

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: 22438
Project Title: Validation of the ATMO gas-capsule localising technique via intestinal ultrasound (GIUS)
Chief Investigator: Professor Peter Gibson
Approval Date: 11/12/2019
Expiry Date: 11/12/2024

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: Dr Phoebe Thwaites, Dr Chu Yao, Dr Kirstin Taylor, Assoc Professor Jane Muir, Ms Rebecca Smith, Dr Kyle Berean

List of approved documents:

Document Type	File Name	Date	Version
Supporting Documentation	361_1073_03_AGC Gen1 app instructions for use	11/04/2019	1
Supporting Documentation	361_1074_03_AGC Gen1 app troubleshooting	11/04/2019	1
Supporting Documentation	361_1053_01_Atmo Investigator Brochure 10 May 2019-SIGNED	10/05/2019	1
Explanatory Statement	ATMO localising study v1	04/11/2019	1
Questionnaires / Surveys	Symptom diary	04/11/2019	1
Clinical Trial Agreement	MTAA Clinical Investigation Research Agreement 19-3150 v1	04/11/2019	1
Supporting Documentation	Atmo localising study flier v2	02/12/2019	v2
Supporting Documentation	Email text-v2 Nov	02/12/2019	2
Supporting Documentation	VOLUNTEERS REQUIRED social media post	02/12/2019	v1

Supporting Documentation	Consent form v2 tracked changes	02/12/2019 2
Supporting Documentation	ATMO localisation study protocol v2 December 2 2019 FINAL	02/12/2019 2
Consent Form	Consent form v2 tracked changes	02/12/2019 2
Supporting Documentation	Amendment summary Dec 2 2019 FINAL	02/12/2019 2
Supporting Documentation	ATMO localising study explanatory statement v2 tracked changes FINAL DEC2	02/12/2019 2
Supporting Documentation	ATMO localising study explanatory statement (signed) clean December 2 V2	02/12/2019 2
Supporting Documentation	Amendment summary Dec 11 2019	11/12/2019 1