

Ethics reference: 2023 AM 17884

15 June 2023

Dr Christopher Harmston

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Tēnā koe Dr Harmston

APPROVAL OF AMENDMENT

Study title: A national, multi-centre study of post-endoscopy colorectal and upper gastrointestinal cancers in Aotearoa New Zealand

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

Non-standard conditions:

- please clarify in the data management plan how identifiable data provided to the lead investigators by MOH will be 'sent to' each site, ensuring that the method used mitigates the risk of privacy breach.

Non-standard conditions must be completed before commencing any changes as a result of this post-approval submission, however they do not need to be submitted to or reviewed by HDEC.

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 \(SOPs\)](#).

Further information and assistance

Please contact the HDECs Secretariat at hdec@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 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
PAF	Data management plan POET_v2 - track changes	07/06/2023	2
PAF	Data management plan POET_v2 - clean	07/06/2023	2

Review Document Type	Review Document File Name	Review Document Version	Date
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