

October 1 2017

Dr Karin Ried
NIIM
21 Burwood Road
Hawthorn VIC 3142

**NIIM trial reference
number:** 0040N_2017
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Dear Dr. Ried,

NIIM HREC Reference number: 0040N_2017

Project title: Screening for Circulating Tumour Cells (CTC) and other rare cells for early detection of cancer risk, and monitoring of treatment effectiveness in cancer patients using the ISET (Isolation by Size of Epithelial/Trophoblastic Tumour Cells, Rarecells) technology

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 26 September 2017.

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 Victoria 3124

[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 Notification of withdrawn sites should also be provided to the NIIM HREC (EC00436) in a timely fashion.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	3	20/9/2017
Patient Information – CTC brochure	3	20/9/2017
Consent form	3	20/9/2017
CTC Test Request Form	3	20/9/2017

Approval of this project from NIIM HREC (EC00436) is valid from 16/10/2017-31/12/2019, 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.

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual 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 Kelly Besim. NIIM HREC (EC00436) Terms of Reference, Standard Operating Procedures, membership and standard forms are available from from the NIIM HREC Administrator Kelly Besim.

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

Yours faithfully,

Kelly Besim
NIIM HREC Administrator

For
Dr Michael Tomlinson
Chairperson
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.