Data Sharing Guidelines

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1 INTRODUCTION

Health Studies Australia National Data Asset (HeSANDA) is a program of the Australian Research Data Commons (ARDC) that aims to build the national infrastructure required to support researchers to access and share data from health studies.

The Health Data Australia (HDA) National Catalogue, is a part of the HeSANDA program, designed for researchers to discover and request access to research data and other research outputs that may be available for secondary use.

HeSANDA aims to list the research outputs produced in clinical trials for the potential benefit of improving overall public health by maximising utilisation of gained knowledge, reducing redundant research, and facilitating scientific innovation.

Health Translation SA (HTSA) is the South Australian project facilitator of the Health Studies Australia National Data Asset (HeSANDA) within South Australia. HTSA supports the use of HeSANDA and the primary principals of research transparency through the sharing of research outcomes and data that are, where ethically and legally possible, made openly accessible to the research and broader community, according to the FAIR Principles: Findable, Accessible, Interoperable and Reusable.

2 SCOPE

This Data Sharing Guideline document applies to studies where the coordinating research centre is based in South Australia and registered within the ARDC Health Data Australia (HDA) portal with the support of HTSA.

The Guidelines are to be used as a guiding document for the use of HeSANDA/HDA and the secondary use of data by a third party (requester).

Where the coordinating research centre, or primary researcher, holds their own data sharing policy or guideline, it is at their discretion whether this Data Sharing Guidelines document is used in conjunction with, or overridden by, their own policy or as outlined within an agreement with the potential requester.

3 DEFINITION

3.1 Data Sharing Agreement

An agreement, Memorandum of Understanding (MOU) or contract between either the Coordinating Research Organisation (CRO), Research Institute or Primary Researcher, and a Requester, which sets out the terms upon the sharing of research data and outputs for the purposes set out in the relevant approved request.

3.2 Research Outputs

A piece of research that may be available to be shared such as;

1. *Individual De-identified Patient Data (IPD)*
2. *Study protocol*
3. *Data dictionary*
4. *Summary results (ANZCTR)*
5. *Data quality statement*
6. *Analytic code*
7. *'CONSORT' statement*
8. *Clinical practice guidelines/recommendations emerging from the trial*
9. *Data management plan*
10. *Unpublished reports*
11. *Statistical analysis plan*
12. *Publications, preprints, and abstracts*

3.3 Custodian

The individual, organisation, body, or committee with responsibility for the relevant Research Output. Typically, this is the principal investigator (PI).

3.4 Coordinating Research Organisation

The Organisation or Institute that monitors and oversees data access and sharing requests in respect of data in a Collection and decides on requests where the study in question no longer has an active Custodian.

3.5 Data Manager

A statistician, PI, organisation, or institute, responsible for preparing research data for secondary use.

3.6 Access Request

A proposal submitted in the ARDC HDA portal by a Requester in accordance with section 5 of this document.

3.7 Requester

An individual or a group of researchers seeking access to research data/outputs from the ARDC HDA portal.

4 RESPONSIBILITIES

4.1 Primary Investigator

- Design research studies and manage research data with the expectation that data will be shared.
- Have in place a data management and sharing plan for current and future research data.
- Identify and share data and outputs from research activities to align with these Guidelines and the terms and conditions of applicable grants and agreements.
- Consider local / regional governance requirements and regulations regarding data sharing.
- Maintain the study ANZCTR record.
- Be willing to enter into a 'Data Sharing Agreement' with the approved requester's organisation.
- Inform and seek approval or advice from their affiliated organisation of the sharing of research outputs and any agreements that may need to be entered.
- Stipulated citation requirements and future requester publications.

4.2 Data Manager

- Provision of participant level data in a format that is useful to a secondary researcher.
- Use a secure platform for the transferring of clinical trial data and research outputs.

4.3 Requestor

- Should be employees of a recognised academic institution, health service organisation,
- Have experience in medical research.
- Should be able to demonstrate through their peer review publications, in the research area of interest, their ability to conduct the proposed use of the requested research output collection.
- Declare any actual or potential conflicts of interest in their application.
- Declare funding sources for the requested work for which the requested dataset or research output will be used.
- Declare conflicts of interest and funding sources in all publications and presentations resulting from the shared dataset.
- Comply with the Primary Investigators request to be included as an author on publications.
- Produce evidence of regulatory approval for the research where appropriate.

4.4 Coordinating Research Organisation
- Provide advice to the Primary Investigator when entering into a data sharing agreement with a requester.
- Support the use of the ARDC HeSANDA/HDA catalogue.

4.5 Health Translation SA
- Communicate data access requests in agreement with the research organisation.
- Provide guidance to researchers, requestors, and organisations for the use of HeSANDA.

5 DATA SHARING GUIDE

5.1 Eligibility
- The sharing of data should be for the purposes of health and medical research and within the constraints of the consent under which the data were originally gathered.

5.2 Ethics and Consent
- For completed studies, the sharing of participant level data to be ethically approved with consent taken into consideration.
- For completed studies where participant consent to share data was not obtained, the Primary Investigator before sharing the data can choose to submit an amendment to the ethics committee to either request a waiver of consent for the release of participant data or obtain participant consent.
- The Primary Investigator can plan with the requester as to who will undertake any additional work required for ethics approvals or waivers.
- Requesters may be required to cover the costs of administering the data sharing (including legal fees if applicable), retrieving, processing, and sending the data. The estimated costs for a particular request will be provided after initial review of the application.

5.3 Approval
- The Primary Investigator will give final approval for the sharing of their research data and the terms on which it will be shared.

5.4 Terms of Sharing
- The requester will enter into a Data Sharing Agreement with the Organisation or Primary Investigator, which meets the Organisation's data sharing requirements and sets out the terms for the secondary use of the data. An example Data Sharing Agreement template can be found here: https://www.datacommissioner.gov.au/sites/default/files/2022-07/ONDC_Legislation_Agnostic_DSA_Template.doc
- Access to data in the Collection will only be permitted to the requestor per application and only under a Data Sharing Agreement.

As a guide to setting the terms, consideration should be given to;
- Citation requirements and future requester publications
- Data being transferred only to Requester(s) named in the original application and as specified in the relevant Data Sharing Agreement.
- Data from the Collection not to be transferred to individuals outside the Requester's research group.
- Supplied data being used only be used for the purpose described in the expression of interest or as further stipulated in the Data Sharing Agreement.
- If the data shared has been de-identified, the Requester and individuals within their research group cannot attempt to identify any individual from the data provided.

- Reporting of inadvertent identification of an individual in de-identified data.
- Linking of de-identified data provided with any other dataset included within the Data Sharing Agreement and in-line with ethics and consent approvals.

5.5 *Data management and sharing processes.*

- Investigators should have in place a data management and sharing plan with the primary goal to create a database resource.
- Typically, such a data management plan would be conceived by investigators in the planning stage.
- When considering the approach to data management / sharing consider:
  - What data outputs will your research generate and what data will have value to other researchers?
  - What documentation will you provide to describe your data?
  - How will other researchers outside the study be able to access the data?
  - Are any limits to data sharing required - for example, to either safeguard research participants or to gain appropriate intellectual property protection?
  - How will you ensure that key datasets are preserved to ensure their long-term value?
  - What resources will you require to deliver your plan?
- The HeSANDA Health Data Australia Catalogue should be used to list the trials where the sharing of data is applicable.
- Health Translation SA acts as the channel between requester and Primary Investigator for the application and approval of data sharing.
- A secure platform to be used for the sharing of data.

6 REFERENCES

- NHMRC 'Principles for accessing and using publicly funded data for health research' https://www.nhmrc.gov.au/sites/default/files/documents/reports/principles-publically-funded-data.pdf
- NHMRC 'Management of Data and Information in Research - A guide supporting the Australian Code for the Responsible Conduct of Research.' https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf
- Wellcome Trust: Policy on Data Management and Sharing https://wellcome.org/grant-funding/guidance/data-software-materials-management-and-sharing-policy
- The George Institute Data Sharing Policy https://www.georgeinstitute.org.au/data-sharing-policy