BOOKLET 42

Griffith University Research Ethics Manual

Banking and retesting of data, samples and biospecimens

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Contents

1.0 Introduction

The reuse of previously collected data or the retesting of samples/materials can be desirable for a variety of reasons. This can include the desire to verify earlier results, to apply a new analysis to existing data/materials, or to follow a new line of enquiry. In the case of banked tissue/genetic or other material such testing can be invaluable.

Even though retesting/reuse can be a matter of convenience to the researcher (avoiding the time and expense of collecting new data), it can also present significant ethical issues for participants (e.g. avoiding the inconvenience/risks of recollecting materials/data that has previously been collected, perhaps from a "over researched" population). In the case of relatively rare medical conditions or unique circumstances, access to existing data/samples/material might be the only way a research project could be conducted.

Despite the fact that there may be practical, resource or even ethical reasons that make the reuse of data or retesting attractive, in the case of human research there are significant ethical issues that must be addressed before such work can be conducted. This Booklet of the *Griffith University Research Ethics Manual* is intended to assist researchers in considering and resolving these matters.

Back to contents

2.0 National guidelines

The National Statement on Ethical Conduct in Human Research (2007 updated 2018) is the Australian reference for human research ethics matters. Chapter 3.1 of the National Statement includes ethical advice with regards to databanks and Chapter 3.2 relates to human biospecimens in laboratory-based research. Section 1 of the National Statement outlines the core principles that apply to all human research – including the retesting/reuse of information/samples/human biospecimens. This Booklet has been produced on the basis of relevant provisions from chapters 3.1 and 3.2 and other appropriate references from the National Statement.

It should also be noted that in its discussion of the responsibilities of researchers responsibility R22 of the Australian Code for the Responsible Conduct of Research (2018) directs researchers to "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."

Depending upon the methodology, 'participants' and context, other booklets of the Griffith University-REM may need to be consulted (e.g. Booklet 32 in terms of research with extracted human biospecimens, Booklet 41 for genomic research and Booklet 33 in terms of waiver of the consent requirement).

Back to contents

Commentary Inset 1 – What does personally identified mean?

When discussing data, samples and human biospecimens, personally identified refer to situations where there are direct identifiers (such as the 'donor's name') or where there is a code that the researchers, and perhaps third parties, can use to identify the individual to whom the data, samples or human biospecimens relate (such as a student number).

The above does not apply if the code key is not available to the researchers and is not available to third parties who have access to the data, samples or human biospecimens.

There can be situations where the researchers, or third party, have access to information that, if cross checked with the data, sample or human biospecimens could render it personally identified.

In recent years it has also been argued that genetic material should always be considered personally identified, because it is always at least theoretically possible (e.g. by forensic officers in a law enforcement agency) to identify the source of the material.

This should be borne in mind when planning a project and seeking ethics clearance for banking, retesting or for the new use of data, samples and human biospecimens.

3.0 Regulatory considerations

A proposed banking or reuse of data/samples/materials may be subject to special regulatory considerations.

If the data or sample is personally identified information (see Commentary Inset 1) there may be a legal requirement for specific consent for the new work. See Booklet 23 of this Manual for more about privacy. In the case of work with banked human biospecimens (see 5.0) the *Transplantation and Anatomy Act* 1979 may apply. Depending upon the specifics of the new work, there may be a range of other regulatory issues that might apply (e.g. customs and import arrangements, guardianship arrangements).

Commentary Inset 2 – Examples of new uses of research data, samples and human biospecimens

Some examples of new research uses include:

i) a new project where existing data about how a government agency conducted a public consultation process for a major infrastructure development will be now be analysed (and supplemented with new data) to explore how community stakeholders respond to such consultations.

ii) a new project where the previously collected video samples were only analysed within a team will now be played to selected elite informants so their reactions and the ensuing discussion can be analysed;

iii) because of how rare/hard to collect the human biospecimens are they will be banked so as to be available to future projects.

Commentary about non-research uses of data, samples and human biospecimens can be found at 10.0. It should be noted that whether a new use will be considered as being for research purposes or for other purposes is likely to be based upon discipline, methodology or event project specific factors.

In some cases, these will be the same as the issues that applied to the original work. However, the body of regulation that applies to research is by no means static, and the new work may be sufficiently different to raise new regulatory issues. When planning for the reuse of data, use of banked data/human biospecimens or other retesting, a researcher is urged to

confirm what regulatory considerations may apply to the work, especially if more than 12 months have passed since the original work or if the new research is substantively different from the original work.

Back to contents

4.0 Banking and retesting/new use of data

This refers to situations where a researcher wishes to keep data beyond its initial use (whether in a personally identified, re-identifiable or non-identifiable form) for either its potential retesting/re-analysis for the same research project or for a new use (e.g. another research project)- See Commentary 2 sidebar for some examples.

Further information about the classification of data as personally identified, non-identifiable or de-identified can be found in Booklet 23 of the Griffith University-REM.

4.1 Personally identified data

In light of the considerations outlined at 2.0 and 3.0 of this booklet, in nearly every case the banking, retesting or the other reuse of data will only be considered ethically appropriate where appropriate consent for it is in place.

An exception to the above is where a human research ethics committee approves a waiver of the consent requirement (see Booklet 33 of this Manual).

Such banking, retesting or new use will either be subject to ethical clearance in its own right (see Booklet 2 of this Manual) or as a variation of a previously ethically reviewed project (see Booklet 6 of this Manual).

The degree to which the new work will be considered appropriate will depend upon a combination of factors:

1. Whether specified, extended or unspecified consent (see Commentary Inset 3) for the bank, retesting or new use is to be sought;
2. The relationship between the original and the banking, retesting or new use;
3. The degree to which the ethical principle of respect for persons means that specific consent for the banking, retesting or new use should be sought (see Commentary Inset 4);
4. The degree to which seeking specific consent for the banking, retesting or new use would place additional burdens upon the potential participants (especially if they are an 'over-researched population' or where approaching them for consent may be a source of risk);
5. The practicalities of obtaining specific consent for the banking, retesting or new use; and

Commentary Inset 3 – Specified, extended or unspecified consent

Consent for future uses of data, samples or human biospecimens can be sought at the point of the original collection / generation / extraction, via a supplementary mechanism, or via a completely separate consent exchange at a later date.

The form of this consent can be described as:

Specified – This is where the participants are given the specific details of the banking, retesting or new use and are asked to indicate their consent for this (see below).

Extended – This is where the participants are asked to consent to categories of future uses (e.g. We would like your permission to use your genetic material for other projects we conduct exploring other autoimmune disorders).

Unspecified – This is where participants are asked for permission to use their data, sample or human biospecimens for other research, without much indication of what that research might be.

See Commentary Inset 4 for guidance with the regard to the design of consent mechanisms for banking, retesting and new uses of data, samples or human tissue/biological material.

6. The likely benefits of the banking, retesting or new use.

When proposing banking, retesting or new use of data, the applicant/researcher (in response to the question(s) in the relevant ethics forms about consent or in her/his variation request) should present an argument (with reference to the above) to justify the use of any approach other than new work specific consent. In the absence of a compelling argument, the ethics reviewers are likely to insist on specific consent for the banking, retesting or new use.

Commentary Inset 4 – Designing consent mechanisms for new uses of research data, samples and human biospecimens

There is not a single approach to obtaining this consent that will be effective or correct for every project. There are a range of project, design, participant and contextual factors that should be considered and addressed.

Experience suggests that some potential participants will prefer some information about future uses, if only in general terms for even unspecified consent.

EXAMPLE: Any future use of your information will be non-identifiable, which means no one will be able to tell who you are and that it was you who shared the information with us. Future research that uses your anonymous information will have to adhere to ethical standards.

Furthermore, experience suggests that giving potential participants the ability to express their precise wishes minimises the likelihood that an individual elects not to participate just because they dislike one of the intended future uses of their data, sample, or tissue/biological material.

Providing individuals with a mechanism to express their wishes about future uses improves the likelihood the ethics reviewers will agree that consent for the new use has already been obtained, rather than expecting new consent will be obtained/a waiver of the consent requirement will be sought.

EXAMPLE: Tick the boxes below for any way that you don't want the recording of your performance used –

[] I don't want other researchers to be able to access and use the recording for their research.

[] I don't want my first name, suburb and age to be used to describe my sample.

[] I don't want the recording to be accessible to students who are studying to be a...

[] I don't want my sample to be included in a web-based resource.

In the example above, an individual could decide to participate in the first study and to agree to some of the unspecified future uses, but to indicate she doesn't want one of the listed options to occur (e.g. their sample being identified with their first name, age and suburb).

Conversely there may be situations where a researcher needs individuals to agree to all of the potential uses, so doesn't give them the kind of choice in the example above. In which case the researcher isn't concerned that some individuals might decide not to participate at all.

It is important for researchers to share their reflections on the above matters in their application for research ethics review.

4.2 Re-identifiable data

Re-identifiable data (otherwise sometimes referred to as coded data) is not in a form where the researchers can immediately associate specific data with an individual participant.

The manner in which the proposed banking, retesting or new use of the data will be handled will depend upon whether the researcher(s) have access to the code key that can be used to re-identify the data.

If the researcher has access to the key, then the proposed banking, retesting or the reuse of data should be handled as though it is identified information (see 4.1 of this Booklet). If the researcher does not have access to the key (including situations where the key no longer exists or the key is under the control of a third party), then the proposed retesting or the other reuse of data or materials should be handled as though it is non-identifiable information (see 4.3 of this booklet).

4.3 Non-identifiable data

Work with non-identifiable data is often the least ethically sensitive kind of retesting or other reuse. Nevertheless, the considerations outlined in sections 2.0 and 3.0 of this booklet may still apply. The re-use of archival, aggregated or otherwise non-identifiable data is common especially in some disciplinary areas.

Even though in some cases such work may not require ethical clearance, this is dependent on a combination of factors:

1. Does the retesting/new use involve more than negligible risk?
2. If the retesting/new use does involve more the negligible risk, did the consent for the original work cover the future use of non-identifiable data;
3. If the consent did not anticipate the future use, is the data sensitive or are/were the participants vulnerable;
4. The consent for the original work should not explicitly exclude such retesting or other new use – requiring the researcher to confirm the nature of the original consent; and
5. The nature of the new work and its relationship to the original work does not mean that the ethical principle of respect for persons demands that specific consent for the new work should be sought.

Otherwise, such research will either be subject to ethical clearance in its own right (see Booklet 2 of this Manual) or as a variation of a previously approved protocol (see Booklet 6 of this Manual). In which case, the question of project specific consent would be resolved using the test outlined in section 4.0 of this booklet.

Commentary Inset 5 – Reasons to have a custodian of banked data, samples or human biospecimens

Setting up such a custodian and the necessary governance arrangements might at first glance appear to be a distraction from 'actually conducting' research. There are however some distinct advantages to having a custodian in place.

1. Information about individuals can be replaced with a unique code, with the code key being only accessible to the custodian. Such an arrangement means that the participatory status of individuals can be concealed from the researchers – perhaps safeguarding the voluntary nature of participation and managing the risks.

2. The custodian will be able to process a participant's decision to withdraw their consent (i.e. the custodian will be able to destroy that individual's data, sample, or tissue/biological material, even though the researchers don't know to which individual the items relate).

3. If there is a situation where an individual participant needs to be debriefed about their results the custodian will be able to make arrangements for the debriefing to occur without necessarily having to identify the individual to the researchers.

These arrangements should be explained to potential participants (e.g. in the consent materials).

Research/databanks with the kind of arrangements discussed above should not be described as being non-identifiable, because the custodian can identify individual participants. The implication being that the custodian might need to identify individuals under the kind of circumstances described above. Furthermore a court, law enforcement or regulatory body might seek to compel the custodian to release identifying information. It may be appropriate to indicate that there are systems in place to protect the identity of participants.

Ideally the custodian will be independent of the researchers and not subordinate to them. The expectations in this regard should be seen as proportionate to the risks and ethical sensitivity of the work (i.e. the more personally and ethically sensitive the work and/or the greater the risks, the greater the expectation that the custodian be independent from the researchers).

4.4 Participant coded data

A variant of non-identifiable data (see 4.3) is participant coded, where individual participants create a unique code, which allows data to be matched across stages (e.g. repeated surveys over a long study where it is necessary for the researcher to be able to compare an individual's surveys over time, but not know who they are). To help participants to remember their code some researchers will suggest a formula, which will produce a code they will remember but which the researcher cannot crack. See Commentary 8 sidebar in Booklet 23 of the Griffith University-REM for further information about self-coding.

4.5 Databanks

Pages 32 -34 and paragraphs 3.1.40 – 3.1.62 provide ethical guidance with regard to the collection, , use, management and sharing of data for human research and Chapter 3.2 of the **National Statement** provides guidance about human biospecimens. In summary the content of this material includes the following matters:

1) Defining data.
2) Defining the confidentiality state of data that is stored.
3) The use of data that may not have originally been collected for research purposes.
4) The principles and guidance found in the **National Statement** apply to data collection by researchers, and by others whom they authorise to collect data or to whom they outsource the collection and then outlines the application of the principles to other databank situations:
    i. That the collection, storage and disclosure of data must adhere to the **National Statement.** This must be central to the design of the project and discussed in the application for research ethics review. A data management plan should be developed to make data collected and stored, accessible in such a way that they can be used in future research projects.
    ii. The research use of data must be in accord with the express wishes of the providers of the data (e.g. with regard to anonymity/identifiability).
5) The responsibilities of the custodians of the data with regard to the responsible and respectful use of the data, and in situations where it may be necessary to contact the participants (e.g. because of information that is of import to their health). Guidance is also provided with regard to situations where it may be necessary for there to be a custodian who is independent of both the data collectors and research users (see Commentary Inset 5 for a discussion about some of the advantages of such an arrangement).
6) Because some of the uses of banked data may be detrimental to the people to whom the data relates researchers and/or custodians may justifiably deny, or at least restrict, access to data where it is intended that the data be utilised for those purposes.
7) Paragraphs 3.1.23 – 3.1.39 provide guidance with regard to consent, including consent for the storage and/or future use of that data.

Back to contents

5.0 Banking and retesting/new use of samples

In this context samples relates to non-biological material obtained from or about humans. Examples include (but are not limited to): a recording of speech; motion capture of a person undertaking a physical task; samples of a school student's work; a finger print; and an audio-visual recording of a workshop.

The guidance provided at 4.0 for the banking and retesting/new use of data should also be used for samples. As is the case with data, a key factor for samples includes whether the samples are identified, re-identifiable or non-identifiable, and also includes consent requirements.

Additional ethical guidance about audio-visual matters, including still images, can be found in Booklet 36 of the Griffith University-REM and ethical advice on the use of computers in human research and can be found in Booklet 37.

Back to contents

6.0 Banking and retesting/new use of human biospecimens

The types of human biospecimens included within the scope of these arrangements can include (but is not limited to) organs (whether complete or in part), blood, bones, tears and other bodily fluids, genetic material and bodily waste.

The guidance provided at 4.0 for the banking and retesting/new use of data should also be used for human biospecimens. A key factor for biospecimens includes whether they are identified, identifiable or non-identifiable, and also includes consent requirements.

Additional ethical guidance about research with human biospecimens can be found in Booklet 32 of the Griffith University-REM and guidance with regards to genetic research can be found in Booklet 41.

Back to contents

7.0 Consent for banking and retesting/new use

At 4.0 of this Booklet, and in Commentary 3 sidebar there is discussion about situations where consent will be required for banking, retesting and new uses of data. This can equally apply to work with samples (see 5.0) and work with human biospecimens material (see 6.0).

Provisions 2.2.14 to 2.2.18 of the **National Statement** discuss consent that is specific, extended or unspecified. In the case of banking, retesting a new use of data, samples and biospecimens this would equate to either:

i) testing only for the specific project and as described in the consent materials;

ii) additional testing for the specific project, new phases of the project, and in the "same general area of research" which the **National Statement** refers to as extended consent; or

iii) unspecified future research.

Where only specified consent has been obtained, new consent would be required prior to any retesting or other new use of the data, samples or biospecimens. Alternatively a waiver of the consent requirement could be sought from a HREC (e.g. because it is impossible to seek new consent and there is public interest justifications for doing the new testing/work). Booklet 32 of this Manual discusses the issue of consent and work with human biospecimens and Booklet 33 discusses how to obtain a waiver of the consent requirement.

Because of the provisions of these sections of the *National Statement,* a researcher conducting a project where they consider there is a reasonable possibility of retesting/new uses should consider an explicit discussion of this issue in the consent materials for the project – thus seeking consent for this retesting and increasing the chances the new work will be considered ethically appropriate.

Preferably, there should be an option within the consent process where the participant can indicate their decision about retesting/new uses (i.e. enabling them to exercise and express two discrete decisions on the current project and the retesting/new uses). Obviously the more specific the described retesting the greater the chance the ethics reviewers will accept the consent for a particular new project (even if the work is very sensitive), but the more limited the scope will be for its use for other projects. This is often achieved with a tick box within the consent materials.

Refer to Booklet 22 of this Manual for more about devising consent mechanisms.

Back to contents

8.0 Withdrawal of consent

In most cases if the data, samples or human biospecimens are being stored in an identified or re-identifiable form, there must be a mechanism by which an individual or their next of kin (if applicable) can withdraw their consent. If consent is withdrawn the corresponding data, samples or biospecimens must be appropriately destroyed.

The consent materials should explain whether consent can be later withdrawn, the mechanism to do this, and how the data, samples or human biospecimens will be appropriately destroyed. In the case of biospecimens researchers should be mindful of any relevant cultural beliefs, practices or protocols that may need to be respected and followed.

In situations where there is a custodian managing the bank they may be the only person who can identify and destroy the data, sample or human tissue/biological materials (see Commentary Inset 5). If the data, sample or biospecimens are in a non-identifiable form it may not be possible to action a withdrawal of consent. Where relevant, this must be discussed in the consent materials.

Back to contents

9.0 Third party agreement

In addition to ethical clearance and whatever consent requirements may apply (see 11.0 of this Booklet), some proposed banking, retesting or new use of data, samples of human biospecimens will require the agreement or approval of third parties (such as a government agency or private organisation). This is most likely to be the case when the agreement or approval of third parties was required for the original work.

The researcher should confirm this prior to seeking ethical clearance for the new work (including seeking a variation of an existing clearance), and discuss the situation in their proposal. In some cases, third parties will not authorise/approve the conduct of the work before the University has ethically reviewed it. In such cases it is appropriate for the researchers to indicate that they know the organisation will need to approve the banking, retesting or new use, the organisation requires prior review by the University, the researcher will not commence the new activity until it has been received from the University and the organisation, and the researcher will provide a copy of the approval once it has been received.

Refer to Booklet 19 of this Manual for more about the approval or agreement of other bodies.

Back to contents

10.0 Non-research uses

The new use of data, samples or human biospecimens may not be directly related to the research or considered an output from the research. This is most common with samples (e.g. the artwork produced by school students during a project may be published to a website, or the language samples from participants might be added to a publically available repository).

The same approach should be taken to these new uses as would be taken to a new research use. Considerations of matters such as identifiability, risk and consent also apply to non-research uses.

Back to contents

11.0 Research ethics review

The material at 4.0, 5.0, 6.0 and 7.0 of this Booklet can assist a researcher to determine whether a proposed banking, retesting or new use of data, samples or human tissue/biological materials must be submitted for prior research ethics review, and to identify some of the ethical considerations (such as consent requirements) that need to be addressed.

The creation of a new bank for data, sample or human biospecimens must be submitted for research ethics review. See Booklet 2 of the Griffith University-REM for more about research ethics review. After consulting this material a researcher may wish to consult a Research Ethics Adviser (see Contacts) in their area for advice.

Back to contents

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).

Manager, Research Ethics and Integrity

Tel: (07) 373 54375
research-ethics@griffith.edu.au

Policy Officer, Research Ethics and Integrity

Tel: (07) 373 58043

Research Ethics Systems and Support Officer

Tel: (07) 373 5 2069

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

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