

**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 Number:** 9780  
**Project Title:** The Postpartum Sleep Study for Mothers (POSSUM) Project  
**Chief Investigator:** Dr Bei Bei  
**Approval Date:** 13/02/2018  
**Expiry Date:** 13/02/2023

**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.

Thank you for your assistance.

Professor Nip Thomson

Chair, MUHREC

CC: Miss Sumedha Verma, Dr Bei Bei, Professor Shanthakumar Wilson Rajaratnam

**List of approved documents:**

Document Type	File Name	Date	Version
Questionnaires / Surveys	01_Duke_Screening	21/11/2017	1
Questionnaires / Surveys	02_Duke_Full	21/11/2017	1
Questionnaires / Surveys	03_Duke_Insomnia_T3	21/11/2017	1
Supporting Documentation	03_Recruitment_Email	21/11/2017	1
Supporting Documentation	04_Inc_Exc_Criteria	21/11/2017	1
Supporting Documentation	06_Int_Outline	21/11/2017	1
Supporting Documentation	07_Luminette_Voucher	21/11/2017	1
Supporting Documentation	08_SafetyReport_Luminette2	21/11/2017	1
Explanatory Statement	01_ES_POSSUM	21/11/2017	1
Consent Form	02_Screen_Consent_Form	21/11/2017	1
Supporting Documentation	05_Timing_Assessment	21/11/2017	1
Questionnaires / Surveys	T1_Questionnaire	21/11/2017	1
Questionnaires / Surveys	T2_Questionnaire	21/11/2017	1

Questionnaires / Surveys	T3_Questionnaire	21/11/2017	1
Questionnaires / Surveys	T4_Questionnaire	21/11/2017	1
Psychological inventories	05_Timing_Assessment	21/11/2017	1
Supporting Documentation	02_ES_POSSUM_V2	04/02/2018	2
Supporting Documentation	04_Ethics_Response	04/02/2018	1