Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011
hdecs@health.govt.nz

Ethics reference: 21/NTA/169

29 November 2021

Miss Nurina Maria Katta

School of Psychology, Speech and Hearing ,University of Canterbury ,Private Bag 4800
Christchurch
8025
New Zealand

Tēnā koe Miss Katta

APPROVAL OF APPLICATION

Study title: An investigation into whether a new delivery modality of micronutrients can improve emotion dysregulation and irritability in children between 5-10 years of age.

I am pleased to advise that your application was **approved** by the Northern A Health and Disability Ethics Committee (the Committee) with non-standard conditions. This decision was made through the RMDF pathway.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. Please further consider the wording of the advertising as this still implies a proven benefit by stating that it is dosing and dispensing methods that are now undertrial when efficacy in children is also of interest.
2. Please ensure that data collected from potential participants who are screened, and ineligible is deleted and that this is referred to in the abridged screening PISCF. This also applies if participants contact the researcher by phone as they are invited to do in the advertising and are asked the screening questions.
3. Please remove the YES/NO options in the Consent Forms unless these items are truly optional.

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:

- 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 address all outstanding ethical issues raised by the Committee

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 29 November 2022.

Participant access to compensation

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.

Further information and assistance

Please contact the HDECs Secretariat at hdecs@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 B: statement of compliance and list of members

Appendix A: Documents submitted

Document Type	File Name	Date	Version
CV for Coordinating Investigator	Nurina Katta's CV, outlining her education, academic achievements, and work and volunteer experience to date.	19/08/2021	CV for CI (1)
Default	Participant information sheet for parents.	19/08/2021	PIS/CF for persons interested in welfare of non-consenting participant (1)
PIS/CF	Information sheet for children.	19/08/2021	PIS/CF (1)
Default	Participant information sheet for other significant adults in the children's lives.	19/08/2021	PIS/CF for persons interested in welfare of non-consenting participant (1)
CV's for Other Investigators	CV of secondary supervisor Neville Blampied.	19/08/2021	CVs for other Investigators (1)
CV's for Other Investigators	CV of primary supervisor Julia Rucklidge.	19/08/2021	CVs for other Investigators (1)
Other	Advertisement poster SUNNY trial	19/08/2021	Other (1)
Other	Advertisement poster with contact details.	19/08/2021	Other (1)
Other	All questionnaires that will be administered in the proposed study.	19/08/2021	Survey/questionnaire (1)
CV's for Other Investigators	CV of the study physician (psychiatrist) Matt Eggleston.	19/08/2021	CVs for other Investigators (1)
Other	Advertising brochure for the SUNNY trial.	19/08/2021	Other (1)
Covering Letter	Cover letter for the SUNNY trial.	19/08/2021	Covering Letter (1)
Other	Confirmation letter from the Ngāi Tahu Consultation and Engagement Group approving the study process.	19/08/2021	Other (1)
Protocol	Study protocol of the SUNNY trial outlining the study background, the study design and procedure, measures and statistical methods.	19/08/2021	Protocol (1)
Evidence of Scientific Review	Scientific peer review SUNNY trial.	19/08/2021	Evidence of scientific review (1)
MDF Doc	Form Submission	27/08/2021	NZ/1/866B14

Review Document Type	Review Document File Name	Review Document Version Date
Response to PA Document	advertisement contact details PhD_clean version.docx	17/11/2021
Response to PA Document	advertisement contact details PhD _highlighted changes - Copy.docx	17/11/2021
Response to PA Document	brochure PhD clean version.pub	17/11/2021
Response to PA Document	brochure PhD highlighted changes.pub	17/11/2021
Response to PA Document	Children information sheet and assent form_clean version.doc	17/11/2021
Response to PA Document	Children information sheet and assent form_tracked changes.doc	17/11/2021
Response to PA Document	HDEC other adult_clean version.doc	11/11/2021
Response to PA Document	HDEC other adult_tracked changes.doc	11/11/2021
Response to PA Document	HDEC PIS legal guardian_clean version.docx	11/11/2021

Response to PA Document	HDEC PIS legal guardian_tracked changes.docx	11/11/2021
Response to PA Document	HDEC response letter_Nurina Katta.docx	17/11/2021
Response to PA Document	HDEC-data-only-management-template-Oct-2021.docx	04/11/2021
Response to PA Document	poster PhD clean version.pptx	17/11/2021
Response to PA Document	poster PhD highlighted changes.pptx	17/11/2021
Response to PA Document	STUDY PROTOCOL_clean version.docx	17/11/2021
Response to PA Document	STUDY PROTOCOL_tracked changes.docx	17/11/2021

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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Catherine Garvey (Lay (the law)), Dr Karen Bartholomew (Non-lay (intervention studies)), Dr Kate Parker (Non-lay (observational studies)), Dr Sotera Catapang (Non-lay (observational studies)), Mr Johnathan Darby (Lay (the law/ethical reasoning)), Dr Leonie Walker (Lay (ethical/moral reasoning)), Ms Jade Scott (Non-lay (observational/intervention studies)).

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