

Ethics reference: 2022 FULL 12045

25 May 2022

Professor Jeremy Krebs

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6021
New Zealand

Tēnā koe Professor Krebs

APPROVAL OF APPLICATION

Study title: An Aotearoa New Zealand Diet for Metabolic Health and Whānau Wellbeing: He Rourou Whai Painga

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 FULL 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:

- please include ethics reference number to poster advertisement.

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 23rd May 2023.

Participant access to compensation

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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

A handwritten signature in black ink, appearing to read 'K O'Connor', with a long horizontal flourish extending to the right.

Ms Kate O'Connor

Chair

Northern B Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix B: statement of compliance and list of members

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Protocol	HRWP Main Study Protocol V4 17Mar22	17/03/2022	4
AI Impact and Risk Assessment	Passio Privacy Policy	17/03/2022	1
AI Impact and Risk Assessment	Passio Terms of Use Agreement	17/03/2022	1
Advertisement	Advertisement V1 17Mar22	17/03/2022	1
PIS/CF	Consumer Insights Focus Groups PISICF MAIN V1 17Mar22	17/03/2022	1
PIS/CF	Consumer Insights Interviews PISICF MAIN V1 17Mar22	17/03/2022	1
PIS/CF	Consumer Insights Survey PISICF MAIN V1 17Mar22	17/03/2022	1
PIS/CF	Household whanau PIS and consent V1 17Mar22	17/03/2022	1
PIS/CF	Index participant PIS and Consent V1 17Mar22	17/03/2022	1
PIS/CF	PIS and Assent 5-10y V1 17Mar22	17/03/2022	1
PIS/CF	PIS and Assent 11-13y V1 17Mar22	17/03/2022	1
PIS/CF	PIS and Assent 14-15y V1 17Mar22	17/03/2022	1
PIS/CF	Sub-study use of phone app PIS, V1 17Mar22	17/03/2022	1
PIS/CF	Tissue Banking V1, 17Mar22	17/03/2022	1
Surveys/questionnaires	Health-self-assessment-SF-36	17/03/2022	1
Surveys/questionnaires	Kaupapa Ma āori Wellbeing and Quality of Life Questionnaire_Adults V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Kaupapa Ma āori Wellbeing and Quality of Life Questionnaire_Rangatahi V1 17Mar22	17/03/2022	1
PIS/CF	Tissue Banking V1, 17Mar22	17/03/2022	1
Data and Tissue Management Plan	Data Tissue Management Plan V1 17Mar22	17/03/2022	1
CV for Coordinating Investigator	Jeremy Krebs CV V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Child Three Factor Eating Questionnaire r17 V1 17Mar22	17/03/2022	1
Surveys/questionnaires	COM-B Questionnaire for ethics_HRWP V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Dietary Habits Questionnaire 5-10yrs V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Gastro intestinal symptom rating scale V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Impact Evaluation for BCS_ ethics_ HRWP V1 17Mar22	17/03/2022	1
Surveys/questionnaires	NZPAQ_physical activity questionnaire V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Short FFQ_hrwpFINAL_NZ V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Sub-study use of phone app questionnaire V1 17Mar22	17/03/2022	1
Surveys/questionnaires	ThreeFactorEatingQ-r18 V1 17Mar22	17/03/2022	1
Surveys/questionnaires	Visual analogue scale V1 17Mar22	17/03/2022	1
Other	Consumer Insights Study TOPIC GUIDES V1 17Mar22	17/03/2022	1
Other	Sub study phone App Interview Topic Guide v1 17Mar22	17/03/2022	1
Scientific Peer Review	HRWP external peer review V1 17Mar22	17/03/2022	1
Response to PA Document	Cover letter response to HDEC ref 12045 12May22	12/05/2022	1
Response to PA Document	IPAQ_English_self-admin_long	12/05/2022	1
Response to PA Document	HRWP Main Study Protocol V5 12May22 tracked	12/05/2022	5
Response to PA Document	HRWP Main Study Protocol V5 12May22 CLEAN	12/05/2022	5
Response to PA Document	Krebs Indemnity 12May22	12/05/2022	1
Response to PA Document	HRWP Adverts 12May22	12/05/2022	1
Response to PA Document	Focus Gps PISCF V2 12May22 CLEAN	12/05/2022	2
Response to PA Document	FOCUSG~2	12/05/2022	2
Response to PA Document	Interviews PISICF V2 12May22 CLEAN	12/05/2022	2
Response to PA Document	INTERV~2	12/05/2022	2

Response to PA Document	Index PIS and Consent V2 12May22 CLEAN	12/05/2022	2
Response to PA Document	Index PIS and Consent V2 12May22 tracked	12/05/2022	2
Response to PA Document	Whanau PIS and consent V2 12May22 CLEAN	12/05/2022	2
Response to PA Document	Whanau PIS and consent V2 12May22 tracked	12/05/2022	2
Response to PA Document	PIS and Assent 5-10y V2 12May22 CLEAN	12/05/2022	2
Response to PA Document	PIS and Assent 5-10y V2 12May22 tracked	12/05/2022	2
Response to PA Document	PIS and Assent 11-13y V2 12May22 CLEAN	12/05/2022	2
Response to PA Document	PIS and Assent 11-13y V2 12May22 tracked	12/05/2022	2
Response to PA Document	PIS and Assent 14-15y V2 May22 CLEAN	12/05/2022	2
Response to PA Document	PIS and Assent 14-15y V2 May22 tracked	12/05/2022	2
Response to PA Document	SUB-ST~2	12/05/2022	2
Response to PA Document	SUB-ST~1	12/05/2022	2
Response to PA Document	Tissue Banking PISCF V2 12May22 CLEAN	12/05/2022	2
Response to PA Document	Tissue Banking PISCF V2 12May22 tracked	12/05/2022	2

Appendix B: Statement of compliance and list of members

Statement of compliance

The Northern B Health and Disability Ethics Committee

- is constituted in accordance with its Terms of Reference
- operates in accordance with the [Standard Operating Procedures for Health and Disability Ethics Committees](#), and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Mrs Kate O'Connor (Lay (ethical/moral reasoning)), Mrs Leesa Russell (Non-lay (observational/intervention studies)), Ms Susan Sherrard (Lay (consumer/community perspectives)), Mr Barry Taylor (Non-lay (observational/intervention studies)), Ms Alice McCarthy (Lay (the law)).

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference).

<http://www.ethics.health.govt.nz>