

Ethics reference: 2022 AM 9877

10 February 2022

Tēnā koe

APPROVAL OF AMENDMENT

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 amendment was **approved** by the Northern A Health and Disability Ethics Committee (the Committee) with non-standard conditions. This decision was made through the post-approval pathway.

Non-standard conditions:

- Please consider whether it will invariably be appropriate to offer copies of the video and audio recordings to the participants and whether it may be desirable to provide for these to be viewed with therapist support,
- the Consent Form has the word "social" in error (alongside consent for video and audio recordings).

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 FAQ](#).

Nāku noa, nā



Ms Catherine Garvey

Chair

Northern A Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Non-Review Document	KETIMDEP_PISv14nrh Tracked	18/01/2022	14
Non-Review Document	KETIMDEP_PIS v14 Final	18/01/2022	14
Non-Review Document	KETIMDEP_Protocolv14nrh Tracked	18/01/2022	14
Non-Review Document	KETIMDEP_Protocol v14 Final	18/01/2022	14
Non-Review Document	Cover Letter v3 Final	18/01/2022	3

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