

18 July 2023

A/Prof Karin Ried  
NIIM  
21 Burwood Road  
Hawthorn VIC 3122

**NIIM trial reference  
number:** 0124N\_2023  
**Phone:** +613 9912 9586  
**Fax:** +613 9804 0513  
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Dear A/Prof Ried,

**NIIM HREC Reference number:** 0124N\_2023  
**Project title:** *The Cognitive Preservation Project*

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 6 June 2023.

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  
21 Burwood Road  
Hawthorn VIC 3122

Swinburne University of Technology  
Swinburne Neuroimaging Facility  
John Street  
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 Notification of withdrawn sites should also be provided to the NIIM HREC (EC00436) in a timely fashion.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
HREC_Application-Form_cognitionproject	V8.0	11/7/2023
Protocol_cognition project	V8.0	11/7/2023
PICF_cognition project	V7.0	11/7/2023
Q_TICS-M Australian Version Manual	V1.0	8/5/2023
SOP_MMSE	V1.0	8/5/2023
Q_MMSE	V1.0	8/5/2023
SOP_SDMT	V1.0	8/5/2023
Q_SDMT	V1.0	8/5/2023

SOP_HVLT-R	V1.0	8/5/2023
Q_HVLT-R	V1.0	8/5/2023
MRI Checklist and consent form	V1.0	8/5/2023
WellRed Coronet Manual	V1.0	8/5/2023
HBOT patient questionnaire	V1.0	8/5/2023
HBOT Consent Form15 3a_XP fundraising	V2.0	15/6/2023
XP fundraising	V1.0	8/5/2023
CV_Karin Ried_Apr23 short	V1.0	8/5/2023
CV_Avni Sali AM Jan 2022	V1.0	8/5/2023
CV_Lisa Rapley	V1.0	8/5/2023
Acceptability	V1.0	15/6/2023
Fundraising summary	V1.0	8/5/2023

Approval of this project from NIIM HREC (EC00436) is valid from 18 July 2023 to 17 July 2026, 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.

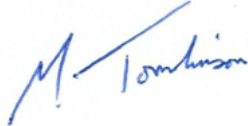
A copy of this ethical approval letter must be submitted by all site Principal Investigators at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

**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 Secretary. NIIM HREC (EC00436) Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the NIIM HREC Secretary at [hrec@niim.com.au](mailto:hrec@niim.com.au).

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

Yours faithfully,



Dr Michael Tomlinson  
Chair  
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.