

November 28th 2018

Dr Tamara Nation
NIIM
21 Burwood Road
HAWTHORN VIC 3122

**NIIM trial reference
number:** 0047E_2018
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Email:
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Dear Dr Tamara Nation,

NIIM HREC Reference number: 0047E_2018

Project title: Randomised placebo-controlled trial investigating the effect of supplementation with probiotics and vitamin D before and after routine childhood immunisation on physiological and behavioural responses in 4-24 month-old infants.

Thank you for submitting the above research project for single ethical review. This project was considered by the National Institute of Integrative Medicine Human Research Ethics Committee EC00436 (NIIM HREC) at its meeting held on 23rd October 2018.

I am pleased to advise you that the above research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* and ethical approval for this research project has been granted by NIIM HREC (EC00436).

The nominated participating site/s in this project is/are:

NIIM Melbourne
21 Burwood Road
HAWTHORN VIC 3122

[Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify NIIM HREC (EC00436). Notification of withdrawn sites should also be provided to the NIIM HREC (EC00436) in a timely fashion.

The approved documents include:

Document	Version	Date
E1 VISS Study HREC Application Form	V2	26.09.18
E2 VISS Participant Information Sheet	V4	19.11.18
E3 VISS Informed Consent Form	V4	19.11.18
E4 Protocol VISS Study	V2	26.09.18
Q0 Baseline Screening Questionnaire	V1	19.11.18
Q1 Infant Home Diary	V1	26.09.18
Q2 VISS Study Other Symptoms Questionnaire	V1	26.09.18

Q3 Carer Bond Lader Mood Questionnaire	V1	26.09.18
Q4 Parent Sleep Questionnaire	V1	26.09.18

Approval of this project from NIIM HREC (EC00436) is valid from 28/11/2018-28/11/2021, subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the NIIM HREC (EC00436) of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with NIIM HREC EC00436) policy and procedures.
- The Coordinating Principal Investigator will report to the NIIM HREC (EC00436) annually in the specified format and notify the NIIM HREC (EC00436) when the project is completed at all sites.
- The Coordinating Principal Investigator will notify the NIIM HREC (EC00436) if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the NIIM HREC (EC00436) of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Coordinating Principal Investigator will notify the NIIM HREC (EC00436) of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- The changes to documentation as set out below are made.

A copy of this ethical approval letter must be submitted by all site Principal Investigators at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Should you have any queries about the NIIM HREC's (EC00436) consideration of your project please contact the HREC Administrator. NIIM HREC (EC00436) Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the NIIM HREC Administrator.

The NIIM HREC (EC00436) wishes you every success in your research.

Yours faithfully,



Alan Hayes
Chair person

National Institute of Integrative Medicine Human Research Ethics Committee (EC00436)

Disclaimer:

This HREC, in granting ethical approval for this study:

- is carrying out its duties and obligations under the National Statement on Ethical Conduct in Research Involving Humans;
- although registered with NHMRC, carries out its duties entirely independently of NHMRC;

The decision by this HREC to grant ethics approval for this research proposal does not reflect the views of NIIM, NHMRC or any of the personnel of either organisation, nor is any such decision to be regarded as an endorsement by NIIM or NHMRC of this study or its conclusions.