Clinical Trial Data Sharing Toolkit

Introduction and use of this toolkit

Supporting Safe and Effective Data Sharing

This toolkit has been developed to support safe and effective clinical trial data sharing practices. The toolkit introduces important clinical trial data sharing governance practices.

Some governance responsibilities apply to data providers (clinical trialists) or data recipients (researchers accessing clinical trial data sets for new research projects). Some responsibilities apply to both data providers and data recipients.

Clinical Trial Data Sharing

refers to making individual participant data, aggregated data, and/or supporting documents (such as protocols, statistical analysis plans, and study results) available to other researchers, clinicians, or the public.

More detailed information on clinical trial data sharing governance can be found in:

- The Ethics Submission and Review Guide, which provides researchers and ethics review body members with guidance on the requirements for the ethics review of clinical trial data sharing applications under relevant laws and guidelines.
- The Responsibilities for the Secondary Sharing of Clinical Trial Data in Australia (Governance Framework), which provides detailed information on the application of specific Australian laws and regulations relevant to clinical trial data sharing.
- The Data Glossary, which includes definitions of key data sharing terms.

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Be LEADeRS in Clinical Trial Data Sharing Frameworks

L	**Learn** the benefits and risks of data sharing
E	**Engage** with stakeholders Engage with consumers and participants Engage with ethics review bodies, institutions and data stewards
A	**Assemble** research projects for future sharing
De	**Determine** permission for sharing clinical trial data
R	**Risks** Assess and mitigate the risks of the sharing request
S	**Share** securely Secure approvals for sharing Enter into Data Sharing Agreements Retain and dispose of data

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LEARN: The Benefits and Risks of Clinical Trial Data Sharing

CLINICAL TRIAL DATA SHARING HAS IMPORTANT BENEFITS, SUCH AS TO:

- ✓ Increase return on research investment by allowing existing trial data to be used for new research questions
- ✓ Respect trial participants by making the most of the data they have provided
- ✓ Reduce research costs and duplication
- ✓ Allow a better understanding of trial validity by replicating and reproducing its results
- ✓ Avoid having to start new clinical trials

Watch Dr Jonathan Williams, NHMRC CTC, discuss the benefits of data sharing

Access by clicking here

CLINICAL TRIAL DATA SHARING ALSO COMES WITH RISKS

Loss of privacy. The risks to privacy will depend on the identifiability of data you are sharing, collecting or using.

Harm to communities, especially if the data can stigmatise groups to which the trial participants belong.

Loss of public trust in medical research if data is shared in ways that don't meet community expectations

Spectrum of privacy risks

Aggregate data.

Participant-level data for which individual identifiers have been removed and other steps taken to prevent reidentification.

Participant-level data for which individual identifiers have been replaced with a code

Data items that contain an attribute that could readily be traced back to an individual.

Data items that include individual identifiers such as names, addresses, or Medicare numbers.

Additional resources:

Health Studies Australian National Data Asset (HeSANDA): Reusing data to accelerate research and better health outcomes

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ENGAGE: Consumers and participants

Researchers should engage early with consumers and participants to understand how they want their clinical trial data to be treated. This can help align data sharing projects with community expectations.

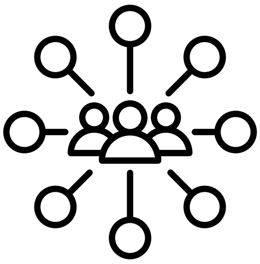
GUIDANCE ON INVOLVING AND ENGAGING WITH CONSUMERS IS AVAILABLE IN THE ACTA/CT:IQ CONSUMER INVOLVEMENT AND ENGAGEMENT TOOLKIT.

This includes information on working with consumers to:

- ✓ Prioritise research topics
- ✓ Develop research protocols and Participant Information and Consent Forms
- ✓ Collect and analyse data
- ✓ Disseminate research results

Engaging with consumers will be especially important for clinical trial data about Aboriginal and Torres Strait Islander people and rare disease groups.

✓ **Indigenous Data Sovereignty**
Historically, Indigenous communities have not had control over the way their data has been used. Indigenous Data Sovereignty allows Aboriginal and Torres Strait Islander peoples and communities to regain control over their data. As explained in the Maiam Nayri Wingara Communique:



> *Exercising Indigenous Data Governance enables Indigenous peoples, our representative and governing bodies to accurately reflect our stories. It provides the necessary tools to identify what works, what does not and why. Effective Indigenous Data Governance empowers our peoples to make the best decisions to support our communities and First Nations in the ways that meet our development needs and aspirations.*

✓ **Rare disease data**
Patients with rare diseases are often willing to be involved with research, which can help them to access a diagnosis and, ideally, inform a treatment plan. However, due to their smaller population, rare disease patients are at risk of reidentification. Research has shown that rare disease patients are often willing to share health data for research but may still want control when it came to data sharing.

Additional resources:

- ACTA/CT:IQ Consumer Involvement and Engagement Toolkit.
- Lowitja Institute Indigenous Data Sovereignty Readiness Assessment and Evaluation Toolkit
- Maiam NayriWingara Communique, Indigenous Data Sovereignty (2018)

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ENGAGE: Ethics review bodies, institutions, and data custodians

Engaging early with people and committees responsible for data sharing can make the process smoother and more effective.

DATA RECIPIENTS SHOULD:

✓ Identify relevant data custodians and ask if they are willing to share the clinical trial data and under what conditions.

? **How do I find the data custodian for a clinical trial data set?**
While roles and responsibilities vary, the data custodian for a clinical trial data set will commonly be the principal investigator or chair of the study Steering Committee.

✓ Talk with the Ethics Review Body (ERB) that will be reviewing the research project to learn about:

- The application form and submission platform
- The required documentation
- Any submission fee
- The availability of lower-risk review pathways

✓ If the project will use data linkage, ask the data linkage agency how much linkage will cost, how long it will take, and any specific requirements for linking such as review by a particular ERB or HREC.

DATA PROVIDERS SHOULD:

✓ If the clinical trial has not been set up with data sharing in mind, talk with the ERB that reviewed their clinical trial to understand any requirements for sharing the clinical trial data.

DATA RECIPIENTS AND DATA PROVIDERS SHOULD

Ask their institutions about the governance requirements for data sharing, including the institution's:

✓ Data management policies, such as transfer and storage practices, trusted research environments, the use of specific networks

✓ Privacy policies

✓ Any required or available data sharing agreements

TIP

ERBs, including HRECs and low risk bodies, are responsible for deciding whether a research proposal is ethically acceptable and meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2025). A list of registered HRECs is available here

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ASSEMBLE: Research Projects for Future Sharing

Clinical trial data sharing works best when data providers and data recipients design research with sharing in mind from the start.

DATA PROVIDERS SHOULD

Draft a clear Participant Information and Consent Form (PICF).

✓ Data providers should use the National Data Sharing Statement in the InFORMed template: www.informedpicf.com.au

✓ Key information in the PICF includes:
- Option to consent to future data sharing
- How to get information about the research for which their data will be shared.
- Limitations on withdrawing consent to data sharing.

> Seeking consent preferences at the outset of a clinical trial provides the best legal and ethical ground to share data in the future

Develop a data management plan

Data providers should have in place a data management plan for their clinical trial datasets, including:

- A custodian for the clinical trial data
- How data will be used, shared, stored, and disposed, and a plan for managing any intellectual property rights resulting from the trial
- The purposes for which the trial data will be used and/or disclosed, including for future research
- The conditions under which access to the data may be granted to others, including researchers in Australia and/or overseas, for public and privately sponsored research, for all or some health conditions.
- Processes to ensure physical, network, and system security, including any training for the trial team

DATA RECIPIENTS SHOULD

Develop a data management plan for the new research data set

✓ Data recipients should have in place a data management plan for the new research data sets they create, including:

- A custodian for the new research data
- How the new research data will be used, shared, stored, and disposed, and a plan for managing any intellectual property rights from the research, including with data providers
- Purposes for which the new research data will be used and/or disclosed
- Conditions under which access to the new research data may be granted to others, including trial participants
- Processes to ensure physical, network, and system security, including any training for the research team

Additional resources:

NHMRC - Management of Data and Information in Research (2019) - https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf

The Australian Research Data Commons gives a number of examples of data management plans

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DETERMINE: Permission for Sharing Clinical Trial Data

After finding clinical trial datasets that meet a data sharing project's needs, the next step is to check if the right permissions are in place for data sharing.

Data providers should check that they have permission to share clinical trial data for the research project. Data recipients should ask data providers for evidence of their permission to share the clinical trial data.

1. REVIEW THE CONSENT PROVIDED BY TRIAL PARTICIPANTS

✓ Data providers should assess the consent that trial participants provided for data sharing in the Participant Information and Consent Form/s (PICF).

✓ Three main variations exist when it comes to consent for sharing clinical trial data:

- 🔴 The trial PICF advised that data would not be used for future research or would be destroyed at the end of the trial. Sharing requires reconsent from trial participants.
- 🟡 The trial PICF was silent on whether the data could be used for future research. Sharing requires reconsent from trial participants and/or a waiver of the requirement for consent from an ethics review body.
- 🟢 The trial PICF provided for consent for future sharing. Use will depend on the strength of the consent provided and how well the new use aligns with the original trial consent.

- **Specific consent**: a participant has agreed for their data to be shared for a specific research project.
- **Extended consent**: a participant has agreed to share data for certain kinds of future research.
- **Unspecified consent**: a participant has agreed to share their data for a wide range of future research projects.

2. REVIEW THE TRIAL DATA MANAGEMENT PLAN

✓ Data providers should review their trial's data management plan to understand how it applies to the data sharing project. If the data management plan does not clearly support the data sharing, data providers should seek approval from the data custodian, their ethics review body, and their institution for any necessary changes.

Additional resources:

More information on assessing the adequacy of PICFs for sharing clinical trial data is available in the Ethics Submission and Review Guide.

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RISKS: Assess and mitigate the risks of the sharing request

Data providers and data recipients should assess the risks of each data sharing request and consider opportunities to minimise such risks. Data providers and data recipients should check with their local institution on what risk mitigation strategies are required or available for data sharing.

THE FIVE SAFES PRINCIPLES CAN HELP RESEARCHERS TO THINK ABOUT AND MINIMISE THE RISKS OF DATA SHARING:

Safe Projects
Whether the data is being used for appropriate purposes and is likely to be in accordance with community expectations.

- Risk minimisation: seeking ethics and governance approvals and undertake consumer engagement.

Safe People.
The knowledge, skills and trustworthiness of the researcher.

- Risk minimisation: train researchers in confidentiality and the use of data sharing agreements

Safe Data.
The disclosure risks inherent in the data being shared.

- Risk Minimisation: limit the number of variables collected, remove direct identifiers, and consider changing indirect identifiers, such as age, that may carry disclosure risks

Safe Settings.
The access controls in place, such as use of a trusted research environment.

- Risk minimisation: store identifiers and content information separately, and use trusted research environments (TREs) such as the Secure eResearch Platform (SeRP) and KeyPoint.

Safe Outputs.
Whether any published results could reveal the identity of individuals.

- Risk minimisation: suppress small sample sizes, apply privacy-preserving techniques, eg by replacing postcodes with a metropolitan/rural category

Additional resources:

- For more information on the use of the Five Safes principles, see: https://www.abs.gov.au/about/data-services/data-confidentiality-guide/five-safes-framework#five-safes-framework
- For more information on trusted research environments, see https://ardc.edu.au/resource/trusted-research-environments-framework/

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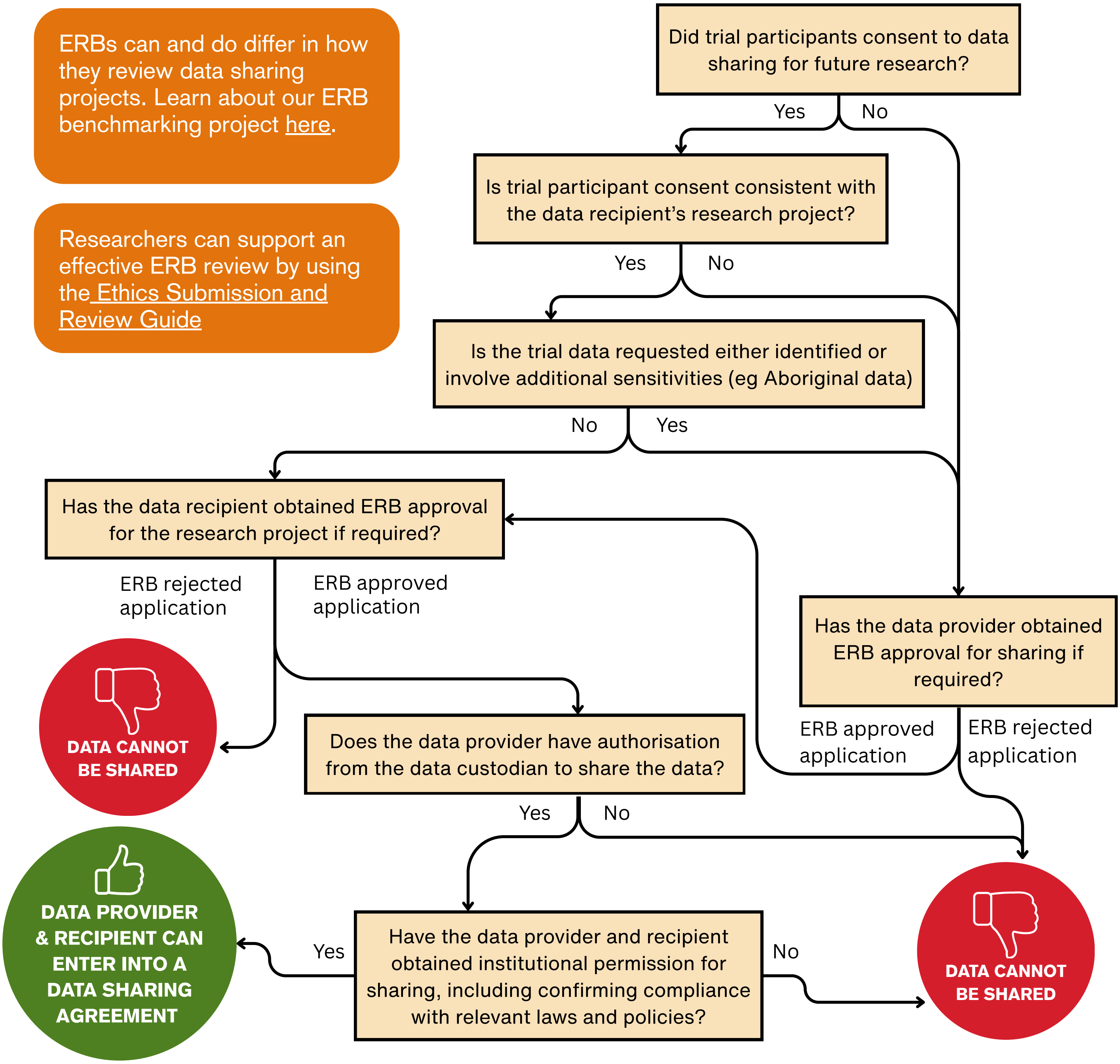
SHARE SECURELY: Secure Approvals for Sharing

Data providers and data recipients must get all necessary approvals prior to sharing, including from an Ethics Review Body (ERB) and the data custodian. Data providers and data recipients are both responsible for ensuring that sharing is compliant with relevant laws.

ERBs can and do differ in how they review data sharing projects. Learn about our ERB benchmarking project here.

Researchers can support an effective ERB review by using the Ethics Submission and Review Guide



Did trial participants consent to data sharing for future research?

Yes / No

Is trial participant consent consistent with the data recipient's research project?

Yes / No

Is the trial data requested either identified or involve additional sensitivities (eg Aboriginal data)

No / Yes

Has the data recipient obtained ERB approval for the research project if required?

ERB rejected application / ERB approved application

Has the data provider obtained ERB approval for sharing if required?

ERB approved application / ERB rejected application

DATA CANNOT BE SHARED

Does the data provider have authorisation from the data custodian to share the data?

Yes / No

Have the data provider and recipient obtained institutional permission for sharing, including confirming compliance with relevant laws and policies?

Yes / No

DATA PROVIDER & RECIPIENT CAN ENTER INTO A DATA SHARING AGREEMENT

DATA CANNOT BE SHARED

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SHARE SECURELY: Enter into Data Sharing Agreements

Before sharing or collecting data, data providers and data recipients should enter into a data sharing agreement (DSA) to set out the rules for how data will be shared and retained. Researchers should ask their institutions if there is a DSA template they should use to share data securely.

KEY DSA PROVISIONS WILL INCLUDE:

- Definitions of key terms, including defining the data set being shared
- Purpose of sharing, which specifies how the disclosed data can be used
- Confidentiality, which stops the data recipient from sharing with others except under specified conditions
- Privacy and prohibition on reidentification, which requires the parties to comply with relevant privacy laws. It may include a requirement to deidentify the data, not to seek to reidentify, and/or to notify the other party of any privacy breaches
- Intellectual property (IP), specifying how IP will apply to information shared under the Agreement and to new information created
- Conditions on publication, including authorship and acknowledgement requirements
- Warranties, which provides assurances that the parties are entitled to take the actions specified in the Agreement and will comply with relevant laws, policies, and approvals.
- Data security and storage, which requires the parties to comply with data quality and data security standards and maintain relevant safeguards
- Data transfer, including any conditions on transfer
- Fees, to specify any charges that might apply from the data provider
- Indemnification and insurance, including the insurance the parties need to cover loss and any compensation in the event of loss or damage arising from a breach of the Agreement
- Termination and variation, including any requirements to return or destroy data on termination
- Dispute resolution

Additional resources:

- Some DSA templates are freely available online, eg Sydney Health Partners' is available here: https://sydneyhealthpartners.org.au/resources/data-sharing-accord/
- https://www.ga4gh.org/document/model-data-access-agreement-daa-clauses/
- The ARDC has developed Data Sharing Agreement Development Guidelines, which include additional information on when a DSA is required and typical inclusions.

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SHARE SECURELY: Retain and Dispose of Data

Each research institution should have a policy for managing research data, including storage, retention and disposal.

Clinical trial data providers and data recipients must have a plan for data retention and disposal. Retention and disposal requirements are set out in the Universities Australia and NHMRC Management of Data and Information in Research

- ✓ By default, research data should be stored for at least 5 years.
- ✓ Clinical trial data must be stored for at least 15 years.
- ✓ Clinical trial sponsors may need to store data for longer than 15 years to satisfy product liability requirements.
- ✓ Data related to genetic research, including gene therapy, must be stored permanently. Research and clinical trial data relating to minors must comply with specific state and territory retention requirements. Most commonly, data must be stored for 15 years after the participant reaches (or would have reached) the age of 18.
- ✓ A researcher who collects and/or modifies clinical trial data, including by integrating with other datasets, must store the data for at least 5 years.
- ✓ Storing and disposing of data with or about Aboriginal and Torres Strait Islander people and communities should be handled in accordance with Indigenous Data Sovereignty and governance principles

The data minimisation principle under state and federal privacy laws specifies the need for researchers to take reasonable steps to destroy or deidentify information once it is no longer required for the purpose for which it may be used or disclosed. Data destruction requirements under privacy laws will need to be balanced with data retention requirements.

Additional resources:

- CT:IQ and ARDC Governance Framework Table of data retention and disposal requirements
- VCCC Alliance, Data Storage and Retention, available: https://vcccalliance.org.au/research/clinical-trial-innovations/investigator-initiated-trials/data-management/data-storage-and-retention.
- Jung et al, Retention and Disposal of Research Data: from current to best practices (2023), available: https://ardc.edu.au/project/retention-and-disposal-of-research-data-confirming-obligations-establishing-practice/