

Monash University Human Research Ethics Committee
Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project ID: 36674
Application Type: HREC Review
Project Title: ARCHIMEDES study: Investigating clonal haematopoiesis in atherosclerosis progression
Chief Investigator: Professor Stephen Nicholls
Approval Date: 23/08/2023
Expiry Date: 23/08/2028

Terms of approval - failure to comply with the terms below is in breach of your approval and the *Australian Code for the Responsible Conduct of Research*.

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
7. Annual Report - continued approval of this project is dependent on the submission of an Annual Report.
8. Final Report - should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date.
9. Monitoring - the project may be subject to an audit or any other form of monitoring by MUHREC at any time.
10. Retention and storage of data - The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Kind Regards,

Professor Nip Thomson

Chair, MUHREC

CC: Ms Julie Butters, Mr Domenic Sacca, Dr Kristen Bubb

List of approved documents:

Document Type	File Name	Date	Version
Supporting Documentation	2023-MPR-NSE-187-RadiationRiskAssessment	14/06/2023	1
Consent Form	ABC_Participant_Information_4a_v3.3	16/06/2023	1
Questionnaires / Surveys	Assessment of cardiovascular disease risk	24/06/2023	1
Supporting Documentation	ARCHIMEDES_CHIP_Participant_Report_v1	24/06/2023	1
Ionising Radiation Form	Victorian-Medical-Physics-Risk-Assessment-Form_ARCHIMEDES 260731	31/07/2023	2
Consent Form	MUHREC consent form ARCHIMEDES_20230731	31/07/2023	2
Consent Form	MUHREC consent form ARCHIMEDES_20230731	31/07/2023	2
Supporting Documentation	ARCHIMEDES - Contact letter_18082023	18/08/2023	3

Document Type	File Name	Date	Version
Explanatory Statement	MUREC explanatory statement ARCHIMEDES_20230818_v3	18/08/2023	3