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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 ~~(including the suspension or termination of approval).~~

2 SCOPE

This SOP pertains to ~~the MUHC Research Ethics Board (REB)~~ REBs that ~~reviews~~ review human participant research in compliance with applicable regulations and guidelines. ~~The term Chair in this SOP includes REB Co-Chairs.~~

3 RESPONSIBILITIES

All REB members and designated REB ~~Office Personnel~~ staff 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.¹

The Researcher is responsible for notifying the REB and the ~~organization~~ institution of any suspensions or terminations of the research by the Sponsor or regulatory agency and for providing a detailed explanation for the action.²

A researcher may decide to voluntarily suspend or terminate some or all of the research activities³; 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 his/her own; however, the REB Chair or designee is authorized to suspend REB approval, ~~which must be~~ The suspension is then reported to the REB at its next Full Board meeting. The REB is authorized to terminate REB approval following its review at a Full Board meeting.⁴

The REB Chair or designee shall notify the Researcher, and the Organizational institution's Official(s), of any suspension or termination of REB approval of the research ~~and~~ The REB Chair or designee has the authority to notify the relevant regulatory authorities (as applicable).

4 DEFINITIONS

See Glossary of Terms.

¹ Modèle de règles de fonctionnement d'un comité d'éthique de la recherche, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter "Modèle", s. 4.2; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.1.2.

² Modèle, s. 13.2.

³ See also REB SOP on Research Completion.

⁴ Modèle, s. 4.2; ICH GCP, s. 3.1.2; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 6.3.

5 PROCEDURES

As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate REB approval⁵; for example, if the risks to the research participants are determined to be disproportionately unreasonably high in relation relative to anticipated the benefits; for example, cases in which there are significant numbers of unexpected serious adverse events, or when there is evidence that the Researcher is not conducting the research in compliance with applicable regulations and guidelines, might reasonably be expected.⁶

The REB also has the authority to suspend new enrollment while additional information is requested.

A decision to suspend or to terminate the REB's approval of the research must include consideration of the safety, rights and well-being of the participants already enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

~~The REB has the authority to suspend or to terminate the REB's approval of the research.~~

~~A Researcher may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of REB approval.~~

5.1 Suspension or Terminations of Research by the Sponsor

- 5.1.1 The sponsor of the research may suspend or terminate the research (e.g., following 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 action⁷;
- 5.1.3 Reports of suspensions or terminations of the research by the sponsor will be forwarded to the REB Chair or designee for review;

⁵ Modèle, s. 4.2; ICH GCP, s. 3.1.2; TCPS2, art. 6.3.

⁶ Civil Code of Québec (CCQ), c. CCQ-1991, art. 20 and 21; Modèle, s. 10.3; TCPS2, p. 20-23, art. 2.9, art. 11.4 (a); Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 6.2.1.2; Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le Ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec, Part I, vol. 35, 1998, hereafter "Avis", p. 1039; 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, hereafter "PAM", p. 23.

⁷ Modèle, s. 13.2.

5.1.4 If the REB Chair or designee decides to suspend **REBethics** approval of the research, he/she 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 **oversight/continuing review** of the research that are related to new information or to the conduct of the research, 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 is associated with unexpected serious harm to 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., under a suspension or approval with modifications),
- **Failure to apply for annual renewal of ethics approval prior to the expiry date; such failure entails *de facto* suspension.** Failure to submit **application for continuing review by the expiry date may lead to a suspension, failure to submit application/request** for continuing review within 30 days **offollowing** the expiry date may **lead to result in the termination of the research project,**
- Repeated or deliberate failure to properly obtain or document consent from research participants **or to properly document the consent process,**
- Repeated or deliberate failure to limit administration of the 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, by the **sponsor/Sponsor,** or by regulatory agencies,
- Repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB;

5.2.15.2.2 The REB Chair or designee is authorized to suspend **REBethics** approval of research. If the Chair or designee suspends approval of the research, he/she must notify the REB at **itsthe** next **REB** Full Board meeting **or as per applicable requirements;**

~~5.2.25.2.3~~ The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;

~~5.2.35.2.4~~ Prior to suspending or terminating REB approval, the REB must consider:

- Risks to current participants,
- Actions ~~to protect the safety, rights and well-being of currently enrolled participants,~~
- The appropriate care and monitoring of research participants,
- Whether ~~withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,~~
- Whether participants should be informed of the termination or suspension,
- Whether adverse events or outcomes should ~~continue to thereafter~~ be reported to the REB,
- Identification ~~of a time frame in which the corrective measures are to be implemented;~~

~~5.2.45.2.5~~ **When the REB** suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;

~~Unless otherwise stated by the REB, when the REB Chair or design~~

~~5.2.55.2.6~~ If the research is suspended or terminated, the REB Chair or designee will ~~notify and~~ issue a formal letter to the Researcher with the reason(s) for the REB action and the corrective measures proposed by the REB, if any;

~~5.2.65.2.7~~ If REB approval of a research or if the conduct of the research has been suspended, the suspension may be lifted after corrective actions are completed to the ~~REB or the co-chair satisfaction of the REB and other third parties involved, if any.~~

5.3 Reporting Suspensions or Terminations

The REB Chair or designee will report any suspension or termination of REB approval to the ~~appropriate Organizational Official(s)~~ Official formally mandated to authorize research in the institution or network and has the authority to notify the ~~relevant~~ regulatory authorities (as applicable), and the sponsor.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|--------------------------|---------------------|--|
| MUHC-REB-SOP- | 2017-02- | Original Version <u>version</u> |

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8 APPENDICES