



Hamilton Integrated Research Ethics Board

Jan-02-2019

Project Number: 5371

Project Title: PROTOTYPE VALIDATION FOR AN ELECTRONIC PATIENT DECISION AID FOR GUARDIANS MAKING SURGICAL TREATMENT DECISIONS ABOUT CONGENITAL ADRENAL HYPERPLASIA

Principal Investigator: Dr Luis Braga

This will acknowledge receipt of your letter dated November 14, 2018 which enclosed revised copies of the Information/Consent Form, Advertisement and the Application Form along with a response to the additional queries of the Board for the above-named study. These issues were raised by the Hamilton Integrated Research Ethics Board at their meeting held on November 7, 2018. Based on this additional information, we wish to advise your study had been given *final* approval from the full HiREB.

The following documents have been approved on both ethical and scientific grounds:

Document Name	Document Date	Document Version
Appendix A Information Brochure for Alpha Testing	Nov-14-2018	1.1
Appendix B Telephone and Email Recruitment Script for alpha testing	Oct-01-2018	1.0
APPENDIX C_Prototype Validation for an Electronic Patient Decision Aid for Guardians Making Surgical Treatment Decisions about CAH-V1.1_ALPHA	Nov-14-2018	1.1
APPENDIX D_Prototype Validation for an Electronic Patient Decision Aid for Guardians Making Surgical Treatment Decisions about CAH-V1.1Beta	Nov-14-2018	1.1
Appendix E SUS and UEQ	Aug-29-2018	1.0
Appendix G PPEET and Demographic Survey	Aug-29-2018	1.0
Appendix H-BUDGET	Aug-29-2018	1.0
PROTOTYPE VALIDATION FOR AN ELECTRONIC PATIENT DECISION AID FOR GUARDIANS MAKING SURGICAL TREATMENT DECISIONS ABOUT CAH_Protocol Version 1.1	Nov-14-2018	1.1

The following documents have been acknowledged:

Document Name	Document Date	Document Version
GCP Certificate Braga; Certificate # 8278698	Jul-16-2012	1.0

Please Note: All consent forms and recruitment materials used in this study must be copies of the above referenced documents.

We are pleased to issue final approval for the above-named study for a period of 12 months from the date of the HiREB meeting on November 7, 2018. Continuation beyond that date will require further review and renewal of HiREB approval. Any changes or revisions to the original submission must be submitted on a HiREB amendment form for review and approval by the Hamilton Integrated Research Ethics Board.

PLEASE QUOTE THE ABOVE REFERENCED PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

Sincerely,

Dr. Frederick A. Spencer, MD
Chair, Hamilton Integrated Research Ethics Board

The Hamilton Integrated Research Ethics Board (HiREB) represents the institutions of Hamilton Health Sciences, St. Joseph's Healthcare Hamilton, Research St. Joseph's-Hamilton, and the Faculty of Health Sciences at McMaster University and operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada, and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations; For studies conducted at St. Joseph's Healthcare Hamilton, HiREB complies with the Health Ethics Guide of the Catholic Alliance of Canada