
Amendment Letter

Date: 25 November 2022

HREC Reference number: HREC1006**Project title: Impact of a primary care health assessment and guided service navigation on Aboriginal youth mental health and wellbeing outcomes. Listening and Understanding, Co-design and Pilot (Phase 1)**

Dear Professor Sandra Eades

Thank you for submitting the above amendment which was considered by the WA Aboriginal Health Ethics Committee (WAAHEC) and approved the following amendment/s:

1. Change of title to Impact of a primary care health assessment and guided service navigation on Aboriginal youth mental health and wellbeing outcomes.
2. Addition of Phase 2 - Noongar boodjar youth wellbeing project: Phase 2 trial.

Documents:

APPENDIX A, Psychological health screening- Information Statement & Consent Form (V1, 4/11/2022)

APPENDIX B, Plain language statement (Trial) (V1, 4/11/2022)

APPENDIX C, Consent form (Trial) (V1, 4/11/2022)

APPENDIX D, Mature Minor assessment guideline (V1, 4/11/2022)

APPENDIX E, Mature Minor assessment form (V1, 4/11/2022)

APPENDIX F, Screening and demographics tool (V1, 4/11/2022)

APPENDIX G, Health assessment tool (Intervention arm) (V1, 4/11/2022)

APPENDIX H, Health assessment tool (Control arm) (V1, 4/11/2022) APPENDIX I, Outcome measure tools (V1, 4/11/2022)

APPENDIX J, Distress protocol (V1, 4/11/2022)

APPENDIX K, Health resources list (V1, 4/11/2022)

APPENDIX L, Guided service navigation trial protocol (V1, 4/11/2022)

Noted Documents:

Nil.

Should you have any queries about the WAAHEC's consideration of your amendment please contact ethics@ahcwa.org

It should be noted that all requirements of the original approval still apply. Failure to abide by these conditions may result in suspension or discontinuation of approval and/or disciplinary action.

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Conditions:

1. The WAAHEC will be notified in writing, giving reasons, if the project is discontinued before the expected date of completion.
2. The approval period is 23/10/2020 to 23/10/2023. Research projects should commence and conclude within that period of time. Projects must be resubmitted if extension over three years becomes necessary and will submit any associated required documentation. A request for an extension should be submitted prior to the expiry date.
3. Information about publications and/or conference presentations are incorporated into Progress and Final Reports. This enables the WAAHEC to maintain a record of publications.
4. Aboriginal and Torres Strait Islander communities are formally acknowledged for their contribution to this research project reporting for Publications, Reports and Presentations.
5. Projects that do not commence within 12 months of the approval date may have their approval withdrawn and the project closed. The Chief Investigator must outline why the project approval should remain.
6. The Chief Investigator will provide a Progress Report by 30 June each year in the specified format.
7. The Chief Investigator will notify the HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments to approved documents, or any new documents, for ethics approval. Amendments cannot be implemented until ethics approval is given.
8. The HREC has the authority to audit the conduct of any project without notice if some irregularity has occurred, a complaint is received from a third party or the HREC decides to undertake an audit for quality improvement purposes.
9. The HREC may conduct random monitoring of any project. The Chief Investigator will be notified if their project has been selected.
10. All adverse events to participants or local organisations and communities must be reported immediately. These may include any serious or unexpected effect, unforeseen events and information that may compromise or invalidate the ethical integrity of the study.
11. The investigators recognise the reviewing HREC is registered with the National Health and Medical Research Council and that it complies with the current version of the National Statement on Ethical Conduct in Human Research.
12. The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

The WAAHEC wishes you every success in your research.

Kind Regards



Peter Miller

For, **Vicki O'Donnell**
Chairperson, WAAHEC

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)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The process this HREC uses to review multicentre research proposals has been certified by the NHMRC.