

E-mail: [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au) ; [cameron.lutman@health.nsw.gov.au](mailto:cameron.lutman@health.nsw.gov.au)  
<https://www.swslhd.health.nsw.gov.au/ethics/>



**Please note, the Research Directorate will be closed from 24 December 2022 and will re-open from 9 January 2023. Please see below for relevant submission closing dates to assist with your future planning in your research applications.**

**SWSLHD Ethics and Governance submission deadlines:**

- Closing submission date for new Greater than Low Risk Ethics Applications – 25/11/2022
- Closing submission date for new Low risk ethics applications – 02/12/2022
- Closing submission date for new Site specific applications (inclusive of all Head of Department support) – 28/11/2022
- Closing date for all other submissions – 16/12/2022

**From:** no\_reply@regis.health.nsw.gov.au [mailto:no\_reply@regis.health.nsw.gov.au]  
**Sent:** Thursday, 22 December 2022 3:20 PM  
**To:** X.Zhu@westernsydney.edu.au  
**Cc:** SWSLHD-Ethics <SWSLHD-Ethics@health.nsw.gov.au>  
**Subject:** 2022/ETH02353: Application HREA - Approved \*\*\*\* ETHICS APPROVAL ONLY  
 \*\*SITE SPECIFIC AUTHORISATION REQUIRED\*\*

Date of Decision Notification: **22 Dec 2022**

Dear Xiaoshu Zhu,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

**2022/ETH02353:** Baduanjin mind-body exercise for cancer-related fatigue in cancer participants receiving adjuvant chemotherapy: a randomised control feasibility trial

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **South Western Sydney Local Health District Human Research Ethics Committee** at its meeting.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

**This email constitutes ethical and scientific approval only.**

**This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.**

This project has been Approved to be conducted at the following sites:

- **Liverpool Hospital**

The following documentation was reviewed and is included in this approval:

Documentation Title	Version	Date
Human Research Ethics Application	Version 3.0	12.12.2022
Protocol	Version 1.1	19.12.2022
MASTER Participant Information Sheet	Version 1.1	19.12.2022
MASTER Consent Form	Version 1.1	19.12.2022
MASTER Revocation of Consent	Version 1.0	28.09.2022
MASTER BDJ Advertisement	Version 1.1	19.12.2022
Baduanjin Instructional Video Link	Version 1.0	28.09.2022
MASTER Final Feedback Form (Week 9)	Version 1.0	28.09.2022
Baduanjin Mind-body Exercise Instruction Handbook	Version 1.0	09.2022
MASTER Baduanjin Mind-body Exercise Logbook	Version 1.0	28.09.2022
MASTER Screening Checklist Form	Version 1.0	28.09.2022
MASTER Case Report Form	Version 1.0	28.09.2022
MASTER Adverse Events Form	Version 1.0	28.09.2022
Research Data Management Plan	Version 1.1	19.12.2022

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.02

Date: 19 Dec 2022

The approval is for a period of 5 years from the date of this e-mail (**22 Dec 2022**)

Please note the following conditions of approval:

**\*\*Condition of approval: Please ensure that the restrictions and social distancing for COVID-19 are followed until the restrictions have been lifted\*\***

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including: any serious or unexpected adverse events; and unforeseen events that might affect continued ethical acceptability of the project.
1. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
1. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
1. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

1. The Principal Investigator must reassure participants about confidentiality of the data.
1. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.
1. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health District and Hospital policies available from:  
<https://www.swslhd.health.nsw.gov.au/ethics/policies.html>

**Interpreter use:** If this study will involve the use of interpreters, you are required to contact SWSLHD Interpreter Services on 8738 6088 and/or [Interpreters.Bookings@sswahs.nsw.gov.au](mailto:Interpreters.Bookings@sswahs.nsw.gov.au). This is required even if you have access to interpreters for clinical purposes, as SWSLHD Interpreter Services are required to review and approve the use of interpreters for any research work. Once you have contacted SWSLHD Interpreter Services, please ensure that you include the provided quote/s (if any) with your SSA submissions for your project.

Should you have any queries about your project please contact **our office** on the telephone number 8738 8304. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: <https://www.swslhd.health.nsw.gov.au/ethics/>

Please quote the above Ethics number in all correspondence. The HREC wishes you every success in your research.

Yours faithfully,

**Dr Shakti Shukla**

*on behalf of*

**Professor Murray Killingsworth**

Chairperson, SWSLHD Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Kind regards,

Dr Cameron Lutman

Ethics and Research Governance Coordinator

Research Directorate

South Western Sydney Local Health District

Email: [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au)

Phone: 8738 8305

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