Title	Researcher Qualifications and Responsibilities
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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.

2 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3 RESPONSIBILITIES

All Researchers, 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

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, for the conduct of research, are appropriate.[1]

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

5.1 Researcher Qualifications

5.1.1 The Researcher must make available to the REB his/her current CV and medical license number (if applicable) and his/her relevant training and experience, in sufficient detail for the REB to make an objective judgment regarding the Researcher's qualifications, if necessary[2];

5.1.2 If applicable, the Researcher must be a physician with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;

5.1.3 The Researcher must have completed appropriate training regarding the requirements for conducting and overseeing research;

5.1.4 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.

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[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. 9.3, 10.3; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.1.3; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 5.1, 5.3.7, 6.2.3.1; *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.

[2] *Modèle*, s. 10.3; *LDO*, s. 5.3.7; ICH GCP, s. 3.1.3.

5.2 Researcher Responsibilities

5.2.1 The Researcher is responsible for complying with the decisions and SOPs set out by the REB, as well as with all applicable regulations.

Note: (if applicable) The obligations of a Researcher holding a Clinical Trial Application (CTA) with *Health Canada* (i.e. Sponsor-Researcher) include both those of a Sponsor and those of a Researcher. If the institution assumes the role of Sponsor, then the institution assumes these responsibilities as well.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 601.001	2020-03-20	Original version

8 APPENDICES