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Building on the past, planning for the future

Changes in National Ethics Policy for Managing and Sharing Human Research Data

NCRIS
National Research Infrastructure for Australia
An Australian Government Initiative

Funders and Publishers: data management and sharing
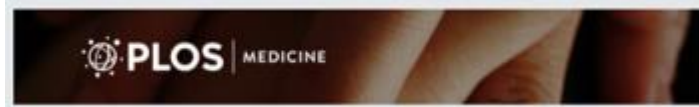
Code for Responsible Conduct of Research

Principles of responsible research conduct: P3 Transparency in declaring interests and reporting research methodology, data and findings

Share and communicate research methodology, data and findings openly, responsibly and accurately.

Institutions: R8 Provide access to facilities for the safe and secure storage and management of research data, records and primary materials and, where possible and appropriate, allow access and reference.

Researchers: R22 Retain clear, accurate, secure and complete records of all research including research data and primary materials. Where possible and appropriate, allow access and reference to these by interested parties.

'Management of Data and Information in Research' guide accompanying the Code

R27 Cite and acknowledge other relevant work appropriately and accurately.   *Data citation too!*
https://www.ands.org.au/working-with-data/citation-and-identifiers/data-citation

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National Statement on Ethical Conduct in Human Research

- HREC decisions and policies based on Statement
- Updated mid 2018 – new Section 3
- Full implementation expected by 1 Jan 2019
- HREA being updated to align, by end of year

- Element 4: Collection, Use and Management of Data and Information

- ARDC webinar 'Data management in NHMRC's revised National Statement on Ethical Conduct in Human Research'
  https://www.ands.org.au/news-and-events/presentations/2018

National Statement on Ethical Conduct in Human Research

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

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Mediated access

- Not all data that is shared is open
- Mediated – committee, individual, archive…
- F.A.I.R. data (http://www.ands.org.au/working-with-data/fairdata)
  - Findable
  - Accessible
  - Interoperable
  - Reusable
- Five Safes risk management framework
  - Safe projects: is the use of the data appropriate?
  - Safe people: can the users be trusted to use it in an appropriate manner?
  - Safe settings: does the access facility limit unauthorised use?
  - Safe data: is there a disclosure risk in the data itself?
  - Safe outputs: are the statistical results non-disclosive?

Desai, T. Ritchie, F., and Welpton, R. Five Safes: designing data access for research. 2016. DOI: 10.13140/RG.2.1.3661.1604

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Data management plans

3.1.45 For all research, **researchers should develop a data management plan** that addresses their intentions related to generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information, the risks associated with these activities and any strategies for minimising those risks. The plan should be developed as early as possible in the research process and should include, but not be limited to, details regarding:

(a) physical, network, system security and any other technological security measures;

(b) policies and procedures;

(c) contractual and licensing arrangements and confidentiality agreements;

(d) training for members of the project team and others, as appropriate;

(e) the form in which the data or information will be stored;

(f) the purposes for which the data or information will be used and/ or disclosed;

(g) the conditions under which access to the data or information may be granted to others; and

(h) what information from the data management plan, if any, needs to be communicated to potential participants.

Researchers should also clarify whether they will seek:

(i)   extended or unspecified consent for future research (see paragraphs 2.2.14 to 2.2.16); or

(j) permission from a review body to waive the requirement for consent (see paragraphs 2.3.9 and 2.3.10).

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Data management

Overview
What institutions need to consider in formulating data management frameworks and strategies

Institutional data management frameworks
Strategic planning to build and support effective data management

Institutional policies and procedures
Guides and examples of institutional policies and procedures fundamental to good data management

Funder guidelines
Summary of Australian and international funder policies and requirements affecting research data

Data management plans
Example plans and elements to consider when developing institutional data management plans

Data capture
Projects and reusable software to collect and manage data, and improve its metadata

Storage
Choices around data storage and the implications for metadata management and access

File wrangling
Careful thought about files at the beginning of a research project can save a lot of time, money and heartache later in a project

Data preservation
Advice on ensuring enduring data assets and supporting their reuse

Data versioning
Advice on creating a new version of a dataset when an existing dataset is reprocessed, corrected or appended

For researchers
Practical strategies and considerations for maximising the impact of your research data

Research data management in practice Guide
Outlines data management roles and responsibilities of institutions and researchers

https://www.ands.org.au/working-with-data/data-management

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Consent for data sharing

3.1.36 If researchers are planning to add data obtained in a research project to an open or mediated access repository or make the data or materials available for re-use, any implications of these plans should be provided to participants. The use of 'extended consent' or 'unspecified consent' (see 2.2.14 to 2.2.16) may be appropriate for this purpose.

2.2.14 (b) 'extended': given for the use of data or tissue in future research projects that are:
(i) an extension of, or closely related to, the original project; or
(ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);
(c) 'unspecified': given for the use of data or tissue in any future research.
2.2.15 Extended or unspecified consent may sometimes need to include permission to enter the original data or tissue into a databank or tissuebank.
2.2.16 When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.

3.1.37 When researchers seek consent to collect information that is considered to be of historical, cultural or other long term value, they should obtain consent for its perpetual retention, including any planned re-use and sharing with others.

Consent for data sharing

- Topics that can be covered in Data Management Plan/Participant info

  - Governance
  - Access – during and once project is complete
  - Use and reuse
  - Privacy
  - *3.1.31 In any information provided to potential participants during the consent process,* *researchers should include information on data management and storage*

- Data that is re-used still needs to comply with original consent – therefore consent conditions need to be documented - metadata

- Options for participants?
  - Levels of aggregation or identifiability

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Consent for data sharing

Example wording in ANDS Publishing and Sharing Sensitive Data guide e.g. "Other genuine researchers [may] have access to this data only if they agree to preserve the confidentiality of the information as requested in this form."
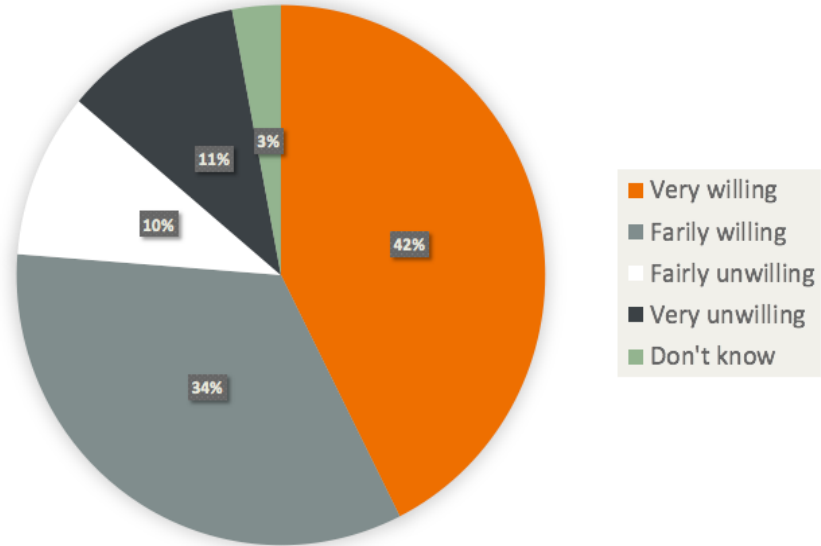
Alternative options if needed

opt out and waiver (2.3) are options

Attitudes to reuse of medical data

Australia Speaks (Research Australia)

- Strongly Support — 48%
- Somewhat support — 45%
- Oppose — 7%
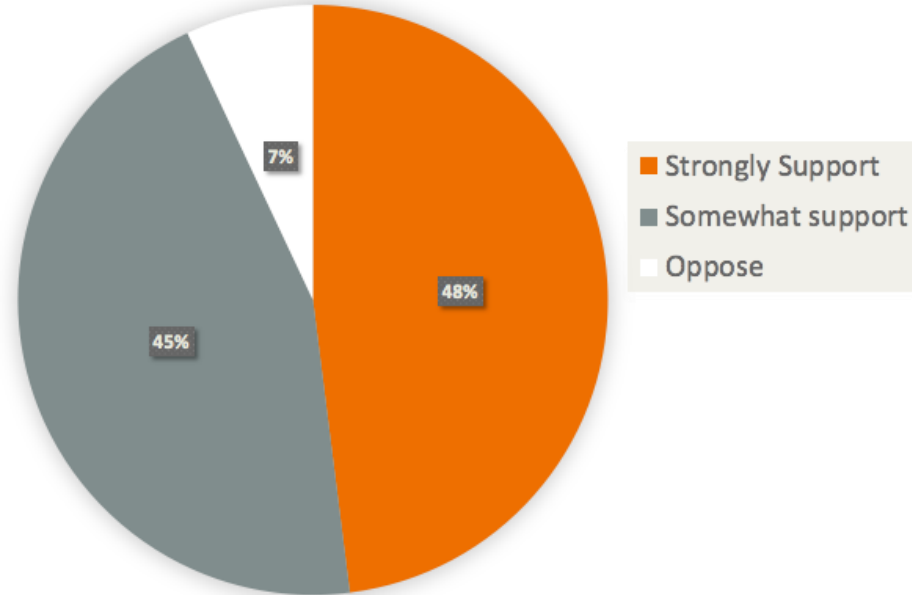
Medical records in medical research if data was anonymised (UK)

- Very willing — 42%
- Farily willing — 34%
- Fairly unwilling — 10%
- Very unwilling — 11%
- Don't know — 3%

Australia Speaks. Research Australia. 2017. Available from
https://researchaustralia.org/reports/public-opinion-polling-2017/   Page 13

Wellcome Monitor. Wellcome Trust. 2015. Available from
https://wellcome.ac.uk/what-we-do/our-work/public-views-medical-research

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'How do people feel about the use of data?" https://understandingpatientdata.org.uk/how-do-people-feel-about-use-data

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Spencer K, Sanders C, Whitley EA, Lund D, Kaye J, Dixon WG. Patient Perspectives on Sharing Anonymized Personal Health Data Using a Digital System for Dynamic Consent and Research Feedback: A Qualitative Study. Eysenbach G, ed. *Journal of Medical Internet Research*. 2016;18(4):e66. doi:10.2196/jmir.5011.

Charlotte J. Haug. N Engl J Med 2017; Whose Data Are They Anyway? Can a Patient Perspective Advance the Data-Sharing Debate? 376:2203-2205 DOI: 10.1056/NEJMp1704485

Use MY data http://www.usemydata.org/

Sensitive data resources

ands.org.au/working-with-data/sensitive-data

Publishing and sharing sensitive data Guide

Data sharing considerations for Human Research Ethics Committees Guide

De-identification Guide

Safely sharing sensitive data
Sensitive data CAN be published: advice and examples

Ethics and data sharing
Ethical considerations when sharing human data

De-identifying your data
Processes for removing identifying information from datasets to protect privacy

10 medical and health research data Things
A flexible learning resource for people working with medical, clinical or health data

Medical and health data
ANDS hub for medical and health data issues and advice

Indigenous data
Data that pertains to Indigenous peoples is a complex legal and ethical terrain

Data management and sharing

The management, retention, and appropriate sharing of research data is increasingly recognised as an important part of ethical and reproducible research. This is being incorporated into national policies, such as the new version of the National Statement on Ethical Conduct in Human Research.

Appropriate consent should be obtained for reuse of data, and there are alternative options if needed.

Institutional data management policies and procedures, and ethics policies can support data management and appropriate reuse of research data.

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NCRIS
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