108.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; to ensure compliance with the principles, guidelines, and regulations applicable to the ethics review and oversight of research involving humans; and to facilitate training of new personnel.

**2 SCOPE**

This SOP pertains to research ethics boards (REBs) that review human-participant research in compliance with applicable regulations and guidelines.

**3 RESPONSIBILITIES**

The Academic Affairs and Research Ethics Directorate, all REB members, and all RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

## 4 DEFINITIONS

See glossary.

## 5 PROCEDURES

Written SOPs provide the framework for promoting ethical standards in the review, oversight, and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants in such research are overseen and protected in a uniform manner.

### 5.1 Development, review, revision, and approval of policies and procedures

- 5.1.1 The Academic Affairs and Research Ethics Directorate and the REB Chair establish written SOPs for the REB to follow.<sup>54</sup>
- 5.1.2 The qualified RRO staff that supports the REB will review the SOPs as needed. As a minimum, applicable SOPs will be reviewed when changes to regulations, guidelines, or standard practice warrant revisions to or the creation of new SOPs.
- 5.1.3 SOPs may be revised for a number of reasons including, but not limited to: changes to regulations or guidelines, the creation of new policies, or changes to the REB or administrative practices.
- 5.1.4 The qualified RRO staff that supports the REB will make the necessary changes to existing SOPs, or draft one or several new SOPs.
- 5.1.5 As SOPs are modified, new drafts will be indicated by the addition of “DRAFT, version date” instead of the previous “FINAL VERSION, date.” Once the SOP content is approved, the draft version date will be removed, and the date of the approved version will be entered as the “Final version date.” The history of revisions will be recorded in the “SOP history” section of each SOP.
- 5.1.6 SOP approval will be indicated by the word “Approved,” followed by the approval date, added by the authorized representative of the Academic Affairs and Research Ethics Directorate. The new final version of the SOP supersedes any previous versions.

### 5.2 Distribution and communication

- 5.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the “Responsibilities” section of each SOP.

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<sup>54</sup> *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.3, hereafter GCP; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 1 and 3, hereafter OG.

- 5.2.2 The SOPs will be available to researchers and research sites, sponsors, and regulatory authorities, as required.
- 5.2.3 A qualified member of the RRO staff that supports the REB will inform and, if needed, train members of the REB and the REB support staff on any new or revised policy and/or relevant procedure, as applicable.
- 5.2.4 Each new REB member must review the applicable policies and procedures prior to undertaking their responsibilities as an REB member.
- 5.2.5 Each new member of the RRO staff that supports the REB must review the applicable policies and procedures prior to undertaking their responsibilities with the REB office.
- 5.2.6 Evidence of training, where applicable, must be documented and updated.

**5.3 Forms, memos, and guidance documents**

- 5.3.1 Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled.
- 5.3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOPs.
- 5.3.3 As needed, memos and guidance documents will be made available to the researchers and research sites.
- 5.3.4 A qualified member of the RRO staff that supports the REB and/or the REB Chair or designee will evaluate the need to create new forms, memos, or guidance documents, or to revise existing ones.

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 108.001		

# REB-SOP 201.001

Research Ethics Board  
Standard Operating Procedure

<b>Title:</b>	Composition of the REB
<b>SOP code:</b>	REB-SOP 201.001
<b>N2/CAREB SOP code:</b>	SOP 201.002
<b>Effective date:</b>	2021-09-30

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## 1 PURPOSE

This standard operating procedure (SOP) describes the membership composition requirements 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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for ensuring that the composition of the REB meets the applicable regulatory requirements.

#### **4 DEFINITIONS**

See glossary.

#### **5 PROCEDURES**

Individual members of an REB must be qualified through training, experience, and expertise to ascertain the acceptability of proposed research in terms of ethical principles, and applicable regulations, guidelines, and standards pertaining to the protection of human participants.<sup>55</sup>

To promote the complete and adequate review of the type of research commonly reviewed by the REB, the composition of the REB must be appropriately diverse<sup>56</sup>; therefore, members must be selected based on their professional expertise (scientific and non-scientific) to assess the research submitted for review. Important considerations also include sex, cultural background, clinical and research experience, organizational affiliation, and sensitivity to such issues as broad representation of organizations served by the REB.

##### **5.1 Selection of REB members**

- 5.1.1 REB members will be selected based on the needs of the REB, as outlined below and according to applicable regulations, guidelines, and standards.
- 5.1.2 In the selection of REB members, equal consideration shall be given to qualified persons of both sexes. No appointment shall be made solely on the basis of sex.
- 5.1.3 The REB will make every effort to include members of cultural and ethnic minorities, so as to represent the population from which research participants are recruited, to the extent that these individuals have expertise needed to carry out their duties.
- 5.1.4 The REB membership will not consist entirely of members of one profession.

##### **5.2 Composition of the REB**

- 5.2.1 The membership of the REB will be in compliance with applicable laws, regulations, and guidelines.

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<sup>55</sup> *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 6.1, hereafter *Modèle*; *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.2.1., hereafter GCP.

<sup>56</sup> *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 4, hereafter OG.



- 5.2.2 The REB Chair or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions.
- 5.2.3 The REB will include at least five members<sup>57</sup> from the following categories:
- At least two members with expertise in relevant research disciplines, fields, 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>58</sup>
  - At least one member who is primarily experienced in a non-scientific discipline.<sup>59</sup>
  - At least one member with expertise in ethics.<sup>60</sup>
  - At least one member with legal expertise, knowledgeable in the laws applicable to the types of research being reviewed.<sup>61</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>62</sup> and who is not part of the immediate family of a person who is affiliated with the institution.
- 5.2.4 A member may fulfill more than one representative capacity or discipline.
- 5.2.5 Members will include men and women,<sup>63</sup> a majority of whom are Canadian citizens or permanent residents under the *Immigration and Refugee Protection Act*.<sup>64</sup>
- 5.2.6 Membership, when required, should include at least one member with expertise in complementary or alternative care, or pediatric health research.

At least one member, when relevant, should be from an Indigenous community or centre, when the REB is reviewing research that recruits Indigenous participants.

<sup>57</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, p. 1039, hereafter Avis; Food and Drug Regulations, C.R.C., c. 870, s. C.05.001, under "research ethics board"; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Gouvernement du Québec, Ministère de la Santé et des Services sociaux, June 1998, p. 21, hereafter PAM; GCP, s. 3.2.1 a; Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics, 2014, art. 6.4, hereafter TCPS2.*

<sup>58</sup> *Avis, p. 1039; Food and Drug Regulations, s. C.05.001 (b) (i); PAM, p. 21; Modèle, s. 6.1; TCPS2, art. 6.4a).*

<sup>59</sup> *Food and Drug Regulations, s. C.05.001 (b) (iv); GCP, s. 3.2.1 b; Modèle, s. 6.1.*

<sup>60</sup> *Avis, p. 1039; Food and Drug Regulations, s. C.05.001 (b) (ii); PAM, p. 21; Modèle, s. 6.1; TCPS2, art. 6.4b).*

<sup>61</sup> *Avis, p. 1039; Food and Drug Regulations, s. C.05.001 (b) (iii); PAM, p. 21; Modèle, s. 6.1; TCPS2, art. 6.4c).*

<sup>62</sup> *Avis, p. 1039; Food and Drug Regulations, s. C.05.001 (b) (v); Modèle, s. 6.1; GCP, s. 3.2.1 c; TCPS2, art. 6.4d) and p. 81. N.B.: According to the PAM (p. 21), this person must use the services of the institution.*

<sup>63</sup> *Food and Drug Regulations, s. C.05.001 (b); Modèle, s. 6.1; TCPS2, art. 6.4.*

<sup>64</sup> *Food and Drug Regulations, s. C.05.001 (b).*

5.2.7 The ethics specialist on the RRO staff that supports the REB can act as REB member if they have similar knowledge, qualifications, and training to those expected of other REB members.<sup>65</sup> The staff member designated as an REB member shall attend meetings to which they are invited and participate in the discussions that take place but shall not be counted in the quorum and shall not vote.

5.2.8 The RRO staff that supports the REB will update the list of potential REB members, as well as the U.S. Office for Human Research Protections (OHRP) register, where applicable, to reflect any change to the composition of the REB.

### 5.3 Alternate members

5.3.1 The REB Chair or designee may ask an alternate REB member to attend an REB meeting to draw on their expertise in an area that may be relevant to that meeting's deliberations or to establish a quorum for a meeting. The REB Chair or designee may also ask an alternate REB member to attend an REB meeting in the absence of a regular REB member.

5.3.2 Only alternate REB members with comparable knowledge, qualifications, and training may substitute for an REB member (a non-scientific member may not substitute for a scientific member).<sup>66</sup>

### 5.4 REB Chair

5.4.1 Whenever possible, the REB Chair is an experienced REB member who is familiar with the applicable regulations and guidance documents.

5.4.2 To exercise their mandate, the REB Chair must first be appointed as an REB member.

### 5.5 Ad hoc advisors

5.5.1 At their discretion, the REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.<sup>67</sup>

5.5.2 All ad hoc advisors shall sign a *Confidentiality of Information and Conflict of Interest Agreement*.

5.5.3 The ad hoc advisor shall not participate in REB deliberations and their presence or absence shall not be considered in establishing a quorum. They can, however, participate in the discussion and answer specific questions prior to deliberations.

5.5.4 The minutes will document the presence of ad hoc advisors, as well as their expertise and contributions, where applicable.

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<sup>65</sup> SOP N2/CAREB-ACCER Canada, 204.003.

<sup>66</sup> TCPS2, p. 82.

<sup>67</sup> *Avis*, p. 1039; GCP, s. 3.2.6; PAM, p. 22; OG, s. 4.6; *Modèle*, s. 6.8.

**5.6 Observers at REB meetings**

- 5.6.1 The REB may allow observers to attend its meetings.
- 5.6.2 Administrators of the institution may not serve as observers at REB meetings where their presence might influence REB deliberations.
- 5.6.3 Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the REB conflict of interest and confidentiality policies.
- 5.6.4 Where the REB finds that an observer qualifies as an expert in relation to the research under review, the observer may be allowed to contribute to the meeting if their input is relevant and significant to the discussion.
- 5.6.5 Observers shall not participate in REB deliberations, consensus, or voting on an application.
- 5.6.6 The minutes will reflect the presence of any observers as well as their expertise and contributions, where applicable.

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 201.001		

<b>Title:</b>	Management of REB membership
<b>SOP code:</b>	REB-SOP 202.001
<b>N2/CAREB SOP code:</b>	SOP 202.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the management of the membership 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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for supervising the REB membership in the performance of their duties.

#### **4 DEFINITIONS**

See glossary.

#### **5 PROCEDURES**

REB membership must be adequately managed to continue to meet applicable regulatory composition requirements and to maintain the appropriate diversity, experience, and expertise for the type and volume of research projects reviewed.

##### **5.1 Appointments – regular members and alternates**

- 5.1.1 REB members, including alternates, are appointed by the Board of Directors of the institution, on the recommendation of the REB Chair.
- 5.1.2 The Board of Directors can appoint an REB member for a term that combines more than one representative capacity or discipline.
- 5.1.3 When recommending REB members, the REB Chair will ensure that the terms of office do not all end at the same time, so as to ensure adequate continuity as regards the experience and expertise of the REB; this can be done by adjusting the length of terms, if need be.
- 5.1.4 Candidates selected to serve on the REB will be asked to sign a *Confidentiality of Information and Conflict of Interest Agreement*.
- 5.1.5 Administrators of the institution cannot act as REB members.

##### **5.2 Appointments – REB Chair and Vice-Chair**

- 5.2.1 The REB Chair and Vice-Chair are appointed by the Board of Directors. They must be REB members or concurrently appointed as REB members.

##### **5.3 Terms of appointment**

- 5.3.1 Each REB member will serve for a term specified by the institution.
- 5.3.2 The REB Chair and Vice-Chair will serve for a term specified by the institution.

##### **5.4 Qualifications and training of REB members**

- 5.4.1 Each REB member will follow qualification and training procedures.

## 5.5 Resignations and removals

- 5.5.1 An REB member may resign before the conclusion of their term upon provision of notice to the REB Chair or designee.
- 5.5.2 An REB member should resign immediately upon determination of research misconduct, mismanaged conflict of interest, or any other relevant behaviour that could be perceived as compromising their ethical judgment and, in the case of research misconduct, resign if the allegation is substantiated.
- 5.5.3 The REB Chair or designee may ask the Board of Directors to remove an REB member at any time, if they are not fulfilling the duties designated to them by the REB in a timely, competent, and ethical manner. This can also be done for other serious concerns considered incompatible with the role and function of the REB.<sup>68</sup>
- 5.5.4 An REB member may be asked to step down if they consistently miss a significant percentage of scheduled full board meetings during their term.<sup>69</sup>
- 5.5.5 If necessary, every effort will be made to recruit a similarly qualified alternate prior to the departure of a member, in order to preserve the level of experience and expertise and to ensure the continuity of the REB's functions.

## 5.6 Compensation

- 5.6.1 Compensation and reimbursement of expenses for REB members will be according to the policies of the institution.

## 5.7 Liability and insurance

- 5.7.1 All REB members are insured by the institution's insurance policy for their work related to research ethics reviews, subject to the terms and conditions of that policy.

## 5.8 Documentation

- 5.8.1 The RRO staff that supports the REB will maintain an updated electronic REB membership list.<sup>70</sup>
- 5.8.2 The current REB membership list and archived lists are kept in and available through the RRO office.

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<sup>68</sup> *Modèle*, s. 6.6.5.

<sup>69</sup> *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 6.6.5.

<sup>70</sup> GCP, s. 3.2.1, para. 2.

- 5.8.3 CVs, other supporting documents related to the appointment, education, and expertise, and confidentiality agreements for all current and past REB members will be kept in the RRO office.<sup>71</sup>
- 5.8.4 A detailed membership list will be kept in the RRO office. This list will contain the REB members' contact information and additional information on areas of expertise for the purposes of communication and reviewer assignment. It will be kept confidential for access only by RRO staff that supports the REB.
- 5.8.5 The REB Chair or designee will update the REB register with the U.S. Office for Human Research Protection (OHRP), where applicable.

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 202.001		

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<sup>71</sup> OG, s. 10.2.

<b>Title:</b>	Duties of REB Members
<b>SOP code:</b>	REB-SOP 203.001
<b>N2/CAREB SOP code:</b>	SOP 203.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the duties of the members 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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

REB members are responsible for fulfilling their duties as specified in this SOP.



#### **4 DEFINITIONS**

See glossary.

#### **5 PROCEDURES**

Each REB member will ensure that any research application submitted for their review safeguards the dignity, safety, welfare, and rights of human participants in a research study.<sup>72</sup> Each REB member will also ensure the promotion of quality research. In order to fulfill their duties, each REB member must be versed in regulations governing

biomedical research ethics and the protection of human participants, as well as in policies associated with the protection of human research participants.<sup>73</sup>

##### **5.1 Attendance**

5.1.1 REB members are expected to attend REB meetings to which they are convened.

5.1.2 REB members must notify the REB office if they will be absent for an REB meeting to which they are convened, in order to ensure that quorum can still be met and/or so that an alternate may attend in their place.

##### **5.2 Duties**

5.2.1 All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review by the REB or brought to its attention by the Chair and the RRO staff that supports the REB, so as to be prepared to discuss them at the meeting. In so doing, they will pay particular attention to items involving the areas of expertise expected of their mandate and for which they were called to serve on the REB.

5.2.2 All REB members participating in a delegated ethics review are expected to review the relevant materials submitted for each item under review or consideration by the REB, and to submit their comments or be prepared to discuss them within the time frame specified by the REB.

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<sup>72</sup> *Good Clinical Practice: Consolidated Guideline*, Health Canada, 1997, s. 3.1.1, hereafter *GCP*; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 4.1, hereafter *Modèle*; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 2, hereafter *OG*.

<sup>73</sup> Mainly, but not only, the Tri-Council Policy Statement. See: *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, hereafter *TCPS2*.

5.2.3 REB members appointed for their expertise in scientific matters, ethics, or law will pay particular attention to elements involving the areas of expertise expected of their mandate and for which they were called to serve on the REB.<sup>74</sup>

5.2.4 Community members are expected to provide input regarding their knowledge of the local community and be able to discuss issues and research from that perspective. As such, they help the REB to broaden the perspectives and value base of the institution, and thus advance dialogue with, and accountability to, local groups.<sup>75</sup>

### 5.3 REB Chair

5.3.1 The REB Chair provides overall leadership to the REB and facilitates the REB review process based on the institution's policies and procedures.<sup>76</sup> This includes the following:

- The REB Chair can delegate any of their responsibilities, as appropriate, to the Vice-Chair or other qualified individual(s).
- Any responsibilities that are delegated by the REB Chair must be documented.
- The REB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs, and applicable regulations and guidelines.
- The REB Chair or designee monitors the REB's decisions for consistency.
- The REB Chair or designee ensures that all REB members are free to participate in discussions during REB meetings.
- The REB Chair or designee can ask an hoc advisor to attend an REB meeting in order to draw on their expertise in an area that may be relevant to the REB's review and deliberations of the research.
- The REB Chair or designee determines whether the research is appropriate for delegated review.
- The REB Chair or designee ensures that REB decisions are accurately entered in the minutes and clearly communicated to the researchers in writing.
- For REB approval of clinical trials approved by Health Canada, the REB approval letter and REB attestation, if not already included in the approval letter, is signed by the REB Chair or designee.
- The REB Chair or designee can suspend the conduct of any research project if they deem that a change has rendered it unacceptable to:
  - place participants at a new unacceptable risk level; and
  - wait for the next REB full board meeting to discuss it.

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<sup>74</sup> *Modèle*, s. 6.7.2; TCPS2, p. 80 and 81.

<sup>75</sup> *Modèle*, s. 6.7.2; TCPS2, p. 81.

<sup>76</sup> TCPS2, p. 83.

The change in risk may be related to circumstances including, but not limited to, a researcher not adhering to the REB-approved protocol or to the REB’s policies and procedures.

- The REB Chair or designee will report on the activities of the REB to the Academic Affairs Committee of the institution’s Board of Directors on an annual basis.
- The REB Chair, in conjunction with the REB team leader, shall assess the need for ethics training and education of REB members and RRO staff that supports the REB.
- As needed, the REB Chair or designee advises the Academic Affairs and Research Ethics Directorate of the need to review REB policies and procedures, to ensure that REB SOPs meet all current standards.

**5.4 REB Vice-Chair**

5.4.1 In addition to performing the responsibilities delegated by the REB Chair, the REB Vice-Chair is responsible for performing the responsibilities of the REB Chair when the latter is unable to do so.

**5.5 Training and education**

5.5.1 REB members are expected to follow training and education procedures.<sup>77</sup>

**5.6 Conflict of interest**

5.6.1 REB members are expected to follow conflict of interest procedures.<sup>78</sup>

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 203.001		

<sup>77</sup> For this purpose, see SOP 103.001.

<sup>78</sup> For this purpose, see SOP 105A.001.

<b>Title:</b>	REB Submission Requirements and Administrative Review Procedures
<b>SOP code:</b>	REB-SOP 301.001
<b>N2/CAREB SOP code:</b>	SOP 301.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the Research Ethics Board (REB) submission requirements and the administrative review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments, or changes to approved research, and any new information.

**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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

**4 DEFINITIONS**

See glossary.

## 5 PROCEDURES

REB members must rely on the documentation provided by the researcher for initial and continuing review. Therefore, the materials submitted must provide sufficient information to conduct the review and to make the required determinations.

The REB is supported by administrative procedures that ensure that REB members not only have sufficient time for the assessment of the proposed research, but that the materials they receive allow them to adequately assess whether the research submission meets the criteria for REB approval.

The administrative requirements for REB submissions are made available to all researchers. The RRO staff that supports the REB are responsible for maintaining and disseminating this information to researchers.

### 5.1 Submission requirements

5.1.1 The requirements regarding contact persons, documents, and submission procedures are outlined on Nagano. Submission requirements include, but are not limited to, the following:<sup>79</sup>

- REB application form;
- Submission format;
- Relevant documentation;
- Language in which documents are to be submitted;
  
- Submission deadline and associated review dates;
- Notification of receipt of applications, including communication that an application is incomplete;
- Expected time frame for notification of the decision following review;
- Time frame for filing the supplementary information and/or document revisions requested by the REB;
- Fee structure, if any, for reviewing an application;
- Submission checklist;
- Continuing Review form;
- Amendment and/or Administrative Change form;
- Change in Researcher/Coordinator form;
- Change in Research Personnel form;
- Serious Adverse Event Reporting form;

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<sup>79</sup> *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 9.2, hereafter *Modèle*; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 5.2, hereafter *OG*.

- Research Completion form.

5.1.2 The REB may request any additional documentation it deems necessary to the ethics review or for research ethics oversight.

5.1.3 Administrative requirements related to the research project: The research question and methodology are written in sufficient detail to permit REB members to evaluate the merits of the project.<sup>80</sup> The research should include all of the required elements applicable to the research, such as, but not limited to, the following:<sup>81</sup>

- Application form, signed and dated;
- Proposed research protocol (including a description of ethical considerations associated with the proposed research) or management framework for data banks or biobanks;
- For clinical trials, the Investigator's Brochure or the product monograph and No Objection Letter from Health Canada, or a document justifying their absence;
- The information and consent form;
- Questionnaires and/or other materials for the research participants;
- Recruitment documents;
- Relevant sections of the agreement with the sponsor;
- Budget;
- Results of the scientific review by recognized peer review committees:
  - The following shall constitute recognized peer review committees: • the scientific committee formed by another institution in the health and social services network; • the scientific committee of a Québec-based or federal funding agency or of an agency (national or international) recognized by one of the latter, whether or not the project is funded; • the scientific committee of a university or college in Québec or another Canadian province, or a scientific committee recognized by such an institution (e.g., program committee, thesis committee, departmental authority).<sup>82</sup>
- Results of other REB reviews, if any.

## 5.2 Administrative review procedures

5.2.1 A unique number is assigned to each submission at the time of application.

5.2.2 The submission is screened by the RRO staff that supports the REB for overall completeness.

<sup>80</sup> *Modèle*, s. 9.3.

<sup>81</sup> *Modèle*, s. 9.3; OG, s. 5.3; *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s 3.1.2, hereafter GCP.

<sup>82</sup> *Cadre de référence ministériel pour la recherche avec des participants humains*, MSSS 2020.

- 5.2.3 If the submission is incomplete (e.g., documents are missing or incorrect documents were uploaded), the REB will follow up with the researchers and/or research coordinator to request the required information for inclusion with the submission.
- 5.2.4 Upon receipt of a complete submission, the REB Chair or designee determines whether the research requires a full board review or is appropriate for delegated review.
- 5.2.5 For submissions requiring a full board review, the proposed research will be added to the agenda of the next full board meeting.
- 5.2.6 When it is determined that a submission meets the criteria for a delegated review, one or more REB members will be assigned to the review.

## **6 REFERENCES**

See footnotes.

## **7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 301.001		

# REB-SOP 302.001

Research Ethics Board  
Standard Operating Procedure

<b>Title:</b>	REB Meeting Administration
<b>SOP code:</b>	REB-SOP 302.001
<b>N2/CAREB SOP code:</b>	SOP 302.002
<b>Effective date:</b>	2021-09-30

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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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.



#### 4 DEFINITIONS

See glossary.

#### 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>83</sup>

REB meetings are held behind closed doors.

The REB meeting agenda outlines the meeting content. It also provides an overview of all items that have been previously reviewed and approved (i.e., during the period between two REB meetings) by delegated review procedures, a list of items that are pending review by the full board, and the 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 why 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 submissions (e.g., new studies, amendments, continuing review applications, reportable events) by the RRO staff that supports the REB and the determination of the review type by the REB Chair or designee, the team leader of the RRO staff that supports the REB adds any submission requiring a full board review to the agenda for the next full board meeting.
- 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 RRO staff that supports the REB attaches to the agenda any previous REB meeting minutes for review and approval by the full board, as well as for approval by REB members present at that meeting. The RRO staff that supports the REB then add any other items for information or discussion at the REB meeting (e.g., SOPs, educational articles, presentations, reports, etc.).

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<sup>83</sup> *Good Clinical Practice: Consolidated Guideline*, Health Canada, 1997, s. 3.2.3, hereafter *GCP*; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 10.6, hereafter *Modèle*; *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 6.9, hereafter *TCPS2*; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 4.5.2, hereafter *OG*.

- 5.1.4 The RRO staff that supports the REB, 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 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 The ad hoc advisors or guest experts 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 RRO staff that supports the REB, 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 they are 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 will 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>84</sup> a quorum is present when at least five REB members<sup>85</sup> are present from the following categories:
- At least two members with expertise in relevant research disciplines, fields, and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who is

<sup>84</sup> *Modèle*, s. 10.6 and 11; TCPS2, art. 6.9; GCP, s. 3.2.3; OG, s. 4.5.2.

<sup>85</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, p. 1039, hereafter *Avis*; *Food and Drug Regulations*, C.R.C. c. 870, s. C.05.001, under "research ethics board"; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 21, hereafter *PAM*; GCP, s. 3.2.1 (a); *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 6.4, hereafter *TCPS2*.

a physician, dentist, or pharmacist and who is in good standing with the Council of Physicians, Dentists and Pharmacists (CPDP)).<sup>86</sup>

- At least one member who is primarily experienced in a non-scientific discipline.<sup>87</sup>
- At least one member with expertise in ethics.<sup>88</sup>
- At least one member with legal expertise, knowledgeable in the laws applicable to the types of research being reviewed.<sup>89</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>90</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 through early departures), the REB may not make further decisions<sup>91</sup> unless quorum can be restored.
- 5.4.3 The REB may use any technology at its disposal, including videoconference or teleconference, to hold its meetings.<sup>92</sup>
- 5.4.4 A member who cannot attend the meeting can exceptionally send in their 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 them for approval.
- 5.4.5 Ad hoc advisors will not be used to establish a quorum.<sup>93</sup>
- 5.4.6 REB members recusing themselves due to a conflict of interest are not counted toward quorum.
- 5.4.7 In exceptional circumstances (e.g., public health alerts and quarantines), the REB Chair or designee may, at their discretion, and if members do not have access to technology to participate in virtual meetings, 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 deliberations and final decision regarding approval.

<sup>86</sup> *Avis*, p. 1039; *Food and Drug Regulations*, s. C.05.001 (b) (i); PAM, p. 21; *Modèle*, s. 6.1; TCPS2, art. 6.4a).

<sup>87</sup> *Food and Drug Regulations*, s. C.05.001 (b) (iv); GCP, s. 3.2.1 b; *Modèle*, s. 6.1.

<sup>88</sup> *Avis*, p. 1039; *Food and Drug Regulations*, s. C.05.001 (b) (ii); PAM, p. 21; *Modèle*, s. 6.1; TCPS2, art. 6.4b).

<sup>89</sup> *Avis*, p. 1039; *Food and Drug Regulations*, s. C.05.001 (b) (iii); PAM, p. 21; *Modèle*, s. 6.1; TCPS2, art. 6.4c).

<sup>90</sup> *Avis*, p. 1039; *Food and Drug Regulations*, s. C.05.001 (b) (v); *Modèle*, s. 6.1; GCP, s. 3.2.1 c; TCPS2, art. 6.4d) and p. 81. N.B.: According to the PAM (p. 21), this person must use the services of the institution.

<sup>91</sup> OG, s. 7.3.

<sup>92</sup> TCPS2, art. 6.9 and 6.10.

<sup>93</sup> TCPS2, art. 6.9.

5.4.9 Observers may be invited or permitted to attend REB meetings, subject to the agreement of the REB and signature of a confidentiality agreement. The rules regarding conflict of interest apply.

5.4.10 If requested, researchers may attend an REB meeting to present their research and respond directly to any comments or questions raised by the REB members.

5.4.11 Any individual not on the official REB membership list may not participate in the decisions of the REB.

## **5.5 Preparation of meeting minutes**

5.5.1 The REB Chair or designee, or the RRO staff that supports the REB will draft the REB meeting minutes.

5.5.2 The key REB discussions and decisions, abstentions and dissensions regarding the submissions are recorded in the minutes.<sup>94</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 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 to provide additional reference information for the preparation of the final version of the minutes.

5.5.5 The minutes should be completed within 10 working days.

## **5.6 Approval of meeting minutes**

5.6.1 The minutes are made available to members at the next appropriate REB meeting, where they are presented for review and approval.<sup>95</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 (in person, teleconference, videoconference), and names of REB members absent;<sup>96</sup>
- Names of RRO staff that supports the REB present at the meeting;<sup>97</sup>

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<sup>94</sup> OG, s. 6.1.3.

<sup>95</sup> OG, s. 6.1.3.

<sup>96</sup> *Modèle*, s. 8.5.2.

<sup>97</sup> *Modèle*, s. 8.5.2.

- Presence of observers, use of ad hoc advisors and their specialty;<sup>98</sup>
- Exact title of each research project reviewed or submitted, along with the name of the applicant;<sup>99</sup>
- A summary of key discussions and controversial issues and their resolution, for each submission, as applicable;<sup>100</sup>
- The basis for requiring changes or for disapproving submissions;<sup>101</sup>
- REB member(s) recused due to conflicts of interest, for each submission requiring a decision;
- The key REB discussions and decisions, abstentions, and dissensions, for each submission;<sup>102</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>103</sup> or for at least 25 years in the case of clinical trials.<sup>104</sup>

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

5.7.4 If required for inspection purposes in accordance with SOP 701.001, the relevant parts of the minutes could be released. The individuals designated by the Minister are subject to due discretion and confidentiality.<sup>105</sup>

## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

SOP code	Effective date	Summary of changes
REB-SOP 302.001		

<sup>98</sup> *Modèle*, s. 8.5.2.

<sup>99</sup> *Modèle*, s. 8.5.2.

<sup>100</sup> TCPS2, art. 6.17; *Modèle*, s. 8.5.2.

<sup>101</sup> TCPS2, art. 6.17; *Modèle*, s. 8.5.2.

<sup>102</sup> *Modèle*, s. 8.5.2.

<sup>103</sup> GCP, s. 3.4; OG, 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*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, Measure 5, hereafter PAM.

<sup>104</sup> *Food and Drug Regulations*, C.R.C. c. 870, s. C.05.012; HEALTH CANADA, *Guidance for records related to clinical trials*, Guide 0068.

<sup>105</sup> *Ibid.*

<b>Title:</b>	Document Management
<b>SOP code:</b>	REB-SOP 303.001
<b>N2/CAREB SOP code:</b>	SOP 303.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the requirements for document management, including document retention and document archiving. This SOP applies to documents submitted to the Research Ethics Board (REB) for initial or continuing review, as well as to all REB administrative documents.

**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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

### 4 DEFINITIONS

See glossary.

### 5 PROCEDURES

The REB office must retain all relevant records<sup>106</sup> (e.g., all documents related to research projects submitted, REB meeting minutes, correspondence with researchers, SOPs, REB membership list, etc.), in order to provide a complete history of all actions related to REB activities. Such records must be retained for the length of time required by applicable regulations and guidelines.

Upon request, relevant records must be made accessible to authorized regulatory authorities, representatives of the Academic Affairs Committee of the institution's Board of Directors, researchers, and funding agencies within a reasonable time.

#### 5.1 Research files

5.1.1 Research files include, but are not limited to, the following (as applicable):

- Applications for initial and continuing REB reviews and all associated attachments;
- Correspondence between the REB and the researcher;
- Approval letters;
- Reports of any complaints managed by the REB regarding a particular research project.

#### 5.2 REB administrative documents

5.2.1 REB administrative documents may include, but are not limited to, the following:

- Agendas and minutes of all REB meetings;
- Reviews submitted by REB members;

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<sup>106</sup> *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, Measure 5, hereafter PAM; *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.4, hereafter GCP; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 10, hereafter OG; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 14.1, hereafter *Modèle*; *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 6.17, hereafter TCPS2.

- REB member records:
  - Current and obsolete REB membership lists;
  - CVs and training/qualification documents for current and past REB members;
- Signed conflict of interest and confidentiality agreements;
- Current and obsolete documentation on the REB Chair's or designee's delegation of authority, responsibilities, or specific functions;
- REB working notes;
- REB correspondence;
- REB internal memos;
- REB annual reports;
- Records of registration of the REB and the institution with the US Office of Human Research Protection and Federalwide Assurance, as well as REB membership updates.

### **5.3 Document confidentiality**

5.3.1 All research files held by the REB are considered confidential.

5.3.2 The following REB information and administrative documents are considered confidential:

- Agendas and minutes of all REB meetings;
- Reviews submitted by REB members;
- Current and obsolete documentation on the REB Chair's or designee's delegation of authority, responsibilities, or specific functions;
- REB correspondence, including discussions on Nagano;
- REB internal memos;
- REB annual reports;
- Names of individuals reviewing the research or, where applicable, constituting the quorum;
- Conflict of interest statements.

### **5.4 Access to documents<sup>107</sup>**

5.4.1 Research files:

- All individuals working for the REB may access the research files when required in the performance of their duties.

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<sup>107</sup> *Modèle*, s. 14.3; GCP, s. 3.4.



- Individuals responsible for reviewing institutional suitability, as well as the person formally mandated to authorize the research, have access to the research files, as per the terms of the institutional regulatory framework.
- All other individuals who wish to access the research files must communicate with the principal investigator.

#### 5.4.2 REB administrative documents:

- The following may access REB administrative documents:
  - Everyone: SOPs, RRO/REB procedures and policies.
  - Researchers: Up-to-date REB membership list specifying members' qualifications (profession and professional affiliations) and role; true copies of excerpts from the REB minutes relevant to the research project.
  - Sponsors or funding agencies or regulatory authorities: Up-to-date REB membership list specifying members' qualifications (profession and professional affiliations) and role.
  - A representative of the Minister for audit or inspection purposes: Annual report and up-to-date REB membership list specifying members' qualifications (profession and professional affiliations) and role.
  - A representative of the Board of Directors: All REB files.

#### 5.4.3 Anyone with access to confidential REB records is subject to the duty of confidentiality.<sup>108</sup>

### 5.5 Document retention and archiving

5.5.1 REB records are securely housed in locked premises or on secure servers. Back-up and recovery systems are in place.

5.5.2 The REB office will keep all research-related materials submitted for REB review, whether they were approved, rejected, or stamped as received.<sup>109</sup>

5.5.3 The REB will keep all administrative documents related to REB review activities.<sup>110</sup>

5.5.4 Files will be kept for:<sup>111</sup>

- 25 years, for research files related to research regulated by Health Canada;
- 7 years or more, according to local requirements, for research files related to all other research;
- 25 years after the date of the last REB research review, for REB administrative documents.

<sup>108</sup> *Modèle*, s. 14.3.

<sup>109</sup> *Modèle*, s. 14.4.3; PAM, Measure 5; OG, 10.7 to 10.12; TCPS2, art. 6.17.

<sup>110</sup> GCP, s. 3.4; OG, 10.1 to 10.6; *Modèle*, s. 14.1; TCPS2, p. 94.

<sup>111</sup> GCP, s. 3.4; OG, 10; *Modèle*, s. 14.4.3.

**5.6 Document destruction**

5.6.1 At the end of the retention period, all documents will be destroyed according to the institution's policies.

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 303.001		

<b>Title:</b>	REB Review Decisions
<b>SOP code:</b>	REB-SOP 401.001
<b>N2/CAREB SOP code:</b>	SOP 402.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the decisions that the Research Ethics Board (REB) may make resulting from its review of the ethical acceptability of a proposed research project.

**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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for ensuring that a decision is made for every submission that is reviewed by the REB, and that the decision is clearly communicated to the researcher and documented in the REB minutes.

#### 4 DEFINITIONS

See glossary.

#### 5 PROCEDURES

The REB has the authority to approve, approve with modifications, or reject the submitted research.<sup>112</sup> This decision must be made within a reasonable time frame.<sup>113</sup> If there are questions that must be addressed prior to a decision being made, the REB may defer its decision.

When the full board review procedure is used, decisions will be made by consensus or a majority vote of the REB members who are present at a full board meeting<sup>114</sup> at which there is a quorum.<sup>115</sup> Full board review is the default option for most initial submissions received by the REB.<sup>116</sup>

Some research submissions may be eligible for delegated review, in accordance with the SOP on that topic. The REB member(s) assigned to the delegated review may approve the research or ask for modifications or further information before approving the research. However, they do not have the power to reject a research project; only full board reviews may reject research.<sup>117</sup>

REB members with a conflict of interest related to the research under review must not participate in the deliberations or vote of the REB,<sup>118</sup> in accordance with the institution's conflict of interest policies and the SOP on conflicts of interest.

Researchers have the right to request another review or to appeal the REB's decision.<sup>119</sup>

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<sup>112</sup> *Good Clinical Practice: Consolidated Guideline*, Health Canada, 1997, s. 3.1.2 and 3.3.9, hereafter GCP; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 4.2, hereafter *Modèle*.

<sup>113</sup> GCP, s. 3.1.2; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 6 and 8, hereafter OG; *Modèle*, s. 11.4.1.

<sup>114</sup> OG, s. 7.6; *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, p. 89, hereafter TCPS2.

<sup>115</sup> *Modèle*, s. 10.6 and 11; TCPS2, art. 6.9; GCP, s. 3.2.3; OG, s. 4.5.2 and 7.3.

<sup>116</sup> TCPS2, p. 87.

<sup>117</sup> TCPS2, p. 87.

<sup>118</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, p. 1040, hereafter *Avis*; TCPS2, art. 7.3; OG, s. 7.1.

<sup>119</sup> TCPS2, art. 6.19 and 6.20.

## 5.1 REB decisions

5.1.1 REB decisions are made either by consensus or a majority vote of the REB members present at a full board meeting,<sup>120</sup> with the exception of those who have recused themselves in accordance with the conflict of interest policies. If consensus cannot be reached, the decision will proceed to a vote.<sup>121</sup>

An REB member who disagrees with a decision may express dissent or abstain; this will be recorded in the minutes.<sup>122</sup>

5.1.2 The REB must reach one of the following decisions as a result of its review of research submitted for initial or continuing review:<sup>123</sup>

- **Approval** (approve the application as submitted, including the consent form):
  - When the research meets the ethical standards and the regulatory criteria required for approval, it may be approved as submitted;
  - The approval is effective as of the date of the REB's final approval, for at most one year from this date.<sup>124</sup>
- **Approval with modifications:**
  - Even if the research meets the ethical standards and satisfies the regulatory criteria required for approval, the REB members may require a modification or further information before granting final approval. Such decisions may include clarifications on how to review the modifications made.<sup>125</sup>
  - Except where otherwise indicated by the REB, the REB Chair or designee has the responsibility for reviewing and approving the modifications or clarifications brought by the researcher. This responsibility may be delegated to one of the following:
    - One or more designated REB members who were present at the REB meeting or who submitted written comments on the application;
    - A subgroup of REB members designated by the REB Chair or designee, or by the REB;
    - One or more designated REB members with sufficient knowledge and experience regarding the research and the regulations.
  - The researcher has 3 months to respond to a request from the REB, after which date the file will be closed and the research would have to be resubmitted.

<sup>120</sup> OG, s. 7.6; TCPS2, p. 89.

<sup>121</sup> OG, s. 7.6.

<sup>122</sup> TCPS2, p. 89.

<sup>123</sup> GCP, s. 3.1.2; *Modèle*, s. 4.2; TCPS2, art. 6.3.

<sup>124</sup> *Modèle*, s. 11; TCPS2, p. 90.

<sup>125</sup> *Modèle*, s. 11.

- If the researcher's response is deemed complete and satisfactory, approval can be issued.
- If the researcher's response is incomplete and does not fully address the matters raised, requests for further information, modifications, or clarification should be sent to the researcher.
- The reviewers may decide, upon reviewing the researcher's response, that the decision should be deferred and that the response should be reviewed at a subsequent full board meeting (see "Deferral" process below).
- The ethics approval is effective ("effective date") as of the date of REB final approval, for at most one year.<sup>126</sup> The expiry date is calculated from the effective date; however, the final ethics approval letter is not issued until all of the conditions for approval have been met.
- When the REB recommends "Approval with modifications," the REB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified at the next REB meeting and included in the minutes.
- **Deferral:**
  - The REB will defer its decision to a subsequent full board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met.
  - The REB Chair or designee should ensure that all additional information, modifications, or clarifications that are required are specifically identified at the full board meeting.
  - The researcher has 3 months to respond to the REB requests.
  - The research shall be reviewed at a subsequent full board meeting.
- **Disapproval:**
  - The REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive decision.
  - Disapproval cannot be decided through the delegated review mechanism. If the recommendation under delegated review is to disapprove the research, a final decision must be made by the REB at a full board meeting.
  - If the research is disapproved, the REB Chair or designee should ensure that the reasons for the disapproval are clearly identified and communicated to the researcher.<sup>127</sup> The researcher will be given an opportunity to respond in person or in writing, to request reconsideration of the decision, and to file an appeal.<sup>128</sup>

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<sup>126</sup> *Modèle*, s. 11; TCPS2, p. 90.

<sup>127</sup> *Modèle*, s. 11; OG, s. 7.9 and 8.13.

<sup>128</sup> *Modèle*, s. 11.

### 5.1.3 Delegated reviews:

Delegated reviews may be performed in accordance with the SOP on that topic.

## 5.2 Reconsideration and appeal of REB decisions

5.2.1 A researcher may ask that the REB's decision be reconsidered if the researcher can justify the grounds for the request,<sup>129</sup> within 30 days. The researcher shall have the right to be heard at the next full board meeting at which they will present the arguments in favour of the case.<sup>130</sup>

5.2.2 After reconsideration, the REB will hand down its verdict within 10 days. If the REB maintains its decision to disapprove the research, the REB may offer the researcher another hearing, in front of a quorum separate from the REB. If the researchers agree, the decision of that second quorum is final.

5.2.3 If the researcher does not accept a hearing in front of a quorum separate from the REB, an appeal may be launched for procedural or substantive reasons.<sup>131</sup>

5.2.4 The appeal will take place before one of the REBs of the Quebec Health and Social Services Network (*Réseau de la santé et des services sociaux du Québec*), to be determined jointly between the REB and the researcher.

5.2.5 The appeals committee will review the research proposal. In so doing, it may approve or disapprove the research, or request modifications.<sup>132</sup> The decision of the appeals committee must be justified and shall be final. The decision shall be communicated to the researcher and the REB in writing.<sup>133</sup>

## 5.3 Documenting REB decisions

5.3.1 The REB meeting minutes will contain the following: membership attendance, research proposals, documents examined, review types, items reviewed (see Appendix), requests for modification and clarification, decisions taken, and abstentions and dissensions along with their respective reasons.<sup>134</sup>

5.3.2 The REB shall notify the researcher in writing of its decision.<sup>135</sup>

5.3.3 If the REB defers its decision or asks for modifications, the letter to the researcher should include the issues of concern and the additional information required.<sup>136</sup>

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<sup>129</sup> TCPS2, art. 6.18.

<sup>130</sup> TCPS2, art. 6.13; *Modèle*, s. 11.

<sup>131</sup> TCPS2, art. 6.19.

<sup>132</sup> *EPTC2*, TCPS2, art. 6.20.

<sup>133</sup> TCPS2, p. 98.

<sup>134</sup> *Modèle*, s. 8.5.2; TCPS2, art. 6.17.

<sup>135</sup> OG, s. 8; TCPS2, art. 6.13.

<sup>136</sup> *Modèle*, s. 11.4.2.

5.3.4 The final approval letter should include standard conditions of approval to which the researcher must adhere, such as the duration of approval and the need to obtain authorization from the person formally mandated before starting the research.<sup>137</sup>

5.3.5 When the decision to approve a submission is given by electronic means (e.g., Nagano), the notification or correspondence to the researcher may be issued by the RRO staff that supports the REB.

#### **5.4 Cancellation of REB review**

5.4.1 The REB may terminate the review process or cancel the initial approval of a research proposal if the researcher has not responded and/or submitted the requested documents to the REB within 3 months since the last REB correspondence to the researcher.

5.4.2 Before the end of the 3-month period, the researcher may submit a request for a deadline extension. This request must be, in the opinion of the REB, adequately and sufficiently justified.

### **6 REFERENCES**

See footnotes.

### **7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 401.001	YYYY-MM-DD	DRAFT, 2021-01-18

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<sup>137</sup> *Modèle*, s. 11.4.2.



<b>Title:</b>	Delegated Review
<b>SOP code:</b>	REB-SOP 402.001
<b>N2/CAREB SOP code:</b>	SOP 401.002
<b>Effective date:</b>	Page 73 of 142

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**1 PURPOSE**

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for a delegated ethics review and the associated delegated review procedures.

**2 SCOPE**

This SOP pertains to research ethics boards (REBs) that review human-participant research in compliance with applicable regulations and guidelines.

**3 RESPONSIBILITIES**

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

The REB Chair or designee determines whether the research is appropriate for delegated review. In some circumstances, the REB Chair or designee may delegate this task to qualified REB support staff; however, the responsibility for oversight remains with the REB Chair or designee.<sup>138</sup>

The REB Chair or designee, or qualified REB member(s), is responsible for conducting the delegated review.

#### **4 DEFINITIONS**

See glossary.

#### **5 PROCEDURES**

REBs should adopt a proportionate approach to the ethics review, such that the level of review is determined by the level of risk associated with the research: the lower the risk level, the looser the review will be, and the higher the risk level, the greater should be the care in assessing the research.<sup>139</sup> In all cases, proportionate review implies a consideration of foreseeable risks, potential benefits, and ethical implications of the research in question.<sup>140</sup>

In practice, the proportionate review implies different levels of REB review for different research projects. The two levels typical used by REBs are full board review or delegated review by one or more experienced REB members, as determined by the REB Chair or designee.<sup>141</sup>

Approval is effective as of the date of delegated REB approval (final or initial, depending on the site), for at most one year from this date.<sup>142</sup> The letter of approval, however, is not issued until all the conditions for approval have been met.

If the research cannot be approved by delegated review, a full board review will be done.

##### **5.1 Determination of qualification for delegated review**

5.1.1 Full board review is the default option.<sup>143</sup>

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<sup>138</sup> TCPS2, p. 89.

<sup>139</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 2.9 and 6.12, hereafter TCPS2.<sup>139</sup> TCPS2, art. 2.9 and 6.12.

<sup>141</sup> TCPS2, art. 2.9 and 6.12; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 10.2, hereafter *Modèle*; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 6.3, hereafter OG.

<sup>142</sup> *Modèle*, s. 11; TCPS2, p. 90.

<sup>143</sup> TCPS2, p. 87.

- 5.1.2 New research projects that fall under Article 21 of the *Civil Code of Québec*<sup>144</sup> cannot be evaluated by delegated review at the time of the initial REB review.<sup>145</sup>
- 5.1.3 Submissions that meet the following criteria are eligible for delegated review:
- (a) Initial review of research projects that involve no more than a minimal risk;<sup>146</sup>
  - (b) Research projects that do not interfere with the integrity<sup>147</sup> of a minor or of a person of full age incapable of giving consent;<sup>148</sup>
  - (c) Changes to approved research that have no impact on the risk/benefit ratio<sup>149</sup>;
  - (d) Annual renewal of ethics approval, when authorized in accordance with applicable rules and regulations<sup>150</sup>, for the following:
    - minimal-risk research;<sup>151</sup>
    - research that is more than minimal risk and for which enrolment is permanently closed and all research-related interventions for all participants are complete;<sup>152</sup>
    - research that is more than minimal risk, where the remaining research activities are limited to data analysis;
    - research that is more than minimal risk, where no participants have been enrolled and no additional risks have been identified;
    - research that is more than minimal risk, where there has been little or no modification of the research;
    - research that is more than minimal risk and where there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB;
  - (e) The response by the researcher to REB requests for modifications and/or clarifications, unless otherwise stated by the REB;
  - (f) Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures;
- 5.1.4 Reportable events, including adverse events and drug safety updates, are reviewed according to the SOP on activities related to ongoing REB reviews.

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<sup>144</sup> *Civil Code of Québec*, art. 21.

<sup>145</sup> *Modèle*, s. 10.2.

<sup>146</sup> TCPS2, p. 88.

<sup>147</sup> *Civil Code of Québec*, art. 21.

<sup>148</sup> *Modèle*, s. 10.2.

<sup>149</sup> *Good Clinical Practice: Consolidated Guideline*, Health Canada, 1997, s. 3.3.5, hereafter GCP; TCPS2, p. 88.

<sup>150</sup> TCPS2, p. 88.

<sup>151</sup> TCPS2, p. 88.

<sup>152</sup> TCPS2, p. 88.

5.1.5 The REB Chair or designee may use delegated review procedures to review other types of minor changes<sup>153</sup> including, but not limited to, the following:

- Participant materials such as recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards;
- Address changes.

5.1.6 The REB Chair or designee may review miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a full board meeting.

5.1.7 When determining whether an initial research review or modifications to previously approved research are eligible for delegated review, the REB Chair or designee will take into consideration the methods used to conduct the research, the recruitment practices, the participant population, the confidentiality of the data, and all regulatory and ethics guidance requirements, as applicable.

## 5.2 Delegated review process

5.2.1 The REB Chair or designee, or a member of the qualified support staff, will determine whether the submission meets the criteria for delegated review.<sup>154</sup>

5.2.2 For research that meets the criteria, the delegated review may be conducted by the REB Chair, or by one or more qualified REB members as designated by the REB Chair or designee.<sup>155</sup>

5.2.3 The authority of the REB member(s) conducting a delegated review is similar to that of the REB, but without the power to disapprove a research project.<sup>156</sup>

5.2.4 The REB member(s) conducting a delegated review may request the expertise of an ad hoc advisor, where applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research.<sup>157</sup>

5.2.5 If the REB Chair or designee subsequently determines that the level of risk related to the submission is greater than minimal, the submission will be referred to a full board meeting for review.

## 5.3 Notification of the REB

5.3.1 At its next full board meeting, the REB will be informed of any research that was reviewed and approved using delegated review procedures.

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<sup>153</sup> GCP, s. 3.3.5.

<sup>154</sup> OG, s. 6.3; TCPS2, p. 86 and 87.

<sup>155</sup> TCPS2, p. 87.

<sup>156</sup> TCPS2, p. 87.

<sup>157</sup> TCPS2, art. 6.5; OG, s. 4.6; GCP, s. 3.2.6.

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### 5.4 Documentation

5.4.1 The type of REB review conducted (i.e., full board or delegated) is documented in the REB records and noted in the decision letter issued to the researcher, where applicable.

5.4.2 The REB meeting agendas and minutes will include a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous REB meeting was issued.

### 6 REFERENCES

See footnotes.

### 7 REVISION HISTORY

SOP code	Effective date	Summary of changes
REB-SOP 402.001		

<b>Title:</b>	Initial Review – Criteria for REB Approval
<b>SOP code:</b>	REB-SOP 403.001
<b>N2/CAREB SOP code:</b>	SOP 403.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the minimum requirements that research proposals involving human participants must meet in order to be approved by the Research Ethics Board (REB), independent of the type of review (i.e., full board or delegated review).

**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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

The REB members are responsible for determining whether the research meets the criteria for approval.

#### 4 DEFINITIONS

See glossary.

#### 5 PROCEDURES

All research involving human participants must meet certain criteria before REB approval may be granted. Initial REB approval of the research is based on the review of a complete submission to the REB. The REB and/or RRO staff that supports the REB may consult the researcher for additional information, as necessary. The ethics specialists from among the RRO staff that supports the REB will first make sure that the minimal criteria are met. The initial duties are identified and described in their description of duties.

Following initial review of the research, in accordance with the relevant SOPs, the REB will make a determination.

##### 5.1 Minimal criteria for approval of research

In order for the research to receive REB approval, the REB will take the following into consideration:

5.1.1 The application has been signed by the researcher or designee.<sup>158</sup> The REB may require the researcher to submit the following documents demonstrating their qualifications to conduct the research:<sup>159</sup>

- Their CV;
- For clinical trials, their licence to practice;
- Proof of research privileges.

5.1.2 Any conflicts of interest (real, potential, or perceived) are declared and managed appropriately to prevent any compromises to the safety or welfare of the participants or to the integrity of the data.<sup>160</sup>

5.1.3 Where relevant, there is a state of clinical equipoise.

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<sup>158</sup> *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, s. 9.3, hereafter *Modèle*.

<sup>159</sup> *Modèle*, s. 9.3 and 10.3; *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.1.3, hereafter GCP. *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 5.1, 5.3.7 and 6.2.3.1, hereafter OG; *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, p. 1039, hereafter *Avis*; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 23, hereafter PAM.

<sup>160</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 7.4 and p. 107, hereafter TCPS2; *Modèle*, s. 10.3. See also the SOP on Conflicts of Interest – Researcher.

- 5.1.4 The research will generate knowledge that could be generalized and lead to improvements in health or welfare.<sup>161</sup>
- 5.1.5 The methodology is scientifically sound and capable of answering the research question.<sup>162</sup> This methodological validity has been established by a recognized peer review committee or by the institution's scientific committee.<sup>163</sup> Even if research is approved by a recognized scientific committee, the REB's mandate includes reviewing the ethical implications of the research methods and design.<sup>164</sup>
- 5.1.6 The risks to participants are minimized by:
- Using procedures that are consistent with sound research methods and that do not expose participants to unnecessary risk.
  - By using procedures already being performed on the participants for diagnostic or treatment purposes, whenever appropriate.
- 5.1.7 The risks to participants are reasonable in relation to the anticipated benefits, if any, and to the importance of the knowledge that will be generated.<sup>165</sup>
- 5.1.8 The selection of participants is equitable, i.e., inclusive for anyone who might benefit from the research.<sup>166</sup> Participants are not to be excluded for reasons of culture, language, religion, race, disability, sexual orientation, ethnic origin, gender, or age. Such exclusions would require sound scientific and ethical reasons.<sup>167</sup> In performing this review, the REB will take into account the purpose of the research and the research setting.
- 5.1.9 There are sound scientific and ethical reasons for excluding persons who might benefit from the research.
- 5.1.10 When some or all of the participants are more likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research.<sup>168</sup> Vulnerability may depend on participant status, role in the institution, or circumstances surrounding participation in the study.

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<sup>161</sup> *Modèle*, s. 10.3; TCPS2, p. 22 and 23; *Avis*, p. 1039.

<sup>162</sup> *Modèle*, s. 10.3; OG, s. 6.2.

<sup>163</sup> See SOP 301.001

<sup>164</sup> *Cadre de référence ministériel pour la recherche avec des participants humains*, MSSS 2020.

<sup>165</sup> *Civil Code of Québec*, art. 20 and 21; *Modèle*, s. 10.3; TCPS2, p. 22-25 and art. 2.9 and 11.4 (a); OG, s. 6.2.1.2, *Avis*, p. 1039; PAM, p. 23.

<sup>166</sup> TCPS2, art. 4.1; OG, s. 2 and 6.2.2.4; *Modèle*, s. 10.3; *Avis*, p. 1039; PAM, p. 23.

<sup>167</sup> TCPS2, art. 4.1.

<sup>168</sup> TCPS2, art. 3.1 and p. 28-30.



- 5.1.11 The amount paid to participants to cover losses and constraints and the method of payment used are appropriate to ensure that there is no coercion or undue influence.<sup>169</sup> Information regarding payment to participants, including method, amounts and schedule, is provided to participants, where applicable.<sup>170</sup>
- 5.1.12 The informed consent form will be consistent with the REB's models, and the consent process will be in accordance with applicable standards and relevant SOPs.<sup>171</sup>
- 5.1.13 The informed consent process will be documented in appropriate manner, in accordance with regulations and relevant SOPs.<sup>172</sup>
- 5.1.14 The REB requires that informed consent forms for clinical trials be drafted using the Standard Legal Clauses for Informed Consent Forms of the *Ministère de la santé et des services sociaux du Québec*, available in both French and English. Any changes, deletions, or additions must be justified by exceptional circumstances.
- 5.1.15 There will be provisions for ongoing data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research, if any.<sup>173</sup> The REB may recommend the use of a data and safety monitoring board (DSMB) to enhance participant protection.
- 5.1.16 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.<sup>174</sup>
- 5.1.17 There will be adequate provisions for continued access to the study product or adequate replacement of the study product after the research is completed, as appropriate.<sup>175</sup>
- 5.1.18 For clinical trials, there will be adequate provisions for the timely publication and dissemination of all the research results, except where additional delays are deemed justifiable by the Contracts Office after consultation with the REB.<sup>176</sup>

<sup>169</sup> "A person's participation in research that could interfere with the integrity of his person may not give rise to any financial reward other than the payment of an indemnity as compensation for the loss and inconvenience suffered." See: *Civil Code of Québec*, art. 25, para. 2. Also see: TCPS2, p. 27; GCP, s. 3.1.8; OG, 5.3.12, 5.3.13 and 6.2.3.10; *Modèle*, s. 9.3.GCP, s. 3.1.9.

<sup>170</sup>

<sup>171</sup> *Civil Code of Québec*, art. 10, para. 2; TCPS2, art. 3.1, 3.2 and 3.9; OG, 6.2.5 and 5.3.11; *Modèle*, s. 9.3 and 10.3; *Avis*, p. 1039; PAM, p. 23; GCP, s. 3.1.9.

<sup>172</sup> *Civil Code of Québec*, art. 24; TCPS2, art. 3.12.

<sup>173</sup> TCPS2, p. 183 and art. 11.7; OG, s. 6.2.1.6.

<sup>174</sup> TCPS2, art. 5.1-5.3; *Québec Charter of Human Rights and Freedoms*, CQLR c. C-12, art. 5; *Civil Code of Québec*, art. 3 and 35-37; *Act respecting health services and social services*, s. 19; *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR, c. A-2.1, art. 53; OG, s. 6.2.4; *Modèle*, s. 10.3; *Avis*, p. 1039; PAM, p. 23.

<sup>175</sup> OG, s. 6.2.3.6 and 6.2.3.8.

<sup>176</sup> TCPS2, art. 11.12; OG, s. 6.2.1.8.

5.1.19 If applicable, the research has been or will be registered in an internationally recognized clinical trial registry, and a registration number has been/will be submitted to the REB.<sup>177</sup> The researchers shall provide the REB with the registration number upon registration.<sup>178</sup>

**5.2 Additional criteria**

5.2.1 In cases where it is impossible, practically impossible, or impractical to obtain individual consent, the Director of Professional Services (DPS)<sup>179</sup> may grant access to medical record data for research purposes. The REB must first approve the waiver of consent.

5.2.2 Additional criteria may apply depending on the type of research.

**5.3 Length of approval period**

5.3.1 The REB shall review research at periods appropriate to the degree of risk, and at least annually.<sup>180</sup>

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 403.001		

<sup>177</sup> TCPS2, art. 11.3.

<sup>178</sup> TCPS2, p. 181.

<sup>179</sup> *Act respecting health services and social services*, art. 19.2.

<sup>180</sup> GCP, s. 3.1.4; *Modèle*, s. 11; TCPS2, p. 90; OG, s. 2.

<b>Title:</b>	Recruitment and Informed Consent Requirements
<b>SOP code:</b>	REB-SOP 404.001
<b>N2/CAREB SOP code:</b>	SOP 701.002
<b>Effective date:</b>	2021-09-30

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## 1 PURPOSE

This standard operating procedure (SOP) describes the requirements for recruitment<sup>181</sup> and informed consent<sup>182</sup> (including waiver thereof), as well as the REB review of these requirements.

<sup>181</sup> *Avis*, p. 1039; PAM, p. 23; *Modèle*, s. 10.3.

<sup>182</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, p. 1039, hereafter *Avis*; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 23, hereafter PAM; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 10.3, hereafter *Modèle*;

## 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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

The researcher is responsible for providing the REB with:

- The informed consent form in accordance with institutional templates;
- A description of the recruitment methods and recruitment materials (where applicable),<sup>183</sup> including all promotional materials<sup>184</sup> and social media components;
- A description of the informed consent process, with relevant forms;<sup>185</sup>
- Justification of any request for waiver of the usual consent process.

The researcher and the research sponsor, if any, are jointly responsible for ensuring that the consent form contains all of the required elements.

The REB is responsible for determining whether:<sup>186</sup>

- Recruitment methods are appropriate;
- The informed consent process meets ethical and legal requirements;
- The informed consent exemptions or waivers are acceptable;
- The informed consent form contains all the required elements.

## 4 DEFINITIONS

See glossary.

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*Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 6.2, hereafter OG.

<sup>183</sup> *Modèle*, s. 9.3.

<sup>184</sup> GCP, s. 3.1.2.

<sup>185</sup> *Modèle*, s. 9.3; Good Clinical Practice: Consolidated Guideline, Health Canada, September 1997, s. 3.1.2, hereafter GCP.

<sup>186</sup> *Avis*, p. 1039; PAM, p. 23; *Civil Code of Québec*, art. 20 and 21, para. 4; *Modèle*, s. 10.3 and 13.1; OG, s. 6.2.2 and 6.2.5.

## 5 PROCEDURES

All procedures and documents concerning recruitment and consent must be described, justified, and submitted to REB review in accordance with the REB SOP on initial review.<sup>187</sup>

### 5.1 REB review of recruitment methods

- 5.1.1 Recruitment methods should be adapted to research objectives and to potential participants. When potential participants are also patients of the clinician-researcher, measures must be taken to minimize therapeutic misconception. Special precautions must be taken when recruiting vulnerable individuals to ensure freedom of participation. If the research staff are employees of the health network, they should not be recruited by a supervisor. Home care and service patients may be referred by staff at the institution, although specific measures must be taken to ensure their freedom of participation if they are in a therapeutic relationship (e.g., nurse, social worker).
- 5.1.2 A clinician-researcher in a therapeutic relationship with the potential participant may approach the patient directly, but in no way should the latter feel pressured or under any obligation to take part in the study. In such cases, consent should be obtained by someone other than the researcher. “Ideally, treatment and research functions should be performed by different people. However, there may be instances in which the participants’ best interests are served by having their primary care clinician involved in recruitment and consent. In these cases, the research proposal shall indicate what other measures will be taken to minimize therapeutic misconception.”<sup>188</sup>
- 5.1.3 The research project can be advertised to the public by various means, including social media, posters, and conferences.
- 5.1.4 Potential patient-participants should be contacted by someone from the health care facility where they received treatment or who provides them with home care and services. The researcher may contact the patient-participant if the latter was informed of the recruitment process by a staff member and expressed interest in being contacted.
- 5.1.5 The consultation of medical records to identify patients who meet the eligibility criteria requires either authorization from the Director of Professional Services (DPS) or consent. However, if the research is part of the institution’s legally defined mandate, neither of these is necessary..<sup>189</sup>

### 5.2 REB review of the informed consent process

- 5.2.1 The consent process should be adapted to research objectives and to potential participants. When potential participants are also patients of the clinician-researcher, measures must be taken to

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<sup>187</sup> *Modèle*, s. 9.3 and 10.3; OG, s. 6.2.2. *et seq.*

<sup>188</sup> TCPS2, art. 11.6, p. 183.

<sup>189</sup> *Act Respecting Health Services and Social Services*, CQLR c. S-4.2, art. 88.

minimize therapeutic misconception. Special precautions must be taken during the consent process when recruiting vulnerable individuals, to ensure freedom of participation.

- 5.2.2 REB members will review the proposed consent process to ensure that it follows institutional guidelines and all applicable regulations.
- 5.2.3 An REB review of the consent process includes the following:
- (a) Components of the recruitment process: how, when, where, and by whom potential participants are to be contacted, including any and all materials used (e.g., research fact sheets).<sup>190</sup>
  - (b) Potential undue influence (relationship of power, trust, dependency), evidence of coercion or incentives leading to underestimation of potential research risks, which could undermine free and informed consent.<sup>191</sup>
  - (c) Manner in which the research is to be advertised.<sup>192</sup>
  - (d) Specific measures related to the translation or interpretation of informed consent documents, in accordance with paragraph 5.4.
  - (e) Specific and exceptional measures for safeguarding participant safety and privacy.
  - (f) The researcher's plans regarding the identification and disclosure of incidental findings, if any.
- 5.2.4 The REB usually requires written consent<sup>193</sup> on an REB-approved informed consent form, dated and signed by the participant or legal representative thereof and by the person obtaining consent. Other means of obtaining consent (oral consent, deferred consent, field notes, implied consent by return of a questionnaire) may nonetheless be approved by the REB under certain circumstances.<sup>194</sup>
- 5.2.5 Minors aged 14 years and over may consent on their own to participate in a research study if, according to the REB, the risk is minimal and circumstances justify it.<sup>195</sup>
- 5.2.6 In cases where research projects involve participants who do not have the capacity to consent, the REB will examine how the consent of the participant's legal representative is obtained and documented. The REB will ensure that, when required, assent is documented.

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<sup>190</sup> *Modèle*, s. 10.3; OG, s. 6.2.2; Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics, 2014, p. 28, hereafter TCPS2.

<sup>191</sup> *Modèle*, s. 10.3; OG, s. 6.2.5 *et seq.*; TCPS2, art. 3.1a) and p. 28-30; *Civil Code of Québec*, art. 10, para. 2.

<sup>192</sup> *Modèle*, s. 9.3 and 10.3.

<sup>193</sup> *Civil Code of Québec*, art. 24, para. 1; TCPS2, art. 3.12.

<sup>194</sup> "Consent to research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent" (CCQ, art. 24, para. 2).

<sup>195</sup> *Civil Code of Québec*, art. 21, para. 5.

5.2.7 The REB may approve the use of any technological means it deems appropriate for the conduct of the consent process and its documentation.

5.2.8 Researchers are not required to obtain participant consent for the secondary use of non-identifying information.

### 5.3 REB review of the informed consent form

5.3.1 The REB will review only those forms consistent with institutional templates.

5.3.2 The REB will review proposed informed consent forms for clarity, language level (Grade 8), content, and inclusion of all required elements.

5.3.3 The REB will ensure that there is complete disclosure of all information required for informed decision-making. Such information generally includes:

- (a) Logo of the institution;<sup>196</sup>
- (b) Identity of the principal researcher(r);
- (c) Identity of the funding agency or sponsor;
- (d) Invitation to participate in a research project;<sup>197</sup>
- (e) Statement of research objectives;
- (f) Expected duration and nature of participation;
- (g) Description of the research procedures;
- (h) Explanation of the responsibilities of the participant, when relevant;<sup>198</sup>
- (i) Description of potential benefits, both to the participants themselves and generally, that may arise from participating in the research;<sup>199</sup>

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<sup>196</sup> In the case of multicentre research, the researcher submits their documents in a format easy to use by multiple institutions. Since more than one public institution in the health and social services network will be offered the opportunity to conduct the research, the final version of the related documents will reflect this. The consent form must be in French and may be accompanied by a translation in another language. It will be written in a format easy to use in several public institutions of the health and social services network, taking into account, among other things, the fact that each institution has its own complaints commissioner, and compiling the administrative data, which may vary from one institution to another, as much as possible in an appendix to the main document. The consent form approved by the reviewing REB will not refer to any specific institution and will clearly indicate the spaces for entering administrative information, such that the form may be used by each of the institutions participating in the same research project. *Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l'autorisation de la recherche menée dans plus d'un établissement*, MSSS, 2016, p. 18.

<sup>197</sup> TCPS2, p. 31 point a).

<sup>198</sup> TCPS2, p. 31 point b).

<sup>199</sup> TCPS2, p. 31 point c).

- (j) Description of any and all risks associated with the research procedures indicating, where possible, the severity and frequency thereof;
- (k) An assurance that prospective participants:
- are under no obligation to participate;<sup>200</sup>
  - are free to withdraw and/or to verbally withdraw their consent at any time, without prejudice to the care and services to which they are entitled or to their relationship with the medical team;<sup>201</sup>
  - will be given, in a timely manner throughout the course of the research project, information relevant to their decision to continue or withdraw from participation;<sup>202</sup>
  - will be given information on their right to request the withdrawal of data or human biological materials,<sup>203</sup> including any limitations on the feasibility of that withdrawal;
- (l) Circumstances not permitting the withdrawal of data or human biological materials already collected.
- (m) The manner in which the researcher informs the participant's primary physician of their participation in the research, where applicable, and the manner in which the participant consents to have their primary physician informed.
- (n) Information concerning the possibility of commercialization of research findings;<sup>204</sup>
- (o) Real, potential, or perceived conflicts of interest on the part of the researchers or any other relevant party, as reported to the REB, that the REB finds relevant to disclose to participants;<sup>205</sup>
- (p) The methods used to disseminate the research results, including the safeguards for protecting participant privacy;<sup>206</sup>
- (q) The identity and contact information of a designated representative (member of the research team, research coordinator, research assistant or student) who can explain the research to the participants;<sup>207</sup>
- (r) The identity and contact information of individuals outside the research team whom participants may contact regarding possible research-related issues, notably the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal's local service quality and complaints commissioner and of the institution's ombudsman;<sup>208</sup>

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<sup>200</sup> TCPS2, p. 31 point d).

<sup>201</sup> *Civil Code of Québec*, art. 24, para. 3; TCPS2, art. 3.1b), p. 30 point b) and p. 31 point d).

<sup>202</sup> OG, s. 6.2.5.4; TCPS2, art. 3.1b), p. 30 point b) and p. 31 point d).

<sup>203</sup> TCPS2, art. 3.1c), p. 30 point c) and p. 31 point d).

<sup>204</sup> TCPS2, p. 31 point e).

<sup>205</sup> TCPS2, p. 31 point e).

<sup>206</sup> OG, s. 6.2.6.7 and TCPS2, p. 31 point d).

<sup>207</sup> TCPS2, p. 32 point g).

<sup>208</sup> TCPS2, p. 32 point h).



- (s) Personal information collected about participants and for what purpose;<sup>209</sup>
- (t) Specific authorization request to access the participant's Québec Health Record, where justified;<sup>210</sup>
- (u) A description of how confidentiality will be protected, as per the confidentiality clause in the institution's template, adapted for each research project;<sup>211</sup>
- (v) Planned or anticipated secondary uses of the data and samples obtained in the course of the primary research project;
- (w) Financial compensation and reimbursement for participation-related expenses;
- (x) Compensation for injury;<sup>212</sup>
- (y) Information on the rules for stopping the research, and the situations in which participants might be withdrawn.<sup>213</sup>

5.3.4 The REB may require a separate consent form for optional procedures or sub-studies (e.g., tissue, blood, genetic testing, or specimen banking).

#### 5.4 Language requirements for informed consent

5.4.1 Except where there is a justification deemed appropriate by the REB, informed consent forms should be available in both French and English.

5.4.2 If applicable/acceptable, a qualified interpreter—fluent in French or English as well as the research participant's native language—orally interprets the REB-approved consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form.

5.4.3 For projects funded by a private sponsor, the REB requires that the research team attest to the accuracy of the translated informed consent form or requires an attestation from a translator certifying that the translated informed consent form accurately reflects the contents of the REB-approved informed consent form. In the case of other projects, the translation is required to be validated by a qualified person.

5.4.4 If a research participant asks that the informed consent form be read to them, an impartial witness must be present during the reading and the entire informed consent discussion. The consent is

<sup>209</sup> *Act respecting health services and social services*, CQLR, c. S-4.2, s. 19; *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR, c. A -2.1, s. 53, 59 and 125; *Civil Code of Québec*, art. 35 and 37; *Modèle*, s. 10.3; OG, s. 6.2.4, etc.

<sup>210</sup> *Civil Code of Québec*, art. 35 and 37.

<sup>211</sup> TCPS2, p. 32 point i).

<sup>212</sup> TCPS2, p. 32 point j); GCP, s. 3.1.9.

<sup>213</sup> TCPS2, p. 32 point l); GCP, s. 6.2.3.2.

documented, along with the impartial witness's attestation that the information was accurately explained to the research participant and that the latter gave their consent.

5.4.5 Where a participant cannot express consent by signing, consent may be given verbally or with a written mark, provided that a witness is present and attests to it in writing.

## 5.5 Changes to information relevant to consent for ongoing and completed research participants

The REB will review and approve any new information to be provided to participants of ongoing research, the disclosure of potential long-term health effects during or after participation in a research project, as well as any changes to the consent form related to the transmission of new information to participants.<sup>214</sup>

5.5.1 The researcher must inform participants of any new information that might affect their willingness to continue participating in the research (e.g., significant changes to the research or potential risks thereof)<sup>215</sup> or that may affect their long-term health, even if they have completed their participation in the research.

5.5.2 The REB will determine:

- (a) The nature of the new information to be given to ongoing participants and the required documentation;
- (b) Whether a modified consent form is required for incorporating the updated information;
- (c) The process by which to allow participants to reconsider whether or not to continue participating in the research.<sup>216</sup>

5.5.3 If applicable, the REB may allow consent to be obtained orally during a phone conversation with the research participant, during which they will be provided with the updated information.<sup>217</sup> Their agreement to continue participating in the research will be documented.

5.5.4 The researcher must inform former research participants of any new information that may be relevant to their long-term health by contacting them by phone or mail, or in person, as applicable.

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<sup>214</sup> *Modèle*, s. 10.4.

<sup>215</sup> TCPS2, art. 3.3.

<sup>216</sup> Consent may be withdrawn at any time, even verbally (CCQ, art. 24, para. 3).

<sup>217</sup> *Civil Code of Québec*, art. 24, para. 2.

## 5.6 Waiver or alteration of informed consent

5.6.1 The REB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, provided that the researcher submits satisfactory justification thereof and that the REB finds and documents the following:

- The regulatory guidance framework for research and all previously expressed wishes support the waiver;
- The research involves no more than minimal risk to the participants;<sup>218</sup>
- It is impossible, practically impossible, or inopportune to seek consent or to obtain fully informed consent;
- The changes to the informed consent are unlikely to adversely affect the welfare of the participants or their relations;<sup>219</sup>
- The research could not practicably be carried out without the waiver or alteration;<sup>220</sup>
- The information is used in a manner that will ensure its confidentiality;<sup>221</sup>
- Whenever appropriate, participants will be provided with additional relevant information after participation.

5.6.2 The REB may allow research in health emergencies, by obtaining deferred informed consent of the participant or of an authorized third party, provided that the researcher submits satisfactory justification and that the REB finds and documents the following:<sup>222</sup>

- The regulatory guidance framework for research supports the waiver;
- A serious threat to the prospective participant requires immediate intervention;
- Either no standard efficacious care exists, or the research offers a real possibility of direct benefit to the participant in comparison with the standard care;
- Either the risk of harm is not greater than that involved in the standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant;
- The prospective participant is unconscious or lacks the capacity to understand the risks, methods, and purpose of the research project;
- Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so;

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<sup>218</sup> TCPS2, art. 3.7A (a).

<sup>219</sup> TCPS2, art. 3.7A (b).

<sup>220</sup> TCPS2, art. 3.7A (c).

<sup>221</sup> The REB ensures respect for the legal framework for the protection of privacy and confidentiality of personal information: *Modèle*, s. 10.3; OG, s. 6.2.4, *et seq.*; Act respecting health services and social services, CQLR, c. S-4.2, s. 19 and 19.2; Act respecting Access to documents held by public bodies and the Protection of personal information, CQLR, c. A -2.1, s. 53, 59 and 125; *Civil Code of Québec*, art. 35 and 37; *Québec Charter of Human Rights and Freedoms*, CQLR, c. C-12, art. 5.

<sup>222</sup> TCPS2, art. 3.8.

- No relevant prior directive by the participant is known to exist.
- Informed consent will be sought in a timely fashion as soon as the participant regains decision-making capacity or a legal representative is found, as a condition of continued participation.

## 5.7 Consent for research involving individuals who lack capacity

5.7.1 For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether or not to participate, the REB must ensure that the following minimum conditions are met:

- Insofar as possible, the researcher will involve each participant in the decision-making process and document their assent.<sup>223</sup> Any participant who dissents while understanding the nature and consequences of the study may not participate in the research.<sup>224</sup>
- The researcher seeks consent from the prospective participant's legal representative.<sup>225</sup> This legal representative cannot be the researcher or any other member of the research team.<sup>226</sup>
- Whether or not the research affects the integrity of the prospective participant, the researcher must demonstrate that:
  - if the research involves only one participant, it is being carried out for their health; if the research involves a group of participants, it is being carried out for the benefit of persons of the same age, disease, or disability characteristics as the group members.<sup>227</sup>
  - the inherent risks of the research, considering the participant's state of health and personal condition, shall not be disproportionate to the benefits one can reasonably expect.<sup>228</sup>

5.7.2 When consent was granted by the legal representative, and the participant acquires or regains capacity during the research, the researcher will seek the participant's consent, insofar as possible, as a condition of continued participation.<sup>229</sup>

## 6 REFERENCES

See footnotes.

<sup>223</sup> TCPS2, art. 3.9.

<sup>224</sup> *Civil Code of Québec*, art. 21, para. 3.

<sup>225</sup> *Civil Code of Québec*, art. 21, para. 5 and 6. Maintaining consent on an ongoing basis: TCPS2, art. 3.3 and 3.9 (b).

<sup>226</sup> TCPS2, art. 3.9 (c).

<sup>227</sup> *Modèle*, s. 10.3; TCPS2, art. 3.9 (d). Research interfering with the integrity of the person: *Civil Code of Québec*, art. 21, para. 2.

<sup>228</sup> *Modèle*, s. 10.3; TCPS2, art. 3.9 (d). Research interfering with the integrity of the person: *Civil Code of Québec*, art. 10 and 21, para. 1.

<sup>229</sup> TCPS2, art. 3.9 (e).

**REB-SOP 404.001**

Research Ethics Board  
Standard Operating Procedure

**7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 404.001		

<b>Title:</b>	Ongoing REB Review Activities
<b>SOP code:</b>	REB-SOP 405A.001
<b>N2/CAREB SOP code:</b>	SOP 404.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This SOP describes the procedures related to the ongoing review activities that occur after the initial Research Ethics Board (REB) approval of a research project and prior to the next formally scheduled annual ethics approval renewal.

**2 SCOPE**

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

**3 RESPONSIBILITIES**

All REB members, RRO staff that supports the REB, and researchers are responsible for ensuring that the requirements of this SOP are met.

The researcher is responsible for reporting to the REB *any new information* generated throughout the course of the research that might affect the rights, safety, and welfare of research participants, including reportable events that meet the reporting criteria as per this SOP.

The researcher is responsible for reporting to the REB *any information about the conduct of the research* that could affect the rights, safety, and welfare of research participants, including information about any serious or continuing non-compliance.

When action is taken by the REB to protect the rights, safety, and welfare of participants (e.g., in the event of an unanticipated problem involving risks to participants or others), the REB is responsible for communicating the decision to the researcher and, at the discretion of the board, to the relevant organizational official(s). The REB has the authority to notify the sponsor and/or the appropriate regulatory authorities of any event or exceptional circumstances that meet the reporting criteria. The REB may delegate the task of reporting to the regulatory authorities to the organization.

The REB Chair or designee is responsible for reviewing all reportable events submitted to the REB as well as any proposed amendment to the research, and for determining the type of review (i.e., delegated or full board) or actions required. The REB must find that the approval criteria have been met before giving its approval.

The REB members are responsible for reviewing any new information, reportable events, or proposed amendments that are assigned to them or to a full board meeting, and for recommending the appropriate course of action, where applicable.

#### **4 DEFINITIONS**

See glossary.

#### **5 PROCEDURES**

In addition to the formally scheduled annual ethics approval renewal, the REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety, and/or welfare of research participants, and/or for which a preventive or corrective action is possible.

Such information may include: amendments, reportable events, relevant reports, or any other new information that may affect the safety and welfare of the research participants or the conduct of the research.

Except where necessary to eliminate apparent immediate hazards to the participants, modifications may not be initiated without prior REB approval. If changes are made to eliminate immediate hazards, the researcher must notify the REB immediately.

#### **Multicentre research in Québec**

- The REB will apply this SOP to studies for which it acts as the reviewing REB for multicentre research within the Québec health and social services network.

- In a multicentre study conducted by different researchers at participating institutions with the same sponsor, each investigator is responsible for submitting reportable events to the reviewing REB. The local researcher must submit in accordance with this SOP.
- Should researchers consider that the reportable event requires institutional involvement to ensure the safety and welfare of local participants, they may choose to inform the mandated person (“personne formellement mandatée”).
- An investigator within the Québec health and social services network who submits an amendment for approval to the reviewing REB must forward the approved amended documents, as well as a copy of the original document with the approved changes highlighted, to the mandated person at each public institution where the research is taking place.
- For multicentre trials within the Québec health and social services network, all participating sites covered by the reviewing REB’s approval will be considered local.
- Requests to convert a research project into a multicentre project or to add a site must be submitted via the Nagano platform, using the appropriate form.

## 5.1 Amendments to approved research

- 5.1.1 The researcher is responsible for submitting to the REB any change to an approved research project. Changes may include, for example, modifications to the research protocol, to the consent form, to the Investigator’s Brochure (IB) or product monograph (PM), to the participant materials (e.g., wallet cards, diary, recruitment materials), to the researcher, etc.
- 5.1.2 When the amendment is the result of a sponsor safety notice or action letter, this document must be appended to the amendment request.
- 5.1.3 When the amendments include a change to the consent form, the researcher must indicate their recommendation as to whether the new information should be provided to the current and/or past research participants.<sup>230</sup>
- 5.1.4 The REB Chair or designee pre-reviews the amendment to determine the appropriate level of REB review required (i.e., full board or delegated review) in accordance with REB SOP Delegated Review. If the proposed change represents more than minimal risk, it must be reviewed by the REB at a full board meeting. Amendments that may be classified as more than minimal risk may include:
- Addition of genetic testing, new genetic tests, or tissue banking where genetic testing may or will be performed;
  - Addition of an open label extension phase following a randomized trial;
  - Emergency amendments that arise because of participant safety, which may include, but are not limited to:

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<sup>230</sup> *Civil Code of Québec*, art. 10, para. 2, 20 and 21.



- A change in the recruitment that may affect confidentiality or create the perception of coercion;
- A change in the experimental procedures or the research population.

5.1.5 For amendments requiring full board review, the designated RRO staff that supports the REB places the amendment on the agenda of the next available full board meeting. For amendments that meet the criteria for delegated review, the designated RRO staff that supports the REB will assign the amendment to the designated reviewer(s).

5.1.6 When an amendment involves revisions to the consent form, the REB will consider the recommendations of the researcher in determining if, how, and when the new information should be provided to the research participants and whether re-consent is required.

5.1.7 Except when necessary to eliminate an immediate hazard to the participants, amendments to approved research may not be implemented prior to REB approval. Changes to a research project that was initiated without prior REB review in order to eliminate an immediate hazard to the research participants must be reported to the REB immediately by the researcher.

5.1.8 Amendments considered to be administrative in nature (e.g., change of address or change in administrative research staff) that have no impact on the participants, or their welfare may be submitted at the time of the annual research project renewal.

5.1.9 The REB must find that the approval criteria are still met in order to approve the amendments. The REB may simply acknowledge receipt of some documents submitted in the context of an amendment.

## **5.2 Reportable events**

The researcher is responsible for submitting reportable events or new findings that meet the REB's reporting criteria, in accordance with this SOP and within the time frame specified in section 5.4. All reports submitted to the REB must have all research participant identifiers removed (i.e., participant number only); The researcher must determine if an event meets the REB reporting criteria:

As a general rule, any new information that would require a modification to the Investigator's Brochure, the research itself, or the consent form, or would prompt an action by the REB to ensure protection of the research participants; any unanticipated problem, event, or report that could significantly impact the overall conduct of the research or alter the participants' willingness to participate or the REB's approval or favourable opinion to continue the research, must be reported to the REB.

The researcher must report the following situations to the REB, via Nagano, within the time frame specified by the REB in section 5.4.

5.2.1 Local serious adverse events (SAE):

- The researcher must report to the REB any local serious adverse event that, in the opinion of the researcher, meets all of the following criteria:
  - (a) Unexpected;
  - (b) Related or possibly related to participation in the research;
  - (c) Suggests that the research places research participants or others at a greater risk of harm than previously identified at time of review and approval.
  
- The report submitted to the REB, via Nagano, must include all of the following information:
  - (a) The description of the adverse event;
  - (b) Previous safety reports concerning similar events, if available;
  - (c) An analysis of the significance of the adverse event in question;
  - (d) If applicable, the proposed modifications to the conduct of the research project and/or to the consent form and/or to a list of corrective actions to be taken in response to the event;
  - (e) A copy of the sponsor's report, if available.
  
- Any applicable form required by the sponsor, if any, (e.g., SAE form), must be uploaded to Nagano.
  
- Once a local SAE is reported to the REB, subsequent important follow-up reports related to the SAE should be submitted as soon as available. The follow-up reports from the sponsor must be transmitted when updating the reportable event. All initial and subsequent follow-up reports will be retained with the initial declaration.

#### 5.2.2 Non-local (external) serious adverse events (SAE):

- The researcher must report to the REB any non-local serious adverse event that, in the opinion of the researcher, meets all of the following criteria:
  - (a) Unexpected;
  - (b) Related or possibly related to participation in the research;
  - (c) Suggests that the research places research participants or others at a greater risk of harm than previously identified at time of review and approval;

**AND**

- (d) Requires a change to the research conduct and/or to the consent form and/or requires immediate notification to the participants for safety reasons.
  
- The report submitted to the REB, via Nagano, must include all of the information listed in section 5.2.1.

#### 5.2.3 Deviations from previously approved research

The researcher must report to the REB, in Nagano, any local deviation that meets the following reporting criteria:

- Deviations that, in the opinion of the researcher, jeopardize the safety of research participants, the research efficacy, data integrity, or that could otherwise impact the participants' rights, safety, or welfare;
- Any sponsor-approved waiver to the participant eligibility criteria;
- Any change in the approved process for obtaining consent (e.g., improper translation, current consent form not used);
- Any deviation that leads to an SAE.

#### 5.2.4 Privacy breaches

The researcher must report to the REB, in Nagano, any unauthorized collection, use, or disclosure of personal information including, but not limited to:

- The collection, use, and disclosure of personal information that is not in compliance with local legislation or the applicable regulations;
- Circumstances where personal information is stolen, lost, or subject to unauthorized use or disclosure, or where records containing personal information are subjected to unauthorized copying, modifications, or disposal;
- Any unauthorized collection, use, or disclosure of personal information done in the context of the research project, but that was not authorized for that research project or approved by the REB.

The breach must be reported to the REB and, as applicable, to the appropriate organizational official(s) as soon as the researcher becomes aware of the breach.

#### 5.2.5 Research participant complaint

The researcher must report to the REB, in Nagano, any concern raised by a participant about their rights as a research participant or about ethical issues related to the research, in accordance with SOP 406.001.

#### 5.2.6 Other reportable events and information

The researcher is responsible for reporting to the REB, using the appropriate Nagano forms, circumstances such as:

- Any change to the risks or potential benefits of the research, including:
  - An interim analysis indicating that participants have a rate of response to treatment different than expected;
  - Safety monitoring indicating that a particular side effect is more severe or more frequent than expected;
  - Information published from another research project showing that an arm of the research is of no therapeutic value;

- A change in Health Canada or FDA safety labelling, a modification to the approval status, or the withdrawal from market of a drug, device, health product, genetic therapy, or biologic used in the research project;
- Any unanticipated problem or other event that could significantly impact the conduct of the research at the site (e.g., concerns of non-compliance, institutional feasibility issues, etc.);
- Findings of an inspection or audit relevant to the safety and welfare of the participants: Following a Health Canada inspection, an FDA or other regulatory audit, an internal quality assurance audit, or other audits at the site, the researcher must report to the REB a summary of any relevant audit or inspection findings relevant to the safety and welfare of the participants.

### 5.3 Other reports

The researcher is responsible for submitting to the REB, using Nagano, reports related to the research project in accordance with section 5.4:

- If the sponsor requires the submission to the REB of reports that are generated in accordance with the research protocol or that are routine or random **and that do not require action** to protect the safety and welfare of research participants, these reports may be submitted at the time of the annual renewal of ethics approval. The REB will acknowledge receipt of such reports.

### 5.4 Time frames for reporting events to the REB

The REB must be notified of reportable events, as described in this SOP, in accordance with the following timelines:

REB notification of...	Time delay (calendar days)	Follow-up required
<b>5.4.1 Amendments</b>		
(a) Undertaken immediately to protect participants	Immediately	REB review and approval of amendments
(b) All other amendments	Report prior to introducing any change	REB review and approval are required prior to implementation of the amendment
<b>5.4.2 All reportable events as described herein</b>		
(a) Reportable events in the context of death and/or life-threatening reactions	Within 7 days of researcher becoming aware of the event	A detailed report containing an analysis of the event, its consequences, and corrective measures taken must be submitted within 8 days of the first report
(b) All other reportable events	Within 15 days of researcher becoming aware of the event	
(c) Any new information that may adversely affect the safety of the research participants or the conduct of the research	Within 15 days of researcher becoming aware of this information	

REB notification of...	Time delay (calendar days)	Follow-up required
<b>5.4.3 Other reports</b>		
Scheduled, routine, or random reports without identified impact on participant safety or welfare or required changes	Submit at the time of annual renewal of ethics approval if required by the sponsor	REB acknowledgement letter will be sent

**5.5 Review of reportable events by the REB**

5.5.1 The RRO staff that supports the REB will screen the report for completeness and to ensure that the reportable event form was attached, where applicable.

5.5.2 The RRO staff that supports the REB may send the submission back to the researcher to request clarifications, missing documents, or additional information.

5.5.3 The RRO staff that supports the REB will assign the submission to REB reviewer(s).

5.5.4 The assigned REB reviewer(s) will conduct a review of the reports and determine if any action or follow-up is required. The assigned reviewer(s) may request further information from the researcher.

5.5.5 When reviewing a reportable event, the REB must:

- Assess the appropriateness of any corrective or preventive measure proposed by the sponsor and/or researcher;
- Consider any additional appropriate measure that may or may not have been identified or proposed by the sponsor and/or researcher;
- Consider whether the project still meets the requirements for REB approval, in particular whether the risks to research participants are still minimized and reasonable in relation to the anticipated benefits (if any), and whether the knowledge that may reasonably be expected to accrue from the project is sufficiently important;
- Consider whether some or all of the research participants should be notified of the events (i.e., if they may affect participants’ willingness to continue participating in the research);
- Consider whether suspension or termination of the ethics approval for the research project is warranted.

5.5.6 Privacy breaches are reviewed by the REB Chair or designee, and any recommendation, including remedial action, is determined in consultation with the institution’s representatives.

5.5.7 If the event does not raise concerns and does not appear to involve risks to the research participants or others, the REB Chair or designee acknowledges the report, and no further action is required.

5.5.8 If the REB Chair or designee determines that immediate action is required to protect the safety and welfare of research participants, they may:

- Put recruitment of new participants on hold, including participants in the screening process;
- Suspend ethics approval of the research (put the project on hold);
- Take any other action deemed necessary.

5.5.9 If the event raises concerns or involves risk to research participants such that REB action is required, the event must subsequently be reviewed at a full board meeting.

5.5.10 For reportable events reviewed at a full board meeting, the REB determines whether further action is required. Possible actions that could be taken by the REB include, but are not limited to:

- Placing the research on hold pending receipt of further information from the researcher;
- Requesting modifications to the research;
- Requesting modifications to the consent form;
- Requesting additional information be provided to past participants;
- Requesting current participants be notified when such information might affect their willingness to continue taking part in the research, and requiring that current participants re-consent to ongoing participation;
- Altering the frequency of the annual renewal of ethics approval;
- Observing the research or the consent process;
- Requiring additional training by the researcher and research staff;
- Terminating or suspending the research;
- If the REB determines that the event does not raise concerns about risks to the research participants, the REB may decide that no further action is required.

5.5.11 Amendments to consent:

5.5.11.1 Information relevant to consent that becomes available during a research project or after it has been completed:

- The REB reviews and approves the new information to be brought to the attention of participants in an ongoing project, the process for disclosing potential long-term health effects during or after research participation, and changes to the consent form that require that new information be transmitted to participants.<sup>231</sup>

5.5.11.2 The researcher informs the participants of any new information that may affect their willingness to continue participating in the research (e.g., significant change in the project or its associated risks),<sup>232</sup>

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<sup>231</sup> *Modèle*, s. 10.4.

<sup>232</sup> TCPS2, art. 3.3.

as well as any new information regarding the potential impacts of the research project on their long-term health, even if their participation has already ended.

5.5.11.3 The REB will determine:

- (a) The nature of the new information to be transmitted to participants whose participation is ongoing, and the documentation that is required;
- (b) Whether a modified consent form, containing the new information, is required;
- (c) The process that must be put in place to allow participants to re-consent to participating in the ongoing research project.<sup>233</sup>

5.5.11.4 If applicable, the REB may allow consent to be obtained verbally via a telephone conversation during which the updated information would be provided to a research participant.<sup>234</sup> The participant's consent to continue participating will be documented.

5.5.11.5 The researcher must inform former research participants of any new information that may be relevant to their long-term health by contacting them by phone, mail, or in person, where applicable.

## 6 REFERENCES

See footnotes and the following references:

- Canadian Association of Research Ethics Boards. History of the Development of the Guidance on Reporting of Unanticipated Problems Including Adverse Events to Research Ethics Boards in Canada, July 2010.
- ICH E2A, II.A.1
- ICH E6: Good Clinical Practice (GCP), 5.17
- N2/CAREB-ACCER REB SOP, published September 29, 2014 [Online], <https://oicronca.app.box.com/s/95k7ydj574579ajvbe06/folder/3403170068> (Consulted January 28, 2019).
- Office for Human Research Protections (OHRP) and Department of Health and Human Services (HHS) – Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, <http://www.hhs.gov/ohrp/policy/advevtguid.pdf> (Consulted January 28, 2019).
- Canadian Institutes of Health Research (CIHR), 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, 2014 (TCPS2) [Online] [[http://www.ger.ethique.gc.ca/pdf/fra/eptc2-2014/EPTC\\_2\\_FINALE\\_Web.pdf](http://www.ger.ethique.gc.ca/pdf/fra/eptc2-2014/EPTC_2_FINALE_Web.pdf)] (Consulted January 28, 2019).
- U.S. Food and Drug Administration. Code of Federal Regulations, Title 21, Part 56.108 (b).

<sup>233</sup> Recall that consent to participate in research may be withdrawn at any time, even verbally. See: *Civil Code of Québec*, art. 24, para. 3.

<sup>234</sup> *Civil Code of Québec*, art. 24, para. 2.

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- U.S. Department of Health and Human Services. Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting, January 2009. [Online] <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079753.pdf> (Consulted January 28, 2019).

**7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 405A.001		



# REB-SOP 406.001

Research Ethics Board  
Standard Operating Procedure

<b>Title:</b>	Annual Review – Renewal of REB Approval
<b>SOP code:</b>	REB-SOP 406.001
<b>N2/CAREB SOP code:</b>	SOP 405.002
<b>Effective date:</b>	2021-09-30

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## 1 PURPOSE

This standard operating procedure (SOP) describes the procedures and criteria for the annual renewal of ethics approval by 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 designated REB staff are responsible for ensuring that the requirements of this SOP are met.

## 4 DEFINITIONS

See glossary.

## 5 PROCEDURES

REBs must establish procedures for reviewing applications for annual renewal of ethics approval for approved research involving human participants.<sup>235</sup> Renewal of ethics approval takes place at appropriate intervals, but at least once a year.<sup>236</sup> Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

### 5.1 Review of the application for annual renewal

- 5.1.1 The level of REB review (full board meeting or delegated review) will be determined according to criteria set out in the REB SOP on Delegated Review.
- 5.1.2 The REB may determine that the research ethics approval requires renewing more often than once per year, by considering the following:<sup>237</sup>
- The risks posed by the research;
  - The vulnerability of the population under study;
  - The belief by the REB that, for whatever other reason, more frequent review is required.
- 5.1.3 At a minimum, the REB requires that an application for annual renewal of ethics approval be submitted once per year until the end of the research (see REB SOP on Research Completion).<sup>238</sup>
- 5.1.4 The researcher is required to submit an application for annual renewal of ethics approval, at a frequency to be determined by the REB and which will be defined at the time of initial approval of the research, or at any other time.<sup>239</sup>

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<sup>235</sup> *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, measure 15, hereafter PAM; *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 9, hereafter OG; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 13, hereafter *Modèle*; *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, p. 1040, hereafter *Avis*; *Note de clarification relative au concept de suivi continu de l'éthique des projets*, Note 2, Gouvernement du Québec, Direction générale adjointe de l'évaluation, de la recherche et des affaires extérieures, Unité de l'éthique, May 2007, hereafter Note 2.

<sup>236</sup> *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.1.4; hereafter GCP; *Modèle*, s. 11; Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics, 2014, p. 90, hereafter TCPS2; OG, s. 2.

<sup>237</sup> TCPS2, p. 91.

<sup>238</sup> GCP, s. 3.1.4; *Modèle*, s. 11; TCPS2, p. 90; OG, s. 2.

<sup>239</sup> TCPS2, art. 6.14; *Avis*, p. 1040; *Modèle*, s. 13; OG, s. 9; GCP, s. 3.3.4.

- 5.1.5 If the researcher receives instructions from the sponsor to report events or submit documents not required by the REB according to the SOP on activities related to current review, the researcher may nonetheless submit them to the REB at the time of the annual renewal of ethics approval.
- 5.1.6 Applications for annual renewal of ethics approval are due at least four weeks prior to the deadline for ethics approval, regardless of the type of review.
- 5.1.7 To assist the researchers in submitting on time, courtesy reminder(s) prior to the deadline may be sent.
- 5.1.8 The designated REB support staff reviews the application for completeness. Incomplete applications may be returned to the researcher.
- 5.1.9 The designated REB support staff will add the application to the agenda of the next REB meeting, if the research meets the criteria for full board review according to the related SOP.
- 5.1.10 The REB support staff will forward the application to the designated REB reviewer(s). A member of the REB support staff may also process the application if this is specifically provided for in the REB delegation log.
- 5.1.11 The REB may request additional information or clarification, as necessary, and will make a decision regarding annual renewal of ethics approval for continued conduct of the research.
- 5.1.12 Decisions of delegated reviews of applications for annual renewal of ethics approval will be added to the agenda of the next REB full board meeting.

## **5.2 Criteria for REB determinations**

- 5.2.1 To grant annual renewal of ethics approval for the research, the REB must determine that:
- Any and all material changes have been reported to the REB;
  - Any new information that might affect the safety or the welfare of research participants has been reported to the REB;
- 5.2.2 The REB may also:
- Request changes to documents related to the study;
  - Request changes to the interval for renewal of ethics approval;
  - Impose special precautions;
  - Suspend or terminate REB approval.

**5.3 Applications for annual renewal of ethics approval not received by the expiry date**

- 5.3.1 If an application for annual renewal of ethics approval review is not submitted by the expiry date, a warning, suspension notice, or notice of closure could be issued to the researcher.
- 5.3.2 At the expiry of ethics approval, the researcher must suspend all research activities associated with the research project, as long as the termination does not endanger the safety of the participants. The researcher is responsible for notifying the REB if there is a need to continue research-related medical treatment to ensure the safety and welfare of the current participants.
- 5.3.3 The researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses.
- 5.3.4 Renewal granted by the REB is not retroactive, i.e., there will be no ethics approval for the period covering the lapse.

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 406.001		

# REB-SOP 407.001

Research Ethics Board  
Standard Operating Procedure

<b>Title:</b>	Suspension or Termination of REB Approval
<b>SOP code:</b>	REB-SOP 407.001
<b>N2/CAREB SOP code:</b>	SOP 407.002
<b>Effective date:</b>	2021-09-30

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### 1 PURPOSE

This standard operating procedure (SOP) describes the procedures associated with the suspension or termination of the Research Ethics Board’s (REB) approval of research.

### 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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

The REB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of REB approval for the research being considered.<sup>240</sup>

The researcher is responsible for notifying the REB and the institution of any suspensions or terminations of the research by the sponsor or by a regulatory agency, and for providing a detailed explanation for the action.<sup>241</sup>

A researcher may decide to voluntarily suspend or terminate some or all of the research activities;<sup>242</sup> however, this is not considered a suspension or termination of approval by the REB.

The REB Chair or designee is not authorized to terminate REB approval on their own; however, the REB Chair or designee is authorized to suspend REB approval. The suspension is then reported to the REB at its next full board meeting. The REB is authorized to terminate its approval following its review at a full board meeting.<sup>243</sup>

The REB Chair or designee shall notify the researcher and the institution's official(s), of any suspension or termination of REB approval of the research. The REB Chair or designee also has the authority to notify the regulatory authorities (as applicable).

#### **4 DEFINITIONS**

See glossary.

#### **5 PROCEDURES**

As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate ethics approval,<sup>244</sup> for example, if the risks to the research participants are determined to be unreasonably high relative to the benefits that might reasonably be expected.<sup>245</sup>

The REB also has the authority to suspend participant recruitment pending the receipt of additional information.

A decision to suspend or terminate the REB's approval of the research must take into account the safety, rights, and welfare of the participants already enrolled in the research, specifically, how to continue to ensure the quality of care received by the participants, and how and when to notify participants of the suspension or termination of the research.

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<sup>240</sup> *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 4.2, hereafter *Modèle*; *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.1.2, hereafter GCP.

<sup>241</sup> *Modèle*, s. 13.2.

<sup>242</sup> See also the SOP on Research Completion.

<sup>243</sup> *Modèle*, s. 4.2; GCP, s. 3.1.2; Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics, 2014, art. 6.3, hereafter TCPS2.

<sup>244</sup> *Modèle*, s. 4.2; GCP, s. 3.1.2; TCPS2, art. 6.3.

<sup>245</sup> *Civil Code of Québec*, art. 20 and 21; *Modèle*, s. 10.3; TCPS2, p. 22-25 and art. 2.9 and 11.4 (a); OG, s. 6.2.1.2, *Avis*, p. 1039; PAM, p. 23.

## 5.1 Suspension or termination of research by the sponsor

- 5.1.1 The research sponsor may suspend or terminate the research (e.g., after reviewing the results of interim analyses, due to inadequate drug availability, in response to a Data and Safety Monitoring Board (DSMB) recommendation, due to pre-planned stopping criteria, etc.).
- 5.1.2 The researcher must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action.<sup>246</sup>
- 5.1.3 Reports of suspensions or terminations of research projects by the sponsor will be forwarded to the REB Chair or designee for review.
- 5.1.4 If the REB Chair or designee decides to suspend ethics approval of the research, they must notify the REB at its next full board meeting.
- 5.1.5 If REB approval is suspended, a subsequent review must be conducted, and the REB suspension must be lifted prior to resumption of the research following the sponsor's lifting of a suspension.

## 5.2 Suspension or termination of REB approval

- 5.2.1 If any concerns are raised during the REB's continuing review of the research that are related to new information, to the conduct of the research, including complaints to the administrative authorities designated in the consent form or to the person responsible for the conduct of the research project, the REB may suspend or terminate its approval of the research, as appropriate. These concerns may include:
- Continuation of the research not permitting an acceptable potential risk/benefit ratio;
  - The research not being conducted in accordance with the REB-approved protocol or REB requirements;
  - The research being associated with unexpected or serious harm to the participants (i.e., as may be determined following REB review of reportable events or DSMB reports);
  - Falsification of research records or data;
  - Failure to comply with prior conditions imposed by the REB (i.e., in the case of a suspension or approval with modifications);
  - Failure to apply for an annual renewal of ethics approval prior to the expiry date, which entails *de facto* suspension. Failure to submit an application for continuing review within 30 days following the expiry date may result in the termination of the research project;
  - Repeated or deliberate failure to properly obtain consent from research participants or to properly document the consent process;

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<sup>246</sup> *Modèle*, s. 13.2.

- Repeated or deliberate failure to limit administration of an investigational drug or device to those research participants under the researcher's supervision;
- Repeated or deliberate failure to comply with conditions placed on the research by the REB, the sponsor, or regulatory agencies;
- Repeated or deliberate failure to obtain prior REB approval of amendments or modifications to the research;
- Repeated or deliberate failure to maintain accurate research records or to submit required reportable event reports to the REB;

5.2.2 The REB Chair or designee is authorized to suspend ethics approval of research. If the REB Chair or designee suspends approval of the research, they must notify the REB at its next full board meeting.

5.2.3 The REB is authorized to terminate its approval of the research following a review at a full board meeting.

5.2.4 Prior to suspending or terminating its approval, the REB must consider:

- The risks to current participants;
- The actions to protect the safety, rights, and welfare of current participants;
- The appropriate care and monitoring of research participants;
- The safety impact of withdrawing enrolled participants and the specific procedures for their safe withdrawal;
- Whether participants should be informed of the termination or suspension;
- Whether adverse events or outcomes should subsequently be reported to the REB;
- Identification of a time frame in which the corrective measures are to be implemented.

5.2.5 When the REB suspends or terminates ethics approval, no further activities can take place other than the request for amendments or the submission of reportable events.

5.2.6 If research approval is suspended or terminated, the REB Chair or designee will issue a formal letter to the researcher with the reason(s) for the REB's action and the corrective measures proposed by the REB, if any.

5.2.7 When REB approval of a research project or its conduct has been suspended, the suspension may be lifted after corrective actions have been taken to the satisfaction of the REB and other third parties involved, if any.

### **5.3 Reporting suspensions or terminations**

5.3.1 The REB Chair or designee will report any suspension or termination of REB approval to the official formally mandated to authorize research in the network institution and has the authority to notify the regulatory authorities (as applicable), the affiliated academic institutions, and the sponsor.



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## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

SOP code	Effective date	Summary of changes
REB-SOP 407.001		

<b>Title:</b>	Research Completion
<b>SOP code:</b>	REB-SOP 408.001
<b>N2/CAREB SOP code:</b>	SOP 406.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the procedures for the closure of research with 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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

**4 DEFINITIONS**

See glossary.

## 5 PROCEDURES

The completion of research must be reported to the REB.<sup>247</sup> This final report by the researcher will enable the REB to close its files.

The final report contains information required by the REB<sup>248</sup>.

### 5.1 Determining when research can be closed with the REB

- 5.1.1 The researcher will submit a research closure report to the REB<sup>249</sup> when there are no further participants under REB jurisdiction, all new data collection is complete, the analysis for the study objective has been completed according to the conditions set out in the research protocol approved by the REB, and the sponsor closeout activities, where applicable, have been completed.
- 5.1.2 The researcher will also submit a research closure report to the REB when the study is prematurely, but permanently, stopped.
- 5.1.3 The REB Chair or designee or a designated support staff member will review the research closure application and request any outstanding information, clarification, or documentation from the researcher, if needed.
- 5.1.4 The REB Chair or designee or a designated support staff member will review the submission and issue a letter of acknowledgement to the researcher. The research status will change from “*Approved*” to “*Closed*.”
- 5.1.5 Once a research project is “*Closed*,” no further submissions for that research will be permitted. If required, however, the researcher may still submit relevant documents for the REB’s consideration. If applicable, further investigation and/or action may be undertaken by the REB.
- 5.1.6 If the sponsor requests additional data following the closure of the research, a request for approval shall be made to the REB. Access to patient or user records requires the consent of the patient or user (or their legal representative) or the authorization of the Director of Professional Services (DPS) at the institution.

## 6 REFERENCES

See footnotes.

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<sup>247</sup> *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 9.6, hereafter OG; *Modèle de règles de fonctionnement d’un comité d’éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 13.2, hereafter *Modèle*.

<sup>248</sup> *Modèle*, s. 13.2.

<sup>249</sup> OG, s. 9.7.

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**7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 408.001		

<b>Title:</b>	Communication of REB Decisions
<b>SOP code:</b>	REB-SOP 409.001
<b>N2/CAREB SOP code:</b>	SOP 601.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes communications between the Research Ethics Board (REB) and the researcher and their research team.

**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 RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

**4 DEFINITIONS**

See glossary.

**5 PROCEDURES**

In the interest of enhancing the protection of human research participants, it is important for the REB to foster collaboration and open communication between and among the REB, researchers, research staff, and institution

officials. This applies not only to communications related to a specific research project, but also to communications related to ethical issues and to REB policies and procedures.

All researchers participating in an REB-approved research project shall be informed, in writing, of all determinations made by the REB regarding a specific research project.<sup>250</sup>

Feedback from researchers is encouraged and is considered an opportunity to review and improve the functioning of the REB as well as the procedures of the REB office.

In order to facilitate clear and accurate communication with researchers and research staff, the REB will follow standardized notification and documentation procedures.

Communications between REB members and researchers or other parties involved in a review application will be documented in REB records.<sup>251</sup>

## 5.1 Notification of REB decisions

5.1.1 The REB will notify the researcher and their research staff, in writing and within a reasonable time frame, of the REB's decision following a review for ethics approval of new research (except under special circumstances, within 15 business days or less<sup>252</sup> or, in the case of multicentre trials, 5 business days or less<sup>253</sup>).

5.1.2 The REB will notify the researcher and their research staff, in writing and within a reasonable time frame, of the REB's decision regarding an application for modifications to approved research, an application for continuing review, or reportable events<sup>254</sup>.

5.1.3 The document specifying the REB decision (official document on Nagano) will be sent to the researcher(s).<sup>255</sup>

5.1.4 All communications regarding a research project will take place on the Nagano platform. In the rare instances where communication takes place outside Nagano (e.g., conflict of interest declarations, if any), the researcher will be asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB. All communications outside Nagano will be uploaded to Nagano, using appropriate security measures to ensure confidentiality, where applicable.

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<sup>250</sup> *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 8, hereafter OG; *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, art. 6.13, hereafter TCPS2.

<sup>251</sup> OG, s. 10.8; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 14, hereafter *Modèle*.

<sup>252</sup> Ministère de la Santé et des Services sociaux, *Mesures correctives relatives au mode de fonctionnement des comités d'éthique de la recherche*, Rapport d'enquête, 2007.

<sup>253</sup> Ministère de la Santé et des Services sociaux, *Cadre de référence pour l'examen éthique des projets de recherche multicentrique*, April 2016.

<sup>254</sup> OG, s. 6 and 8; TCPS2, art. 6.13; *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.1.2, hereafter GCP; *Modèle*, s. 11.4.

<sup>255</sup> *Modèle*, s. 11.4.2.

5.1.5 Upon receipt of the researcher’s response to the REB decision document, the REB will follow-up with the researcher and/or their staff to request any additional clarifications, as needed.

5.1.6 Once all the REB conditions have been met, the REB will issue an approval document,<sup>256</sup> accompanied by or including any other attestation required from the REB (e.g., REBA, FWA, CTSU, etc.).

## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

SOP code	Effective date	Summary of changes
REB-SOP 409.001		

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<sup>256</sup> *Modèle*, s. 11.4.

<b>Title:</b>	REB Review During Publicly Declared Emergencies
<b>SOP code:</b>	REB-SOP 501.001
<b>N2/CAREB SOP code:</b>	SOP 501.002
<b>Effective date:</b>	2019-01-04

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**1 PURPOSE**

This standard operating procedure (SOP) describes the research ethics review procedures during a publicly declared emergency.

**2 SCOPE**

This SOP pertains to research ethics boards (REBs) that review human-participant research in compliance with applicable regulations and guidelines.

**3 RESPONSIBILITIES**

All REB members and RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

**4 DEFINITIONS**

See glossary.



## 5 PROCEDURES

A publicly declared emergency is an emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official in accordance with legislation and/or public policy.<sup>257</sup> Publicly declared emergencies arise suddenly or unexpectedly and require urgent or rapid responses. Examples include natural disasters, large communicable disease outbreaks, environmental disasters, and humanitarian emergencies. Such emergencies may represent significant risks for research participants in ongoing research or in new research. Potential research participants who may not normally be considered vulnerable may become so by the very nature of the public emergencies, while those already vulnerable may become acutely so.<sup>258</sup> Special attention and effort should be given to upholding the core principles of Respect for Persons, Concern for Welfare, and Justice.<sup>259</sup>

During publicly declared emergencies, the REB must have established procedures in place to continue to provide the necessary research ethics oversight.<sup>260</sup> Research ethics review during publicly declared emergencies may require the use of innovative practices. Depending on the nature of the emergency, REBs might not be able to meet in person, and delegated review procedures may have to be designed to respond to urgent opportunities for research. Any relaxation of the usual procedural requirements for review should be proportionate to the complexity and urgency of the emergency, as well as to the risks posed by the research under review.<sup>261</sup> Any modifications made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified.

### 5.1 Procedures for ethics review in emergency situations

- 5.1.1 Subject to a publicly declared emergency, exceptional ethics review processes may be instituted.<sup>262</sup>
- 5.1.2 The REB Chair or designee may suspend the currently established REB meeting quorum, in which case delegated review with the necessary expertise would be established for the duration of the publicly declared emergency.
- 5.1.3 The expertise required for the quorum may be established in the following order of priority:
- REB members from the institution;
  - REB members from another institution in the network;
  - Other individuals with the required expertise;
- 5.1.4 The current REB Chair or designee, or any other individual appointed as interim, may serve as acting REB Chair.
- 5.1.5 Annual renewals of ongoing research may be done by delegated review or by support staff named by the REB Chair or designee.

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<sup>257</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – Interagency Advisory Panel on Research Ethics*, 2014, p. 96, hereafter TCPS2.

<sup>258</sup> TCPS2, p. 98.

<sup>259</sup> TCPS2, p. 96.

<sup>260</sup> TCPS2, art. 6.21.

<sup>261</sup> TCPS2, art. 6.23.

<sup>262</sup> TCPS2, art. 6.22.

- 5.1.6 The REB Chair or designee may refer the ethics review of new research and the oversight of ongoing research to another member REB of the Québec health and social services network.
- 5.1.7 Any modifications made to the application of policies and procedures for the review and oversight of research during a publicly declared emergency must be documented and appropriately justified.
- 5.1.8 Any modifications made to the application of policies and procedures for the review and oversight of research during a publicly declared emergency will cease as soon as is feasible after the emergency has officially ended (i.e., as declared by an authorized public official).<sup>263</sup>
- 5.1.9 All delegated reviews of research following a publicly declared emergency must be assessed by members to determine whether a subsequent full board review is required after the end of the publicly declared emergency, or whether simply informing the full board is sufficient.
- 5.1.10 The person mandated by the institution to authorize research may delegate that authority during the emergency period. In the absence of institutional procedures, the REB Chair or designee, an REB member, or an REB support staff employed by the institution may authorize research on a temporary basis. As soon as possible, the REB will inform the person mandated by the institution to authorize research of any such research for endorsement.
- 5.1.11 At the conclusion of the publicly declared emergency, the REB Chair or designee, the REB support staff, and the members of the REB sub-committee should evaluate the effectiveness of the emergency procedures and make recommendations for improvement.

## **7.1 Order of priority for REB reviews in a publicly declared emergency:**

### **5.1.12 New research reviews:**

- All research linked with a publicly declared emergency should be sent to the REB Chair or designee.
- Any research linked with a publicly declared emergency is a priority item.
- Research not linked to a publicly declared emergency can be postponed until the necessary resources are available for the review.

### **5.1.13 Reviews in progress at the time the emergency is declared:**

- The initial review of research linked with a publicly declared emergency is a priority item.
- Any initial review of research with possible therapeutic value is prioritized according to the availability of resources.
- The initial review of research not linked to a publicly declared emergency can be postponed until the necessary resources for the review are available.

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<sup>263</sup> TCPS2, art. 6.22.

**5.1.14** Continuing review of ongoing research:

- The researcher will advise the REB of any research that is suspended, if the suspension impacts or could impact the health or safety of participants.
- Reviews will proceed in the following order of priority:
  - annual renewals;
  - requests for major amendments and adverse event reports;
  - all other requests;
  - end-of-study reports;

At the REB Chair or designee’s discretion, and subject to applicable regulations, review procedures may be delayed or temporarily suspended, depending on volume.

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 501.001	January 4, 2019	Original version

<b>Title:</b>	Researcher Qualifications and Responsibilities
<b>SOP code:</b>	REB-SOP 601.001
<b>N2/CAREB SOP code:</b>	SOP 801.002
<b>Effective date:</b>	2021-09-30

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## 1 PURPOSE

This standard operating procedure (SOP) describes the qualifications and responsibilities of the researcher who engages in research involving human participants.

## 8 SCOPE

This SOP pertains to research ethics boards (REBs) that review human-participant research in compliance with applicable regulations and guidelines.

## 9 RESPONSIBILITIES

All researchers, REB members and RRO staff that supports the REB are responsible for ensuring that the requirements of this SOP are met.

## 10 DEFINITIONS

See glossary.

## 11 PROCEDURES

Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. The REB must have assurance that the qualifications of new researchers are appropriate for the conduct of research.<sup>264</sup>

Researchers are required to conduct the research in compliance with applicable regulations and guidelines and must comply with all REB and institution policies.

### 11.1 Researcher qualifications

- 11.1.1 The researcher must have institutional research privileges before they can submit their research project on Nagano. If they do not have such privileges, they must follow the institution's granting procedure, which is designed to confirm their research qualifications.<sup>265</sup>
- 11.1.2 The researcher must also make available to the REB their current CV and medical license number (if applicable), as well as their relevant training and experience, in sufficient detail for the REB to make an objective judgment regarding the researcher's qualifications, if necessary<sup>266</sup>.
- 11.1.3 If applicable, the researcher must be a physician with qualifications in their specialty and with professional qualifications entitling them to provide health care under the applicable laws.
- 11.1.4 The researcher must have completed appropriate training regarding the requirements for conducting and overseeing research.
- 11.1.5 Any concerns raised in the REB review of the researcher's qualifications will be communicated to the researcher and must be satisfied prior to REB approval of the application.

### 11.2 Researcher responsibilities

- 11.2.1 The researcher is responsible for complying with the decisions and SOPs set out by the REB, as well as with all applicable regulations.

**Note:** (Where applicable) The obligations of a researcher who submits a Clinical Trial Application (CTA) to Health Canada (i.e., sponsor-researcher) include both those of a sponsor and a researcher. If the institution assumes the role of sponsor, then the institution assumes these responsibilities as well.

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<sup>264</sup> *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Minister of Health and Social Services, DGAERA, 2004, s. 9.3 and 10.3, hereafter *Modèle*; *Good Clinical Practice: Consolidated Guideline*, Health Canada, September 1997, s. 3.1.3, hereafter *GCP*. *Operational Guidelines for Ethics Committees that Review Biomedical Research*, World Health Organization, 2000, s. 5.1, 5.3.7 and 6.2.3.1, hereafter *OG*; *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, p. 1039, hereafter *Avis*; *Cadre de référence ministériel pour la recherche avec des participants humains*, *MSSS 2020*.

<sup>265</sup> <https://www.ciuisswestcentral.ca/about-us/academic-affairs/research-review-office/research-privileges/>

<sup>266</sup> *Modèle*, s. 10.3; *OG*, s. 5.3.7; *GCP*, s. 3.1.3.

**12 REFERENCES**

See footnotes.

**13 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 601.001		

<b>Title:</b>	Quality Assurance
<b>SOP code:</b>	REB-SOP 701.001
<b>N2/CAREB SOP code:</b>	Adapted from SOP 901.002 and 902.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the procedures to be followed before, during, and after external inspections.

**2 SCOPE**

This SOP pertains to research ethics boards (REBs) that review human-participant research in compliance with applicable regulations and guidelines.

### **3 RESPONSIBILITIES**

All REB members, RRO staff that supports the REB, and researchers are responsible for ensuring that the requirements of this SOP are met.

### **4 DEFINITIONS**

See glossary.

### **5 PROCEDURES**

Quality Management programs, and Quality Assurance (QA) and Quality Control (QC) activities, such as inspections of the REB and of researchers, aim to ensure the protection of human participants in research studies. Findings of these activities are measured against established policies and procedures and all applicable ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.

#### **5.1 Inspections by the institution, MSSS, and OHRP**

The Board of Directors of the institution may request an inspection of REB activities. Appropriate measures should be taken to avoid conflict of interest on the part of the inspectors. Thus, neither the Research Centre nor the Research Director's office may conduct the inspections.

The Ministère de la Santé et des Services sociaux (MSSS) may appoint a group or an individual to conduct quality control visits of designated REBs at any time, in accordance with article 21 of the *Civil Code of Québec*.<sup>267</sup> The individuals designated by the Minister are obliged to respect confidentiality and show discretion.<sup>268</sup>

The U.S. Food and Drug Administration (FDA) has the authority to audit researcher sites involved in studies conducted under a U.S. Investigated New Drug Application (IND) or an Investigational Device Exemption (IDE), to assess compliance with relevant regulations and guidelines. The U.S. Office for Human Research Protection (OHRP) has the authority to audit Canadian REBs that oversee studies supported by the U.S. federal government.

#### **5.2 Inspections related to research studies**

Sponsors, funding entities, or other entities authorized by regulations (e.g., Health Canada) or agreements concluded with the organizations may have the authority to audit or inspect research-related documents and procedures.

These audits or inspections may involve the REB. The researcher is responsible for notifying the REB of any planned audits or inspections of research projects overseen by the REB.

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<sup>267</sup> *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec. Ministère de la Santé et des Services sociaux, June 1998, p. 24, hereafter PAM.

<sup>268</sup> *Ibid.*



### **5.3 Annual REB report**

**5.3.1** Every year, the REB submits a report of all REB activities to its governing body.<sup>269</sup> To preserve REB independence, the report does not have to be approved by the governing body, but merely acknowledged.

**5.3.2** The REB also submits an annual report of its activities to the MSSS.<sup>270</sup>

**5.3.3** The annual report, drafted in accordance with MSSS requirements,<sup>271</sup> may contain the following:

- Roster of REB members, including their qualifications and roles within the REB;
- Number of REB meetings held in the year;
- List of research applications received;
- Continuing reviews throughout the year;
- Any other item that the REB wishes to bring to the attention of the MSSS.

### **5.4 Preparing for an inspection**

**5.4.1** The REB Chair or designee will verify the purpose of the inspection, the project(s) undergoing inspection, and the inspection plan and procedures.

**5.4.2** The REB Chair or designee will notify the RRO staff that supports the REB of the inspection.

**5.4.3** The REB Chair or designee will arrange for access to the appropriate REB documents for the inspector.

**5.4.4** The REB Chair or designee will confirm that the REB members and REB support staff are available for interviews or to assist the inspector.

### **5.5 Participating in an inspection**

**5.5.1** The REB Chair or designee will meet with the inspector, as scheduled. Prior to being granted access to the research-specific documentation by the REB, the inspector must produce proof of authority or authorization to conduct the inspection.

**5.5.2** The REB Chair or designee will record the name, contact information, and title of the inspector and retain any written notices of inspection for the REB files.

**5.5.3** The REB Chair or designee will provide a brief orientation to the inspector of REB procedures.

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<sup>269</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; Civil Code of Québec, CQLR c. CCQ-1991, art. 21; Modèle de règles de fonctionnement d'un comité d'éthique de la recherche, Minister of Health and Social Services, DGAERA, 2004, s. 15.1, hereafter Modèle.*

<sup>270</sup> PAM, p. 24; *Modèle*, s. 15.1.

<sup>271</sup> PAM, p. 24; *Modèle*, s. 15.2.

- 5.5.4 The REB Chair or designee will provide access to the research-specific documents requested by the inspector and maintain a list of the documents reviewed.
- 5.5.5 The REB Chair or designee will accompany the inspector at all times while in confidential areas of the REB office and/or the institution.
- 5.5.6 The REB Chair or designee will ensure that the inspector’s questions are answered by the most appropriate personnel. The REB Chair or designee, and the RRO staff that supports the REB, must make every reasonable effort to be available and to accommodate the inspector’s requests.
- 5.5.7 The REB Chair or designee will request meetings with the inspector at the end of each day, as needed, to discuss any observations. If questions are asked or observations are made during the daily meetings, the REB Chair or designee will research the issues and provide the inspector with clarifications as soon as possible once the information is available.
- 5.5.8 The REB Chair or designee will ensure that the required personnel are present at the exit interview and that the observations are understood before the inspector leaves the institution.
- 5.5.9 The REB Chair or designee will record any observations made by the inspector, as well as any discussion, and will determine whether a written response is required.

**5.6 Follow-up after an inspection**

- 5.6.1 The REB Chair or designee will request a copy of the inspection report.
- 5.6.2 The REB Chair or designee and any other designated individuals will review any findings relevant to the REB and prepare, where applicable, a written response to each item or observation, including any clarification or corrective action required.
- 5.6.3 The REB Chair or designee and any other designated individuals will institute any corrective actions deemed relevant and will revise the REB SOPs as needed.
- 5.6.4 The REB Chair or designee will file the inspection documents and the relevant responses in the appropriate files (e.g., quality assurance).

**6 REFERENCES**

See footnotes.

**7 REVISION HISTORY**

SOP code	Effective date	Summary of changes
REB-SOP 701.001		

<b>Title:</b>	Non-Compliance with the Responsible Conduct of Research
<b>SOP code:</b>	REB-SOP 702.001
<b>N2/CAREB SOP code:</b>	SOP 903.002
<b>Effective date:</b>	2021-09-30

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**1 PURPOSE**

This standard operating procedure (SOP) describes the Research Ethics Board (REB) process for responding to reports of non-compliance, and the actions that the REB may take as a result of its review of reports of serious and/or continuing non-compliance.

**14 SCOPE**

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

**15 RESPONSIBILITIES**

All REB members, RRO staff that supports the REB, and researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions to obtain approval from the REB.

The RRO staff that supports the REB, and the REB members are responsible for bringing any and all allegations of non-compliance with the responsible conduct of research to the attention of the REB Chair or designee.

The REB is responsible for reporting any incidents of serious or ongoing non-compliance to the person responsible for overseeing the responsible conduct of research at the institution.

If intentional, serious or continuing non-compliance is established, the REB may determine relevant corrective action.

## **16 DEFINITIONS**

See glossary.

## **17 PROCEDURES**

Applicable procedures are covered in the institution's Policy on the Responsible Conduct of Research.

## **18 REFERENCES**

See footnotes, if any.

## **19 REVISION HISTORY**

<b>SOP code</b>	<b>Effective date</b>	<b>Summary of changes</b>
REB-SOP 702.001		



**GENERAL APPENDIX  
GLOSSARY OF TERMS IN STANDARD OPERATING PROCEDURES**

<b>Terminology used</b>	<b>Definition</b>
<b>Ad hoc advisor</b>	A person with relevant knowledge and qualifications, consulted by a Research Ethics Board (REB) for a specific research ethics review, and for the duration of that review, in the event that the REB lacks specific expertise or knowledge to review the ethical acceptability of a research proposal. The ad hoc advisor is not a member of the REB and will not be counted in the quorum or allowed to vote on REB decisions.
<b>Adverse event (AE)</b>	Any untoward medical occurrence in a research participant who is administered an investigational product, including an occurrence that does not have a causal relationship with this product. An AE can therefore be any unfavourable and unintended sign (e.g., abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product, whether or not related to the investigational product.
<b>Alternate member</b>	A person formally appointed by the Board of Directors to carry out the duties of a member of the REB. The alternate may substitute for a regular member of the REB. An alternate REB member's presence at an REB meeting is used to establish quorum.
<b>Amendment</b>	A written description of one or more changes to a previously approved research study. Amendments include any changes to the protocol or related research documents, such as changes to the consent form, revisions to the Investigator's Brochure, updated participant material, etc.
<b>Anonymized information</b>	The information is irrevocably stripped of direct identifiers, a code is not kept to allow for future re-linkage, and the risk of re-identifying individuals from the remaining indirect identifiers is low or very low.
<b>Anonymous information</b>	The information never had identifiers associated with it (e.g., anonymous surveys) and the risk of identifying individuals is low or very low.
<b>Assent</b>	Affirmative agreement to participate in research by an individual unable to provide consent.
<b>Authorized signatory</b>	Individual(s) authorized to sign documents on behalf of an organization.
<b>Authorized third party</b>	Any person with the necessary authority to make decisions on behalf of the prospective participant who lacks the capacity to consent to participate, or to continue to participate, in a particular research project. (Also known as a "legally authorized representative.")
<b>Coded information</b>	Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the researcher retains a list that links the participant's code name with their actual name so data can be re-linked if necessary).

Terminology used	Definition
<b>Confidentiality</b>	<p>Refers to the agreement between the researcher and the participant as to how personal data will be managed and used, and an ethical and/or legal responsibility to safeguard information from unauthorized use, disclosure, modification, loss, or theft. The term also refers to the REB's ethical and/or legal responsibility to safeguard information in its custody from unauthorized use, disclosure, modification, loss, or theft.</p>
<b>Conflict of interest (COI)</b>	<p>Circumstance of a person (e.g., researcher or Research Ethics Board (REB) member) or organization in a real, perceived, or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.</p> <p>Example: COI may occur when an individual's judgments and actions or an organization's actions in relation to research are, or could be, affected by personal, organizational or other interests, including, but not limited to, business, commercial, or financial interests, whether of the individuals concerned, their family members, their friends, or their former, current or prospective professional associations, or of the organization itself.</p> <p>Examples of secondary interests for a researcher include the following:</p> <ul style="list-style-type: none"> <li>• Is receiving or expecting to receive compensation from the sponsor, the value of which could be affected by the outcome of the study;</li> <li>• Acts as an officer, director, or agent of the sponsor;</li> <li>• Their job status or compensation is impacted by the research (e.g., payment for speaking or leading study groups on behalf of the sponsor);</li> <li>• Is receiving a finder's fee for the recruitment of research participants;</li> <li>• Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product;</li> <li>• Has (or family, spouse, close relationships have) any equity interest in the sponsor;</li> <li>• Receives payments of other types, which are made by the sponsor, exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultations, or honoraria);</li> <li>• Is intending to recruit their own patients as research participants;</li> <li>• Has identified themselves for any other reason as having a conflict of interest (i.e., organizational conflict that may impact the research).</li> </ul> <p>Examples of secondary interests for an REB member include the following:</p>

Terminology used	Definition
	<ul style="list-style-type: none"> <li>• Is a researcher or sub-researcher on the protocol;</li> <li>• Is directly involved in the conduct of the research;</li> <li>• Their job status or compensation is impacted by the research (e.g., research coordinator, payment for speaking/leading study groups on behalf of the sponsor);</li> <li>• Is receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study;</li> <li>• Acts as an officer, director, or agent of the sponsor;</li> <li>• Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product;</li> <li>• Has any equity interest in the sponsor that when aggregated for the member and the member's spouse and dependent children;</li> <li>• Any equity interest in the sponsor (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices);</li> <li>• Significant payments of other sorts, which are payments made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria);</li> <li>• Is in direct competition with the researcher of the research project for limited resources, funding, sponsorship, or research participants; acts as a consultant for the sponsor; is considered a personal or professional adversary of the researcher;</li> <li>• Has identified themselves for any other reason as having a conflicting interest.</li> </ul>
<b>Continuing research ethics review (also referred to as “continuing review”)</b>	Any review of ongoing research (except for annual renewals) conducted by a Research Ethics Board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable, in accordance with the principles in the Policy.
<b>Controlled forms</b>	Documents that are appended to the SOP and, as such, require formal change control, and that form part of the permanent record of Research Ethics Board (REB) operations and processes.
<b>Data and Safety Monitoring Board (DSMB)</b>	A multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data, assessing the safety and efficacy of research procedures, and monitoring the overall conduct of the research.
<b>Delegated review (also referred to as “expedited review”)</b>	The level of Research Ethics Board (REB) review assigned to minimal risk research studies, to minor changes in approved research, and to continuing review applications that meet the delegated review criteria.



<b>Terminology used</b>	<b>Definition</b>
	Delegated reviewers are selected from among the REB membership to conduct the review.
<b>Designee</b>	May refer to a member of the Research Ethics Board (REB) or to the REB Office Personnel, depending on the context of the statement and the accompanying requirements of the organization.
<b>Directly identifying information</b>	The information identifies a specific individual through direct identifiers (e.g., name, social insurance number, health insurance number).
<b>Expiry date</b>	The first day that the Research Ethics Board (REB) approval of the research is no longer valid without further review and approval by the REB. When the REB determines that a review is required more than annually, the expiry date will be determined by the REB (e.g., six months from the approval date).
<b>Full Research Ethics Board (REB) review</b>	The level of Research Ethics Board (REB) review assigned to above minimal risk research studies. Conducted by the full membership of the REB, it is the default requirement for the ethics review of research involving human participants.
<b>Human genetic research</b>	The study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment.
<b>Impartial</b>	Without prejudice or bias, fair; a principle of justice holding that decisions should be based on objective criteria, rather than on the basis of bias, prejudice, or favouritism.
<b>Impracticable</b>	Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.
<b>Incentive</b>	Anything offered to research participants, monetary or otherwise, to encourage participation in research.
<b>Incidental findings</b>	Unanticipated discoveries made in the course of research that are outside the scope of the research. “Material incidental findings” are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological, or social. If, in the course of research, material incidental findings are discovered, researchers have an obligation to inform the participant.
<b>Indirectly identifying information</b>	The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, or unique personal characteristic).
<b>Inspection</b>	A systematic examination and evaluation of study-related activities and documents in comparison to specified requirements and standards.
<b>Institutional conflicts of interest</b>	An incompatibility between two or more substantial institutional obligations that cannot be adequately fulfilled without compromising one or another of the obligations.

<b>Terminology used</b>	<b>Definition</b>
<b>Investigational product</b>	Refers to new or new uses of drugs, biologics, medical devices, or natural health products.
<b>Local adverse event</b>	Those adverse events experienced by research participants enrolled by the researcher at the centre(s) under the jurisdiction of the Research Ethics Board (REB).
<b>Mature minor</b>	Is an individual who demonstrates adequate understanding and decision-making capacity.
<b>Medical device trials</b>	Clinical trials that test the safety and/or efficacy of one or more instruments used in the prevention, diagnosis, mitigation, or treatment of a disease or abnormal physical condition, or the restoration, correction, or modification of body functions or structures.
<b>Minimal risk</b>	Research in which the probability and magnitude of possible harms arising from participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
<b>Minor change</b>	Any change that would not materially affect an assessment of the risks and benefits of the research or the integrity of the data, and that does not substantially change the specific aims or design of the study.
<b>Multicentre</b>	Multicentre means that the research is reasonably expected to be conducted at more than one centre.
<b>Natural health product (NHP) trial</b>	A clinical trial testing the safety and efficacy of one or more natural health products (NHP). The term NHP is used to describe substances such as vitamins and minerals, herbal medicines, homeopathic preparations, energy drinks, probiotics, and many alternative and traditional medicines.
<b>Non-compliance</b>	Failure to follow applicable guidelines and regulations governing human-participant research; failure to follow the protocol approved by the Research Ethics Board (REB), or failure to follow stipulations imposed by the REB as a condition of approval.
<b>Non-controlled forms</b>	Documents that are not part of the permanent record of Research Ethics Board (REB) operations and processes. Non-controlled forms will also contain version dates.
<b>Non-local (external) adverse event (EAE)</b>	Those adverse events experienced by research participants enrolled by researchers at centres/organizations <u>other</u> than those under the jurisdiction of the Research Ethics Board (REB).
<b>Ongoing research</b>	Research that has received Research Ethics Board (REB) approval but has not yet been completed.
<b>Organizational official</b>	An official representative who offers assurance to human participants, making a commitment on behalf of the organization to comply with

Terminology used	Definition
	regulation 45 CFR 46 (U.S. Code of Federal Regulations) covering the protection of human participants, and with Health Canada regulations.
<b>Participant</b>	An individual whose data or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to as “human participant” or, in other policies/guidance, as “subject” or “research subject.”
<b>Periodic safety update or summary report</b>	A summary report, created by the sponsor, listing all of the reported unexpected serious adverse events that have occurred in a given reporting period, and which includes any significant areas of concern and the evolving safety profile of the investigational product.
<b>Personal health information</b>	<p>Personal health information (PHI) is a subset of personal information which is identifiable information about an individual. (See “Personal information,” also referred to as “Identifying information”.)</p> <p>Personal health information is identifying information about an individual, either transmitted verbally or recorded in a form, if the information:</p> <ul style="list-style-type: none"> <li>• Relates to the individual’s physical or mental health, including family health history;</li> <li>• Relates to the provision of health care, including the identification of persons providing care;</li> <li>• Is a plan of service for an individual requiring long-term care;</li> <li>• Relates to payment or eligibility for health care;</li> <li>• Relates to the donation of body parts or bodily substances, or is derived from the testing or examination of such parts or substances;</li> <li>• Is the individual’s health insurance number;</li> <li>• Identifies an individual’s substitute decision-maker.</li> </ul> <p>Any other information about an individual that is included in a record containing personal health information is also included in this definition. This definition does not include information about an individual if the information could not reasonably be used to identify the individual.</p>
<b>Personal information (also referred to as “identifying information”)</b>	Information that identifies an individual and/or that could reasonably be expected to identify an individual, alone or in combination with other available information.
<b>Privacy</b>	<p>An individual’s right to be free from intrusion or interference by others.</p> <p>Privacy refers to persons and their interest in controlling the access of others to themselves (their personal information).</p>
<b>Privacy breach</b>	The unauthorized collection, use, or disclosure of personal information or personal health information (PHI) in the custody of an individual, a

Terminology used	Definition
	health information custodian (HIC), the organization, or its affiliated partners.
<b>Proportionate approach to research ethics review</b>	The assessment of foreseeable risk to determine the level of scrutiny the research will receive (i.e., delegated review for minimal risk research or full board review for research above minimal risk), as well as the consideration of foreseeable risks, potential benefits, and ethical implications of the research in the context of initial and continuing review.
<b>Protocol deviation</b>	The term “protocol deviation” is not well defined by regulations or guidelines, but deviations are identified as any unplanned or unforeseen change to a Research Ethics Board (REB) approved protocol or protocol procedures. Deviations are different from amendments in that they generally apply to a single event or participant and are not intended to modify the entire protocol.
<b>Quorum</b>	<p>Quorum shall include at least five (5) voting members, including (at minimum):</p> <ul style="list-style-type: none"> <li>• Two (2) members with expertise in the relevant disciplines, fields, and methodologies covered by the REB (for 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);</li> <li>• One (1) member who is primarily experienced in non-scientific disciplines;</li> <li>• One (1) member knowledgeable in ethics;</li> <li>• One (1) member from the community who has no affiliation with the organization(s) and who is not part of the immediate family of a person who is affiliated with the organization;</li> <li>• One (1) member knowledgeable in the relevant laws (for biomedical research);</li> <li>• Additional representation as required by applicable legislation or guidelines.</li> </ul> <p>For research subject to the U.S. Code of Federal Regulations, quorum shall also include a majority (50%+1) of voting members.</p>
<b>Reportable event</b>	Includes anything that could significantly impact the conduct of the research or alter the Research Ethics Board’s (REB) approval or favourable opinion to continue the research.
<b>Research</b>	An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
<b>Research Ethics Board (REB)</b>	A body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines), established by an organization to review the ethical acceptability of all research

Terminology used	Definition
	involving humans conducted within the organization’s jurisdiction or under its auspices.
<b>Research Ethics Board (REB) of record</b>	The Research Ethics Board (REB) that has been granted ultimate authority for the ethics review and oversight of a research study.
<b>Research Review Office (RRO)</b>	Office comprised of Personnel that coordinate and support the institutional suitability and ethics review of research projects conducted at the CIUSSS du Centre-Ouest-de-l’Île-de-Montréal and at the facilities and sites it administers, or involving its care and service users, under the authority of the person formally mandated to authorize the research.
<b>Researcher</b>	The leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. (Also known as “qualified Investigator.”)
<b>Risk</b>	The possibility of the occurrence of harm. The level of foreseeable risk due to involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties.
<b>RRO staff</b>	Employees from the CIUSSS du Centre-Ouest-de-l’Île-de-Montréal who perform their duties within the RRO
<b>Suspension</b>	A temporary or permanent halt to all research activities pending future action by the Research Ethics Board (REB), by the sponsor, and/or by the researcher.
<b>Termination</b>	A permanent halt by the Research Ethics Board (REB), by the sponsor, and/or by the researcher to all or some research activities.
<b>Unanticipated issues</b>	Issues that occur during the conduct of research, that may increase the level of risk to participants or have other ethical implications that may affect participants’ welfare, and that were not anticipated by the researcher in the research proposal submitted for research ethics review.
<b>Unanticipated problem</b>	Any incident, experience, or outcome (including an adverse event) that meets <b>all</b> of the following criteria:  <b>*Unexpected</b> (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the research protocol, the informed consent document, or the Investigator’s Brochure approved by the Research Ethics Board (REB); and (b) the characteristics of the research participant population being studied; <b>and</b>  <b>+Related or possibly related</b> to participation in the research, (“possibly related” means there is a reasonable possibility that the incident,

Terminology used	Definition
	<p>experience, or outcome may have been caused by the [investigational product(s)] or procedures involved in the research); <b>and</b></p> <p>Suggests that the research <b>places the research participants or others at a greater risk of harm</b> (including physical, psychological, economic, or social harm) than was previously known or recognized.</p> <p><b>*Unexpected:</b> An event is “unexpected” when its specificity and severity are not accurately reflected in the protocol-related documents, such as the research protocol, the Investigator’s Brochure, or the current informed consent document approved by the Research Ethics Board (REB), or other relevant sources of information, such as product labelling and package inserts; or when the event is not associated with the expected natural progression of any underlying disease, disorder, predisposing risk factor, or condition of the participant(s) experiencing the adverse event.</p> <p><b>+Related to the research procedures:</b> An event is “related to the research procedures” if, in the opinion of the researcher or sponsor, the event was more likely than not to be caused by the research procedures.</p>