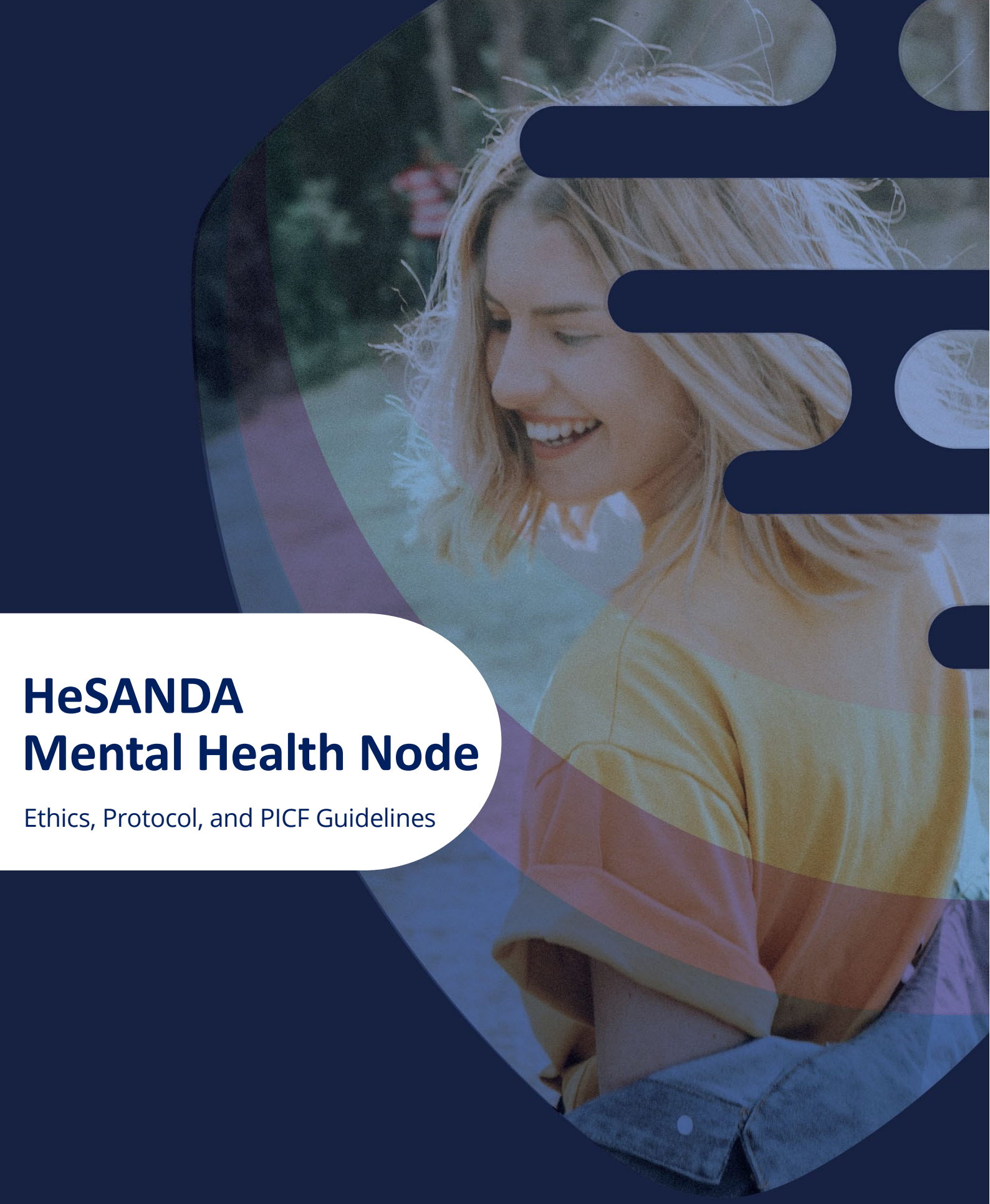

HeSANDA Mental Health Node

Ethics, Protocol, and PICF Guidelines

Mental Health Node

sheba
Secure Health Data and Biobank Platform

Barwon Health

DEAKIN UNIVERSITY

Version 1: 7/7/23

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Introduction

Thank you for including your project in the HeSANDA data sharing initiative. This guide will assist you in answering questions in your ethics application as it relates to data sharing, will guide you on how to seek extended and unspecified consent from participants for the sharing of their health data, and will help you explain HeSANDA and data sharing in your study protocol.

Data sharing as a national initiative driven by the Australian Research and Data Commons (ARDC) and implemented by the Deakin University as the Mental Health Node. The answers to Human Research Ethics Application questions should be adopted to suit your site and project.

If you have any questions or your HREC request further clarification regarding data retention or sharing, please contact Marko Milicevic at m.milicevic@deakin.edu.au for assistance.

Human Research Ethics Application (HREA)

The following guidelines are delineated by the questions as listed in the HREA Ethics Review Manager. Note that this is based on Barwon Health studies. These answers can be adopted to suit any HREA and site.

M2.7.2.1 Describe which biospecimens will be retained, any intended future use/s and any arrangements for future access to the biospecimens?

For studies with collection of biospecimens only

For the purposes of this study, extended and unspecified consent will be sought. For consenting participants, pertaining to retention of data, all information (clinical and microbiologic in nature) will be stored securely and indefinitely within a secure data entry system (e.g., REDCap) in accordance with local regulations, under password and username protection. However, data storage is subject to participants' discretion (i.e., whether participants have provided extended and unspecified consent). For participants who do not wish for their data to be shared for future research, their data will be destroyed after 15 years[#]. Indefinite data storage follows NHMRC policies on data retention for data sharing, (as specified under The Australian Code for the Responsible Conduct of Research, Code R22). Only unidentifiable data collected from this study will be made available for third party researchers for secondary analyses upon request and appropriate ethical approvals. This may be true in the case of individuals involved in the study consenting to use of samples in future ethically approved studies. Participants or their legally authorised representative/parent/guardian may also provide written request for removal from the study at any point.

Q3.9 Do you plan to disclose any personal information/data in this project to a third party?

☐Yes
☒No

Explanatory note: any data sharing will be with de-identified data, so no personal information or personal data will be disclosed to a third party

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.

Pertaining to retention of data, all information and (clinical and microbiologic in nature) will be kept within a secure data entry system (e.g., REDCap) indefinitely in accordance with local regulations, under password and username protection, to allow for data sharing practices. Indefinite retention of data allows for secondary analysis from third party researchers and follows NHMRC policies on data retention for data sharing. However, data storage is subject to participants' discretion (i.e., whether participants have provided extended and unspecified consent). For participants who do not wish for their data to be shared for any future research, their data will be destroyed after 15 years[#].

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

All information will be kept within a secure data entry system (e.g., REDCap) indefinitely (or in the case of opting out of data sharing, destroyed after 15 years[#]) in accordance with local regulations, under password and username protection. This is detailed in Q3.14.

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

For the purpose of this project, we will be requesting extended or future studies consent. Individuals consenting will be agreeing to having their samples/specimens and data from this research retained indefinitely for potential use in future studies conducted by researchers outside of the current study team (third party researchers). For participants who do not wish for their data to be shared for any future research, their data will be destroyed after 15 years[#]. HREC will be required to approve any future studies that analyse the data from this study. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that participants cannot be identified.

The data from this study will be available for secondary analysis as part of the Health Studies National Data Asset (HeSANDA) initiative, led by the Australian Research Data Commons (ARDC). HeSANDA is a national infrastructure that supports the sharing and reuse of health research data to benefit the Australian community. Data sharing as part of the initiative brings value to the community by allowing important health research questions to be answered using previously collected data through secondary analyses. Secondary analyses could include re-analysis of datasets, using previous independent variables as dependent variables, and pooling of de-identified research data for example for use in meta-analyses. Such secondary analyses can benefit the health of Australia's population through extending scientific discoveries and creating new knowledge.

Deakin University is the lead organisation for Mental Health data sharing through the HeSANDA Mental Health Node. We intend to allow the data collected from this study to be available for secondary analyses by researchers from external institutions across Australia. Researchers will be able to search the HeSANDA catalogue and generate a request to access de-identified data for secondary analyses and eventual publication. Use of data for secondary analyses will be subject to approval from the original Chief Investigator of the study and subject to HREC approval.

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

Non-identifiable data may be used for future research if a participant provides extended or unspecified consent, which is outlined in the PICF. This will be subject to the Chief Investigator granting approval. All data collected in this study will be completely deidentified. All data accessed by third party researchers will not be re-identifiable in any way. Any secondary data analysis by third party researchers may be performed through the Secure Health data and Biobank platform (SHeBa), which is a digital platform built in partnership between Deakin University and Barwon Health. The analyses will take place in a secure virtual "room". This will ensure that no data can be downloaded or shared beyond the agreement between the holders of this ethics application and the third-party researcher. Participants will have the option to opt-out of having their data be available for secondary analyses.

[Data Custodian name] will be the data custodian for this study.

[#]*Edit to suit project/local policy/institutional policy on data retention and destruction.*

Barwon Health Data Management Checklist

The below guidelines are for the Barwon Health Data Management Checklist*. A template can be downloaded here. This document should be included in the HREA.

This section should be based on how data will be destroyed for participants who opt-out of data sharing.

How will your data be destroyed? (tick all that apply):

☐Shredding
☐File deletion
☐Database closure

Do not tick any boxes

**Based on checklist for Barwon Health projects. Data management plans should outline that data will be stored indefinitely and suit site data management requirements. However, for participants who do not wish for their data to be shared for future research, their data should be destroyed after 15 years, or follow project/local policy/institutional policy on data retention and destruction.*

Victorian Specific Module (VSM)

The following guidelines are delineated by the questions listed in the VSM section of the Ethics Review Manager*.

2.1(b) For what purpose(s) will participants' consent be sought to use the collected information?

☒This research (specific consent)
☒Future research related to this project (extended consent)
☒Any future research (unspecified consent)

2.1(c) Does the research project involve the establishment of a databank?

☐Yes
☒No

2.1(d) Does the Participant Information and Consent Form explain the following:

A description of the terms of the unspecified consent (if you are seeking unspecified consent?)

☒Yes
☐No
☐N/A

The period for which the records relating to the participant will be kept?

☒Yes
☐No
☐N/A

If permission is being sought to enter the information into a databank?

☐Yes
☐No
☒N/A

2.7(d) For how long will the information be retained?

☐Specified time period
☒Indefinitely
☐Until the youngest participant turns 25

2.7(e) How will the information be disposed of at the end of the retention period?

The data from this study will be stored on a secure data entry system (e.g., REDCap) indefinitely. This is to allow for data sharing purposes with third party researchers for secondary analysis. Data sharing is in accordance with NHMRC data retention and sharing policies. No identifiable data will be shared with researchers outside of this ethics application. For participants who do not wish for their data to be shared for future research, their data will be destroyed after 15 years#.

2.8 Discuss any other ethical issues to the collection, use or disclosure of information proposed in this project
Include an explanation of how these issues have been addressed.

Any access to data from third party researchers for secondary analysis will be strictly subject to approval by the Chief Investigator and relevant ethical approvals. Both privacy considerations and limitations are delineated within participant consent forms and participants will be made aware of these prior to providing consent.

[*]Based on HREA for projects in Victoria. This guide can be adopted to suit other state modules.

[#]Edit to suit project/local policy/institutional policy on data retention and destruction.

Site Specific Module (SSM)

The following guidelines are for the Site-Specific Module* for data sharing.

4.2(a) Data source and storage at this site

Length of information retention

All data will be retained indefinitely for data sharing purposes (in accordance with NHMRC data sharing and retention policies) in the case of participants who provide unspecified and extended consent. For participants who do not wish for their data to be shared for future research, their data will be destroyed after 15 years#.

Method of disposal

For participants who consent for their data to be shared for future research, their data will be stored indefinitely and securely in a data repository (e.g., REDCap). For those who do not consent for their data to be shared, their data will be destroyed via *[insert method of disposal]*.

**For HREA for projects based at Barwon Health. This can be adopted to suit other site-specific modules.*

#*Edit to suit project/local policy/institutional policy on data retention and destruction.*

Participant Information Consent Form (PICF)

HeSANDA has partnered with the CT:IQ to create the InFORMed project. This project has developed a PICF template and user guide for Australian clinical trials.

This project uses the new nationally consistent, simplified, and more respectful PICF template for the written communication of participant information about research which enables participants to make an informed decision whether to participate. It also provides wording for keeping participants informed regarding how their data will be shared for future research.

For a comprehensive guide on how to create a concise and detailed PICF with data sharing considered, please visit the InFORMed project by the CT:IQ website at https://www.informedpicf.com.au/.

Project Protocol

Project protocols must explain how participant data will be managed. The following excerpt can be included within the Data Management section of a project protocol.

Data storage and security

Pertaining to retention of data, all information (clinical and microbiologic in nature) will be kept within the secure data entry system (e.g., REDCap) indefinitely in accordance with local regulations, under password and username protection to allow for data sharing practices, specifically as part of the ARDC HeSANDA initiative. However, data storage is subject to participants' discretion (i.e., whether participants have provided extended and unspecified consent). For participants who do not consent for their unidentifiable data to be shared for any future research by third party researchers, their data will be destroyed after 15 years[#]. Indefinite data storage follows NHMRC policies on data retention for data sharing. Any future research analysing the data collected from this study will be subject to the Chief Investigator granting approval, including any appropriate HREC ethical approvals. All data accessed by third party researchers will not be identifiable or re-identifiable in any way. Participants or the authorized representative/parent/guardian may provide written request for removal from the study at any point.

[#]*Edit to suit project/local policy/institutional policy on data retention and destruction.*

Contact and support

For more information and support on establishing your project in line with data sharing principles, please contact the Mental Health Node.

General Enquiries
Email: mentalhealth_n@deakin.edu.au

Collaborations and Mental Health Node enquiries
Position: Project Lead
Name: Professor Alison Yung
Email: alison.yung@deakin.edu.au

Project setup, SOP, ethics, and research enquiries
Position: Mental Health Node Project Manager (Researcher Liaison)
Name: Marko Milicevic
Email: m.milicevic@deakin.edu.au

SHeBa enquiries
Position: SHeBa Data Manager
Name: Dr Lourdes Llorente Escrina
Email: lourdes.llorente@barwonhealth.org.au

Technical enquiries
Position: Mental Health Node Project Manager (Technology Liaison)
Name: Nemanja Zivanov
Email: n.zivanov@deakin.edu.au

Researcher resources
mentalhealthnode.org (coming soon)
sheba.com.au (coming soon)
researchdata.edu.au/health
magnetctn.com (includes useful resources for clinical trialists)
informedpicf.com.au
ctiq.com.au