Australian Research Data Commons

# Health Studies Australian National Data Asset (HeSANDA) and Health Data Australia (HDA)

## Frequently Asked Questions

14/05/2024

NCRIS National Research Infrastructure for Australia An Australian Government Initiative

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## Acknowledgement of Country

We acknowledge the traditional custodians throughout Australia and their continuing connection to, and deep knowledge of, the land and waters. We pay our respects to Elders both past and present.



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# FREQUENTLY ASKED QUESTIONS

# 1. About Us

## 1.1 What is HeSANDA?

The Health Studies Australian National Data Asset (HeSANDA) is a national program that makes health and medical research data easier to find and request. It facilitates access, sharing and reuse of research data, resulting in a reduction in research waste, improvements in researcher collaboration, and an opportunity to answer new research questions. It aims to support more efficient and effective research to help improve health outcomes.

The research community across Australia has been working together through HeSANDA to develop Health Data Australia, a catalogue for health and medical researchers to register a description of their research so it's easy to discover. A federated structure of partners across Australia then links researchers and facilitates data sharing and data access. This is possible through the searchable online catalogue and a secure access request portal.

Importantly, the researchers who created the data always maintain control over their data and determine with whom it is shared.

In Phase 1, HeSANDA focussed on investigator-initiated and academic clinical trials. Phase 2 (2023-2028) will provide the following opportunities:

- Consolidate the capability for HeSANDA to include a wider variety of investigator-led clinical trials (i.e. interventional studies)
- Extend the approach to other health study types (i.e. observational studies) including cohort studies, and registries
- Deploy new capabilities such as secure access environments.

## 1.2. Who funds HeSANDA?

HeSANDA is a co-investment between the ARDC and HeSANDA Node Network partner organisations across Australia that collect and manage clinical trial data. The ARDC is funded by the Australian Government through the National Collaborative Research Infrastructure Strategy (NCRIS).

## 1.3. Who Manages HeSANDA

HeSANDA is a major strategic initiative of the Australian Research Data Commons (ARDC). The ARDC mission is to accelerate research and innovation by driving excellence in the creation, analysis and retention of high-quality data assets, thereby providing a competitive advantage for Australian researchers.

ARDC has designed and implemented HeSANDA in close collaboration with the Australian research community. The HeSANDA Advisory Committee includes key national health research organisations:

- Australian Clinical Trials Alliance
- Australian Health Research Alliance
- Australian New Zealand Clinical Trials Registry
- Cochrane Australia
- Consumers Health Forum of Australia
- National Health & Medical Research Council
- Population Health Research Network
- Research Australia

See list here under the title 'The Partners' to see if your institute is affiliated with HeSANDA.

## 1.4. What is the HeSANDA Node Network?

ARDC has established a network of 9 infrastructure nodes representing 72 research organisations, covering the majority of Australia's states and territories, and significant coverage in key health areas of cancer and mental health. These organisations will work together to deliver coherent data practices and coordinated data services at a national scale. These include:

- Melbourne Academic Centre for Health (MACH) Clinical Trial Consortium Node
- Mental Health Node
- Monash and Partners Node
- National Cancer Cooperative Trials Groups Node
- Northern Australia Node
- Queensland Node
- South Australia Node
- Sydney Health Partners Node
- Western Australia Node

## 1.5. What are the aims of the HeSANDA program?

The three main aims of HeSANDA are to:

- Get consensus from the health research community on data standards and practices required to support ethical and appropriate development and use of a national catalogue of health and medical research data
- Build the infrastructure and processes needed to enable: a) researchers to contribute to a national catalogue of research data; and b) researchers to search the catalogue and request access to data and information
- Develop policies and use communication, education and awareness raising to create a culture in which data sharing in health research is trusted, valued and enabled.

## 1.6. How does the Health Data Australia platform work?

Health Data Australia consists of two components: the clinical trial metadata catalogue and data access request system. Click here to see a short video about the Health Data Platform

Researchers who are part of a HeSANDA Node provide metadata about their clinical trials to the Health Data Australia catalogue i.e. types of data collected, measurements taken, and tests conducted. The catalogue entry is created by combining metadata already supplied as part of ANZCTR trial registration with a new Health Data Australia metadata record created via the HeSANDA node network. The Health Data Australia metadata record includes a Digital Object Identifier (DOI) for the data, and additional information about the available data and any restrictions on its use.

The Health Data Australia catalogue does not hold any of the clinical trial data itself or the research outputs developed as part of the trial. It describes the types of clinical trial datasets that are available for a given trial and any restrictions on its use. It also provides links to publications and other documents about the trial.

Following the successful search of the Health Data Australia catalogue, researchers are able to complete a form via the data access request system, which will send the request to the Node, relevant researcher, research team or data custodian. For more information, it is best to contact your local HeSANDA Node Network as this process does vary. The decision about whether to share data and the process of sharing the data rests with the original research team / data custodian.

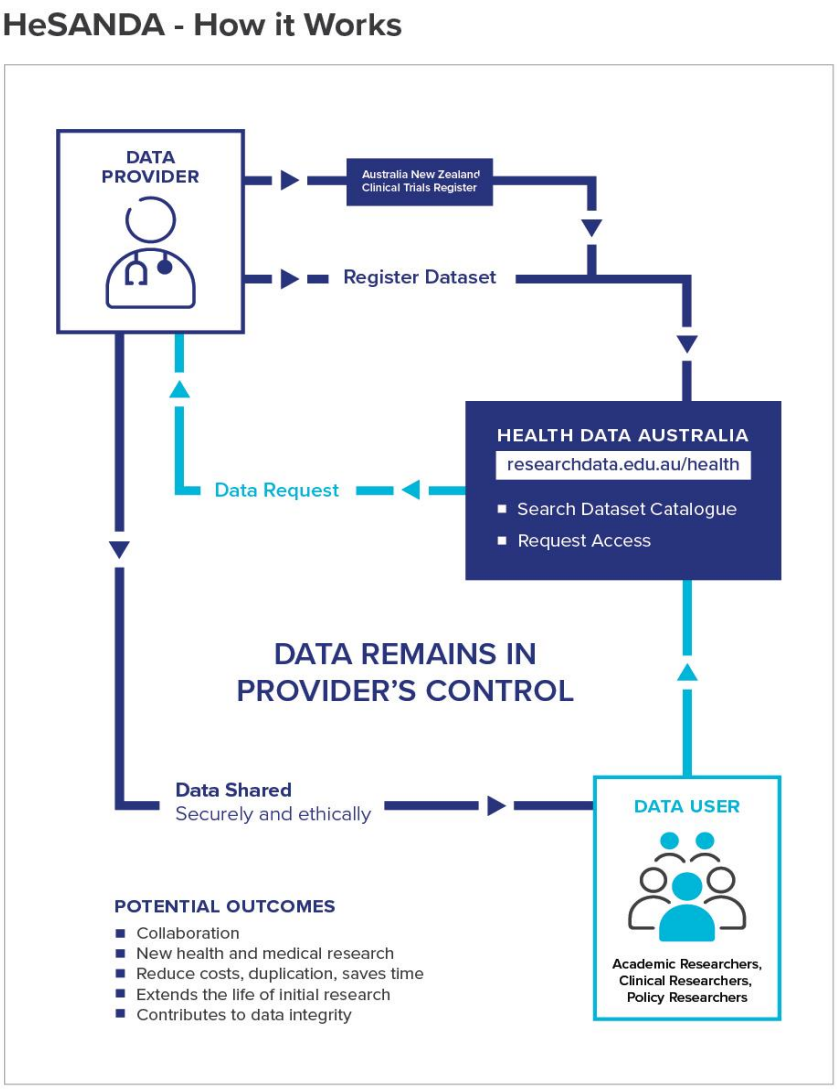



**Figure 1: Flowchart outlining the Health Data Australia platform process**

## 1.7. Why are some states, territories and organisations absent from the HeSANDA node network?

The Node network was established in 2021 as part of an open call process. Unfortunately we did not receive applications from all jurisdictions. We are keen for opportunities to expand our coverage and extend our support for Australian researchers. If you are interested in getting involved please email contact@ardc.edu.au

# 2. Using Health Data Platform

## 2.1. Who can use the Health Data Australia platform?

Anyone can search the Health Data Australia catalogue. In order to request access to clinical trial data through the Health Data Australia platform, a researcher or organisation must be registered with the Australian Access Federation.

## 2.2. Do I have to pay to use the Health Data Australia catalogue?

The Health Data Australia catalogue is maintained by ARDC as a free service to the research community. There is no user cost associated with accessing the catalogue or submitting a request.

## 2.3. Do I have to pay to access the data?

HeSANDA Nodes, research partners, or data custodians may charge fees to access data. These charges will be made clear to any researcher seeking to use the data.

## 2.4. Do I have to use Health Data Australia to gain access to trial data for secondary research purposes? Can I just contact a research team directly to access their data?

The Health Data Australia catalogue does not replace existing direct methods of requesting access to data from clinical trials. However, it will provide a more comprehensive view of trials for which datasets are available and increase the efficiency of making requests for data sharing, as all the information you need is within one platform, allowing you to view and request data across multiple sources.

## 2.5. How does the Health Data Australia catalogue add to / differ from existing mechanisms for sharing and accessing clinical trial data for secondary purposes?

Sharing of data from clinical trials is not a new concept. Current methods for finding out about available clinical trial data and contact details for the lead researcher(s) include:

- Via a clinical trials registry:

Information about clinical trials recruiting in Australia (completed or in progress) is available through the Australian and New Zealand Clinical Trials Registry (ANZCTR). The ANZCTR search function allows for basic or advanced searches of clinical trials listed on the ANZCTR database and provides contact details for the person listed as the 'public contact' on the trial record. Access to data from a clinical trial can be

requested through direct contact with the research team leading the original research. Similarly clinicaltrials.gov lists details of clinical trials that are recruiting participants in Australia.

- Via a publication:

A number of peer-reviewed journals require authors to sign a data sharing statement as part of their publication policy, and to show evidence of a data sharing plan in the trial's registration.

- Via a data registry / warehouse:

Some researchers may also contribute aggregated data to a registry or other data warehouse for use in future research.

The capabilities of the methods above are restricted as they rely on contact details in registries and publications to be up to date to provide limited information about the data available for sharing. Health Data Australia incorporates broader capabilities by using a more sophisticated and streamlined process, which provides a centralised source of information about available clinical trial data. This includes more detailed information about available data, lists information in a consistent way, and makes it easier to request access to data using a centralised process.

## 2.6. Has ANZCTR been involved in the development of Health Data Australia? How will this benefit the end users of both platforms?

ANZCTR has been involved in the discussions from the beginning of the program to determine the best way for both platforms to interact. There have been several changes to the ANZCTR interface to allow for more specific information to be garnered to HDA, such as the opportunity to include a data dictionary in the section on data sharing. By deriving key metadata from ANZCTR, the amount of data input for the user is reduced, and having one authoritative source of truth for these metadata can ensure consistency as records are updated.

## 2.7. Does Health Data Australia have datasets other than clinical trials?

Currently, the Health Data Australia platform has been built for investigator-initiated clinical trials. The ARDC HeSANDA team is currently undertaking public consultation with cohort studies and clinical quality registries. It is anticipated the inclusion of other research study types will be included.

# 3. Sharing Data

## 3.1. Why is data sharing useful / important in health research?

Sharing data and information is an important way of getting maximum benefit and value from health research. Data sharing can be justified scientifically, economically and ethically.

At a scientific level, data sharing can:

- inform and allow for testing of new research hypotheses
- increase the strength of research data by combining and comparing results from different studies in meta-analyses
- allow research findings to be validated and re-examined
- generate new findings or conclusions through different analyses.

Economically, data sharing can maximise the value of research funding by reducing duplication of effort or unnecessary repetition.

From an ethical perspective, data sharing respects the generosity of research participants by increasing the utility and value of their contribution.

## 3.2. What are the benefits and incentives of sharing data?

**For Australia**

Increases Australia's return on investment in health and medical research by enabling researchers to reuse existing data to inform new research questions and initiate new research collaborations. This will accelerate research answers and extend the value of consumer/participant contributions in a systematic and meaningful way.

**For Research Organisations**

- Raises the profile, status, research reputation and ranking of institutions and the researchers through increased citations, collaborations and grant applications
- Creates more opportunity for impactful projects
- Enhances research rigour i.e. by making research easier to reproduce
- Increases productivity through the increase in the number of research outputs
- Could lead to a positive impact on the number of students, commercialisation and quality and value of research grants.

**For the Researcher Who Created the Data (Data providers) -** Provides a consistent and reliable approach for researchers across Australia to:

- Gain increased recognition and visibility for their research
- Extend the life of their research
- Create more citable resources
- Meet their responsibilities to share data from publicly funded research projects
- Facilitate new collaborations to expand their research impact.

For Research Participants and the Community

- Allows participants to contribute to more research without requiring more of their time or effort
- Makes the most out of the data that participants provide
- Participants may view this as a meaningful contribution to more than one research project.

**For Health Services**

- Supports improved research practices in health services
- Raises the profile, status and researcher reputation through increased citations, collaborations and grant applications
- Increases the use of research data that has been created and supported through health service funding

**For Researchers Seeking Data (Data users)**

- Inspires new research questions and provides opportunities to build richer and more extensive datasets
- Provides a systematic and clear mechanism to create new collaborations
- Reduces research costs and duplication and saves time by hosting a catalogue of available research in one place and a clear pathway to request data
- Accelerates research discovery

**For the Funder(s)**

- Increases the return on investment through the reuse of research data
- Could lead to a positive impact on the value of the research grant and enhanced awareness of the funding body.

**Across all domains and roles mentioned above, it is anticipated that this will lead to:**

- Increased ability to understand and answer specific questions and generate new hypotheses

- More publications and citations, new students, increase track record to improve chances for successful grants and a sense of helping others across the country
- Better access to guidance, standards and governance around data sharing.

## 3.3. What are some of the key benefits to consumers of a research system that prioritises data sharing?

Current research shows that consumers are generally willing to consent to secondary data sharing as long as the parameters of this are clear and transparent (see additional readings). They have already gone through the risks and inconvenience /pain /discomfort (in the context of clinical trials) as part of the trial, and that experience can be used to answer other important research questions beyond the initial study that they participated in, which ultimately improves the lives of the community at large.

Moreover, utilising existing data allows researchers to focus their efforts on matters of significant value to the community. By refining their research focus using available data, new studies can address issues that truly matter to the people involved.

It is crucial to bring everyone on this journey, not just the research community, to foster trust and collaboration. This inclusive approach ensures that consumers are well-informed and actively engaged, ultimately benefiting both researchers and the community at large.

# 4. Contributing to HeSANDA

## 4.1. Who can contribute?

If your institute is a member of a HeSANDA Node Network, you can contact the node directly. See list here under the title 'The Partners' to see if your institute is affiliated with HeSANDA. If your institute is not affiliated, email contact@ardc.edu.au

## 4.2. What are the requirements for a clinical trial to be listed in Health Data Australia?

Data / information from a clinical trial can be registered in the Health Data Australia catalogue if :

- The clinical trial is registered with the ANZCTR, or the trial is registered with clinicaltrials.gov as having Australian participants. The principal investigator or appropriately delegated individual should ensure the ANZCTR record is complete and up to date before adding a dataset to Health Data Australia.
- The clinical trial has an associated data set that is potentially available for secondary use (sharing)
- The data set has a digital object identifier (DOI) and associated metadata record meeting HeSANDA specifications created using the DataCite service; creation of a DOI requires the data set to be maintained in an appropriate data repository. This process is managed differently at each HeSANDA Node; contact your local Node for specific details.

## 4.3. How will I know if my clinical trial is listed in Health Data Australia?

The Health Data Australia catalogue is automatically updated daily following the completion of the required ANZCTR and DataCite DOI metadata fields. Anyone can search the Health Data Australia catalogue.

## 4.4. Can I list a trial in Health Data Australia if the participant has not provided consent?

Clinical trial metadata can be shared with Health Data Australia regardless of the level of consent given by trial participants for future use of data. This is possible because the metadata distributed in Health Data Australia has been designed to not compromise the trial participants' personal information or privacy (follow this link to see how Health Data Australia works). The catalogue also contains the trial's

Data Sharing Statement registered with ANZCTR, so any information about consent provided in the statement will also appear in Health Data Australia.

The level of consent given by trial participants is a critical factor that determines whether data from a clinical trial can be shared with other researchers. Even if participant consent does allow for future use of data, researchers still need to exercise judgement to preserve the interests of participants. Judgement should err on the side of not sharing data if a material risk is identified that the participant may not have considered, and that reasonably would have caused a participant to decline consent to future use. Under the terms of the National Statement, ethics committees may choose to provide a waiver for researchers to share data without consent, though this must be discussed with the appropriate ethics committee for each trial.

The specific level of consent should be provided in the Data Sharing Statement of the trial in ANZCTR. Specific information about the consent provided and/or ethics approval can be shared optionally in the DataCite Rights field.

## 4.5. Can I list an international clinical trial in Health Data Australia?

Health Data Australia can list datasets from any clinical trial that is registered or listed in ANZCTR. This includes trials registered in ClinicalTrials.gov with an Australian site (i.e. that appear in ANZCTR despite being registered elsewhere). It is important to note that such trials may be under the governance of an international sponsor or lead organisation and therefore decisions to share the data relating to Australian participants may be subject to the data sharing regulations of that organisation.

Examples may also exist of clinical trials that are jointly sponsored by an Australian organisation but that are not recruiting patients in Australia and do not appear in ANZCTR. Data from such trials would not be available through Health Data Australia.

## 4.6. How long is data available for sharing in Health Data Australia?

The Health Data Australia catalogue does not currently have an ‘end date’ after which trial data will no longer be listed. However, individual trials may have restrictions on the period within which data will be made available for sharing. The Data Management Plan and Data Sharing Statement for a trial will outline any timeframes / restrictions within which data will / will not be shared.

# 5. Accessing Health Data Australia

## 5.1. Who can access Health Data Australia?

Anyone can search the Health Data Australia catalogue. In order to request access to clinical trial data through the Health Data Australia platform, a researcher or organisation must currently be registered with the Australian Access Federation in order to sign in and submit a request (NB. alternative sign-in options may be added in the future).

## 5.2. For what purposes may data be requested through Health Data Australia?

The NHMRC National Statement on Ethical Conduct in Human Research requires that researchers planning to share data from research develop a Data Management Plan that addresses their intentions for the sharing of data and proposes the conditions and processes they will adopt to facilitate data sharing. Once approved, this information should also be included in the Data Sharing Statement of the clinical trial's registration on ANZCTR.Secondary use of data from clinical trials listed in the Health Data Australia catalogue must be consistent with any conditions listed in the HREC-approved Data Management Plan and the Data Sharing Statement included trial's ANZCTR registration information.

ARDC recommends that trials have a documented Data Sharing Policy that can be included or cited within their Data Management Plan and/or Data Sharing Statement. Since Health Data Australia catalogue draws information from ANZCTR including the Data Sharing Statement, so if a Data Sharing Policy is included in that section of the trial registration then it will be visible to HDA users.

In broad terms this policy should lay out, in general terms, how an organisation or group will respond to requests to share data, including:

- the types of data agencies have in their custody
- the principles and strategy around the sharing of that data
- the governance and management procedures that should be followed when that data is being shared.

## 5.3. What can I use the data for? / Are there any restrictions on what I can use the data for?

Secondary use of data from a clinical trial must be consistent with any restrictions listed in the Data Management Plan and Data Sharing Statement included at trial registration.

In some situations, researchers will place controls on data sharing and re-use. This may be important to protect the confidentiality and privacy of research participants, to protect intellectual property, and/or to ensure secondary research is using existing data in an appropriate way.

# 6. Governance

## 6.1. Who decides what data are / are not shared?

Clinical trial data catalogued in Health Data Australia remains under the governance of the lead researcher and / or data custodian for the original trial. The decision to grant access to data following a request through the Health Data Australia catalogue rests with the lead researcher / data custodian. Data sharing and secondary use should occur in accordance with the National Statement and with the ethics, consent and data governance and management plans and agreements for the original trials.

## 6.2. What laws, regulations, policies, agreements and plans should guide decisions about data sharing from clinical trials?

Overall, the Australian Government policy around data sharing maintains aims to "where possible, ensure non-sensitive publicly funded research data is made open for use and reuse". Legislation and guidance underpinning decision making by data custodians exists at trial-specific, institutional, state/territory and national levels. These include:

**State / territory / national and international legislation**

- Privacy Act (Cth) 1988
- Australian Human Rights Commission Act
- Freedom of Information Act

**National guidelines and strategies**

- National Statement on Ethical Conduct in Human Research
- Australian Code for the Responsible Conduct of Research
- Code of Ethics for Aboriginal and Torres Strait Islander Research
- Data policies of health research publishers

**Trial-specific plans and agreements**

Limitations, restrictions and conditions around data sharing and re-use described in the trial Data Management Plan.

**Institutional policies**

- Data sharing policy
- Data sharing agreement

## 6.3. What is a Data Management Plan?

The NHMRC National Statement on Ethical Conduct in Human Research states that, when planning to share data or information with other researchers, researchers must develop a Data Management Plan. The Data Management Plan should propose appropriate conditions on the sharing of data and information.

The Data Management Plan for the clinical trial should be a key point of reference when contributing to Health Data Australia and when reviewing requests to access data from a clinical trial through Health Data Australia.

Limitations / restrictions on data use included in the Data Management Plan should be described in the meta-data provided to Health Data Australia so that other researchers understand these limitations.

When responding to requests to access data via Health Data Australia, researchers should consult and adhere to any limitations or restrictions described in the Data Management Plan. Researchers should also consider the value of the data or information for future research when making decisions.

## 6.4. What should a Data Management Plan include?

The National Statement on Ethical Conduct in Human Research states that the Data Management Plan:

'should include, but not be limited to, details regarding:

a. physical, network, system security and any other technological security measures
b. policies and procedures
c. contractual and licensing arrangements and confidentiality agreements
d. training for members of the project team and others, as appropriate
e. the form in which the data or information will be stored
f. the purposes for which the data or information will be used and/or disclosed
g. the conditions under which access to the data or information may be granted to others
h. what information from the data management plan, if any, needs to be communicated to potential participants.'

## 6.5. What are the current policies and expectations of health research bodies on data sharing?

Recognition of the importance of data sharing in health research is increasing in Australia and internationally. It is increasingly common for funding agencies to require that research data is shared, through open access or mediated access arrangements. Leading academic publishers also require

authors to agree to data sharing as part of the process of publishing results in peer-reviewed publications.

The National Statement on Ethical Conduct in Human Research states that:

'In the absence of justifiable ethical reasons (such as respect for cultural ownership or unmanageable risks to the privacy of research participants) and to promote access to the benefits of research, researchers should collect and store data or information generated by research projects in such a way that they can be used in future research projects. Where a researcher believes there are valid reasons for not making data or information accessible, this must be justified.'

## 6.6. Where can I find advice/guidance on the ethics approvals that are required?

Legislation and guidance underpinning decision making by data custodians exists at trial-specific, institutional, state/territory and national levels. The key documentation includes the National Statement on Ethical Conduct in Human Research 2023 and CT:IQ InFORMed Project

## 6.7. What level of ethical review will I need if I want to use the data?

The National Statement on Ethical Conduct in Human Research states that, unless a waiver of the requirement for consent is obtained, access to and use of research data or information must be in accordance with the original consent.

Any research using data from a previous trial will be subject to approval from a Human Research Ethics Committee (HREC). Depending on the type(s) of data being used and the purpose of secondary use, such review may qualify as negligible or low-risk research. However, under the requirements of the National Statement, data cannot be shared / re-used for research that is exempt from ethics review.

## 6.8. What level of ethical review will I need if I want to use the data?

The National Statement on Ethical Conduct in Human Research states that, unless a waiver of the requirement for consent is obtained, access to and use of research data or information must be in accordance with the original consent.
Any research using data from a previous trial will be subject to approval from a Human Research Ethics Committee (HREC). Depending on the type(s) of data being used and the purpose of secondary use, such review may qualify as negligible or low-risk research. However, under the requirements of the National Statement, data cannot be shared / re-used for research that is exempt from ethics review.

## 6.9. What data governance is required to ensure robust data security in the context of research data sharing?

Data governance plays a crucial role in ensuring robust data security, especially in the context of research data sharing. In the realm of health research, where multiple stakeholders are involved, managing sensitive data becomes complex. The 'five safes' framework can serve as a foundation for data governance.

The HeSANDA program has produced resources to support appropriate governance including data sharing agreements and policies.

Health Data Australia, shares only metadata, allowing researchers to maintain complete control over their actual datasets. This approach ensures both the security and integrity of research data, fostering a collaborative yet secure environment for data sharing.

## 6.10. When is the ideal time to identify the intention to make a dataset available in Health Data Australia?

The intention to share data ideally should be determined at the beginning of the research study. The Protocol, Participant Information Sheet and Consent Form (PICF) and Data Management Plan should contain the detail of what data is available, governance processes, and method of how it will be shared. Access provision to these documents will provide the researcher seeking the data (data user) in Health Data Australia with clarity on what data is available.

## 6.11. What type of participant consent is needed to list a trial on Health Data Australia?

Information about any trial can be listed in Health Data Australia catalogue, regardless of whether participant consent has been given for future use and regardless of the level of consent provided. The metadata captures whether consent has been given, the level of consent and any restrictions on uses for which data sharing will be considered (click here to find out more about regulations for participant consent). This information helps researchers frame their request to the primary research team. Even if consent for future use has not been given, there can still be value in researchers connecting via HDA to understand research that has been taken in related fields.

## 6.12. Is there standardised wording which can be used in Participant Information Consent Form to ensure participants and consumers understand what data sharing is?

ARDC through the HeSANDA project has been working with the CTIQ InFORMed Project to provide standardised wording in the PICF regarding data sharing. The PICF template can be accessed via this link [InFORMed: Redesigning Consent to Research (informedpicf.com.au)]

## 6.13. What level of permission does the participant need to provide to allow access to the trial dataset?

The level of consent given by trial participants is the most critical factor that determines whether data from a clinical trial can be shared with other researchers. Even if participant consent does allow for future use of data, researchers still need to exercise judgement to preserve the interests of participants. Judgement should err on the side of NOT sharing data if a material risk is identified that the participant may not have considered, and that reasonably would have caused a participant to decline consent to future use.

Data from clinical trials can only be shared with another researcher if:

- participants have provided the appropriate level of consent to future use of data in research or
- Human Research Ethics Committee (HREC) has waived the requirement for consent to future use of data.

## 6.14. When may a waiver of consent be considered?

A waiver of consent describes a process of approval from a HREC allowing use of a person's personal information or personal health information in a research project without obtaining consent from the individual.

Only a HREC may grant waiver of consent for research using personal information in medical research, or personal health information.

The National Statement on Ethical Conduct in Human Research states that:

Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

a. Involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants
b. The benefits from the research justify any risks of harm associated with not seeking consent

c. It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
d. There is no known or likely reason for thinking that participants would not have consented if they had been asked
e. There is sufficient protection of their privacy
f. There is an adequate plan to protect the confidentiality of data
g. In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
h. The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
i. The waiver is not prohibited by State, federal, or international law.

## 6.15. Population-specific considerations for data sharing; how do I approach working with sensitive data from Aboriginal and Torres Strait Islander peoples?

The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) AIATSIS Guide to applying the AIATSIS AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research states that:

'There is a strong emphasis in the research sector and government for more open data, commonly described by the FAIR principles: Findable, Accessible, Interoperable and Reusable. However, this focus on facilitating data sharing does not fully engage with Indigenous peoples' rights and interests and efforts to assert greater control over the application and use of Indigenous data and Indigenous knowledge for collective benefit. To this end, Australian Indigenous researchers and their international colleagues have developed the CARE principles to overlay data access. These are: Collective Benefit, Authority to Control, Responsibility, and Ethics.

- Collective Benefit: Data ecosystems shall be designed and function in ways that enable Indigenous Peoples to derive benefit from the data.
- Authority to Control: Indigenous Peoples' rights and interests in Indigenous data must be recognised and their authority to control such data be empowered. Indigenous data governance enables Indigenous Peoples and governing bodies to determine how Indigenous Peoples, as well as Indigenous lands, territories, resources, knowledges and geographical indicators, are represented and identified within data.
- Responsibility: Those working with Indigenous data have a responsibility to share how those data are used to support Indigenous Peoples' self-determination and collective benefit.

Accountability requires meaningful and openly available evidence of these efforts and the benefits accruing to Indigenous Peoples.

- Ethics: Indigenous Peoples' rights and wellbeing should be the primary concern at all stages of the data life cycle and across the data ecosystem.'

# 7. Risks

## 7.1. Are there data use/sharing/transfer agreement templates available? Can you provide guidance or templates for putting together a data sharing and management plan?

A standard template for data sharing (policy and agreement) can be created and then modified as needed to fit the specifics of individual research projects or data to be shared or accessed. It should be agreed on whenever there is a need or an intention to share data created by a research project or projects. The policy ensures that all data requests are handled consistently and appropriately. It also ensures that both the data holder and potential data requesters understand the process of making and assessing requests.

Depending on the requirements of the data holder, the agreement might be made at the level of the organisation, the research group or a specific project or dataset. It may be the case that while a larger group or organisation typically follows a set of principles and processes for data sharing, certain datasets require more complex governance requirements or sharing conditions.

## 7.2. Is it possible to have one standard national data transfer agreement for multicentre completed studies based on data retrieval?

It is the responsibility of the data requestor and data provider to refer to and adhere to their individual organisation/institutional governance requirements related to data sharing. At present there is no standard national data transfer agreement. ARDC has produced Data Sharing Development Guidelines to assist organisations in understanding when and why a data sharing agreement is required, what is typically covered in it, and how they should go about producing one. It should also be noted that data transfer arrangements could be specified as part of a collaborative research agreement (follow link to find out more).

## 7.3. How can I ensure my data management plans will enable future data sharing?

The National Statement on Ethical Conduct in Human Research states that the Data Management Plan: ‘should include, but not be limited to, details regarding:

a. Physical, network, system security and any other technological security measures
b. Policies and procedures

c. Contractual and licensing arrangements and confidentiality agreements
d. Training for members of the project team and others, as appropriate
e. The form in which the data or information will be stored
f. The purposes for which the data or information will be used and/or disclosed
g. The conditions under which access to the data or information may be granted to others
h. What information from the data management plan, if any, needs to be communicated to potential participants.'

# 8. Glossary

- **Data management plan:** A living document for a research project, that outlines data creation, data policies, access and ownership rules, management practices, management facilities and equipment, and who will be responsible for what.
    - From ARDC 'Data management plans'
- **Data sharing agreement**: A formal agreement between a data provider and a data requester that refers to a specific case of data sharing.
    - From ARDC information on developing a data sharing agreement
- **Data sharing policy**: A data sharing policy lays out, in general terms, how that organisation or group will respond to requests to share the data. A policy written by an organisation or a group that addresses:
    - the types of data the agencies have in their custody
    - the principles and strategy around the sharing of that data
    - the governance and management procedures that should be followed when that data is being shared.
    - From ARDC information on developing a data sharing policy
- **De-identified information:** De-identified data is information from which personally identifiable details have been removed, safeguarding individual privacy while allowing for analysis and research.
    - See the following for more information https://www.oaic.gov.au/privacy/guidance-and-advice/de-identification-and-the-privacy-act
- **Human Research Ethics Committee (HREC):** A committee that reviews research proposals involving human participants to ensure that the research is ethically acceptable.
    - From NHMRC website: HRECS
    - See list of HRECs registered with the NHMRC.
- **Identifiable data:** Data that contains identifying information (such as name, image, date of birth, signature, contact details).
    - From ARDC: Identifiable data and NHMRC A Consumer to the Principles for accessing and using publicly funded data for health research
- **Individual Participant Data:** Raw line-by-line data collected from each participant in a clinical trial.

- **Meta-analysis:** The statistical combination of results from two or more separate studies.
    - From Cochrane training handbook
- **Metadata:** Metadata can be information about an object or resource that describes characteristics such as content, quality, format, location and contact information.
- **Non-identifiable data:** Data that cannot be used to identify a specific individual. This may be because the data have never been labelled with individual identifiers or because individual identifiers have been permanently removed.
    - From NHMRC A Consumer to the Principles for accessing and using publicly funded data for health research
- **Personal health information:** Any personal information (including opinion) about an individual's health or disability. Examples include notes from a health record, test results, appointment and billing details, genetic information and wishes around future healthcare and organ donation.
    - From OAIC Health Information
- **Personal information:** Includes a broad range of information or opinion that could identify an individual. What is personal information will vary, depending on whether a person can be identified or is reasonably identifiable in the circumstances. Examples include name, signature, address, phone number, date of birth, photographs, employee record information and credit information.
    - From OAIC Personal Information
- **Primary Researcher, Data Provider, Data Custodian:** A person, organisation or agency responsible for managing the use, disclosure and protection of source data generated through research.
- **Re-identifiable data:** Data from which identifiers have been removed and replaced by a code, but from which a specific individual could be re-identified, for example by using the code or linking different data sets.
    - From NHMRC A Consumer to the Principles for accessing and using publicly funded data for health research
- **Secondary use of data:** Any use of data beyond the reason for which the data were first collected (known as the primary use or purpose).
    - From AIHW Secondary use of health information
- **Sensitive data:** Data that requires extra care due to its sensitive nature. Examples include identifiable personal and health / medical data, Indigenous data, ecological data, and commercial-in-confidence data.

- From ARDC Sensitive data

# 9. Additional Reading & Information

If you have any further questions, email us at contact@ardc.edu.au

## About Us

- The HeSANDA program and Nodes have worked together to develop the "Health Studies Australian National Data Asset (HeSANDA) flyer". This can be accessed via this website link https://doi.org/10.5281/zenodo.10199242
- Program page HeSANDA: https://ardc.edu.au/program/health-studies-australian-national-data-asset/
- HDA home page: https://researchdata.edu.au/health/

## Sharing Data

- Ohmann C, Banzi R, Canham S, et al. Sharing and reuse of individual participant data from clinical trials: principles and recommendations. BMJ Open 2017;7:e018647. Doi:10.1136/bmjopen-2017-018647
- Kochhar S, Knoppers B, Gamble C, et al. Clinical trial data sharing: here's the challenge. BMJ Open 2019;9:e032334. Doi:10.1136/bmjopen-2019-032334
- NHMRC National Statement on Ethical Conduct in Human Research. 3.1.50
- National Institutes of Health
- Welcome Trust
- World Health Organization
- VCCC Alliance: Data Sharing

## Accessing Health Data Australia

- NHMRC National Statement on Ethical Conduct in Human Research. Section 3.1.56.
- ARDC Data sharing policy development guidelines 2023

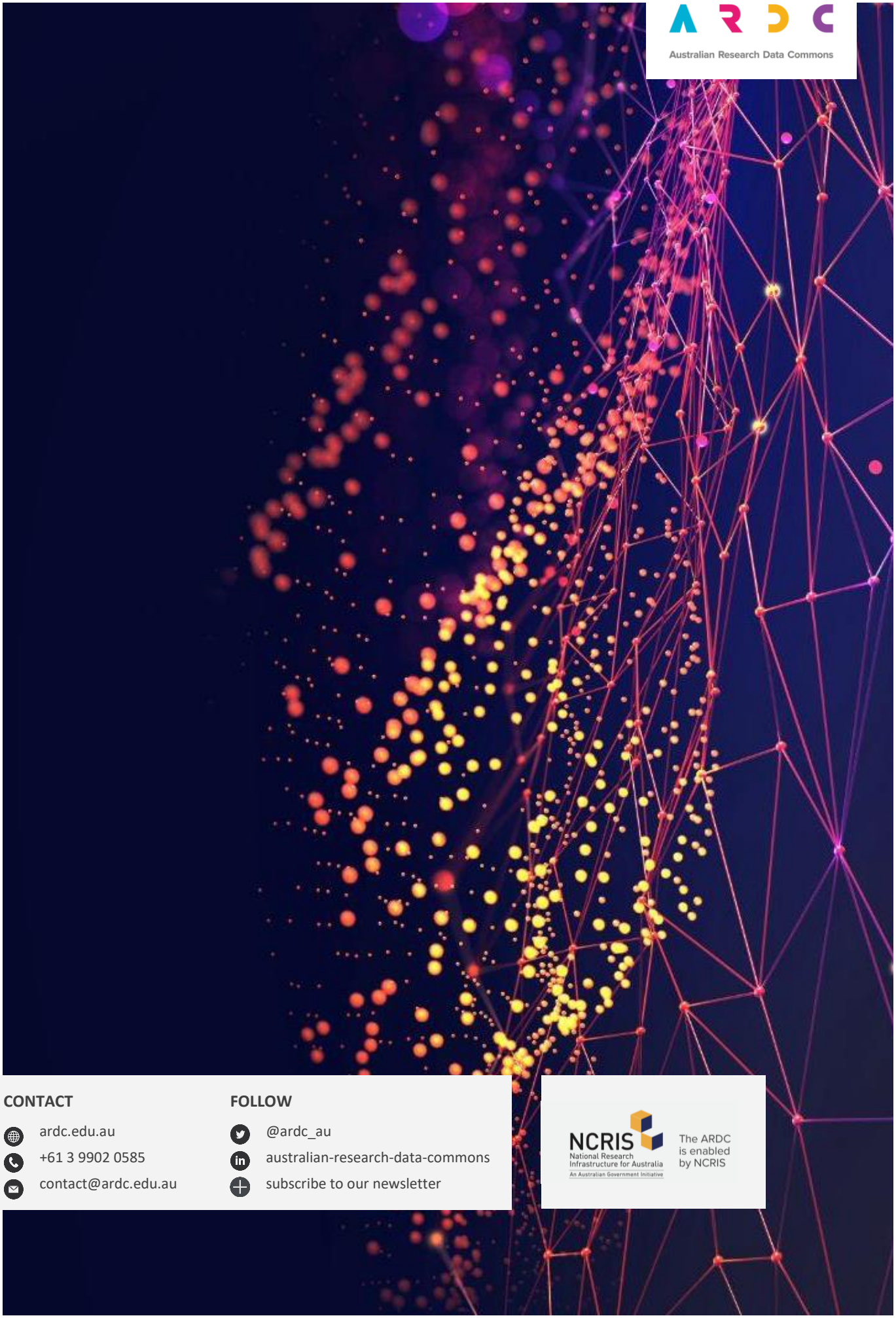
## Governance

- NHMRC National Statement on Ethical Conduct in Human Research.
- NHMRC: Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research
- Australian Government Office of the Information Commissioner. Privacy Act: Health and Medical Research

- Force11 2016, The Fair Data Principles; GIDA (Global Indigenous Data Alliance) 2018, CARE Principles for Indigenous Data Governance; CARE Principles
- NHMRC National Statement on Ethical Conduct in Human Research.
- Australian Institute for Aboriginal and Torres Strait Islander Studies. Code of Ethics for Aboriginal and Torres Strait Islander Research.
- Australian Institute for Aboriginal and Torres Strait Islander Studies. Guide to applying the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research.
- NHMRC National Statement on Ethical Conduct in Human Research. 2.3.9 and 2.3.10
- Data Management Framework for Institutions

## Risks

- Data Sharing Policy
    - https://www.georgeinstitute.org.au/data-sharing-policy
    - https://www.ipc.nsw.gov.au/guide-data-sharing-and-privacy
    - https://ardc.edu.au/resource/data-sharing-policy-development-guidelines/
- Data Sharing Agreement
    - https://ardc.edu.au/resource/data-sharing-agreement-development-guidelines/



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