

**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:** 29500  
**Project Title:** Australian Research on Insomnia Sleep and Emotions (ARISE)  
**Chief Investigator:** Professor Sean Drummond  
**Approval Date:** 01/12/2021  
**Expiry Date:** 01/12/2026

**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: Ms Vivien Vuong, Dr Bei Bei, Dr Alix Mellor, Professor Victoria Visbrough

**List of approved documents:**

Document Type	File Name	Date	Version
Supporting Documentation	Social Media Ad_Man	23/07/2021	1
Supporting Documentation	Social Media Ad_Woman	23/07/2021	1
Supporting Documentation	Insomnia.org.au Expression of Interest Webpage	23/07/2021	1
Psychological inventories	IUS-12_ARISE	06/08/2021	1
Psychological inventories	MCTQ Core	06/08/2021	1
Psychological inventories	MEQr	06/08/2021	1
Psychological inventories	FFS	06/08/2021	1
Psychological	ESS	06/08/2021	1

inventories		
Psychological inventories	DUDIT_ARISE	06/08/2021 1
Psychological inventories	PCL5_ARISE	06/08/2021 1
Psychological inventories	LEC5_Standard_ARISE	06/08/2021 1
Psychological inventories	PROMIS_Anxiety_ARISE	06/08/2021 1
Psychological inventories	PHQ9_ARISE	06/08/2021 1
Psychological inventories	DSPD pre-screening questionnaire	06/08/2021 1
Psychological inventories	FIRST	06/08/2021 1
Psychological inventories	Side Effects Inventory_ARISE	06/08/2021 1
Psychological inventories	WEMWBS_ARISE	06/08/2021 1
Psychological inventories	Pre Sleep Arousal Scale (PSAS)	06/08/2021 1
Questionnaires / Surveys	COVID-19 Symptom Checklist	06/08/2021 1
Psychological inventories	AUDIT_ARISE	07/08/2021 1
Psychological inventories	PSAS_last night	08/11/2021 1
Psychological inventories	SHI	08/11/2021 1
Psychological inventories	PROMIS_Sleep related impairment 8a	08/11/2021 1
Psychological inventories	DBAS_ARISE	08/11/2021 1
Psychological inventories	ARISE ISI Final	08/11/2021 1
Psychological inventories	BSCS	08/11/2021 1
Psychological inventories	BC-CCI	08/11/2021 1
Psychological inventories	CEQ_ARISE	08/11/2021 1
Psychological inventories	CSQ	08/11/2021 1
Psychological inventories	PROMIS_Satisfaction_with_Social_Roles_Activities_8a	08/11/2021 1
Psychological inventories	CAF	08/11/2021 1
Psychological inventories	State_Trait_Anxiety_Inventory	08/11/2021 1
Psychological inventories	Karolinska Sleepiness Scale	08/11/2021 1
Supporting Documentation	Qualtrics Link to Expression of Interest Form	08/11/2021 1
Supporting Documentation	SCISD-R ARISE Version_AM	09/11/2021 1
Supporting Documentation	ARISE SCID5 Adapted Summary Sheet_AM	09/11/2021 1
Supporting	Project ARISE Webpage - Turner Institute for Brain and Mental Health	11/11/2021 1

Documentation			
Supporting Documentation	ARISE Brochure with QR Code	11/11/2021	1
Supporting Documentation	ARISE Poster with QR Code	11/11/2021	1
Explanatory Statement	ARISE Explanatory Statement 11.11.21	11/11/2021	1
Consent Form	ARISE Consent Form 09.11.21	11/11/2021	1
Psychological inventories	ARISE Sleep Diary_BASE overnight sleep study	11/11/2021	1
Psychological inventories	ARISE Sleep Diary_HOME (paper)	11/11/2021	1
Psychological inventories	ARISE Sleep Diary_For pts with Hot Flashes during Pre & Post-treatment Testing Phases (paper)	11/11/2021	1
Questionnaires / Surveys	ARISE Pre-screening Questionnaire 12.11.21	12/11/2021	1
Questionnaires / Surveys	ARISE PI&C Demographic & Screening Questionnaire 12.11.21	12/11/2021	1
Supporting Documentation	ARISE PI&C Health Interview 12.11.21	12/11/2021	1
Supporting Documentation	ARISE Consent release of info	16/11/2021	1