Health and Disability Ethics Committees
Ministry of Health
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**Ethics reference:** 2024 EXP 20096

22 July 2024

Dr Samantha Holdsworth

466 Childers Road
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New Zealand

Tēnā koe Dr Holdsworth

**APPROVAL OF APPLICATION**

Study title: Magnetic Resonance Imaging (MRI) of brain motion as an indicator for raised intracranial pressure

I am pleased to advise that your application was **approved** by the Northern B Health and Disability Ethics Committee (the Committee) with non-standard conditions. This decision was made through the EXP pathway.

**Conditions of HDEC approval**

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or https://clinicaltrials.gov/).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

- As the risk of post-LP headache is 1 in 4 (very common), the risks associated with lumbar punctures cannot be described as 'rare'. Please amend this description accordingly.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the Ethics Review Manager. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see paragraphs 125 and 126 of the *Standard Operating Procedures for Health and Disability Ethics Committees (SOPs)*.

**After HDEC review**

Please refer to the *SOPs* for HDEC requirements relating to amendments and other post-approval processes.

**Your next progress report is due by 16 July 2025.**

As your study is an intervention study involving a new medicine, all progress reports **must** be accompanied by an annual safety report. While there is no prescribed format for annual safety reports, they must be no longer than two pages in length, written in lay language, and include a brief description and analysis of:

- new and relevant findings that may have a significant impact on the safety of participants
- the safety profile of the new medicine and its implications for participants, taking into account all safety data as well as the results of any relevant non-clinical studies
- the implications of safety data to the risk-benefit ratio for the intervention study, and whether study documentation has been or will be updated
- any measures taken or proposed to minimise risks. (Where such a proposed measure would be a substantial amendment, it must be submitted for

HDEC review in the normal way).

For the avoidance of doubt, Development Safety Update Reports may serve as annual safety reports to HDECs provided that they contain the information outlined above. These summaries should be accompanied by comment from the New Zealand coordinating investigator of the study.

Please refer to paragraphs 206 to 208 of the *SOPs* for further information.

**Participant access to compensation**

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialed. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation.

**Further information and assistance**

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our General FAQ and Ethics RM user manual.

Nāku noa, nā

Ms Kate O'Connor

Chair

Northern B Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

**Appendix A: Documents submitted**

| Document Type | File Name | Date | Version |
|---|---|---|---|
| CV for Coordinating Investigator | Samantha Holdsworth CV 2023 | | |
| Scientific Peer Review | Scientific Peer Review HITH | 14/05/2024 | 1 |
| Protocol | HITH Protocol May 29 | 29/05/2024 | 1 |
| PIS/CF | HITH PIS CF May 29 | 29/05/2024 | 1 |
| Data Management Plan | HITH HDEC data tissue management plan Clean may 29 | 29/05/2024 | 1 |
| Response to PA Document | HITH PIS CF tracked changes July | 10/07/2024 | 1 |
| Response to PA Document | HITH PIS CF clean July 2024 | 10/07/2024 | 2 |
| Response to PA Document | HITH Protocol tracked changes | 10/07/2024 | 2 |
| Response to PA Document | HITH Protocol July 2024 clean | 10/07/2024 | 2 |
| Response to PA Document | HITH HDEC data tissue management plan tracked changes July | 10/07/2024 | 1 |
| Response to PA Document | HITH HDEC data tissue management plan clean July | 10/07/2024 | 2 |
| Response to PA Document | Letter responding to HDEC provisional approval HITH | 10/07/2024 | 2 |