BOOKLET 48

Griffith University Research Ethics Manual

Collection, Use and Management of Data and Information

Contents

01.0 Introduction

In a very real and practical sense, the strategies a project will use to generate, collect, access, use, analyse, disclose, store, retain, dispose, share and re-use information and turn it into data for analysis are likely to be fundamental components of a project.

Element 4 of National Statement on Ethical Conduct in Human Research (2007 updated 2018) relates to this topic.

The following booklets relate to research data and will be relevant to most human research projects:

Booklet 01 – Introduction to human research ethics at Griffith University

Booklet 02 – Research ethics review at Griffith University

Booklet 03 – Responsibilities of researchers

Booklet 09 – Risks in human research

Booklet 21 - Recruitment

Booklet 22 - Consent strategies in human research

Booklet 23 - Ethical and regulatory privacy

A number of booklets across the Griffith University Research Ethics Manual (GUREM) relate to data matters in specific situations. Booklet 42 relates to banking, archiving, reuse, wider use and sharing of data.

The following booklets discuss specific research techniques:

- 12 - Clinical research: Ethical and governance considerations

- **31 - Human research and the ethical principle of justice**

- 34 - Ethical issues in questionnaire-based research

- **35 - Ethical issues in focus group research**

- 36 - Ethical issues in the use of audio-visual recording in human research

- 37 - Information technology and online research

This Booklet of the GUREM is intended to assist researchers to design, describe in an ethics application, and implement a successful approach to the collection/generation/access to data.

02.0 National guidance material

The *National Statement on Ethical Conduct in Human Research (2007 updated 2018)* is the Australian standard for the ethical design and conduct for human research ethics.

Given the significance of the ethical considerations associated with the collection/generation/access to data, as well as its analysis in human research projects, it is perhaps surprising that prior to 2018, there was not a chapter of the *National Statement* devoted to these matters. However, across the entire *National Statement,* there are often discussions about specific issues relating to data that may apply to some projects.

In 2018, Chapter 3.1 of the National Statement was updated to describe the elements of ethical project design. Element 4, paragraphs 3.1.40-3.1.63, of Chapter 3.1 discusses collection, use and management of data and information. This booklet describes the University's implementation of Element 4.

03.0 Key questions

The following describes the key questions for Element 4 of Chapter 3.1 of the National Statement.

3.1 Relationship to the research theme or question

Among the key questions for Element 4 of Chapter 3.1 of the National Statement are those relating to the relationship between the data collected and the themes and questions of the research project. A project should collect sufficient data to enable the researchers to address the research theme/questions, and only the information that is necessary to address those matters.

3.2 How and by whom will the information/data be generated, collected and/or accessed

Researchers should specify the strategies that will be used to generate/collect/access the information/data. They should identify who will be conducting those strategies. It is a requirement of both the National

Statement and the relevant privacy legislation that this information is known and recorded. These are matters that will be considered by the relevant human research ethics review bodies.

3.3 Use and storage of the information/data

These are again matters of ethical and legal significance. It should also be clearly established who will be involved in the use and the storage of the information/data.

These matters should be determined in advance and recorded. This may require team members to have specific expertise and/or training/supervision. They will also be considered during the human research ethics review process.

3.4 Disclosure to third parties

Researchers should establish whether any personally identified information might be disclosed to third parties. This includes disclosures that are compelled and elective. See 10.0 of Booklet 40 of this Manual for further guidance on this matter. The application for research ethics review must clearly explain:

     i.   What would be disclosed;

    ii.   To whom it will be disclosed;

   iii.   Why it will be disclosed to them;

   iv.   What, if anything, will be explained to potential/participants; and

    v.   The justification for the described situation.

04.0 Identifiability of information

Element 4 of National Statement Chapter 3.1 discusses the topic of the identifiability of information, its ethical implications and the responsibilities of researchers.

An essential matter to consider if individuals can be associated with data/information is whether there are any risks associated with that identification.

4.1 Prefer to be identified

The National Statement at 3.1.40 recognises that some participants in some circumstances would not only be willing to be identified but would insist on being identified as the source of the data/information. In those circumstances, identification may not only be permissible, it might be preferable and a measure of respect.

4.2 Measures to protect

Where the identity of participants should be protected, 3.1.41 of the National Statement discusses the responsibility of researchers to take measures to do so.

4.3 Publication and identification

3.1.42 of the National Statement describes the responsibilities of researchers to consider and mitigate the possibility that an individual might be identified on the basis of the published data.

4.4 Data linkages and identification

Where data is to be linked to other data, and this linking might facilitate identification, 3.1.43 of the National Statement describes the responsibilities of researchers.

05.0 Data management

The ethical issues and the researcher responsibilities associated with data management are described in Element 4 of Chapter of the National Statement.

5.1 Research collaborations

3.1.44 of the National Statement discusses the responsibilities of researchers collaborating with other researchers (e.g. agreeing on responsibilities).

5.2 Data Management Plan

The need, role and contents of a Data Management Plan are discussed at 3.1.45 of the National Statement. Specific information on Data Management Plans and their implementation can be found here: https://www.griffith.edu.au/library/research-publishing/working-with-data/manage-and-plan

5.3 Proportional approach

At 3.1.46 the National Statement indicates that the components of a Data Management Plan should be proportional to the risks and ethical sensitivity of a planned research project.

5.4 Laws and regulations

Researchers are expected to adhere to and comply with relevant laws and regulations (National Statement 3.1.47).

5.5 Health related effects

National Statement 3.1.48 requires that researchers maintain records so that they are able to contact participants in the event that "evidence emerges of late or long-term health-related effects". It should be noted National Statement 3.1.64 also refers to other significant effects for other areas of research.

5.6 Disposal

When data, information and biospecimens are disposed of (e.g. at the end of the requisite period after the completion of a project), this must be in a matter that is safe and secure, and in a manner that is consistent with the consent obtained from the participants and in accordance with the relevant laws and regulations.

5.7 Data sharing

There are some circumstances where data sharing will not be appropriate or permissible (e.g. where there are regulatory controls on the information, or where there are risks or cultural sensitivities). In the absence of such considerations, Griffith University researchers are urged to format and then share

information/data with other researchers. Funding bodies in Australia (e.g. ARC and NHMRC), also have expectations of sharing and open access to research data.

Australian research funding bodies have guidelines and expectations with regards to these matters (e.g. https://www.arc.gov.au/policies-strategies/strategy/research-data-management............................and https://www.nhmrc.gov.au/about-us/resources/open-access-policy)

06.0 Secondary use of data or information

Element 4 of Chapter 3.1 of the National Statement also discusses situations where a project is a secondary use of an existing set of data or information (e.g. data or information from an earlier research project or from a non-research activity).

This includes administrative data associated with the operation of a service, program, course, etc.

Such secondary use can raise considerations related to:

    i.   consent;

    ii.   privacy;

    iii.   the impracticability of obtaining consent for the secondary use; and

    iv.   respecting the wishes and understanding of the participants.

Element 4 provides guidance on how researchers should approach these matters and the steps they should take. Depending on the circumstances, the project may require a waiver of the informed consent requirement (see 4.1.2.3 of Booklet 23 of this Manual); another option could be the opt out approach (see 19.0 of Booklet 21 of this Manual).

07.0 Sharing of data or information

The topic of the sharing of data or information is discussed in Element 4 of Chapter 3.1 of the National Statement. This relates to the banking of data (regardless of whether it is deposited in an open or mediated access repository or data warehouse) and information, as well as the sharing of data and information with other researchers.

7.1 Data Custodian

In accordance with National Statement 3.1.55 a data custodian must be appointed to oversee appropriate access to the data by researchers and participants. This access may be to data and information in a protected form. The custodian may be the researcher or an agency. The identity of the custodian should be discussed in the application for research ethics review.

7.2 Plans

When sharing data or information with other researchers, or when banking or archiving data/information researchers should establish a plan that includes the features discussed in National Statement 3.1.45.

7.3 Custodians

As per 3.1.57 of Element 4 of Chapter 3.1 of the National Statement, the researcher must brief the data custodian on the data plan and any requirements with regard to privacy, sensitivity and risk – such as might be discussed in the confidentiality agreement.

7.4 Collaborators and sites

The arrangements for the sharing of data and information between collaborators and sites should be secure in a manner that is proportionate to the risks/ethical sensitivities (see 3.1.58 of Element 4 of Chapter 3.1 of the National Statement).

7.5 Plan to share or disclose data/information

As per 3.1.59 of Element 4 of Chapter 3.1 of the National Statement, in an application for human research ethics review or a proposed variation to a project, the researchers should indicate if there is a plan to share data or information. They should also indicate if the sharing is to be with defined individuals, the wider public or is a required disclosure.

7.6 Consent for sharing

When seeking consent from potential participants for their involvement in research, Griffith University researchers are encouraged to seek express consent to allow for the sharing, banking and reuse of data/information. See Booklet 42 for more about the reuse of data and information, also see Booklet 2 of this Manual for more about research ethics review at Griffith University (see 3.1.60 of Element 4 of Chapter 3.1 of the National Statement).

7.7 Consider reidentification

As per 3.1.61 of Element 4 of the National Statement, before publishing data or information, or adding it to a repository/archive/bank, researchers should consider the degree to which it could be personally identified. See ANDS Guide on De-Identification https://www.ands.org.au/working-with-data/sensitive-data/de-identifying-data

7.8 Banked or shared data and human research ethics review

Research that will utilise shared, banked or archived data/information may qualify for review outside of a HREC (e.g. review via the E1 or E2 pathways) but cannot be reviewed via the NR pathway. See Booklet 2 of this Manual for more about review pathways at Griffith University.

Resources

Data sharing considerations for Human Research Ethics Committees | ARDC
https://www.ands.org.au/__data/assets/pdf_file/0009/748737/HREC_Guide.pdf

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

Contacts

There are a number of resources available to assist researchers formulate an appropriate response to a question or challenge about the design and/or conduct of a project. This includes the Griffith University Research Ethics Manual and the Human Research Ethics Information Sheet Series. These documents are available from the URL below.

Research students – The first point of contact for research students for advice on any research ethics matter is always your supervisors.

REAs – All academic elements of the University have been asked to appoint at least one member of academic staff as a Research Ethics Advisor. REAs are a local contact for advice, information and suggestions. The contact details of all the current REAs can be found on the URL below.

Office for Research – Staff in the Office for Research (see below) are available to advise with the process of lodging an application or other administrative matters, procedural or policy questions. However, you will be asked what advice you have sought or received already (e.g. consultation with the REA for your area).

Digital Solutions – eResearch – Staff in eResearch can provide advice and support on choosing tools and solutions that will allow you to comply with the obligations listed in this document. https://www.griffith.edu.au/eresearch-services#contact

Library – Researcher Services support you through the entire research lifecycle, from developing the initial proposal through to publication and dissemination of your findings. https://www.griffith.edu.au/library/research-publishing

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On the ethics web site you will find:

https://www.griffith.edu.au/research/research-services/research-ethics-integrity/human

- The other booklets of the *Griffith University Research Ethics Manual*
- The *Griffith University Human Research Ethics Information Sheet Series*
- Either downloadable copies of, or links to, the various application forms
- Contact information for the Research Ethics Advisers (REA) and other contacts
- Educational and other resource material
- Useful external links