

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: 29476

Project Title: The ORIENT study: imprOving Rural and regional accEss to long acting reversible contraceptioN and medical abortion through nurse-led models of care, Tasksharing and telehealth

Chief Investigator: Professor Danielle Mazza

Approval Date: 23/11/2021

Expiry Date: 23/11/2026

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 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 - 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: Miss Nilab Hamidi, Dr Asvini Subasinghe, Ms Mridula Shankar, Dr Jessica Botfield, Miss Kellie Hamill, Dr Wendy Norman, Prof Kirsten Black, Prof Jane Tomnay, A/Prof Deborah Bateson, A/Prof Kevin McGeechan, A/Prof Tracey Laba

List of approved documents:

Document Type	File Name	Date	Version
Supporting Documentation	ORIENT Flyer_22092021	22/09/2021	version 1
Supporting Documentation	ORIENT_ParticipantLetterOfInvitation_v02	22/09/2021	version 1
Supporting Documentation	ORIENT_ParticipantSummary_v02	22/09/2021	version 1
Explanatory Statement	ORIENT_ParticipantExplanatoryStatement_v01	22/09/2021	version 1
Consent Form	ORIENT_ParticipantConsentForm_v02	22/09/2021	version 1
Supporting Documentation	ORIENT Trial_protocol_V04_210921_ForEthics	22/09/2021	version 1
Questionnaires / Surveys	KAP GP Survey	22/09/2021	version 1
Questionnaires / Surveys	KAP nurse Survey	22/09/2021	version 1
Supporting Documentation	ORIENT_EoIForm_v05	22/09/2021	version 1
Consent Form	ORIENT_Participant_Consent_Withdrawal_Form_v2	22/09/2021	version 1
Consent Form	ORIENT_ParticipantConsentForm_v03-Final	02/11/2021	version 2

Supporting Documentation	ORIENT Trial_protocol_V05_011121_ForEthics	02/11/2021	version 2
Supporting Documentation	ORIENT FlyerV3	10/11/2021	version 2
Supporting Documentation	ORIENT_ParticipantLetterOfInvitation_v03_final	10/11/2021	version 2
Supporting Documentation	ORIENT_ParticipantSummary_v05_final	10/11/2021	version 2
Explanatory Statement	ORIENT_ParticipantExplanatoryStatement_v03-Final	10/11/2021	version 2
Consent Form	ORIENT_ParticipantConsentForm_PM_v02_Final	10/11/2021	version 1
Supporting Documentation	ORIENT_DistressProtocol_v02_20211109	10/11/2021	version 1
Supporting Documentation	Application Cover letter_20211110	10/11/2021	version 1