

Ethics reference: 2023 EXP 15436

11 October 2023

Dr Laird Cameron

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Auckland
1023
New Zealand

Tēnā koe Dr Cameron

APPROVAL OF APPLICATION

Study title: A prospective database for neuroendocrine cancer (NET) patients recommended for peptide radionuclide receptor therapy (PRRT) in New Zealand.

I am pleased to advise that your application was **approved** by the Northern B Health and Disability Ethics Committee (the Committee). 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 *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.

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 11 October 2024.

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 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 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
Data Management Plan	PRRT-Database_DMP_v0.1_30-June-2023	30/06/2023	0.1
Scientific Peer Review	Cameron - Wilson review	12/07/2023	1
Protocol	PRRT-Database_Protocol_v0.8_04-Aug-2023	04/08/2023	0.8
PIS/CF	PRRT_PISCF_v0.4_040823	04/08/2023	0.4
CV for Coordinating Investigator	CV 2023 L Cameron	07/08/2023	1
Response to PA Document	PRRT-Database_Protocol_v2.0_01-Sep-2023_tracked-changes	01/09/2023	2.0
Response to PA Document	PRRT-Database_DMP_v2.0_01-Sep-2023_tracked-changes	01/09/2023	2.0
Response to PA Document	PRRT_PISCF_v2.0_01-Sep-23_tracked-changes	01/09/2023	2.0
Response to PA Document	PRRT-Database_Protocol_v2.0_01-Sep-2023	01/09/2023	2.0
Response to PA Document	PRRT-Database_DMP_v2.0_01-Sep-2023	01/09/2023	2.0
Response to PA Document	PRRT_PISCF_v2.0_01-Sep-23	01/09/2023	2.0
Response to PA Document	PRRT_PISCF_Clinician_v1.0_06-Sep-23	06/09/2023	1
Response to PA Document	PRRT-ethics-resubmission_cover-letter	27/09/2023	1

Review Document Type	Review Document File Name	Review Document Version	Review Document Date
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