



Hamilton Integrated Research Ethics Board

February 27 2017

Project Number:2712-C

Project Title:Evaluation of safety and efficacy of NOACs in Kidney Transplants Recipients

Principal Investigator:Dr. Christine Ribic

This will acknowledge receipt of your Retrospective Review of Medical Charts/Health Records application for the above named study. We wish to confirm that the study has been reviewed by the HiREB Executive and has been given *final approval*. The submission has been approved on ethical, scientific and privacy grounds. The application has been forwarded to Rose Iannone, Manager, Health Information at St. Joseph's Healthcare Hamilton.

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

Document Name	Document Date	Document Version
data collection form verion 2 Feb 24 2017	Feb-24-2017	2
protocol version 3 Feb 22 2017	Feb-22-2017	3

We are pleased to issue final approval for the above-named study for a period of 12 months from the date of this approval letter. Continuation beyond that date will require further review and renewal of REB approval. Any changes or amendments to the protocol or study documents must be approved by the Hamilton Integrated Research Ethics Board.

If you require a listing of chart identifiers for this project, please contact the Manager, Health Information Management (HIM), at SJHH who will be able to assist you with this data extraction. There may be a charge for data extraction so please discuss your requirements to enable Health Information Management to generate an estimate of workload. HIM will require your written consent to pay prior to commencing with the data extraction. If you have questions regarding the billing and consent process, you should discuss this as well.

Once you have the chart identifiers and you require access to the patient's health records through the Health Records Department at St. Josephs Healthcare Hamilton, please submit the listing as follows:

Rose Iannone, Manager, Health Information Services (HIM.) at St. Joseph's Healthcare Hamilton, 905.5221155 Ext. 33676.

If you require any type of computer assistance, including passwords, please contact SJHH- Information Services at (905) 522-1155 Ext. 33040

Sincerely,

Raelene Rathbone, MB BS, MD, PhD
Chair, Hamilton Integrated Research Ethics Board

PLEASE QUOTE THE ABOVE-REFERENCED PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

The Hamilton Integrated Research Ethics Board (HiREB) represents the institutions of Hamilton Health Sciences, St. Joseph's Healthcare 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