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Hôpital Montfort

Un hôpital d'enseignement affilié à l'Université d'Ottawa

A teaching hospital affiliated with the University of Ottawa

Notice of Ethics Approval
Hôpital Montfort Research Ethics Board (REB)

January, 9th 2017

Principal Investigator:

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Project title: « Offre active de services de santé en français : habilitation et mobilisation des gestionnaires / Active offer of health services in French : Empowering and mobilizing managers »

File number: FC-30-11-16

Start date: January 9, 2017

End date: January 8, 2018

Special condition: Please submit to the REB the details of the recruitment process that is specific to each institution once you have validated them.

In accordance with the latest edition of Tri-Council Policy Statement - Ethical Conduct for Research Involving Humans Subjects (TCPS 2), the Standards Council of Canada, Good Clinical Practice: Consolidated Guideline, International Conference on Harmonisation of requirements technical for registration of pharmaceuticals for human use (ICH-GCP E6), the Act of 2004 on the protection of personal health information, applicable laws and regulations in Ontario, I confirm that the Hôpital Montfort Research Ethics Board (REB) **has evaluated** and **approved** the research project and the following documents for the start and end dates mentioned above:

- Research Protocol, version dated Dec. 22, 2016
- **Appendix 1** : Letter to institutions (FR / EN), version dated Nov. 30, 2016
- **Appendix 2a** : Script from local coordinator to unit managers (FR / EN), version dated Nov. 30, 2016
- **Appendix 2b** : Script from local coordinator to people in a unit (FR / EN), version dated Nov. 30,2016
- **Appendix 6** : Script for local coordinator asking permission to user (FR/EN), version dated Jan. 9, 2017
- **Appendix 7** : Script recruitment for patients (FR / EN), version dated Nov. 30, 2016
- **Appendix 8** : Invitation e-mail (FR / EN), version dated Dec. 6, 2016
- **Appendix 3** : Consent form for unit managers (FR), version dated Dec. 22, 2016
- **Appendix 4** : Consent form for unit members (FR), version dated Dec. 22, 2016
- **Appendix 9** : Consent form for the users / patients (FR), version dated Dec. 22, 2016
- **Appendix 5** : Questionnaires and time point (FR et EN), version dated Nov. 30, 2016
- **Appendix 10** : Interview questions (FR / EN) version dated Nov. 30, 2016
- **Appendix 11** : Frequently Ask Questions (FR / EN), version dated Nov. 19, 2016

- Budget of the study
- Figure 1-Study phases and data collection tools
- Service Agreement between « *Société santé en français* » and « *Institut du savoir Montfort* » dated August 12, 2016
- Letter of support from « Thunder Bay Regional Health Sciences Centre » for the research project

The Hôpital Montfort REB is established and operates in a manner consistent with the National Standard of Canada for the Monitoring of Research Ethics Conducting Biomedical Clinical Trials of the Canadian General Standards Board, Clinical Practice Guidelines: Consolidated Guidelines of the International Council for the Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH-BPC E6), Part C, Title 5 of the Food and Drug Regulations, and The applicable regulations, Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations, the "Code of Federal Regulations" of the United States, the Ontario Personal Health Information Protection Act, 2004, and the laws and regulations applicable in Ontario .

The protocol of the study cannot be amended without prior approval of the REB unless there is an immediate safety issue for the participants. You must notify the REB immediately of any changes, adverse event or new information that may increase the risk of the study, changing the course of the study or reach the safety of participants. The changes to the project and recruitment tools must be submitted to the REB.

Please send us **four weeks before the due date of the notice of approval**, a final report to close the file or to request the renewal of the certificate of ethical approval for the study.

If you have any questions, please do not hesitate to contact the Research Ethics Office by phone at 613-746-4621 extension 2221 or by e-mail at ethique@montfort.on.ca.

Richard Carpentier

Richard Carpentier, Ph. D.
Chair, Research Ethics Board — Hôpital Montfort