

Amendment Approval Form

Date: June 13, 2023

Amendment ID: [Pro00112293_AME8](#)

Principal Investigator: [Oleksa Rewa](#)

Study ID: Pro00112293

[Janek Senaratne](#) / pSite00000043 (University of Alberta)

Site Principal Investigators / Study ID: [Jocelyn Slemko](#) / pSite00000044 (University of Alberta)

[Erika MacIntyre](#) / pSite00000050 (University of Alberta)

Study Title: Midodrine for the early liberation from vasopressor support in the ICU – LIBERATE

Protocol Number: version 4.0

Sponsor/Funding Agency: University Hospital Foundation

Approval Expiry Date: November 8, 2023

Thank you for submitting an amendment request to the Health Research Ethics Board - Biomedical Panel. The following has been reviewed and approved on behalf of the committee:

Approved Documents (All Sites):

Protocol/Research Proposal

[LIBERATE multi-site Protocol v4.0_18May2023 - Clean.docx](#)

Other Documents

[LIBERATE CRF v8.0_May_18_2023_clean.docx](#)

Approved Documents (Lead site only):

Consent Forms

[LIBERATE Multisite Information Sheet and Consent Form_March_16_2023_CLEAN.docx](#)

[LIBERATE_MS_Verbal Consent Script and Form- Version 2.0_March_16_2023_CLEAN.docx](#)

[UAH LIBERATE Trial Deferred Consent Version 2.0, March 16, 2023_CLEAN.docx](#)

[UAH LIBERATE_MS_Patient Regained Capacity Consent Version 3.0, March 16, 2023 - CLEAN.docx](#)

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,

Donald W. Morrish, MD, PhD, FRCPC
Associate Chair, HREB Biomedical

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