ADDRESS FOR ALL CORRESPONDENCE
RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL

TELEPHONE: (02) 9515 6766
EMAIL: SLHD-RPAEthics@health.nsw.gov.au
REFERENCE: X22-0086 & 2022/ETH00553

NSW GOVERNMENT Health
Sydney Local Health District

17 May 2022

This letter constitutes ethical approval only. You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.

Dear Dr Amorim,

Re: Protocol no. X22-0086 & 2022/ETH00553 - "Online Mindfulness-Based Stress Reduction for Chronic Musculoskeletal Pain"

The Executive of the Ethics Review Committee, at its meeting of 16 May 2022 considered your correspondence of 13 May 2022. In accordance with the decision made by the Ethics Review Committee, at its meeting of 13 April 2022, ethical approval is granted.

I am pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

This approval includes the following:

- HREA (Version number 1, 15 April 2022)

- Protocol (Version 2, 12 May 2022)

- Appendix 1 – Participant Information Sheet (RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 2 – Participant Information Sheet (Interview with RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 3 – Participant Information Sheet (Interview with Health Care Professionals) (Master Version 2, 12 May 2022)
- Appendix 4 – Consent Form (RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 5 – Consent Form (Interview with RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 6 – Consent Form (Interview with Health Care Professionals) (Master Version 2, 12 May 2022)
- Appendix 7 – Recruitment Email (RCT Participants) (Master Version 2, 12 May 2022)

- Appendix 8 – Recruitment Email (Interview with RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 9 – Recruitment Email (Interview with Health Care Professionals) (Master Version 2, 12 May 2022)
- Appendix 10 – Telephone Recruitment Script (RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 11 – Telephone Recruitment Script (Interview with RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 12 – Telephone Recruitment Script (Interview with Health Care Professionals) (Master Version 2, 12 May 2022)
- Appendix 13 – Study Advertisement (RCT Participants) (Master Version 2, 12 May 2022)
- Appendix 14 – Study Advertisement (Interview with Health Care Professionals) (Master Version 2, 12 May 2022)
- Appendix 15 – Screening Instrument for Eligibility / Expression of Interest (Version 2, 12 May 2022)
- Appendix 16 – N/A
- Appendix 17 – N/A
- Appendix 18 – Patient Interview Guide (Version 1, 25 March 2022)
- Appendix 19 – Clinician Interview Guide (Version 1, 25 March 2022)
- Appendix 20 – Chronic Pain Acceptance Questionnaire – Revised (CPAQ-R) (Revised date (4 October 2006))
- Appendix 21 – Mindfulness Adherence Questionnaire
- Appendix 22 – Referral Questionnaire – Adult, AUS v2.0
- Appendix 23 – Follow-Up Questionnaire – Adult, AUS/NZ v2.0
- Appendix 24 – Mindfulness Training Course book © Copyright of Openground 2014
- Appendix 25 – Participant Information Sheet (Screening Process) (Master Version 1, 12 May 2022)
- Appendix 26 – Participant Consent Form (Screening Process) (Master Version 1, 12 May 2022)
- Appendix 27 – Study Flowchart (Version 1, 12 May 2022)
- Appendix 28 – Screening Flowchart (Version 1, 12 May 2022)
- Appendix 29 – Participant Distress Protocol (Version 1, 12 May 2022)
- Appendix 30 – Meditation-Related Adverse Effects Scale, Mindfulness-Based Program (MRAES-MBP)
- Appendix 31 – Research Data Management Plan (13/5/2022)
- Appendix 32 – Mental Health Telephone Screening

You are asked to note the following:

The Committee noted that authorisation will be sought to conduct the study at the following site:

- Royal Prince Alfred Hospital

- It is a requirement of ethics approval that, before its commencement, this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. The Committee therefore sought details of the Register in which the study has been included and its registration number.

- This approval is valid for **five years**, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **May 2023.** This will be through the submission of a milestone in REGIS.

- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

- **Partnering with Consumers:** As per Standard 2 of The National Clinical Trials Governance Framework, you are asked to provide an annual update with your annual progress report (milestone) on the ongoing involvement of consumers in the planning, design, delivery, measurement and evaluation of the trial.

- **Good Clinical Practice (GCP):** When adding additional sites, it is a condition of approval that the GCP Certificate of Completion be submitted for the principal investigator responsible for the new site.

- You must immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.

- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.

- You must notify the HREC and other participating sites, giving reasons, if the project is discontinued at a site before the expected date of completion.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney Local Health District website.

<u>If you are not using REGIS, a copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.</u>

The Ethics Review Committee wishes you every success in your research.

Regards,

Sanaa Thomas
Executive Officer
Clinical Trials Sub-committee

For:

Rosemary Carney
Executive Officer
Ethics Review Committee (RPAH Zone)