Title	REB Submission Requirements and Administrative Review
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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 designated REB staff are responsible for ensuring that the requirements of this SOP are met.

4 DEFINITIONS

See Glossary of Terms.

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 adequate 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 REB Support Staff are responsible for maintaining and disseminating this information to Researchers.

5.1 Submission Requirements

5.1.1 The required contact information, documents, and submission procedures are outlined on the REB's website and/or other media, as deemed appropriate. Submission requirements include, but are not limited to, the following[1]:

- REB application form,
- Required format for submission,
- Required documentation,
- Language in which documents are to be submitted,
- Number of copies to be submitted,
- Submission deadlines and associated review dates,

[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. 9.2; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR" s. 5.2.

- Notification of receipt of application, including communication that an application is incomplete,
- Expected timeframe for notification of the decision following review,
- Timeframe 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,
- Changes in Research Personnel form,
- Serious Adverse Event Reporting form,
- 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 **Research Requirements:** The research question and methodology is written in sufficient detail to permit evaluation of the merits of the project.[2] The research should include all of the required elements applicable to the research, such as, but not limited to, the following[3]:

- REB application form, signed and dated,
- Research protocol (including a description of ethical considerations associated with the proposed research) or management framework for databanks or biobanks,
- For clinical trials, the Investigator's Brochure or the Product Monograph and No Objection Letter from Health Canada,
- Information and Consent Form,
- Questionnaires and other materials for research participants,
- Recruitment documents (e.g. brochures, advertisements),
- Relevant sections of the sponsorship agreement,
- Budget,
- Peer review results,
- Results of other REB reviews, if any.

5.2 Administrative Review Procedures

[2] *Modèle*, s. 9.3.
[3] *Modèle*, s. 9.3; TDR, s. 5.3; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s 3.1.2.

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

5.2.2 The submission is screened for overall completeness;

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 Researcher 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 Full Board review, the proposed research will be added to the agenda of the next Full Board meeting;

5.2.6 For submissions to be reviewed via delegated review procedures, one or more REB members will be assigned to the review.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 301.001	2020-03-20	Original version

8 APPENDICES