

7 March 2024

Dr Muhd Taufiq Bin Jemain  
Willow Vale Clinic  
Goad Coast QLD 4209

**NIIM trial reference  
number:** 0131N\_2023  
**Phone:** +613 9912 9586  
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Dear Dr Bin Jemain,

**NIIM HREC Reference number:** 0131N\_2023

**Project title:** *The ReDO Cancer Treatment Study*

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 13 February 2024.

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:

- Patient recruitment & blood draw & treatment:
  - Willow Vale Clinic, Gold Coast, QLD 4209
- CTC analysis & Study data analysis:
  - NIIM Melbourne, 21 Burwood Rd, Hawthorn, VIC 3122

The approved documents include:

Document	Version	Date
HREC Form V6.0 ReDO study	V1.7	27.2.2024
Ethics Protocol ReDO	V1.7	27.2.2024
PICF_ReDO	V1.7	27.2.2024
Appendix_QLQ-C30_QoL questionnaire	V1.0	9.10.2023
Q Diet and Physical Activity Questionnaire REDO Study	V1.0	24.1.2024
CV Taufiq BinJemain	V1.0	9.2023
CV Heidi Dahlenburg	V1.0	9.2023
CV Karin Ried	V1.0	24.1.2024
Table 3_ReDO19 meds side effects	V1.0	24.1.2024

Table 4_ ReDO Drug interaction Matrix	V2.0	24.1.2024
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Approval of this project from NIIM HREC (EC00436) is valid from 7 March 2024 to 6 March 2027, 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.