

RESEARCH ETHICS OFFICE **Health Research Ethics Board**

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Amendment Approval Form

Date: Wednesday, November 13, 2024

Amendment ID: Pro00140224 AME1

Principal Investigator: Sean Bagshaw

Study ID: MS1 Pro00140224

LoW Dose-Intensity vs. Standard Dose-Intensity COntinuous Renal Study Title:

ReplaceMent Therapy in Critically III Patients (WISDOM): A Pilot

Randomized Trial

Protocol Number: Version 2

Sponsor/Funding Agency: CIHR - Canadian Institutes for Health Research

Approval Expiry Date: Monday, April 21, 2025

Thank you for submitting an amendment request to the Health Research Ethics Board - Biomedical Panel, which was reviewed by the full board at their meeting on November 13, 2024. The following has been reviewed and approved on behalf of the committee:

Approved Documents:

Consent Forms

WISDOM Deferred Consent[v4]-25Sep2024 clean.docx

WISDOM Particpant SDM ICF[v4]-25Sep2024 clean.docx

WISDOM Regained Capacity Consent[v4]-25Sep2024 clean.docx

Protocol/Research Proposal

WISDOM (Low Dose CRRT)-Protocol[V2]-25Sept2024-CLEAN-signed.pdf

Other Documents

WISDOM CRF pkg v3 15Oct2024 CLEAN.docx

DCCM Informed Consent Tool.pdf

Critical Care Research Deferred Consent Addendum.docx

WISDOM CRF pkg v2 25Sep2024 CLEAN.pdf

Note: Approval for an **amendment** does not change the original approval date of a study.

The membership of the Health Research Ethics Board - Biomedical Panel complies with the membership requirements for research ethics boards as defined in Division 5 of the Food and Drug Regulations and the Tri Council Policy Statement. The HREB - Biomedical Panel carries out its functions in a manner consistent with Good Clinical Practices.

Approval by the REB does not constitute authorization to initiate the conduct of this research. The Principal Investigator is responsible for ensuring required approvals from other involved organizations (e.g., Alberta Health Services, Covenant Health, community organizations, school boards) are obtained, before the research begins.

Sincerely,

Dr. Glen J. Pearson, BSc, BScPhm, PharmD, FCSHP, FCCS Chair, Health Research Ethics Board - Biomedical Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).



