

29 March 2021

Dr. Nicholas Hoeh
Dept of Psychological Medicine
School of Medicine
Building 507 Level 3, Room 3040
Grafton, Auckland 1023

Dear Dr. Hoeh

Re:	Ethics ref:	20/NTA/163
	Study title:	A randomised controlled pilot study of ketamine-assisted therapy: Does fractal priming improve treatment response in treatment-resistant depression?

I am pleased to advise that this application has been approved by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review 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 A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. : Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. 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 *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 28 March 2022.

Participant access to ACC

The Northern A 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 trialled. 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 (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Mrs Kate O'Connor
Acting Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of scientific review: Scientific Peer Review by Dr. Venkat Naga20 September 2020	1	20 September 2020
Survey/questionnaire: MADRS Structured Interview	1	01 October 2020
Survey/questionnaire: ATRQ --previous antidepressants trialed	1	01 October 2020
Survey/questionnaire: Suicide Screening	1	01 October 2020
Survey/questionnaire: QIDS-self report depression questionnaire	1	01 October 2020
Head of Department Approval	1	02 October 2020
CV for CI	1	04 October 2020
PIS/CF: Participant Information Sheet	1	04 October 2020
Protocol: Protocol Document	1	04 October 2020
Survey/questionnaire: Hamilton A	1	04 October 2020
Survey/questionnaire: Big Five Inventory 2	1	04 October 2020
Survey/questionnaire: Hero Wellness Scale	1	04 October 2020
Survey/questionnaire: 5D-ASC	1	05 October 2020
Survey/questionnaire: MODTAS	1	05 October 2020
Application		05 October 2020
PIS/CF: Updated PIS Clean Version 2	V2	27 January 2021
PIS/CF: Updated PIS with tracked changes	V2	27 January 2021
Data Tissue Management Plan	Version 1	27 January 2021
On Line Advertisement	Version 1	27 January 2021
Protocol: Protocol resubmission Version 1 Clean	Version 2	27 January 2021
Unblinding letter	Version 1	27 January 2021
Protocol: Protocol Version 2 with tracked changes	2	27 January 2021
Covering Letter: Letter to HDEC regarding resubmitted documents	2	27 January 2021
Response to Request for Further Information		
KETIMDEP_OnlineAdvert_NHV.docx		
PIS/CF: KETIMDEP_PIS_NHV(2).docx	2.0	
PIS/CF: KETIMDEP_PISMLv7_TRK.docx	7.0	
PIS/CF: KETIMDEP_PISMLv7clean.docx	7.0	
Protocol: KETIMDEP_ProtocolMLv9_TRK.docx	9.0	
Protocol: KETIMDEP_ProtocolMLv9clean.docx	9.0	
PIS/CF: PIS RecentEdits (1).pdf		
SRS.pdf		
CAEQ.pdf		
Covering Letter: Cover Letter for request for further information_22 March 2021.pdf		

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern A 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 [##CommitteeIRBNumber##]) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Kate O'Connor	Lay (consumer/community perspectives)	29/01/2020	29/01/2021
Dr Karen Bartholomew	Non-lay (intervention studies)	18/07/2016	18/07/2022
Dr Sotera Catapang	Non-lay (observational studies)	11/02/2020	11/02/2023
Ms Catherine Garvey	Lay (the law)	19/03/2019	19/03/2022
Dr Michael Meyer	Non-lay (health/disability service provision)	11/02/2020	11/02/2023
Dr Kate Parker	Non-lay (observational studies)	11/02/2020	11/02/2026
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

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>