# HeSANDA Mental Health Node

## Data Sharing Statement Instructions

Mental Health Node

sheba
Secure Health Data and Biobank Platform

Barwon Health

DEAKIN UNIVERSITY

**Version 1:** 7/7/23

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Dr Kristan Kang, ARDC

# Introduction

The ANZCTR holds important information about your trial. This information is called meta-data and will be used to populate your trials listing on the HeSANDA catalogue. An important section on the ANZCTR is the Data Sharing Statement. This section indicates to researchers how the data may be used and includes supporting documents which help researchers understand the trial and data.

This document includes instructions on how to appropriately fill the Data Sharing Statement. Editing a trial should take approximately 15 minutes of your time. You or a delegate will require login credentials to the ANZCTR to update listing information.

For any questions and support, please email:

**Marko Milicevic**
Mental Health Node Project Manager (Researcher Liaison)
m.milicevic@deakin.edu.au

# Supporting Documents

There are a number of important documents that must accompany the meta-data listed in your trial's ANZCTR. Supporting documents must be made **publicly accessible** unless there is a legal or ethical requirement to restrict access. The supporting documents should already exist as part of your trial.

1. **The study protocol.**

A study protocol is a document which describes the project procedures. The protocol is vital for Secondary Users, as it will help them understand how the project was conducted and what sort of data was collected.

2. **The study data dictionary.**

The data dictionary is a document which explains the variables in your dataset. It will assist secondary users to understand how your data is labelled and what it means. The dictionary should list and define all the instruments used in your trial, define acronyms, and explain data formats. This can be a PDF file, excel spread sheet, or Word document. If a data dictionary was not collated manually from the outset of the study, a data dictionary can be exported from an SPSS file or REDCap. The Mental Health Node can help you export the data dictionary if required. If you are unable to generate a data dictionary for any reason, please notify Marko Milicevic m.milicevic@deakin.edu.au.

3. **The summary of results.**

The summary of results are the primary results found from the project. This will help Secondary Users understand what was found from the original analyses and inform them how the data could be used in different ways. If you are still collecting data or awaiting publication of primary results, the summary of results can be updated when they become available.

4. **A copy of your institution's Data Sharing Policy.**

This will be included with any trial included on the HeSANDA federated catalogue. Each institution should have their own policy on data sharing, which is publicly available on their website, or can be found on your institute's intranet. If you are unable to locate it, contact your library/legal team.

There are three options for making supporting documents publicly available on the ANZCTR:

**Option 1 [DOI]** - we strongly recommend creating a DOI for each supporting document. Your institution may be able to create this for you. Alternatively, you may consider creating a DOI by uploading your supporting documents to public/generalist repositories such as Figshare, Dryad, Zenodo, or OSF. These generalist repositories can create a DOI for you. The DOI can then be used in the 'link' option in response to this ANZCTR question. You should speak to your institution first for advice on what options they allow and are best suited for your trial. The Library or Research Office can support with repository choice and DOI considerations.

*Note: If a DOI already exists, for example the protocol or summary results have been published in a journal, a DOI link of the article is sufficient.*

**Option 2 [Web link]** - If it is not possible to mint a DOI for your supporting documents, then provide a link to a web page where the document can be downloaded.

**Option 3 [Attachment]** - If neither of the previous options are available, upload your supporting documents directly onto the ANZCTR. For study protocols please use the prefix "Study Protocol" in the filename of your attachment. For data dictionaries please use the prefix "Data Dictionary" in the filename of your attachment.

# Filling the Data Sharing Statement

Below is a step-by-step guide on how to fill the Data Sharing Statement, including the supporting documents. You must have login credentials to edit the trial. Once the changes have been made, submit them for review by the ANZCTR and email Marko Milicevic at m.milicevic@deakin.edu.au. The changes will be reflected on the HeSANDA catalogue automatically once approved.

| ANZCTR question | ANZCTR description | Guidance for HeSANDA trials |
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| **Will individual participant data (IPD) for this trial be available (including data dictionaries)?** | * Indicate whether there is a plan to make individual participant data (IPD) publicly available for this trial. IPD refers to raw line-by-line data collected from each participant.<br>• Yes; IPD and related data dictionaries are/will be available<br>• No; IPD will not be available | Nominated Trials must select: "Yes; IPD and related data dictionaries are/will be available"<br>If you select "No", you are indicating that you are not willing/able to share your data under ***any*** circumstances - if this is the case, then your trial is ***not*** eligible to be part of HeSANDA.<br>You can answer "Yes" as long as you meet one of the following criteria:<br>1. **You don't have ethics approval (or a waiver of consent) to share data, but you would be willing to seek ethics approval in some circumstances:** If you didn't originally obtain ethics approval to share data, it might not be possible to obtain approval at a later stage to share data for 'unspecified future use' (i.e. the broadest form of approval for data sharing). However, your ethics committee may be willing to provide approval for you to share your data on a case-by-case basis. If you are willing to review requests from others to access your data for a specific project and (potentially) seek ethics approval to share your data with that project, then you can select 'Yes'. You should clarify what kinds of projects and groups you would be willing to do this for in the relevant sections below.<br>2. **You have ethics approval to share data:** This does not need to be approval to share with anyone who requests the data. It just needs to be approval to share data under some circumstances with people outside of the groups |

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| | | running the trial (e.g. a secondary researcher). While it is best practice to obtain consent from trial participants to share data, ethics committees may provide a waiver of consent under some circumstances - this constitutes ethics approval to share data.<br>3. **There are no other restrictions preventing you from sharing your data.** |
| **What data will be shared? * (Mandatory when 'Yes' is selected for IPD question in Step 11)** | Please describe what data will be shared e.g., all of the individual participant data collected during the trial, after de-identification; individual participant data underlying published results only, etc. | Nominated Trials should indicate at least one of the following:<br><br>• All participant data collected<br>• Participant data supporting the publication results<br>• Participant data relating to primary outcomes<br>• Participant safety data<br><br>*Sample response*<br>*"Participant data supporting the publication results*<br>*Participant data relating to primary outcomes"* |
| **When will data be available (start and end dates)? * (Mandatory when 'Yes' is selected for IPD question in Step 11)** | Please outline the timeframe of data availability, i.e., beginning and end dates for when the data is expected to be available, e.g. Immediately following publication, no end date; Beginning 3 months and ending 5 years following main results publication; no end date determined etc. | Nominated Trials should describe when the data will be made available. Options/examples include:<br><br>(Optional) Pick one from the following:<br>• Data are available straight after publication<br>• Data are available ['x' months] after publication<br><br>Pick one from the following:<br>• Data are available for a finite time<br>• Data are available for an indefinite time<br><br>Add the following information (approximate dates are ok):<br>• Start date: [insert date] |

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| | | • End date: [insert date] / [if "data are available for an indefinite time" then insert "Unknown"]<br><br>If dates are subject to change (e.g., if funding ends/is extended) then your trial registration must be updated (as per the general requirements for updating ANZCTR records)<br><br>*<u>Sample response</u>*<br>*Example 1:*<br><br>*"Data are available 5 months after publication*<br>*Data are available for an indefinite time*<br>*Start date: July 2023 (approx)*<br>*End date: Unknown"*<br><br>*Example 2:*<br><br>*"Data are available for a finite time*<br>*Start date: 1 July 2023*<br>*End date: 1 July 2028"* |
| **Available to whom? * (Mandatory when 'Yes' is selected for IPD question in Step 11)** | Please specify who can/will be able to access the data, e.g., anyone who wishes to access it, only researchers who provide a methodologically sound proposal, case-by-case basis at the discretion of Primary Sponsor, etc. | Nominated Trials should specify one or more of the following:<br><br>Data are [potentially] available to (select all that apply):<br>• Researchers from not-for-profit organisations<br>• Commercial organisations<br>• Other<br>Based in (select one):<br>• Australia only<br>• Any location<br>• Other<br>Further information: |

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| | | • [insert further details about the above responses if required]<br>• [insert further information usage permissions if required]<br>• [insert a link to your institutions data sharing policy]<br><br>*Sample response*<br>*"Data are potentially available to:*<br>- *Researchers from not-for-profit organisations*<br>- *Commercial organisations*<br>- *Other*<br>*Based in:*<br>- *Any location*<br>*Further information:*<br>*All data requests will be considered by the primary sponsor on a case-by-case basis. Requests must include a methodologically sound proposal. Specific conditions of use may apply and will be specified in a data sharing agreement (or similar) that the requester must agree to before access is granted. For further information, see our data sharing policy (http://www.university.edu/datasharing policy)."* |
| **Available for what types of analyses? * (Mandatory when 'Yes' is selected for IPD question in Step 11)** | Please clarify if there is a specific type of analysis for which the data are/will be available, e.g. any purpose, only to achieve the aims in the approved proposal, for IPD me | Nominated Trials should indicate at least one of the following:<br><br>• Any type of analysis<br>• IPD meta-analysis or systematic review<br>• Assessed on a case-by-case basis<br>• Any approved protocol<br>• Audit/verification of results<br><br>*Sample response*<br>*"IPD meta-analysis or systematic review*<br>*Assessed on a case-by-case basis"* |

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| **How or where can data be obtained? * (Mandatory when 'Yes' is selected for IPD question in Step 11)** | Please specify how/where data are/will be shared e.g., unrestricted access via web address (provide link), access subject to approvals by Principal Investigator (provide email or other contact details), etc. | Nominated Trials should include the following:<br>- "Access can be requested via the Health Data Australia catalogue (https://researchdata.edu.au/health). Search for the ACTRN number in the catalogue to find datasets associated with this trial."<br>ARDC also recommends including a link to the data sharing policy for the trial (where available). For e.g. "For further information, see our data sharing policy: {insert URL}"<br>Please note that you can use your own processes handling data requests in addition to the HeSANDA platform. If so, you should provide those details in addition to the suggested wording above.<br><br>*Sample response*<br>*"As of 1st July 2023, access can be requested via the Health Data Australia catalogue (https://researchdata.edu.au/health). Search for the ACTRN number in the catalogue to find datasets associated with this trial.*<br>*For further information, see our data sharing policy (http://www.university.edu/datasharing policy)."* |
| **What supporting documents are/will be available? *** | Select all types of supporting information that will be shared. Choose the appropriate type(s) from the list.<br>• No other documents available†<br>• **Study protocol (mandatory)**<br>• Statistical analysis plan<br>• Informed consent form<br>• Clinical study report<br>• Ethical approval<br>• Analytic code<br>• **Other** ††<br><br>† Note that if this option is selected, other options will not be available for selection. | **Nominated Trials are required to make their Study Protocol and Data Dictionary publicly accessible unless there is a legal or ethical requirement to restrict access.**<br>For study protocols, Nominated Trials should tick the "Study Protocol" option. The ANZCTR accepts full protocols for this section or published protocols. If the protocol has been published in a journal, please list the DOI link to the article.<br>For data dictionaries, Nominated Trials should tick the "Other (please specify)" option then specify that you will share your data dictionary. |

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| | †† If 'Other' is selected, please note that it is mandatory to specify the other type of document that is/will be available. | |
| **How or where can supporting documents be obtained? * (Mandatory for each of the documents selected in the previous field)** | Indicate how the corresponding document can be obtained, e.g., citation, link, email, other, attachment. Note that it is mandatory to complete at least one of these.<br><br>Attachment: It is the responsibility of the registrant to ensure that any uploaded documents comply with copyright regulations. Please note that any files attached will be publicly available via the trial ANZCTR registration record. Attached files cannot exceed the maximum size of 35MB per file.<br><br>Maximum number of attachments allowed: 20 | **Supporting documents must be made publicly accessible unless there is a legal or ethical requirement to restrict access**. Nominated Trials should avoid using the Citation, Email, or Other options. ARDC recommends the following:<br>• **Option 1 [DOI]** - ARDC strongly recommends creating a DOI for each supporting document. Your institution may be able to create this for you. Alternatively, you may consider creating a DOI by uploading your supporting documents to public/generalist repositories such as Figshare, Dryad, Zenodo, or OSF. These generalist repositories can create a DOI for you. The DOI can then be used in the 'link' option in response to this ANZCTR question. You should speak to your institution first for advice on what options they allow and are best suited for your trial. The Library or Research Office can support with repository choice and DOI considerations.<br>• **Option 2 [Web link]** - If it is not possible to mint a DOI for your supporting documents, then provide a link to a web page where the document can be downloaded. (NB. The URLs for your supporting documents should also be listed as 'Related Items' (DataCite element 20) in your dataset DOI)<br>• **Option 3 [Attachment]** - If neither of the previous options are available, upload your supporting documents to ANZCTR. For study protocols please use the prefix "Study Protocol" in the filename of your attachment. For data dictionaries please use the prefix "Data Dictionary" in the filename of your attachment. |

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| **<u>Summary results:</u>**<br>**Have study results been published in a peer-reviewed journal? (Step 12)** | **Yes**<br>No†<br>† If your results are awaiting publication, select No and update this field when the results are available. | List the DOI of any published papers which used the dataset.<br><br>*<u>Sample response</u>*<br>**Journal publication details**<br><br>**Publication date and citation/details**<br>Yung AR, Milicevic M, Berk M. Fair funding for mental health research. Australian & New Zealand Journal of Psychiatry. 2023;0(0). https://doi.org/10.1177/00048674231177226 |

# 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