BOOKLET 11

Griffith University Research Ethics Manual

Register of approved procedure

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GRIFFITH UNIVERSITY

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1.0 Introduction

In their review of proposed protocols, ethics committees can often find themselves reviewing the utilisation of the same testing procedures, research design features, etc., across many different projects. This can be a laborious exercise for the ethics committee because it can feel as though it is providing the same advice and having to seek similar clarifications or amendments many times over.

By the same token, it is recognised that few things are more frustrating for applicants than to find that the same testing procedure or research design feature receives a slightly different treatment each time it is submitted for ethics review.

To a certain extent, such duplication and inconsistency is unavoidable. Very similar procedures will be used across many projects and between different areas of the University. Similarly, the membership of ethics committees changes, the regulatory framework is constantly evolving, and a committee's experiences with one situation can colour their approach to subsequent submissions. The University nevertheless considers these to be issues worthy of management. There should be an approach to this repetition that provides an efficient alternative for applicants and the ethics committees. The mechanism should also seek to minimise inconsistency, so changes in position reflect a genuine change in policy. Such an approach was advocated in the Research Ethics Review 2003, which recommended the adoption of a GU Register of Approved Procedures.

Even though *Chapter 5.5 of the National Statement on Ethical Conduct in Human Research (2023)* was primarily discussing 'multi-institution' research, that chapter calls for institutions to minimise duplication in ethics review could equally be applied to the circumstances described above.

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2.0 What can be listed in the Register?

Essentially any test, exercise, data collection tool, or other research design element can be submitted for inclusion in the Register.

A University school, research centre or a team of researchers normally submits items for inclusion in the Register, though an individual researcher can also submit an application. The primary consideration for applicants is

whether the registered procedure is likely to be utilised by more than one project, and so there is some advantage in its listing in the Register.

Below are some examples of items that could be submitted for inclusion in the Register, but the full range of items that could be submitted extends far beyond the list below.

Client satisfaction survey – A data collection tool that explores the experience of customers during a purchase/service/enquiry interaction with a commercial provider, public sector agency, etc. In addition to the instrument itself, the application for inclusion in the Register could discuss the administering of the survey whether face-to-face, over the phone, email and/or online, the informed consent process and/or the handling of data.

A specific non-invasive scan – The use of a particular type of medical scanner might be included in the Register. Previously a listed scanner (DXA) has referred to a scanner located in a University facility where the calibration, safety testing and qualified operation of the testing equipment were elements of the Register application. It could however be valid to submit a category of scanner for inclusion in the Register where matters such as safety testing and the expertise of the operator would be features of any subsequent project application that followed the registration of the approved procedure.

Computer-based reaction time test – Colour words will be displayed on the screen where the word and the actual colour of the letters match (e.g. the word 'Blue' where the colour of the letters is blue), but a small proportion of the words and letter colouring doesn't match (e.g. the word 'Red' where colour of the letters is green). The computer will track whether the selection is correct, reaction time and whether what was displayed matches or was a mismatch.

Image journal recorded by participants – Participants will take photographs with a provided digital device and will then discuss the images and their significance with a researcher. The approved procedure will include the instructions to the participants with regards to the permissions of any persons photographed, respect and appropriateness of the images taken, how the collected images and stories will be analysed/displayed.

Consent strategy for the observation of people in a public space – The approved procedure would be for a workable consent strategy when collecting data in a public space with large number of people moving through the area.

Medical history screening test – A screening questionnaire to assist a research team with the identification of persons who are likely to have an increased risk of harm. Even though limited expertise/training is likely to be needed to administer the test, depending upon the nature of a research project where the test is used, a final assessment of the risks for individual participants may have to be conducted by someone with medical training.

Researchers who wish to discuss whether an item could be usefully included in the Register should discuss this with their local Research Ethics Advisor or the Office for Research (see Contacts).

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3.0 Listing an item in the Register

The listing of an item on the Register will normally occur outside the context of an application for ethics clearance for a specific project. Instead an application for the inclusion of an item in the Register will normally be made by a centre, school or group of researchers to address a specific need (e.g. because they can anticipate a sequence of upcoming project proposals including the item).

On some occasions however, an applicant will seek approval for the inclusion of an item in the Register at the same time as seeking ethics clearance for an individual project.

Requesting the inclusion of an item in the Register is sought by completing and submitting the ethics review form that is appropriate to the risks and ethical sensitivity of the item. The fact that the application is seeking the registration of an item does not alter the required review pathway. See Booklet 2 of the Griffith University REM for more about ethics review at Griffith University.

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Commentary Inset 1 – Matters to cover in a Register application

Generally, all applications to include a procedure in the Register will discuss:

1) the nature of the procedure, test, etc. and what participants will experience;

2) the associated risks and the strategies to address or otherwise mitigate those risks; and

3) text about the procedure that will be included in the informed consent materials for projects that utilise the registered procedure.

Depending upon the nature of the procedure it may be necessary to also provide:

1) any certification, calibration or other documentation that is a regulatory requirement for the procedure;

2) text about the procedure that will be included in the recruitment materials (e.g. to enable individuals to self-screen if they are especially vulnerable to the risks associated with the procedure); and

3) copies of the tests (e.g. a copy of the questionnaire).

There are definite pros and cons for including very specific details about the use of the registered procedure. On one hand it may reduce the matters research teams have to replicate for projects that use the registered procedure. On the other hand, too much information may actually limit the usefulness/relevance to may projects that might have otherwise have incorporated the procedure.

4.0 Accessing and referring to the Register

The Register can be accessed by visiting the Griffith University research ethics website, select 'human research' and then select 'Register of Approved Procedures'.

The online Register provides the title and reference number, as well as a short description of what has been approved for inclusion in the Register. Further details about a registered item can be sought by contacting the research ethics area (see Contacts).

When designing a project that will involve a registered item, the researcher should refer to the detail of the item to see what the relevant ethics committee approved.

When completing the form for ethics clearance for the protocol, the applicant should refer to the registered item, indicate the degree to which the various elements of the procedure will be directly followed or the degree to which the described protections and precautions are relevant to their use in the specific project (see Commentary inset 1 for more).

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5.0 The register and the ethics review pathways

It is generally the case that where a project that is predominately based upon a registered item (see Commentary inset 2 for more) that proposed project will require no more than a level 2 expedited ethics review (even if the work would otherwise require full review by the Griffith University HREC.

When considering a proposed protocol that includes a registered item, the reviewers should not revisit the specifics of the registered item, but only consider project-specific factors (such as the specific context in which the registered item will be used, whether the potential participant pool may be at particular risk of harm from the registered item, etc.).

For example – A registered item is a treadmill based fitness test, and a project involves persons who are recovering from heart surgery and the research team will be using the registered item. In this case, important considerations are qualified screening of the pool, medical supervision during testing, and access to emergency care

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Commentary Inset 2 – Is a project predominantly based upon a Registered procedure?

Some procedures do not relate to the collection of data, instead perhaps relating to the recruitment/screening of potential participants, informed consent arrangements, or perhaps the provision of feedback to participants.

When a registered item does relate to data collection, the question of whether the project qualifies for E2 review is based upon a consideration of the following:

Do any additional data collections procedures (i.e. those beyond the scope of the activities described the registered procedure) involve either: i) more than a low risk of harm; or ii) matters which the National Statement specifies must be reviewed by a HREC.

Even if Griffith University HREC review is required, the approach described in 5.0 will be used for the review of matters relating to the registered procedure.

6.0 Ethical conduct reporting

All Griffith University ethics clearances are subject to the University's monitoring arrangements (as discussed in Booklet 5 of the Griffith University REM). These monitoring arrangements also apply to approved procedures.

The primary purposes of this monitoring of registered procedures are:

i) collating the experience from projects that have utilised the approved procedure to identify any difficulties/concerns that may prompt either a change to the registered procedure or require some reflection on the status of the registration (the person who holds the current ethics clearance for the registered procedure may need to consult with the Office for Research to identify the projects which utilised the registered procedure during the period to be covered by the ethical conduct report);

ii) the report provides a useful prompt for the registrants to consider whether any changes are required to the registered procedure and/or the ethics clearance.

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7.0 Variations, extensions and renewals

The University has a variation mechanism for making modifications to existing ethics clearances. Keeping the ethics clearance current and in sync with the project as it is actually being conducted, and receiving feedback with regards to planned changes to a project are the purposes of the variation mechanisms. These arrangements are discussed in Booklet 6 of the Griffith University REM.

The same arrangement with regards to extensions, renewals and other modifications also apply to procedures registered as per this Booklet.

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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 Officer

Tel: (07) 373 5 2069

Ethics Administration Officer

Tel: (07) 555 29253**On the ethics website 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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