Peter MacCallum Cancer Centre
305 Grattan Street
Melbourne Victoria
3000 Australia

Postal Address
Locked Bag 1 A'Beckett Street
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Phone +61 3 8559 5000
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Locations
Melbourne
Bendigo
Box Hill
Moorabbin
Sunshine

Peter Mac
Peter MacCallum Cancer Centre
Victoria Australia

PETER MACCALLUM CANCER CENTRE HUMAN RESEARCH ETHICS COMMITTEE [EC00235]
ETHICAL APPROVAL

HREC Reference No: HREC/17/PMCC/188
Peter Mac Project No: 17/159
HREC Approval Date: 11 July 2018
Project Title: Light Enhanced Cognitive Behavioural Therapy (CBT+) for Sleep and Fatigue: A Randomized Controlled Trial during Chemotherapy for Breast Cancer

Principal Investigator: Ms Justine Diggens

I am pleased to advise that the above project has **received ethical approval** from the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Ethical approval for this project applies at the following sites:

Site
Peter MacCallum Cancer Centre

Approved Documents
The following documents have been reviewed and approved:

Document	Version	Date
Protocol *CBT+*	---	23 May 2018
Participant Information Sheet and Consent Form	5	21 June 2018
Questionnaires	3	10 April 2018
Intervention Email 1	4	1 May 2018
Intervention Email 2	2	27 November 2017
Intervention Email 3	4	1 May 2018
Intervention Email 4.a	4	1 May 2018
Intervention Email 4.b	3	10 April 2018
Intervention Email 5	4	1 May 2018
Intervention Email 6	3	10 April 2018
Intervention Email 7	2	27 November 2017
Relaxation Email 1	1	27 November 2017
Relaxation Email 2	1	27 November 2017
Sleep Diary	1	6 September 2017
Light Glasses Instruction Manual	3	10 April 2018

Light Therapy Researcher Guide	2	29 April 2018
Actigraphy Instructions	1	6 September 2017
Medical Chart Extraction Details	1	6 September 2017
MINI International Neuropsychiatric Interview, Modules C, H, I, J and K only	7.0.2	8 August 2016
Duke Screening Questions	---	18 May 2018

Governance Authorisation

Governance Authorisation is required at each site participating in the study before the research project can commence at that site. You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site specific assessment application.

Conditions of Ethical Approval

- You are required to submit to the HREC:
  - An Annual Progress Report (that covers all sites listed on the approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
  - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials or https://www.petermac.org/research/doing-research-us/ethics-governance.

The HREC may conduct an audit of the project at any time.

Yours sincerely,

Dr Dianne Snowden
Manager Human Research Ethics & Governance
Ethics Committee Secretariat
T: 8559 7540

E: ethics@petermac.org

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GOVERNANCE AUTHORISATION

SITE SPECIFIC ASSESSMENT (SSA) APPROVAL TO CONDUCT A RESEARCH PROJECT PETER MACCALLUM CANCER CENTRE

Reviewing HREC: Peter MacCallum Cancer Centre [EC00235]
HREC Reference No: HREC/18/PMCC/188
HREC Approval Date: 11 July 2018

Peter Mac Project No: 17/159
SSA Reference No: SSA/18/PMCC/140
SSA Authorisation Date: 11 July 2018

Project Title: Light Enhanced Cognitive Behavioural Therapy (CBT+) for Sleep and Fatigue: A Randomized Controlled Trial during Chemotherapy for Breast Cancer

Principal Investigator: Ms Justine Diggens

I am pleased to advise that the above project is authorised to be conducted at the Peter MacCallum Cancer Centre. This approval is subject to compliance with the conditions set out below and any conditions specified by the reviewing HREC.

Approved Documents:

Document	Version	Date
Protocol *CBT+*	---	23 May 2018
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Duke Screening Questions	---	18 May 2018

Research governance

As Principal Investigator, you are required to:

1. Comply with the Investigator's responsibilities as outlined in the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).*
2. Submit a copy of this letter to the person responsible for radiation safety at Peter MacCallum Cancer Centre. **This condition only applies if** the project involves exposure to ionising radiation that exceeds dose constraints, and the Medical Physicist's report has advised that the project needs to be added to the site's *Licence for Research Involving Human Volunteers* issued by the Department of Health Radiation Safety Section (for more information, visit http://www.health.vic.gov.au/radiation/). *Note: If the Medical Physicist's report has advised that the project needs to be added to the site's licence, the project cannot commence at site until you have confirmed that the project has been added to the site's licence.*
3. Notify the Peter MacCallum Cancer Centre Research Governance Office (RGO) of:
    - The actual start date of the project at Peter MacCallum Cancer Centre.
    - Any amendments to the project after these have been approved by the reviewing HREC.
    - Any adverse events involving patients of Peter MacCallum Cancer Centre, in accordance Peter MacCallum Cancer Centre Governance Guideline001 http://www1.petermac.org/Ethics/standardop_proc_guide.html .
    - Any changes to the indemnity, insurance arrangements or Clinical Trial Research Agreement for this project. This includes changes to the project budget or other changes which may have financial or other resource implications at Peter MacCallum Cancer Centre.
    - Your inability to continue as Principal Investigator or any other change in research personnel involved in this project.
    - Failure to commence the study within 12 months of the Governance authorisation date or if a decision is taken to end the study at this site.
    - Any other unforeseen events.
    - Any other matters which may impact the conduct of the project at Peter MacCallum Cancer Centre.
4. Ensure that HREC approval remains current for the entire duration of the project. Investigators undertaking projects without current Reviewing HREC approval risk their indemnity, funding and publication rights.

5. Submit an annual progress report every 12 months for the duration of the project. Continued SSA approval is contingent on receipt of an annual report by the RGO. In addition, a comprehensive final report should be submitted to the RGO upon completion of the project.

You must also abide by the following requirements:

6. Where applicable, ensure that the CTN has been electronically lodged to the TGA by the sponsor.
7. For clinical trials where Peter MacCallum Cancer Centre is the Sponsor, you are required to contact the Office for Cancer Research [ocr@petermac.org] to organise submission of the electronic Clinical Trial Notification (e-CTN) to the TGA. This must be completed before commencement of your project.
8. It is the Principal Investigator's responsibility to ensure that copies of the complete submitted e-CTN and TGA issued acknowledgement are included in the study Site File for the project at this site.

9. Ensure that the Clinical Trial Research Agreement (CTRA) and Indemnities (or other research agreements as applicable) are fully executed, i.e. signed by all parties; and an original version (or copy) placed in the study file.

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials or www.petermac.org/research

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The RGO may conduct an audit of the project at any time.

Yours sincerely,

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