

Approval Form

Date:	November 26, 2021
Principal Investigator:	Oleksa Rewa
Study ID:	Pro00112293
Study Title:	Midodrine for the early liberation from vasopressor support in the ICU – LIBERATE
Protocol Number:	version 3.0
Approval Expiry Date:	Friday, November 25, 2022
Funding/Sponsor:	University Hospital Foundation

Thank you for submitting the above study to the Health Research Ethics Board - Biomedical Panel, which was reviewed at the August 11, 2021 meeting. All issues arising from the meeting have been addressed. The study is now approved. The following documentation forms part of this approval:

Approved Documents:

Consent Forms

[UAH LIBERATE Trial Deferred Consent Version 1.0, August 24 2021 -CLEAN for REB.docx](#)
[UAH LIBERATE_MS_ Patient Regained Capacity Consent Version 2.0 August 24, 2021 - CLEAN.docx](#)
[112293LIBERATE Multisite Information Sheet and Consent Form_August_24_2021_CLEAN.docx](#)

Protocol/Research Proposal

[LIBERATE multi-site Protocol v3.0 19Oct2021 - Clean.docx](#)

Investigator Brochures/Product Monographs

[Midodrine Product Monograph.pdf](#)

Health Canada No Objection Letter

[LIBERATE multi site_NOL257473.pdf](#)

Other Documents

[LIBERATE Multicenter CRF](#)

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. Subject consent for access to identifiable health information is required for the research described in the ethics application, and appropriate procedures for such consent have been approved by the HREB - Biomedical Panel. In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

Any proposed changes to the study must be submitted to the REB for approval prior to implementation. A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (November 25, 2022), you will have to re-submit an ethics application.

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,

S.K.M. Kimber, MD, FRCPC
Chair, HREB Biomedical

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