Responsibilities for the Secondary Sharing of Clinical Trial Data in Australia

Draft Work Paper

Prepared by

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Acknowledgement of Country

CT:IQ acknowledges Aboriginal and Torres Strait Islander peoples as the traditional custodians of the land on which we meet, work and learn. We pay our respects to Elders past and present.

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Advice to Readers

The purpose of this work paper is to describe the ethical and legal responsibilities for the sharing of clinical trial data for secondary research in Australia. The work paper forms part of the broader ARDC/CT:IQ Project Clinical Research Data Sharing Frameworks. This work paper acts as a guide for data custodians, researchers and clinical trial sponsors who wish to use and disclose clinical trial data for secondary research purposes. Although specific responsibilities may need to be modified in certain use cases, these are general principles which can be applied to a wide variety of research projects. The responsibilities are derived from a review of Australian legislation, regulations and guidelines, as well as a non-exhaustive search of regulatory documents. This draft version is open for feedback until 11 April 2025. Please provide any feedback on the draft through https://forms.office.com/r/FKWBAkb8x0.

This work paper has been developed to provide general information to the Australian research community. It should not be relied upon as legal advice. If you are unsure about your situation, please obtain legal advice.

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Executive Summary

Scope

Increasingly, clinical trial data are being shared for secondary research (Hocking et al, 2019, p. iv). Sharing clinical trial data, including participant-level data, has numerous benefits. These benefits include improved verifiability and reproducibility of results, as well as more effective synthesis of evidence that reduces the need for further clinical trials (Hunter et al., 2024, p. 28; Thorogood and Knoppers, 2017, p. 58). However, it is also important to ensure that secondary uses of clinical trial data are ethical and in compliance with relevant laws and guidelines. The purpose of this work paper is to synthesise legal and ethical responsibilities governing the secondary use of clinical trial data in Australia. It is anticipated that these responsibilities will be used as a general guide for data custodians, researchers and clinical trial sponsors.

The work paper reflects the law in Australia as of 30 November 2024. A more detailed examination of how the principles of clinical data sharing apply in specific contexts is outside the scope of this work paper. In particular, this work paper recommends that Indigenous Data Governance requires special consideration but does not address the full details of those requirements.

Methodology

To synthesise legal and ethical responsibilities governing the secondary use of clinical trial data in Australia, this work paper involved two stages. The first was a comprehensive search for legislation and guidelines governing the secondary use of health data in Australia. This included Commonwealth, state and territory legislation as well as guidelines published by responsible agencies, including the Therapeutic Goods Administration of Australia (TGA), the National Health and Medical Research Council (NHMRC), the Australian Commission on Safety and Quality in Health Care, and state, territory and local health agencies. The second stage involved a comprehensive but non-exhaustive search for guidance documents published on the secondary use of health data in Australia. This search included both guidance documents published by state and territory health agencies, as well as guidance documents with respect to specific data platforms.

Additional information on methodology is available in Appendix 1.

Key Principles for Sharing Clinical Trial Data

Based on the above methodology, seven key principles were identified as best practice to facilitate clinical trial data sharing. These are not intended to be in order of priority or a chronological sequence. Each of these principles might have greater importance for some research projects than others. However, they provide data custodians, researchers and clinical trial sponsors with guidance on what issues to consider with respect to the secondary use of clinical data.

1. **Establish clear, documented governance structures:** Determine the relevant actors in the governance of the clinical trial data. These include data custodians, data access committees or data stewards and ethics review bodies. The respective obligations of these actors should be documented in the data sharing policy of the study protocol (or similar). The obligations of secondary users of data should be documented using data sharing agreements.
2. **Define the data to be shared:** Assess whether the data in question could be defined as personal, re-identifiable or de-identified data. How data is classified will have an impact on how it can be used and disclosed.
3. **Confirm the scope of consent:** Confirm whether an adequate consent has been sought to use personal or re-identifiable data for secondary research purposes.
4. **Optimise collection practices:** Consider how the clinical trial data has been collected from or generated about participants and accommodate these collection practices in sharing frameworks.
5. **Establish data security plans:** Develop a data security plan that applies to data custodians, researchers and sponsors.
6. **Share safely:** Implement documented procedures to assess requests for data sharing, including special considerations when on-sharing data or adding data to a repository.
7. **Engage with participants:** Incorporate community perspectives into data sharing arrangements, including Aboriginal and Torres Strait Islander peoples and individuals with rare diseases.

Part A. Legislative Requirements for Obtaining and Sharing Clinical Trial Data

The legislation and regulations that govern clinical trials can be classified into four categories: approval of clinical trials and data collection; consent for the use, collection and disclosure of clinical trial data; defining personal information; and storage and security using and disclosing of clinical trial data.

Approval of Clinical Trials and Data Collection

- Pursuant to the *Therapeutic Goods Act 1989* (Cth) s 19, clinical trials involving 'unapproved therapeutic goods' (as defined by the Act) must be conducted under either:
  - The Clinical Trial Notification (CTN) Scheme, which involves notification to the TGA along with review by an Australian Human Research Ethics Committee (HREC).
  - The Clinical Trial Approval (CTA) Scheme, which involves a product safety review by the TGA (Australian Clinical Trial Handbook: Guidance on Conducting Clinical Trials in Australia Using "Unapproved" Therapeutic Goods, 2021, pp. 18–22).
- The choice of scheme is to be made by the sponsor and confirmed by an HREC.
- If a clinical trial does not involve an unapproved therapeutic good, it does not need to proceed down either the CTN or CTA scheme. However, the trial will still require approval by an ethics review body before it can commence (Australian Clinical Trial Handbook: Guidance on Conducting Clinical Trials in Australia Using "unapproved" Therapeutic Goods, 2021, p. 7).

Consent for the Collection, Use and Disclosure of Clinical Trial Data

- Consent for the collection, use and disclosure of personal or health information as part of a clinical trial is regulated under federal or state/territory privacy or health legislation. Different privacy legislation applies depending on the legal status of the source of the clinical trial data.
  - If the entity that collected the data is a private institution or a Commonwealth government agency, federal data privacy laws will apply. These include the *Privacy Act 1988* and the *Healthcare Identifiers Act 2010*.
  - If the entity that collected the data is a state or territory public institution, then local jurisdictional privacy and/or confidentiality provisions set out in health information management laws will apply. Some federal data privacy laws also bind state or territory agencies, such as the *Healthcare Identifiers Act 2010*.
  - Specific federal laws may also apply to certain data assets, which may include prohibitions on or requirements relevant to sharing. The My Health Records Act 2012 and associated regulations apply to Australia's summary health care record system My Health Record. The *National Health Act 1953* and associated rules apply to the Pharmaceutical Benefits Scheme and data collected as part of this scheme. The *Health Insurance Act 1973* applies to data collected as part of the Medicare Benefits Schedule.
  - In the Australian Capital Territory, New South Wales and Victoria, both the *Privacy Act 1988* and State/Territory health data privacy laws will apply to private organisations
    - *Health Records (Privacy and Access) Act 1997* (ACT)
    - *Health Records and Information Privacy Act 1998* (NSW)
    - *Health Records Act 2001* (Vic)
  - In Queensland, the Information Privacy Principles apply to government agencies, whereas the National Privacy Principles apply to health agencies (including the department of health and Hospitals and Health Services). In 2025, these will be updated to a single set of Queensland Privacy Principles as part of reforms to the *Information Privacy Act 2009* (QLD).

    - There may be other laws which apply depending on the nature of the research:
        - Public health legislation will apply to health information that is collected by a state health department for public health research or quality improvement
        - Mental health legislation will apply to research involving information collected as part of a mental health service
- All privacy or health information schemes permit the use and disclosure of health information for research purposes either with the consent of the participant or, if no consent is available, if a waiver of the requirement for consent has been approved by an ethics review body.
- The ethics review body can also determine whether an opt out approach or a waiver of the requirement for consent (as opposed to opt in consent) is appropriate for the project if the entity conducting the research applies for an opt out or a waiver. Only a Human Research Ethics Committee (HREC) can approve a waiver of the requirement for consent for research seeking the use or disclosure of personal information in medical research, or personal health information.

Consent for involvement in a clinical trial for individuals who lack capacity is primarily covered under state and territory legislation. The involvement of adults with impaired capacity is covered under guardianship and administration legislation whereas consent for children is covered under common law principles, as well as consent to medical treatment legislation in New South Wales and South Australia. A list of this legislation is contained in **Appendix 2, Tables 1 and 2**.

Guidelines published by the NHMRC interact with relevant privacy laws to allow certain health and medical research to be done without consent. These guidelines include the *National Statement on Ethical Conduct in Human Research*, as well as the guidelines approved under sections 95 and 95A of the Privacy Act 1988.

The Section 95 guidelines apply to medical research where personal information held by a government agency needs to be used without consent. These guidelines define what researchers need to supply to a HREC when seeking to access personal information for medical research without consent (Guidelines Under Section 95 of the Privacy Act 1988, 2024, para. 2.1 to 2.7).

The Section 95A guidelines apply to collecting, using or disclosing health information held by private sector organisations for research relevant to public health or safety (Guidelines Approved under Section 95A of the *Privacy Act 1988*, 2024, para. A1.1). The Section 95A guidelines also apply to private sector organisations which collect and use health information to compile or analyse statistics for public health or public safety purposes (Guidelines Approved under Section 95A of the *Privacy Act 1988*, 2024, para. B1.1). Finally, the Section 95A Guidelines apply to private sector organisations which collect and use health information to manage a health service (Guidelines Approved under Section 95A of the *Privacy Act 1988*, 2024, para. C1.1).

Defining Personal Information

Under Commonwealth and Australian Capital Territory legislation, 'personal information' includes any information about a person who is identifiable or is reasonably identifiable (*Privacy Act 1988* (Cth), s 6; *Information Privacy Act 2014* (ACT), s 8(1)). Under other state and territory legislation, personal information includes any information or opinion about an individual who is identifiable or whose identity can be reasonably ascertained (*Privacy and Personal Information Act 1998* (NSW), s 4(1); *Information Act* 2002 (NT), s 4A(1); *Information Privacy Act 2009* (QLD), s 12; *Personal Information Protection Act 2004* (TAS), s 3, *Privacy and Responsible Information Sharing Act 2024* (WA), s 4). This definition is also used in state and territory data governance documents (National Health Information Standards and Statistics Committee, 2017, p. 3; NT Health Data Release Guidelines, 2018, p. 20; Research Governance Procedures, 2021, p. 50). Until case law determines otherwise, it can be assumed that both definitions are equivalent.

Commonwealth, state and territory privacy and health information management legislation also applies to 'health information'. This definition can encompass information about the health of or health services provided to or by an individual. It can also encompass personal information collected whilst providing a health service, as well as genetic information (*Privacy Act 1988* (Cth), ss 6(1) and 6FA; *National Health Act 1953* (Cth), s 135AC(1); *Health Insurance Act 1973* (Cth), s 129AAD; *Health Records (Privacy and Access) Act 1997* (ACT), Dictionary (definition of 'health information'); *Health Records and Information Privacy Act 2002* (NSW), s 6; *Information Act 2002* (NT), s 4; *Information Privacy Act 2009* (QLD), sch 5 (definition of 'health information'); *Personal Information Protection Act 2004* (TAS), s 3; *Health Records Act 2001* (VIC), s 3; *Privacy and Responsible Information Sharing Act 2024* (WA), s 4). This definition is used across Commonwealth, state and territory guidelines (National Health Information Standards and Statistics Committee, 2017, p. 17).

The scope of public health laws varies more noticeably between different states and territories. New South Wales, Northern Territory and Victorian public health laws cross reference privacy or health information management laws (*Public Health Act 2010* (NSW), s 98; *Public and Environmental Health Act 2011* (NT), s 4; *Public Health and Wellbeing Act 2008* (VIC), section 3). South Australian and Tasmanian public health laws create their own definition of personal information (*Public Health Act 2011* (SA), s 99(4); *Public Health Act 1997* (TAS), s 3). Queensland and Western Australian public health laws apply to 'confidential information' and 'specified information' respectively (*Public Health Act 2005* (QLD), ss 219, 228H, 237, 279AK; *Public Health Act 2016* (WA), s 298). Therefore, before requesting information for research or a clinical trial, a researcher or sponsor should determine if this data is covered under these laws.

Likewise, mental health laws govern information about the delivery of mental health services. These laws vary between different states and territories. The Western Australian Department of Health may request that a mental health service disclose relevant information for research purposes. This relevant information can include information about the treatment or care of a person, as well as (*Mental Health Act 2014* (WA), s 572(3)). Similarly, in the Northern Territory and South Australia, information about an individual's mental health treatment can be disclosed for research purposes (*Mental Health and Related Services Act 1998* (NT), s 91(2)(j); *Mental Health Act 2009* (SA), s 106(2)(f)). Other legislation, such as in New South Wales, Queensland, Tasmania and Victoria, cross references equivalent state privacy laws with respect to when data can be used for research purposes (*Mental Health Act 2007* (NSW), s 189(1)(d1); *Mental Health Act 2016* (NSW), s 778(3)(b); *Mental Health Act 2013* (TAS), s 134 (1)(b); *Mental Health and Wellbeing Act 2022* (VIC), s 671(3)).

Storage and Security of Clinical Trial Data

Depending on the data custodian or sponsor responsible for holding data, either Commonwealth or state and territory legislation will apply to storage and sharing practices. This legislation includes privacy and health information legislation, as well as legislation governing public documents.

Under the *NHRMC Management of Data and Information in Research* guide, how long data needs to be retained depends on the purposes of a research project. For most research projects, the minimum period of retention is 5 years from the date of publication. For clinical trials, data should be retained for a minimum of 15 years. For genomic research, the data may need to be retained indefinitely (National Health and Medical Research Council, 2019, p. 3). In addition, there are state and territory guidelines which apply to the storing and security of records by public sector agencies, including clinical trial data and associated documents. These guidelines are contained in Appendix 2, Tables 3 and 4.

Part B. Principles for Sharing Clinical Trial Data

The following seven key principles were identified as best practice to facilitate clinical trial data sharing. These are not intended to be in order of priority or a chronological sequence. Each of these principles might have greater importance for some research projects than others. However, they provide data custodians, researchers and clinical trial sponsors with guidance on what issues to consider with respect to the secondary use of clinical data.

1. Establish clear, documented governance structures

A foundation for responsible data sharing is the availability of clear governance structures, including roles and responsibilities for data management and sharing decisions. This generally will involve some or all the items below. The data governance structures should be recorded in relevant documentation, including the study protocol, data sharing policy, clinical trial research agreements and/or other relevant trial documentation.

a) Data custodians

A 'data custodian' is any entity, including an organisation, agency or person, responsible for maintaining or reviewing information in a dataset. The data custodian must ensure that the dataset adheres to quality and security standards (NT Health Data Release Guidelines, 2018, p. 18; Rowlands et al., 2024, p. 19). Two or more entities may be joint data custodians if they are jointly responsible for the quality and security of the dataset. If an entity such as a research organisation requests access to a dataset, all data custodians must approve access to that dataset (National Health Information Standards and Statistics Committee, 2017, p. 4).

In some cases, it may be unclear who is responsible for maintaining and reviewing information in a dataset. For example, a government agency may collect clinical trial data and then store this data on a third-party cloud computing provider. In these circumstances, it is unclear whether the data custodian is the agency (which is responsible for collecting the data), or the cloud computing provider. Therefore, the entity which is 'data custodian' should be determined via contract or legal agreement (Moses, 2020, p. 630; Krebs and Moses, 2024, p. 135). Doing so will ensure that responsibility and accountability for the use of data is clear (Adams et al., 2022a, p. 225).

b) Data access committees, data stewards or research governance officer

Depending on the size of the dataset, a data access committee, data steward or research governance officer should be appointed to oversee the overall strategy associated with the dataset (NT Health Data Release Guidelines, 2018, p. 11). These objectives will depend on the overall nature of the project. However, they could include assessing applications to access the data, considering the need for ethics approval, supervising linkage or de-identification, assessing risk and conducting monitoring activities (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 9).

c) HRECS and Other Ethics Review Bodies

Human Research Ethics Committees (HRECs) are specialised committees that protect the welfare and rights of participants in research. HRECs are responsible for ensuring that research proposals are ethically acceptable and that research participants are protected in research protocols, including for clinical trials. Institutions may establish non-HREC ethics review bodies for the ethics review of lower-risk research. (National Statement para 5.1.12)

HRECs and other ethics review bodies should not be responsible for assessing research governance or dataset strategy. These decisions should be determined by a data access committee or a data steward. HRECs should instead focus on whether the benefits of the proposed research outweigh any potential risks and whether participants are treated with respect (Adams et al., 2022a, pp. 225–226).

Approval by an ethics review body is a necessary but insufficient step for sharing decisions. A data custodian or custodians should make the final decision on whether to approve access to the data. Therefore, even if an ethics review body has approved access to a dataset, the data custodian or custodians may refuse access (Guidelines Under Section 95 of the Privacy Act 1988, 2024, para. A1.6, B1.6 and C.16).

d) Data Sharing Agreements

Any external researcher or sponsor that seeks to use a dataset from a clinical trial for secondary purposes should be party to a data sharing agreement. Data sharing agreements are different from data sharing policies because agreements only apply to the parties in a particular project. Any data sharing agreement templates should be approved by the data access committee or the data steward.

The contents of the data sharing agreement will depend on the data being accessed (Research Governance Procedures, 2021, p. 14). However, the agreement should contain at minimum three key provisions:

1. The data sharing agreement should specify the terms on which a researcher or sponsor for a secondary research project can access the clinical trial data, and that data cannot be used for a purpose not covered under the agreement. The agreement should also specify the data that is being shared and the consents that have been obtained for the use of that data. For example, if extended or unspecified consent has only been sought for a subset of a clinical trial dataset, only that subset can be transferred subject to the agreement.
2. The data sharing agreement should specify the privacy and security obligations of the researcher or sponsor accessing the clinical trial data. These privacy and security obligations could include who has access to the dataset and how the dataset can be accessed.
3. Any data breach or loss should be reported to the responsible regulator, as well as any participants who are included in the dataset. The responsible regulator could include the Office of the Australian Information Commissioner or state and territory information privacy commissioner, depending on the identity of the data custodian (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 61). When the datasets affect two or more entities that operate at different jurisdictional layers, the responsible regulator in each jurisdiction should be informed.

The study protocol, clinical trial research agreement, and/or data sharing policy should document the provisions that are required or recommended for inclusion in data sharing agreements.

2. Define the data to be shared

Responsible data sharing requires managing the privacy and confidentiality risk to which participants are exposed by third parties accessing their data. How data is classified will impact the legal and ethical parameters for use and disclosure.

As explained in Part A, federal and state and territory legislation define whether information should be considered ‘personal information’ for the purposes of Australian privacy laws. Under current legislative models, these definitions provide a key step for characterising the information in given clinical trial datasets and associated responsibilities. Under this category-based model, data that falls outside the definition of ‘personal information’ is considered to present little to no privacy risk and generally falls outside the scope of legislative requirements.

However, the 2023 National Statement on Ethical Conduct in Research Involving Humans has moved away from a category-based model to explicitly recognise a continuum when it comes to identifiability of information, and thus the privacy risk to participants. Most notably, it states that "Due to technological advances, risks may arise in relation to data and/or information that has never been labelled with individual identifiers or from which identifiers have been permanently removed." (National Statement on Ethical Conduct in Human Research, 2023, p. 33).

While defining clinical trial data in accordance with the below categories remains crucial for understanding legal and regulatory responsibilities, a continuum-based approach may supersede category-based approaches in the future.

a) Personal Information

Personal information will constitute either individually identifiable information or—in some instances—other participant-level data.

Individually identifiable information is information which can be used to directly identify an individual. This could include, for example, names, addresses, postcodes, full dates of birth or unique personal identifiers such as Medicare numbers (NT Health Data Release Guidelines, 2018, p. 20). Datasets could also contain individually identifiable data where there is only a small number of records with the same data attribute (Data Access and Release Policy, 2023, p. 14); for example, a rare medical diagnosis. Individually identifiable information will always constitute personal information for the purposes of privacy laws.

A dataset will contain ***participant-level data*** (otherwise known as patient-level data, microdata or unit-level data) when it contains information about individuals or individual records. This data could include observations for an individual or an organisation, such as responses to a survey or an administrative form (National Health Information Standards and Statistics Committee, 2017, p. 18). Participant-level data is not necessarily identifiable information or personal information for the purposes of privacy laws, but there is a greater risk of re-identification than with aggregate or non-identifiable data (NT Health Data Release Guidelines, 2018, p. 20). This risk is becoming more acute with the use of artificial intelligence tools to link seemingly deidentified datasets. Therefore, all research involving access to participant-level data which is deemed higher than low risk should be subject to ethics approval by a HREC rather than another ethics review body.

b) Non-Identifiable, Re-Identifiable and Aggregate Data

Non-identifiable or ***de-identified*** data refers to data that has never been labelled with individual identifiers, where identifiers have been permanently removed, or where identifiers have no meaning to recipients (National Health Information Standards and Statistics Committee, 2017, p. 17).

- Non-identifiable data: When data has been rendered non-identifiable, it is impossible without legal or technical means to re-identify individuals or individual records (NT Health Data Release Guidelines, 2018, pp. 18–19).
- Re-identifiable data: Where individual identifiers have been replaced with a code or a pseudonym. Individuals in the dataset can be re-identified using the code. Alternatively, individuals in the dataset can be re-identified if the dataset is combined with another dataset (National Health Information Standards and Statistics Committee, 2017, p. 18).

Data can also be rendered non-identifiable or deidentified by *aggregating* the data. For example, instead of publishing the age of each participant, a journal article might publish how many people in a dataset are of a particular age or age range (National Health Information Standards and Statistics Committee, 2017, p. 18).

Non-identifiable data and aggregate data will not usually meet the definition of 'personal information' for the purposes of Australian privacy laws. However, re-identifiable data can sometimes satisfy the definition of personal information. Therefore, datasets should be treated as identifiable unless de-identification techniques have been applied to them (National Health Information Standards and Statistics Committee, 2017, p. 5).

c) De-Identification Techniques

Before sharing clinical trial data for secondary research, data custodians should consider several steps to reduce the risk of re-identification.

1. The data custodian should consider removing or modifying any personal identifiers in the dataset. If the researcher or sponsor needs to know that multiple records relate to a single participant, these identifiers should be replaced with an encrypted identifier (National Health Information Standards and Statistics Committee, 2017, pp. 5, 8).
2. Unless the precise values of participant level data are required for a research project, the data custodian should consider applying privacy-preserving techniques. For example, dates of birth could be replaced with 5-year age groups, or postcodes could be replaced with a metropolitan/rural category (National Health Information Standards and Statistics Committee, 2017, p. 5). Similarly, the exact date of a hospital admission could be replaced with the month and year of admission.
3. Data custodians should consider suppressing small cell sizes for all releases of data, including aggregate data. Records can be suppressed by grouping values together (National Health Information Standards and Statistics Committee, 2017, pp. 6–7).

There is no one technique that can be used to prevent re-identification and different techniques may impact the validity of data. Instead, data custodians should judge which techniques are most appropriate to minimise the risk that individuals in a dataset will be re-identified. A person with expertise in de-identification may be appointed to choose or oversee these techniques if there is no appropriate expertise in a research team (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 39).

3. Confirm the scope of consent

There is an ethical imperative to share clinical trial data. Therefore, trials should plan from the outset of how they will govern and manage data sharing. This should include how they plan to seek participant consent to sharing data. While the existence of explicit consent may not preclude the sharing of data for secondary research in some circumstances (e.g. if a waiver of the requirement for consent is provided, governance decisions about if and how data sharing can proceed must be informed by the nature and extent of any consent that has been provided by trial participants.

a) Fundamental Principles of Consent

Data custodians or their responsible agents should only collect personal information for research purposes with consent. However, sometimes it may not be possible to obtain consent. For example, individuals may die or lose capacity in between contributing their data to a dataset and the establishment of a research project. If consent has not been obtained, or if the requirements for a valid consent have not been satisfied, then a new consent must be obtained from a valid decision-maker (for example, a next of kin as authorised under applicable guardianship laws) or a waiver of the requirement for consent must be obtained for the use of information in research.

There are four key requirements for valid consent which apply to all forms of consent described in this section:

1. A person must give consent voluntarily. That means they must have sufficient time to understand the proposed request and seek advice. Consent is not voluntary if a person cannot freely refuse to consent. Consent is also not voluntary if a person needs to consent to receive a government service.
2. A person must be given clear information about how their data will be used when their consent is sought, as well as how long their consent will be valid.
3. A person must give as specific a consent as possible to the use of their data, including the types of information being collected and disclosed.
4. An individual must communicate their consent, for example, by signing a physical or digital form, click a button or state that they consent during a recording (*Fact Sheet - Consent,* 2023).

Adults are presumed to have capacity to consent. At common law and under the laws of most Australian states and territories, an adult is any person who is 18 years or older. However, some state legislation sets a different age for capacity to make health care and data sharing decisions. For example, in South Australia, a person will have capacity to consent to medical treatment (including research and involvement in clinical trials) if they are 16 years or older (*Consent to Medical Treatment and Palliative Care Act 1995* (SA), s 4(1), s 12).

If a person has a physical or mental disability, or is suffering from temporary incapacity, their capacity may be impaired. If a person has impaired capacity, someone else will need to consent on their behalf to be involved in a research project or clinical trial. This person could include a legal guardian, a person responsible for the care of the participant or the family member (*Guide - Privacy and Persons with Reduced Decision-Making Capacity*, 2021).

For a participant to validly consent to the collection, use or disclosure of their clinical trial data, they must have the opportunity to access their data. The participant must also be able to request their data be corrected or withdraw their data from use for secondary purposes. (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 19). A participant should also be given the opportunity to refuse their data being used for secondary purposes. This opportunity should be provided without any consequences to the participant should they use it. When seeking consent, the data custodian or researcher must tell the research participant how to access or correct their data. If a research participant asks to access or correct their data, the data custodian or researcher must have a means of fulfilling this request.

b) Alternatives to Specific Consent

Traditionally, consent has been conceptualised as an authorisation for each specific sharing activity. However, modern data sharing practices often seek to rely upon a single consent to authorise multiple data sharing activities. This practice warrants careful attention and legal advice to ensure relevant requirements have been satisfied.

(i) Bundled consent

Bundled consent involves a data custodian seeking a single consent from an individual to use or disclose their data for multiple different purposes. If a data custodian seeks bundled consent from an individual, they should provide sufficient information on all intended purposes to the individual. Since an individual cannot refuse to consent to specific intended purposes with bundled consent, the data custodian should seek bundled consent only for the necessary intended purposes (*Fact Sheet - Consen*t, 2023).

(ii) Unspecified consent

Unspecified or broad consent allows a data custodian to collect, use and disclose data for any future research project subject to specified imitations (eg, future approval by an ethics review body) (Eckstein et al., 2023, p. 507). The gravity of the consequences of unspecified consent should be reinforced to the individual at the point that a participant provides consent to a clinical trial (National Statement on Ethical Conduct in Human Research, 2023, para. 2.2.14-2.2.16; Otlowski, 2012, p. 208).

(iii) Extended consent

Extended consent allows a data custodian to use or disclose data for future research projects that are related to an existing project. Extended consent may also allow a data custodian to use or disclose clinical trial data for future research in the same field as the original trial. Extended consent is not as comprehensive as broad consent, but the data custodian should ensure it obtains explicit extended consent (Eckstein et al., 2023, p. 507; National Statement on Ethical Conduct in Human Research, 2023, para. 2.2.14-2.2.15).

(iv) Dynamic consent

Dynamic consent provides a flexible approach for providing participants with digital tools to control the way in which their data is used (Teare et al., 2021). This allows participants to select different types of consent structures for future research use of samples and data, including specific, unspecified and extended consent. The technologies by which dynamic consent is implemented provides opportunities for participants to review and update these consent preferences over time (Researcher User Guide, 2023, pp. 37–38). However, at the time of writing, researchers in Australia are only rarely using dynamic consent platforms (Haas et al., 2024; Teare et al., 2021). The use of dynamic consent may increase once more platforms become available or existing platforms are developed to support a broader part of the research sector.

c) Sharing With and Without Consent

Under privacy and health information law, whether a data custodian or researcher can share clinical trial data depends on the scope of consent at the time of data collection. If the scope of the consent provided is insufficient to cover the proposed sharing activity, the data custodian or researcher must rely on another legal justification, for example, by seeking a waiver of the requirement for consent. If an individual *refused* consent for the proposed sharing activity, no such sharing should take place.
An HREC or another ethics review body may authorise a waiver of the requirement to seek consent for sharing clinical trial data based on criteria specified in the National Statement and (if relevant) federal, state and territory privacy laws.

For an ethics review body to grant a waiver of the requirement for consent, the research must be lower risk, defined in the National Statement as

Research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden (low risk research) OR research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research) (National Statement on Ethical Conduct in Human Research, 2023, p. 110).

In addition,

- the benefits of the research must outweigh the risk of harm from not seeking consent.
- It must be impracticable to obtain consent. Although the National Statement does not define impracticability, it does explain that it might apply 'due to the quantity, age or accessibility of records' (National Statement on Ethical Conduct in Human Research, 2023, para. 2.3.10(c)). One Framework suggested that if it is possible to obtain the contact details of participants, it may not be impracticable to obtain consent (Research Governance Procedures, 2021, p. 32).
- There must be no reason to think the research participants would not have consented to the use or disclosure of their data.
- The privacy of participants must be sufficiently protected.
- The researcher or sponsor must have a plan to protect the confidentiality of data.
- There must be a plan to make results available to participants to protect their welfare.
- The participants will not be deprived of financial benefits.
- The waiver must not be prohibited by State, federal or international law (National Statement on Ethical Conduct in Human Research, 2023, para. 2.3.10).

In deliberating on these criteria, ethics review bodies should be attuned to the participant group from which data has been obtained and the implications this may have for the ethical acceptability of a waiver of the requirement to seek consent. For example, in accordance with the principles of Indigenous Data Sovereignty, Indigenous-specific ethics review committees should be involved in decision-making for waivers relating to Indigenous data.

If the information satisfies the definition of personal information, additional requirements will apply before a waiver of the requirement for consent for sharing clinical trial data can be authorised. Under the National Statement, only an HREC (as compared with another ethics review body) may grant waiver of the requirement for consent for research using personal information in medical research, or personal health information. The waiver may also need to satisfy the criteria set out in the Guidelines Approved under Sections 95 and 95A of the *Privacy Act 1988*. The Guidelines Approved under Section 95 of the *Privacy Act 1988* apply to personal information held by Commonwealth agencies for the purpose of medical research. The Guidelines Approved under Section 95A of the *Privacy Act 1988* apply to personal health information held by organisations for the purposes of research, or the compilation or analysis of statistics, relevant to public health or public safety. Both Guidelines require that an HREC make an assessment that the public interest in data sharing substantially outweighs the public interest in maintaining privacy protections. The Guidelines specify the information that a researcher must provide to the HREC to allow such an assessment, as well as the factors that should feed into an HREC's public interest assessment.

Some Australian states and territories also specify waiver of the requirement for consent requirements in their privacy laws, typically reliant on a specified public interest test and a requirement that obtaining consent would be 'impracticable'. **Appendix**

2, Table 5 contains a breakdown of these requirements. In addition, in some cases, a particular government department might require its own ethics review body to authorise the use or disclose data held by a state or territory data custodian. For example, the Victorian Department of Justice and Community Safety has an internal research ethics committee (Wright et al., 2019, para. 2.64). Other data custodians may require approval by a HREC acting in accordance with the National Statement (Coombs, 2019; Dickie, 2004, p. 14).

A waiver of the requirement for consent does not necessarily need to be granted by an ethics review body for each use or disclosure of data, depending on the nature of the project. For example, a data custodian might collect data to improve delivery of primary healthcare services. That data could then be shared without the need for consent on the grounds that it is used and disclosed for managing health services (Rowlands et al., 2024, pp. 24–25).

A final point to note is that Federal, state and territory privacy laws permit government agencies and private organisations to collect data without consent in certain circumstances. These circumstances include for public health, serious threats or life to health or where mandated under another law (*Privacy Act 1988* (CTH), s 16A(1), sch 1 cls 6.2(b); *Information Privacy Act 2014* (ACT), s 19(1)(a); *Health Records (Privacy and Access) Act 1997* (ACT), sch 1 cls 9.1(b)-(c), cls 10.2(d)-(e); *Privacy and Personal Information Protection Act 1998* (NSW), s 17(c), s 18(1)(c), s 19(2)(h); *Health Records and Information Privacy Act 2002* (NSW), sch 1 cls 10(1)(b1)-(c), cls 10(1)(b1)-(c); *Information Act 2002* (NT), sch 2 cls 2.1(d), cls 2.1(f); *Personal Information Protection Act 2004* (TAS), sch 1 cls 2(1)(d), 2(1)(f)-(g); *Privacy and Data Protection Act 2014* (VIC), sch 1 cls 2.1(d), 2.1(f)-(g); *Health Records Act 2001* (VIC), sch 1 cls 2.2(c), 2.2(h)). Public health laws also provide extensive powers for state and territory health departments to collect, use and disclose personal information without consent (*Public Health Act 1997* (ACT), s 109; *Public Health Act 2010* (NSW), s 98(6); *Public and Environmental Health Act 2011* (NT), ss 63-65; *Public Health Act 2005* (QLD), ch 3 part 1 div 3, ch 3 part 3 div 3, ch 6 part 1 div 4, ch 6 part 1A div 4, ch 6 part 2 div 4; *Public Health Act 2011* (SA), s 99(2)(a)-(c), s 99(2)(g)-(h), s 100(4)(c); *Public Health and Wellbeing Act 2008* (VIC), ss 55-7; *Public Health Act 2016* (WA), s 299). Further, the Federal Biosecurity Act allows the Commonwealth Department of Health to share information in responding to public health risks (*Biosecurity Act 2015* (CTH), ss 582-585).

These laws authorise data sharing outside the scope of the human research ethics framework with which researchers and clinical triallists would otherwise need to comply. Further, data collected under these laws may be subsequently used for secondary purposes. However, doing so without appropriate consent or consulting with individuals whose information is included in a dataset could substantially disrupt public trust and social licence for that secondary use (Richards and Scheibner, 2022, p. 398). Therefore, personal information collected under these laws should not be assumed to be available for unrestricted secondary use. Wherever possible, individuals whose data has been obtained under these laws should be given control over its subsequent use and sharing. This is particularly important when considering data relating to Indigenous persons.

4. Optimise Collection Practices

It is important to anticipate the possibility of data sharing when designing the collection protocol for a research project or clinical trial (Pellen et al., 2023, pp. 2-3). Where possible, data custodians or researchers should collect personal information from participants directly, including through clear informed consent practices. However, it may not always be possible to collect data from participants, or doing so may result in additional burden to the participant (e.g. recollecting information that the participant has provided to another party). In these circumstances, data custodians and researchers should be cognisant of the additional safeguards that must be satisfied before sourcing data for secondary research.

a) Collecting information from primary care datasets

Primary care datasets can include electronic medical records and electronic health records. These records are compiled by health practitioners such as doctors at various times and in various locations. Under Australian law, health practitioners or their employers own the health records that they have compiled about a patient. Health practitioners also owe a duty of confidentiality to their patients (Adams et al., 2022b, p. 140). Therefore, health practitioners, hospitals and general practices should be treated as the data custodians of these records. These data custodians must seek consent from their patients to enrol their records into research, clinical trials or quality improvement (Rowlands et al., 2024, p. 28), unless a waiver of the requirement for consent is approved by an ethics review body.

The exception to this framework applies to primary care data which is collected under statutory frameworks, such as My Health Record. In these cases, legislation or other guidelines may state who is responsible for collecting information from primary care datasets (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 31).

b) Collecting information from administrative data

Administrative data is any data collected during the routine delivery of a public health or social service (Adams et al., 2022c, p. 15). Most administrative data is collected at the state or territory level, such as hospital admission data or data registries (Schneider et al., 2019). However, some data collections, such as Medicare Benefit Schedule (MBS) or Pharmaceutical Benefit Scheme (PBS) data, are held by the Commonwealth Department of Health and Aged Care (Data Access and Release Policy, 2023, p. 20). These Commonwealth data collections are governed by their own statutory frameworks. The Commonwealth Department of Health and Aged Care can authorise data linkage with these datasets. However, the source dataset is stored separately from the resulting data asset (Multi-Agency Data Integration Project (MADIP) Privacy Impact Assessment Update, 2019, p. 57).

c) Data linkage

Data linkage involves connecting different pieces of information across two or more datasets that belong to the same person, family, place or event (NT Health Data Release Guidelines, 2018, p. 18). For example, data attributes such as names, dates of birth, addresses, sex and medical record numbers can be used to link datasets together (Research Governance Procedures, 2021, p. 31). With data linkage, researchers and government agencies can gain a better understanding of how people interact with healthcare systems. In addition, data linkage can be used to link data that is collected by agencies operating at different jurisdictional levels. For example, the Department of Health and Aged Care has a Data Access and Release Policy for Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) level data (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 27).

However, linking two or more datasets together increases the risk that individuals or individual records can be re-identified (National Health Information Standards and Statistics Committee, 2017, pp. 17–18). Therefore, data linkage must be carried out by a person or entity who is separate from the researcher or sponsor (NT Health Data Release Guidelines, 2018, p. 8; Rowlands et al., 2024, pp. 3–4). The entity that performs data linkage must have expertise in privacy preserving record linkage and must provide linked data sets with no identifiable or re-identifying information (Rowlands et al., 2024, p. 27).

d) Other sources of clinical trial data, including publicly available information

Researchers or sponsors might have access to clinical trial data or datasets via other means, including via publicly available information. This information could include identifiable information or participant-level information. For publicly available datasets, the researcher or sponsor should contact a data access committee or research governance officer. The data access committee or research governance officer will determine what privacy issues could arise from the use of the dataset. Depending on the contents of the dataset, a researcher or sponsor will need to comply with relevant privacy laws and seek ethics approval (National Statement on Ethical Conduct in Human Research, 2023, para. 3.1.51).

5. Establish Data Security Plans

Data security obligations include protecting personal data against theft, loss and unauthorised access, use, disclosure, copying or modification through technical and organisational processes. Trials should have clear plans for the systems and processes they will use to manage data retention, disposal, and access.

a) Data retention and disposal

The data custodian, along with the data access committee or data steward, must ensure the researcher or sponsor has a plan for retaining or disposing of the data (Research Governance Procedures, 2021, p. 30).

By default, research data should be stored for at least 5 years (Management of Data and Information in Research: A Guide Supporting the Australian Responsible Conduct of Research, 2019, p. 3). However, if this data is used for clinical trials, it needs to be retained for at least 15 years. Clinical trial sponsors should also be mindful of product liability issues. Therefore, clinical trial records may need to be retained for longer than this 15-year period, (ICH Guideline for Good Clinical Practice, 2022, Section 5.5.11). Researchers should note the inherent tension between lengthy data retention practices and the data minimisation principle that specifies the need to destroy or deidentify information once it is no longer required for the purpose for which it was collected.

Beyond these data storage requirements, if a data custodian, researcher or sponsor uses records from a Commonwealth authority, it will need to comply with the Commonwealth Archives Act. Likewise, if a data custodian, researcher or sponsor is a state or territory government agency, it will need to comply with applicable state or territory archive laws and regulations. Appendix 2, Table 4 contains a breakdown of the disposal requirements under state and territory regulations.

b) Data access

The data custodian, along with the data access committee or data steward, must ensure that those accessing the data comply with applicable Federal or state and territory privacy laws (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 51). If there is a data breach, the data access committee should report any breaches to the appropriate regulatory agency. This agency could include the Office of the Australian Information Commissioner or an appropriate state and territory office. Where two or more entities operating at different jurisdictional layers are involved in a data breach, each entity should report to the responsible regulatory agency.

Technology systems may be implemented to support secure access to data. One such technology-based approach is the requirement that data be access via a trusted research environment ('TRE') – also known as a secure research environment. A TRE is a remote access computing environment that allows an individual with appropriate credentials to access sensitive data for analytics purposes. The technological and governance controls applied to TREs mitigates the risk of sensitive data being accessed by unauthorised people or being used inappropriately (Rowlands et al., 2024, p. 27; Oppermann, 2017, p. 74). In some cases, the use of a TRE may be a precondition to accessing personal information held by a government agency. Under the *Data Availability and Transparency Act*, a Federal agency listed as an accredited data service provider can share data with designated parties via 'ADSP-controlled access'. This access involves the use of controls to prevent or minimise the risk that individuals may be re-identified from a dataset (*Data Availability and Transparency Act 2022* (CTH), s 16B(6)).

6. Share Safely

The preceding principles and responsibilities address issues that should ideally be addressed at the initiation of a clinical trial to determine the intended approach for managing the sharing of data and documented in the approved protocol. To supplement these principles, data custodians should have a defined approach for assessing data sharing requests at the point they are received.

a) Risk Assessment

Before data sharing occurs (irrespective of whether consent has been sought), the data custodian, data steward or data access committee, or a combination of the three should assess the risk associated with sharing.

A common way of delineating these risks is the 'Five Safes' framework, which provides a way to focus attention on the outcomes and objectives of data sharing. In addition, some statutes mandate the use of the Five Safes framework as a means for assessing risk. For example, all ADSPs under the *Data Availability and Transparency Act* must ensure that any project is compliant with the Five Safes principle before sharing data (*Data Availability and Transparency Act 2022* (CTH), s 13(1)(e)). This model distinguishes between five key issues, each of which warrant attention—both independently and jointly—as part of a data sharing decision. (Desai et al., 2016, p. 4; Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 53). These issues are as follows:

1. **Safe Projects**, or the quality, integrity and transparency of the secondary research. Assessments of safe projects will resemble many frameworks for research ethics. (Oppermann, 2017, p. 70). Projects involving vulnerable populations, sensitive topics or participants from whom informed consent has not been sought could be assessed as having a moderate or low level of safety (Oppermann, 2017, pp. 69–71). See Section 3 for related discussion.

2. **Safe People**, or whether the secondary researcher's intention and character is such that they should be trusted to access and use the data appropriately. This process could involve checking the references and any conflicts of interest of the researcher or sponsor (Oppermann, 2017, p. 69). Under it may also require compliance with any ethics approval processes (*Data Availability and Transparency Code 2022* (CTH), r 7).

3. **Safe Data**, or the disclosure risks inherent in the data being shared. This dimension requires an assessment of whether the granularity of disclosure for which sharing is sought is appropriate in light of the level of safety of the project and people. Depending on the results of this assessment, privacy preserving techniques may be applied and/or governance strategies ('Safe Settings') adopted. (Oppermann, 2017, pp. 76–80). See Section 2 for related discussion.

4. **Safe Settings**, or the access controls in place for a secondary researcher. Systems with no access restrictions in place are at one end of the Safe Settings risk continuum through to, for example, systems with multi-factor authentication, audit trails, and preventing on-sharing (Oppermann, 2017, p. 72). TREs are intended to provide safe settings but specific TREs may rate differently on the continuum. See Section 5(b) for related discussion.

5. **Safe Outputs**, or whether any published statistical results reveal the identity of individuals (Multi-Agency Data Integration Project (MADIP) Privacy Impact Assessment Update, 2019, p. 25). An evaluation of Safe Output requires a consideration of the value of the data being shared and a project's overall level of safety. (Oppermann, 2017, pp. 76–80).

In totality, the aim is to review for 'safe' data sharing conditions, but this does not require each of the dimensions to constitute 'maximum safety' (Ritchie, 2017, p. 2). The framework is highly dependent on judgment, and there is no unambiguous way of quantifying a threshold level of safety for sharing (Oppermann, 2017, p. 71, 76).

b) Special considerations

(i) On-sharing administrative data collections

Administrative data collections are typically held by a state or territory government department or public agency and may require specific authorisations for sharing. In some cases, Commonwealth datasets such as MBS and PBS data will be held by Commonwealth departments, or Commonwealth agencies. For example, the Australian Institute of Health and Welfare (AIHW) is the responsible data custodian for My Health Record data (Framework to Guide the Secondary Use of My Health Record System Data, 2018, pp. 4, 8).

Access to this data for secondary research will require a request to the responsible data custodian. To link two or more datasets together, approval is required from all custodians. This linkage should be conducted by a trusted third party.

In some cases, there may be multiple data custodians responsible for different administrative datasets. For example, general practices in primary health networks might be responsible for enrolling their patients in a particular health program. A government agency might then be responsible for linking that data together (Rowlands et al., 2024, p. 20).

(iii) Sending data overseas or to foreign or dual nationals

Any sharing of clinical trial data with a non-Australian researcher or sponsor requires compliance with Australian law. Depending on which data custodian holds the data, these could include Commonwealth, state or territory laws, or a combination of all three. A data custodian may also have other criteria that they may wish to place on use of or disclosure to a non-Australian researcher or sponsor. These include partnership with an Australian entity, proposed public health benefits to Australians or a requirement that data remain in Australia (Framework to Guide the Secondary Use of My Health Record System Data, 2018, p. 23). In addition, any data which is shared with Australian researchers by overseas researchers may be covered by overseas data privacy laws. These laws include the General Data Protection Regulation (GDPR) from the European Union and the Health Insurance Portability and Accountability Act (HIPAA) from the United States. When data is transferred from an overseas jurisdiction subject to these or other laws, the researcher or sponsor in Australia should ensure that any handling of this data is compliant both with these laws and the applicable law in Australia.

(ii) Adding clinical trial datasets to data repositories

Data repositories are a research infrastructure service that enable researchers to delegate parts or all of their data governance, storage and management, and/or access responsibilities to a third-party provider (Xafis & Labude, 2019). Data repositories create a centralised pool of data from multiple trials designed to be discoverable for researchers to access and reuse (Xafis & Labude, 2019, pp. 256-257). Some but not all data repositories host individual participant-level data (Banzi et al., 2019, p. 6). In addition to providing secondary researchers a single platform to discover data from multiple trials, repositories often providing a mechanism to request access to data, and may also provide secure platforms for accessing and working on data. Repositories vary greatly in terms of which of these features they offer and the level of delegation that data custodians can assign to the repository. For example, in the USA, the Vivli service stores participant data, reviews data sharing requests, and provides a data access platform on behalf of the clinical trials using their service (Banzi et al., 2019, pp. 6-7). In contrast, the Health Data Australia platform does not store data or provide a data access platform. Instead, it consists of a catalogue of data held by Australian data custodians and allows secondary researchers to submit a data sharing request which is sent to the respective custodian to review and respond in accordance with their individual governance requirements. As such, it assists trials who wish to share data but would not be classified as a data repository (Health Data Australia, 2023).

Although not binding in Australia, the European Federation of Pharmaceutical Industries and Associations and the Pharmaceutical Research and Manufacturers of America (PhRMA) have published their own guides on data sharing. These guidelines require pharmaceutical companies to share participant level data from registered clinical trials with qualified researchers, which may include adding data to a repository (Principles for Clinical Trial Data Sharing, 2023, p. 1). Some clinical trial funders and medical journal editors require data management plans, including how the data underpinning clinical trial results will be shared through approaches such as data repositories (Banzi et al., 2019, p. 6).

Participant-level clinical trial data should only be added to data repositories with the informed consent of participants and data should be de-identified before being added (Principles for Clinical Trial Data Sharing, 2023, p. 2). Consent to add clinical trial data to data repositories should be sought from participants when they are enrolled in the original trial (Wizemann et al., 2020, pp. 17–18). De-identification could involve aggregating potentially identifiable data such as survival or adverse event data. Alternatively, participant-level data could be made accessible to researchers via a trusted research environment from which data cannot be downloaded (Modi et al., 2023, pp. 403–405).

7. Engage with Participant Groups

Those developing clinical research data sharing frameworks should consult with relevant consumer groups to incorporate lived experience perspectives. Although each consumer group will have specific considerations relevant to data sharing frameworks, particular attention is warranted for Aboriginal and Torres Strait Islander communities and rare disease patients.

a) Indigenous research participants

Historically, Indigenous communities have not had appropriate control over the way their data has been used. In particular, the use of Indigenous data has often failed to comply with the wishes of Indigenous participants and health consumers and has exposed individuals and their communities to risk.

Through Indigenous Data Sovereignty, Aboriginal and Torres Strait Islander peoples and communities are seeking to regain sovereignty and governance over data that relates to them. The objectives of Indigenous Data Sovereignty are consistent with article 31 of the United Nations Declaration on the Rights of Indigenous People (UNDRIP), which states that Indigenous people have a right to control their cultural heritage.

Under the principles of Indigenous Data Sovereignty, Aboriginal and Torres Strait Islander peoples have a right to exercise control over the creation, development, stewardship, and analysis of their information. This is reflected in the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research. This Code of Ethics advises that processes should be agreed at an early stage for ownership, management and use of, access to, and distribution of research results relating to Indigenous knowledge and data (Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS), 2022, para. 2.7(b)).

Data custodians, researchers and sponsors conducting research relating to Aboriginal and Torres Strait Islander communities should partner with these communities in developing data sharing frameworks. This could be achieved by including Aboriginal and Torres Strait Islander people in existing data access committees or developing new Aboriginal and Torres Strait Islander governance committees (Framework for Governance of Indigenous Data, 2024, p. 13-14). Data custodians should also develop resources to help develop understanding of Indigenous Data Sovereignty, identify datasets that contain Indigenous data and develop specific data access policies (Framework for Governance of Indigenous Data, 2024, p. 15-19).

Data custodians, researchers and sponsors should ensure they collect personal information from Aboriginal and Torres Strait Islander persons according to the Free Prior and Informed Consent Principles (FPIC). Under FPIC, individuals and communities should have the right to withdraw or modify their consent at any time (Schroeder, 2009, pp. 47-8). Accordingly, forms of consent such as bundled and unspecified consent generally should not be used for research involving Aboriginal and Torres Islander people or communities. Instead, individuals should have clear mechanisms to modify or withdraw their consent (Teare et al, 2021, pp. 651-2).

In Aboriginal and Torres Strait Islander communities, there also is a concept of 'community privacy'. Even where a dataset does not contain identifiable data, it may be possible to identify an Aboriginal or Torres Strait Islander community. Any data which could be used to identify a specific community should not be released without that community's consent (NT Health Data Release Guidelines, 2018, p. 7). All research involving data collected from Aboriginal or Torres Strait Islander communities must be approved by an ethics review body with expertise in Aboriginal research.

b) Rare disease patients

Due to small cell sizes, it may be possible to identify patients with rare diseases, even if steps have been taken to de-identify that data. Therefore, data custodians and data access committees/data stewards should determine whether individuals can be identified from such datasets. This risk should be assessed when considering the safe data rating as discussed in Section 6. Depending on the size of the cohort of individuals with the rare disease, in some cases it may be impossible to fully guarantee anonymity, particularly for open data sets (Rubinstein et al., 2020, p. 475). In this situation, the data custodian, researcher or sponsor must ensure that appropriate informed consent is obtained for the use of this data.

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Appendix 1: Methods

Legislative Review

This method involved a purposive search for all legislative instruments that govern the use, collection and disclosure of data for clinical trials. A similar legislative protocol was conducted by Tassé in 2016 of the legal and bioethical frameworks governing the secondary use of data for research purposes (Tassé, 2016, p. 208). This review focused on literature and legislation from Australia, Canada, France, the United Kingdom and the United States. It also included literature from PubMed and Google Scholar. Likewise, another similar protocol was developed by Eckstein, Garrett and Berkman to identify literature on the disclosure of genetic research findings to participants (Eckstein et al., 2014, pp. 192–193). Finally, a similar approach has been used by the Australian Commission on Safety and Quality in Health Care to conduct a review of clinical trials governance frameworks (National Clinical Trials Governance Framework Literature Review, 2018, pp. 4–5). These legislative instruments were separated into three categories. The first category includes legislation relevant to clinical data sharing and secondary use of data, including personal and health information. The second category includes regulation relevant to consent to medical treatment and research, including consent to involvement by a clinical research team. The third category included legislation, regulations and other instruments governing the storage of documents and data relevant to clinical trials.

Grey Literature Review of Data Sharing Frameworks

To identify relevant ethical frameworks in Australia, a purposive search for existing documents was conducted. These included frameworks for secondary data sharing published by Australian government agencies, as well as those published by regulatory bodies. A search was conducted using Google Advanced Search to identify all documents which referred to the terms ‘secondary use health data ethical principles’ on websites with the gov.au domain. Each document was then read and filtered to see whether it contained a set of ethical or operational principles with respect to data sharing. Documents that were more than 10 years old were removed to ensure that only guidelines referencing recent legislation remained. Likewise, other documents (such as protocols and data sharing templates) were excluded. In addition to these documents, a comprehensive but non-exhaustive list of secondary sources, including journal articles and book chapters, were included to supplement these findings.

Appendix 2: Legislation and Guidelines

Table 1: Australian legislation and regulations relevant to clinical data sharing and secondary use of clinical data (including personal and health information), divided by type and jurisdiction:

Jurisdiction	Privacy Legislation	Health Privacy Legislation	Other Health Legislation	Other Heath Regulations
Commonwealth	*Privacy Act 1988*	*Healthcare Identifiers Act 2010* *Healthcare Identifiers Regulations 2020* *My Health Records Act 2012*	*National Health Act 1953* *National Health (Privacy) Rules 2021* *Health Insurance Act 1973* *Australian Institute of Health and Welfare Act 1987* *Biosecurity Act 2015* *Australian Institute of Health and Welfare (Ethics Committee) Regulations 2018* *Therapeutic Goods Act 1989* *Therapeutic Goods Regulations 1990*	Guidelines approved under section 95 of the Privacy Act 1988 (NHMRC) Guidelines approved under section 95A of the Privacy Act Therapeutic Goods Administration, Note on ICH Guideline on Good Clinical Practice, 2018 AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)

Australian Capital Territory	*Information Privacy Act 2014*	*Health Records (Privacy and Access) Act 1997*	*Public Health Act 1997*	
New South Wales	*Privacy and Personal Information Protection Act 1998*	*Health Records and Information Privacy Act 2002* *Health Records and Information Privacy Regulation 2022* *Health Records and Information Privacy Code of Practice 2005* *Health Administration Regulation 2010*	*Mental Health Act 2007* *Public Health Act 2010* *Public Health Regulation 2022*	Information Privacy Commissioner, Statutory Guidelines on Research 2019 Information Privacy Commissioner, Statutory Guidelines on Research (Health Records and Information Privacy Act 2002) 2004 Hunter and New England Health, Guide to Completing the Human Research Ethics Application (HREA) in REGIS 2021
Northern Territory	*Information Act 2002*	N/A	*Medicines, Poisons and Therapeutic Goods Act 2012*	

			Mental Health and Related Services Act 1998 *Public and Environmental Health Act 2011* *Public and Environmental Health Regulations 2014*	
Queensland	*Information Privacy Act 2009*	N/A	*Hospital and Health Boards Act 2011* *Mental Health Act 2016* *Public Health Act 2005* *Public Health Regulation 2018*	Queensland Health, Research User Guide 2023\ Queensland Health, Guideline – Disclosure of Confidential Information for Research 2023
South Australia	N/A	N/A	*Guardianship and Administration Act 1993* *Health Care Act 2008* *Public Health Act 2011* *Mental Health Act 2009* *Transplantation and Anatomy Act 1993*	SA Health, Research Ethics and Governance Policy 2023 SA Health, National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects Standard Principles for Operation 2022
Tasmania	*Personal Information*	N/A	*Mental Health Act 2013* *Public Health Act 1997*	

	Protection Act 2004			
Victoria	*Privacy and Data Protection Act 2014*	*Health Records Act 2001*	*Health Services Act 1988* *Mental Health and Wellbeing Act 2022* *Public Health and Wellbeing Act 2008*	
Western Australia	*Privacy and Responsible Information Sharing Bill 2024*	N/A	*Health Services Act 2016* *Health Services (Information) Regulations 2017* *Mental Health Act 2014* *Public Health Act 2016*	Department of Health, Research Governance Procedure 2021

Table 2: Australian legislation, regulations and policies relevant to consent to medical treatment and research (including clinical research), divided by type and jurisdiction:

	Legislation Governing Consent	Consent Regulations	Policies and Guidelines Relevant to Consent
Australian Capital Territory	*Guardianship and Management of Property Act 1991* *Medical Treatment (Health Directions) Act 2006* *Mental Health Act 2015* *Powers of Attorney Act 2006* *Children and Young People Act 2008*	*Children and Young People (Research) Standards 2023*	
New South Wales	*Guardianship Act 1987*	*Guardianship Regulation 2016*	*Clinical Trials – Insurance and Indemnity 2011* *Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials 2007* *Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations 2017* *Operations Manual: Human Research Ethics Committee Executive Officers 2010* *Operations Manual: Research Governance Officers 2010* *Authorisation to Commence Human Research in NSW Public Health Organisations 2010* *Information and Privacy Commission, Fact Sheet on Consent 2023*

			Information and Privacy Commissioner, Privacy and Persons with Reduced Decision Making Capacity 2021
Northern Territory	*Guardianship of Adults Act 2016* *Advance Personal Planning Act 2013*		
Queensland	*Guardianship and Administration Act 2000* *Child Protection Act 1999*		*Queensland Health Research Management Policy 2022* *Standard Operating Procedures for Queensland Health Research Governance Officers 2022* *Standard Operating Procedures for Queensland Health Human Research Ethics Committee (HREC) Administrators* *Queensland Health Researcher User Guide 2023*
South Australia	*Guardianship and Administration Act 1993* *Consent to Medical Treatment and Palliative Care Act 1995*		*Research Ethics and Governance Policy 2023*
Tasmania	*Guardianship and Administration Act 1995*		*University of Tasmania Clinical Trials Procedure 2023*
Victoria	*Medical Treatment Planning and Decisions Act 2016*		*Research Governance and Site Specific Assessment 2024* Additional advice published by the Victorian State Government
Western Australia	*Guardianship and Administration Act 1990*	*Guardianship and Administration Regulations 2005*	*Research Policy Framework 2022* *Research Governance Policy 2021* *Research Governance Procedures 2021*

Table 3: Australian legislation, regulations and policies relevant to storage, ownership and transfer of clinical data, divided by type and jurisdiction:

	Data Storage Legislation	Other potentially relevant laws	Data Storage Regulations, Policies and Guidelines
Commonwealth	*Archives Act 1983* *Census and Statistics Act 1905*	*Data Availability and Transparency Act 2022* *Copyright Act 1968* *Freedom of Information Act 1982*	*Therapeutic Goods Administration, Note for Guidance on Good Clinical Practice* Australian Code for the Responsible Conduct of Research, Management of data and information in research
Australian Capital Territory	*Health Records (Privacy and Access) Act 1997* *Territory Records Act 2002*	*Births, Deaths and Marriages Registration Act 1997* *Freedom of Information Act 2016*	*Territory Records (Records Disposal Schedule – Health Treatment and Care Records) Approval 2023* *Territory Records (Records Disposal Schedule – Patient Services Administration Records) Approval 2013 (No 1)* *Territory Records (Records Disposal Schedule – Population Health Care Management and Control Records 2009 (No 1)*
New South Wales	*State Records Act 1998*	*Births, Deaths and Marriages Registration Act 1995*	*GDA-17-General Retention and Disposal Authority Public health services: patient/client records* *GDA-21-General Retention and Disposal Authority Public health services: administrative records*

		Data Sharing (Government Sector) Act 2015 *Government Information (Public Access) Act 2009*	
Northern Territory	*Information Act 2002*	*Births, Deaths and Marriages Registration Act 1996*	*Northern Territory Public Sector Organisations Records and Information Management Standard* *Functional Records Disposal Schedules, Department of Territory Families, Housing and Communities* *Records Disposal Schedule, Alcohol and Other Drugs Services, Department of Health (No. 2017/7)* *Records Disposal Schedule, Centre for Disease Control, Department of Health (No. 2014/22)* *Records Disposal Schedule, National Critical Care and Trauma Response, National Critical Care and Trauma Response Centre, Department of Health (No. 2015/10)* *Records Disposal Schedule, Oral Health Services, Department of Health (No. 2017/3)* *Records Disposal Schedule, Patient and Client Medical Records, Department of Health (No. 2022/003)*
Queensland	*Public Records Act 2002*	*Births, Deaths and Marriages*	*Health Sector (Clinical Records) Retention and Disposal Schedule 2021*

		Registration Act 2023	
South Australia	*State Records Act 1997*	*Births, Deaths and Marriages Registration Act 1996* *Public Sector (Data Sharing) Act 2016* *Right to Information Act 2009*	*General Disposal Schedule No. 28: Clinical and Client-Related Records of Public Health Units in South Australia 2014*
Tasmania	*Archives Act 1983*	*Births, Deaths and Marriages Registration Act 1999* *Right to Information Act 2009*	Office of the State Archivist, Disposal Schedule for Functional Records of Health Administration 2023
Victoria	*Public Records Act 1973*	*Births, Deaths and Marriages Registration Act 1996*	Disability Services Functions, Retention & Disposal Authority: PROS 08/13, Public Record Office Victoria Public Health Functions, Retention & Disposal Authority: PROS 08/15, Public Record Office Victoria

		Freedom of Information Act 1982 *Victorian Data Sharing Act 2017*	Patient Information, Retention & Disposal Authority, PROS 11/06, Public Record Office Victoria Statewide Health Service, Retention & Disposal Authority, PROS 12/05, Public Record Office Victoria
Western Australia	*State Records Act 2000*	*Births, Deaths and Marriages Registration Act 1998* *Freedom of Information Act 1992*	*Patient Information Retention and Disposal Schedule for the WA health system 2019* *Western Australian University Sector Disposal Authority 2023*

Table 4: Document retention requirements for different types of state and territory records that are used in clinical trials

State or Territory	Record Type	Disposal Requirements
Australian Capital Territory	External or internal reports evaluating the programs and services provided to patients in hospitals, health centres, clinics or other similar health care facilities that cause a change to policies, procedures or is a significant program, unusual item, system or a first time service Records documenting major research carried out relating to population health care management and control programs and strategies	Retain as Territory Archives
	Records relating to the conduct of clinical research, including recruiting and consent of participants, collection and analysis of data, preliminary findings, surveys and results	Destroy 15 years after last action or date of publication of the research, whichever is later
	Records documenting routine research carried out relating to population health care management and control programs and strategies	Destroy after 10 years
	Records relating to clinical trial projects submitted to Human Research for approval The management of join ventures relating to population health care management and control programs and strategies	Destroy after 7 years

	Records relating to the conduct of non-clinical research, including records related to the collection of data, data analysis, preliminary findings, surveys and results Health records about a health consumer	
	Records relating to clinical and non-clinical research where research did not proceed	Destroy after 3 years
New South Wales	Records relating to the conduct of clinical research Records relating to successful applications for approval of clinical research projects	Retain minimum of 15 years after date of publication or completion of the research or termination of the study
	Records relating to the conduct of non clinical research Records relating to approved applications for non clinical research projects	Retain minimum of 5 years after date of publication or completion of research
	Records of requests relating to projects where the research does not proceed Records relating to applications that were not approved	Retain minimum of 3 years then destroy
Northern Territory	Records documenting Centre for Disease Control research data, including raw data	Retain in organisation
	Clinical Research – gene therapy Final research reports in relation to national critical care and trauma response Final versions of clinical research reports in relation to oral health services Final original research in relation to alcohol and other drug services	Retain and transfer to archives service 10 years after action completed
	Clinical Research – non-gene therapy	Destroy 15 years after last access

	Records documenting draft versions of research reports	Destroy 15 years after action completed
	Research data in relation to oral health services	Destroy 10 years after action completed
	Research data for reference purposes	Destroy when reference ceases
Queensland	Any record related to incidents, allegations, disclosures and investigations of abuse of vulnerable people.	Retain for 100 years after creation of record
	Clinical research records where the patients/clients or subjects were adults, including clinical questionnaires and surveys, laboratory results and consent forms	Retain for 15 years after completing clinical trial or after date of publication or termination of study AND 10 years after last patient/client service provision, whichever comes later
	Clinical research records where the patients/clients or subjects were minors	Retain until patient/client attains 18 years of age AND for 15 years after completing clinical trial or after date of publication or termination of study AND 10 years after last patient/client service provision, whichever comes later
South Australia	Records relating to the screening of applications, including approval or rejection of applications by human research ethics committees Records relating to the evaluation of significant public health unit research programs	Permanent
	Informed consent records Participant recruitment records All research data, including electronic data Records relating to evaluation of minor public health unit research programs Research practice activities	Destroy 15 years after research project completed

Tasmania	Records of continuing value documenting publicly funded research and clinical trials, including summary records of research proposals and detail records of research projects or clinical trials	Retain as state archives
	Medium-term records of research and clinical trials, including agreement and contract registers, contracts and agreements, and records of establishment, membership and abolition of controlling committees/authorities for joint ventures entered by hospitals or health services for research or clinical trials	Destroy 15 years after action completed
	Short-term records documenting the management of publicly funded research and clinical trials	Destroy 15 years after action completed
Victoria	Research findings on chronic disease prevention which are of interest to the community or lead to changes in legislation or agency policy Research outcomes that result in changes to policy, practice or new programs relating to health services Research reports developed to establish best practice within an area and to inform policy and program development	Retain as State Archives
	Research findings on chronic disease prevention which are of a more routine nature and do not lead to changes in legislation or agency policy Research outcomes that do not result in changes to policy, practices or new programs relating to health services	Destroy 15 years after administrative research has concluded

	Research data, data analysis, preliminary findings and surveys collected for research into preventing chronic disease Research that facilitate the development of research reports, including statistics and raw data	Destroy 15 years after research is published
	Health information relating to an individual	Destroy after 7 years
	Consent forms	Depends on the nature of the treatment provided. See Retention & Disposal Authority: Pros 11/06, 2.1 to 2.4
Western Australia	Records of major research that involves gene therapy Research data from major research involving gene therapy Ethics clearances for major research involving gene therapy	Retain 5 years after date of publication or completion of project, then transfer to State Records Office
	Records of minor research that involves clinical trials Minor research data that involves clinical trials Ethics clearances for minor research that involves clinical trials	Destroy 15 years after date of publication or conclusion of project
	Records of minor research that involves children Minor research data that involves children Ethics clearances for minor research that involves children	Destroy 7 years after date of publication or conclusion of project or after the subjects have reached 25 years of age, whatever is later
	Records of minor research that is not covered by other minor research classes Minor research data that is not covered by other minor research classes Ethics clearances for minor research not covered by other classes	Destroy 7 years after date of publication or conclusion of project, whichever is later
	Unsuccessful applications for ethical clearance	Destroy 2 years after action completed

	Research data where consent for use has been withdrawn by the participant	Destroy after notification of withdrawal

Table 5: Breakdown of requirements for a waiver of the requirement for consent under Commonwealth, state and territory privacy and health information laws

Jurisdiction	Use or disclosure of health information for research	Use or disclosure of personal information other than health information for research
Commonwealth	The use or disclosure of health information is necessary for research relevant to public health or public safety, and it is impracticable to obtain consent. The research must also comply with guidelines issued by the NHMRC (including the National Statement on Ethical Conduct in Research) and therefore must be approved by a human research ethics committee (HREC) (*Privacy Act 1988* (Cth) s 16B(3)).	No research exception for personal information in the *Privacy Act 1988* (Cth).
Australian Capital Territory	The use or disclosure is necessary for research in the public interest, it is impracticable to obtain consent and the information is de-identified (*Health Records (Privacy and Access) Act 1997* (ACT), Schedule 1, s 10(3)).	No specific research exemption for personal information in the *Information Privacy Act 2014* (ACT)
New South Wales	The use of the information is reasonably necessary for research in the public interest, and it is impracticable to obtain consent or reasonable steps are taken to de-identify the information. The research must also comply with guidelines issued by the Privacy Commissioner. These guidelines require research involving humans to be approved by a HREC in accordance with the National Statement (Dickie, 2004, pp. 13-22).	The use of the information is reasonably necessary for research in the public interest, and it is impracticable to obtain consent or reasonable steps are taken to de-identify the information. The research must also comply with guidelines issued by the Information and Privacy Commission. These guidelines require research involving humans to be approved by a HREC in accordance with the National Statement (Coombs, 2019, para. 2.2).

Northern Territory	The use or disclosure is in the public interest, no individual will be identified, it is impracticable to obtain consent, and the provider of the health information reasonably believes the recipient will not disclose the information. The research must also comply with the Information Commissioner's Guidelines (*Information Act 2002* (NT) schedule 2, s 2.1(ca); s 86(1)(a)(iv)). These guidelines require research to be approved by a HREC in accordance with the National Statement. The Chief Health Officer (CHO) of the Northern Territory may also authorise the use or disclosure of health information if it takes steps to protect the privacy of persons to whom that information relates (*Public and Environmental Health Act 2011* (NT), s 112(3)).	The use or disclosure is in the public interest, the research uses personal information in a de-identified form, it is impractical to obtain consent and it is reasonably believed the recipient will not disclose the information (*Information Act 2002* (NT), schedule 2, s 2.1(ca)).
Queensland	The use or disclosure is necessary for public health or safety research, it is impracticable to obtain consent, is conducted in accordance with guidelines approved by the Chief Executive of Queensland Health and the agency reasonably believes the information will not be disclosed further (*Information Privacy Act 2009* (QLD) schedule 4, s 2(c)). Queensland Health procedures require approval by a HREC. Health information can also be disclosed pursuant to Chapter 6, Part 4 of the *Public Health Act 2005* (QLD).	The use or disclosure is necessary for research in the public interest, the information is in a de-identified form and seeking consent is impracticable (*Information Privacy Act 2009* (QLD) schedule 3, s 10(f)).
South Australia	Personal information collected by a person engaged or formerly engaged with the South Australian health system can be disclosed for research if the research methodology has been approved by an ethics committee and there is no reason to	No specific research exemption in the Information Privacy Principles Instruction (2020)

	believe the disclosure would be contrary to the person's best interests (*Health Care Act 2008* (SA), s 93(3)(f)). Personal information collected for public health purposes can be disclosed for medical, research or statistical purposes if there is no reason to believe disclosure would be contrary to the person's best interests and the Chief Public Health Officer approves the disclosure (*Public Health Act 2011* (SA), s 99(2)(i)).	
Tasmania	The use or disclosure is for research relevant to public health and safety, it is in de-identified form, it is impracticable to obtain consent, and the information is collected as required by law by competent professionals (*Personal Information Protection Act 2004* (TAS), schedule 1, s 10(4)). Disclosure of public health information can also be authorised for approved study or approved research (*Public Health Act 1997* (TAS), s 147(3)(f)).	The use or disclosure is necessary for research or statistics in the public interest, does not identify any individuals and the agency reasonably believes the recipient will not disclose the information (*Personal Information Protection Act 2004* (TAS), schedule 1, s 2(c)).
Victoria	The use or disclosure is necessary for research in the public interest, it is impracticable for the organisation to seek consent and the information is in a de-identified form. The use or disclosure must also be in accordance with guidelines issued by the Health Complaints Commissioner (*Health Records Act 2001* (VIC), schedule 1, s 2(g)). These guidelines require all research to be approved by a HREC.	The use or disclosure is necessary for research in the public interest and it is impracticable for the organisation to seek consent (*Privacy and Data Protection Act 2014* (VIC), schedule 1, s 2.1(c)).
Western Australia	Health information may be disclosed by the CEO of the Department of Health if disclosure is reasonably necessary, the purpose for which the information is to be disclosed cannot be achieved without personal information and it is impracticable to	

	obtain the consent of the individual to whom the information relates. The information must also be approved by a HREC (*Health Services Act 2016* (WA), s 216; *Health Services (Information) Regulations 2017* (WA), regulation 3)	