1.0 Introduction

This Booklet discusses research ethics review of human research at Griffith University and should be read in conjunction with Booklet 1 of the Griffith University Research Ethics Manual (GUREM). This Booklet does not replicate the content of Booklet 1. Before designing a project and definitely before submitting an application for research ethics review researchers should consult 2.0-3.0 and 7.0-11.0 of GUREM Booklet 1.

The definition of human research can be found at 2.0 of Booklet 1 of this Manual, discussion about what work requires research ethics review can be found at 3.0 of Booklet 1, with discussion about work that is either outside the scope of the University's human research ethics arrangements or otherwise exempt from review can be found in Booklet 17 of this Manual.

Griffith University has established a proportional review framework (with four levels of central review) that are described at 10.0 of Booklet 1 of the GUREM. These four levels of review match the paperwork, review process and timeframe to the risk and ethical sensitivity of a proposed project.

The process of obtaining prior ethical clearance for a proposed research project is a fundamental component of the Australian approach to human research. The University has established human research
ethics arrangements and resources to assist and support researchers in obtaining ethical clearance for their research, with the intention of facilitating excellent and ethical research.

This booklet of the GUREM is intended to provide an introduction to the research ethics review process and provide some useful advice to users of the University's human research ethics arrangements.

2.0 National guidelines

The national guidelines for the design and research ethics review of human research can be found in the National Statement on Ethical Conduct in Human Research (2007 – Updated 2018).

In the Purpose, scope and limits of this document section of the document the National Statement provides a definition of research*, human research and defines what work requires research ethics review.

* Arguably a more helpful definition of human research can be found in the Australian Code for the Responsible Conduct of Research (2018) p5.

Griffith University's interpretation and overview of the University's implementation of the Australian arrangements can be found in Booklet 1 of the GUREM and across the other booklets of this Manual.

3.0 About research ethics review

Research ethics review at an Australian university involves a human research ethics committee (see 3.1) or delegated review body (see 3.2) considering the degree to which the design of a proposed project addresses the core principles articulated by the National Statement (see 8.0 of Booklet 1 of the GUREM), addresses any specific guidance in the National Statement, and the degree to which the proposed work can be considered to be ethically justifiable.

Since the inception of the idea of research ethics review of planned research it has involved persons outside of a research team reflecting upon the ethical implications of individual projects.

An important objective of Griffith University's research ethics review arrangements is facilitating ethical research. The same cannot necessarily be said of the review arrangements of other institutions (Allen & Israel 2017).

3.1 Human research ethics committees (HREC)

Section 5 of the National Statement describes the membership and functioning of a human research ethics committee (HREC). Research that involves more than a low risk of harm must be reviewed by a HREC.

The National Statement also specifies situations where the design features, potential participants and circumstances of a planned project means that the work must be reviewed by a HREC (e.g. such as researchers seeking access to personally identified health information without the prior consent of the individuals named).

See Booklet 9 of the GUREM for more about risks in human research and Booklet 23 for more about privacy.
The Griffith University Human Research Ethics Committee (GUHREC) was established and operates as per NS s5. The GUHREC is registered with the NHMRC and the committee's registration number is EC00162.

Meeting and submission dates for the GUHREC, the committee’s constitution and other information about the committee can be found on the GUHREC web page. Contact details for the GUHREC Chair, Deputy Chair, Secretary and other contacts (such as the Research Ethics Advisers who serve on the GUHREC) can be found on the Research Ethics Advisers web page.

### 3.2 Delegated review

Since 2004 Griffith University has operated a proportional research ethics review arrangement that matches the review process and timeframe, and the paperwork, to the risks and ethical sensitivity of a proposed project. A central element of these research ethics review arrangement is the online proportional review form.

Details of the proportional review pathways can be found at 5.0 of this booklet. An update of this booklet will be produced when the new online form becomes generally available.

Chapter 5.1.18-5.1.23 of the National Statement articulates the national policy basis for research ethics review arrangements that are delegated to bodies other than HRECs.

### 4.0 A constructive approach to research ethics review

The primary objectives of research ethics review at Griffith University is to provide applicants with constructive/collegiate feedback and to facilitate the conduct of excellent ethical research.

Research ethics review does also have the objectives of ensuring that the projects adhere to the National Statement, Griffith University policy and other relevant guidelines/regulations. This includes ensuring that there is due regard for the rights, welfare and dignity of participants. Nevertheless, Griffith University's ethics reviewers strive to ensure that the feedback arising from the review of a proposed project is clear, constructive and facilitates the applicants being able to proceed with the project.

Because of the approach taken to research ethics review by Griffith University there is a reciprocal obligation for applicants to approach her/his ethical responsibilities and the research ethics review process in a reflective way, with integrity, good will and in good faith.

The 2018 update to chapter the National Statement with its discussion of the elements of ethical design provides a useful way to think about the design of a project. These are also the matters considered by research ethics reviewers. See 8.0 of Booklet 1 of this manual for more.

See 11.0 for some Hints and Tips with regard to the research ethics review process, 6.0 (Why, who, what and to what end?) of Booklet 1 of the GUREM about a useful approach to describing a project, and Booklet 3 of the GUREM for more about the responsibilities of researchers.
5.0 Review pathways at Griffith University

At 10.0 of Booklet 1 of the GUREM there is a summary of the University’s ordinary research ethics review pathways. This section expands upon the summary in Booklet 1 and also discusses some of the special pathways and arrangements that complement those review pathways.

5.1 OUTSIDE THE SCOPE

Griffith University defines some work as falling outside the scope of the University’s human research ethics arrangements (and so not requiring human research ethics review). Some of this work is very easy to recognise as being outside the scope (such as animal-based scientific work). However some other work requires reflection upon additional matters and uses specific criteria before it can be determined whether the work is ‘outside the scope’.

These categories are:

i) Evaluation of Griffith University course or service*;
ii) Work conducted while on practicum; and
iii) Teaching and learning activity.

The criteria used to assess whether work falls outside the scope of the University’s human research ethics arrangements are discussed at 3.0 of Booklet 17 of the GUREM.

The University’s online proportional review checklist is available via the Research Information Management System (RIMS). The RIMS includes an optional tool that researchers can elect to use to confirm whether their planned work falls outside the scope of the University’s human research ethics review arrangements. If RIMS indicates the work may be ‘outside the scope’ (and so not require research ethics review) the submitted checklist system will be checked by a staff member in the Office for Research. The staff member may request further information and will confirm by email if the research is exempt from review.

# In the case of such evaluations the work will still need to be authorised by the relevant Head of Element.

5.2 EXEMPT FROM RESEARCH ETHICS REVIEW

Griffith University has decided to exempt some human research from research ethics review. Rather than exempting from review all work of a particular type (e.g. work with an artistic/creative output) individual projects must be tested against specific criteria before it can be considered exempt from research ethics review.

The types of work that might be exempt are:

1) Work that only involves existing data;
2) Work only that involves the analysis of existing documents;
3) Evaluative practice, quality assurance or audit;
4) Final output of the research will be creative (e.g. photographic exhibition, theatrical or music performance, novel); and
5) Output of the research will be journalistic (e.g. a news story or a documentary).
The criteria used to assess whether a project is exempt from review are discussed at 4.0 of Booklet 17 of the GUREM.

The University's new online proportional review checklist is available via the Research Information Management System (RIMS). The RIMS includes an optional tool that researchers can elect to use to confirm whether the planned project is exempt from research ethics review. If planned work is deemed to be exempt from research ethics review the system will offer a certificate that can be printed confirming the same.

Importantly work that is exempt from research ethics review must still adhere to the University’s human research ethics guidelines (e.g. with regard to such matters as consent, the privacy of individuals and management of risks).

5.3 PRIOR REVIEW (PR)

Research that has already been reviewed by another research ethics committee qualifies for a special review pathway at Griffith University.

The University's new online proportional review checklist is available via the Research Information Management System (RIMS). The RIMS includes a short form for prior review – including uploading the application form submitted to the other research ethics committee and the review decision of that committee.

In most cases submitted prior reviews are considered administratively by a member of the Research Ethics & Integrity team. Ordinarily prior review applications are considered in less than 3 days.

Refer to Booklet 8 of the GUREM for more about the operation of Griffith University's prior review arrangements.
5.4 RESEARCH THAT REQUIRES HREC REVIEW

The University’s new online proportional review checklist is available via the Research Information Management System (RIMS). The RIMS includes a test to confirm whether a planned research project involves matters that the National Statement directs must be reviewed by a HREC.

5.5 RISK ASSESSMENT

Proposed projects that are not ‘outside the scope’ (see 5.1) or exempt (see 5.2), or do not qualify for review via the PR pathway (see 5.3), and which have not already been assessed as requiring HREC review (see 5.4), are subject to a risk assessment. This risk assessment is conducted as a step within RIMS.

Inset One (Continued from previous)

The strategies to conceal the identities of individual staff/graduates, hotels and universities, as well as the subject matter mean that the project if likely to qualify for review via the NR pathway.

NR EXAMPLE THREE – INTERVIEWS

A health researcher plans to interview key informants about the design and implementation of a new health program. He is interested in the process of evaluating programs operating in other jurisdiction, client needs assessment, ministerial statements, media commentary, and Treasury analysis.

All of the potential interviewees are current or retired senior bureaucrats, members of parliament, or public commentators. Consequently they are well placed to make informed decisions with regard to risk, privacy and consent. The matters being explored are to some extent already on the public record or accessible to the general public.

In light of the above, the project is likely to qualify for review by the NR pathway.

Refer to Booklet 9 of the GUREM for more about Griffith University’s approach to risks in human research.

5.6 NEGLIGIBLE RISK REVIEW (NR).

Research that involves no more than a negligible risk of harm may qualify for an administrative research ethics review. This work project must also meet a University eligibility test, to confirm the absence of specific significant ethical concerns.

The University’s new online proportional review checklist is available via the Research Information Management System (RIMS). The checklist includes a test to confirm whether a project qualifies for review via the NR pathway and to submit the application for review.

The submitted form is generally considered by a member of the Research Ethics & Integrity team in the Office for Research (see Contacts). Typical processing time for NR applications is around 5 work days. See Commentary Inset One for three example projects that might qualify for review via the NR pathway.

5.7 EXPEDITED RESEARCH ETHICS REVIEW LEVEL 1 (E1)

Research that involves no more than a low risk of harm may qualify for an executive research ethics review by the Chair or Deputy Chair of the GUHREC. This project must also meet a University eligibility test, to confirm the absence of significant ethical concerns.

The University’s new online proportional review checklist is available via the Research Information Management System (RIMS). The checklist includes a test to confirm whether a project involving no more than a low risk of harm qualifies for review via the E1 pathway and to submit the application for review.
Typical processing time for E1 applications is around 5-7 work days. See Commentary Inset Two for three example projects that might qualify for review via the E1 pathway.

5.8 EXPEDITED RESEARCH ETHICS REVIEW LEVEL 2 (E2)

Research that involves no more than a low risk of harm may qualify for research ethics review by a panel of the GUHREC. This project must also meet a University eligibility test. This test confirms the ethical dimensions that disqualified the work from via the E1 pathway (see 5.7) are mitigated by the project’s design.

The University's new online proportional review checklist is available via the Research Information Management System (RIMS). The checklist includes a test to confirm whether a project involving no more than a low risk of harm qualifies for review via the E2 pathway and to submit the application for review.

Research ethics review applications relating to non-health research involving Aboriginal and Torres Strait Islander peoples or issues (see Booklet 30 of the GUREM) are considered by a four person panel1 of the GUHREC. Other E2 review applications are considered by a three person panel2 of the Committee.

Inset Two – Example projects that might qualify for review via the E1 pathway - Below are very short descriptions of three projects that might qualify for executive review via the E1 pathway. It is important to note that the specifics of individual projects will determine whether the NR or a higher level of review is appropriate. These projects correlate to the three NR projects discussed in Commentary 01, to highlight some of the triggers between NR and E1.

E1 EXAMPLE ONE – SURVEY

Unlike the NR survey, the researchers will know the identity of respondents, but individuals will not be identifiable in any publications or reports arising from the research.

Factors that are likely to be determiners of whether review via the E1 pathway is appropriate include (but are not limited to): the risks associated with the research (and the sufficiency of the strategies to negate/minimise or manage those risks); the participation of persons aged under 18; the exposure of illegal behaviour; if the research is conducted outside Australia; the involvement of Aboriginal and Torres Strait Islander People.

E1 EXAMPLE TWO – FOCUS GROUP

A research team plans to conduct a focus group with current Humanities School students discuss how social media activities and apps on smart phones/tablets have been embedded for the time into a course (reflecting on value, advantages, frustrations and suggestions). The collected data will be used to inform/refine future offerings of the course and as the basis for a conference we paper/journal article.

Typical processing time for E2 applications is around 10-15 work days. See Commentary Inset Three for three example projects that might qualify for review via the E2 pathway.

1 As per footnote2 with an additional member who is an Aboriginal or Torres Strait Islander member of the GUHREC.

2 The panel is made of the Chair or Deputy Chair of the GUHREC, an external of the GUHREC and a Research Ethics Adviser on the GUHREC.
5.9 FULL REVIEW VIA THE GUHREC

Only human research (that is not outside the scope or exempt from research ethics review) which hasn’t already been reviewed by another research ethics committee (see PR) which doesn’t qualify or review via the NR, E1, E2 or pathways needs to be submitted for full review (FR) by the GUHREC. In some cases proposed project might involve components where HREC review is required by the National Statement (see 5.4) or because of the risks associated with the project (see 5.5).

Even in situations where a researcher suspects full review is required it is recommended practice to use the proportional review checklist to confirm that full review is indeed required. The University’s online proportional review checklist is available via the Research Information Management System (RIMS).

Full review applications are submitted utilising the Human Research Ethics Application and are considered by a monthly meeting of the GUHREC.

Inset Two (Continued from previous).

The researchers are conscious that students may feel some pressure to participate and may believe that their comments might impact on their grades. So in addition to providing an assurance that participation is anonymous, the team decides that the focus group session will be facilitated by a staff member who is not currently teaching/evaluating the students. The attendance sheet and collected data will be embargoed and not accessible by the other members of the team until after the grades for the semester have been issued. This will be explained in the recruitment and consent materials.

The researcher includes in the focus group instructions to participants to not repeat to third parties any comments made within the focus group.

E1 EXAMPLE THREE – INTERVIEWS

A health researcher plans to interview frontline allied health and nursing staff about the practical delivery of a new health program. He is interested in whether staff perceive the program to be working, the feedback staff have received from clients, and whether the program enjoys the support of the staff.

The researcher appreciates that if the identified comments of individual staff members became known to the relevant supervisor/manager there could be professional risks to the staff member. As such personal identifiers will not appear in the reports/publications arising from the research (including internal identification by inference). In some cases it may be necessary to conceal the participatory status of individuals (i.e. so the supervisor/manager will not know whether an individual staff member has participated).

The arrangements with regard to the above should be described in the application for research ethics review, in the consent materials, and possibly also in the recruitment materials.

5.10 SPECIAL REVIEW PATHWAYS

In addition to the tools and ordinary review pathways discussed above the University has established the following special review arrangements.

5.10.1 Course clearance arrangements

The course clearance arrangements enable a course convenor to obtain an umbrella clearance for short-term research project undertaken by cohorts of postgraduate coursework or undergraduate students. The eligibility criteria and other details can be found in Booklet 20 of the GUREM.

The proportional review form that is accessible via RIMS includes a short ‘course clearance review’ sub-form that course convenors can use to apply for umbrella clearance.
5.10.2 Register of approved procedures

Griffith University has arrangements where a school or research team can register a procedure (such as a DXA scan). Once the procedure has been approved future projects utilising that procedure need not repeat information from the procedure and the project will probably qualify for expedited research ethics review. See Booklet 11 of the GUREM for more about the approved procedures arrangements.

5.10.3 External research conducted at Griffith University/with the participation of the University’s students/staff

Griffith University has special review arrangements in place for situations where external researchers (e.g. researchers from another University) want to conduct research at Griffith University and/or with the University’s students/staff. This does not apply to circumstances where a Griffith University researcher is a member of the team – in which case the prior review arrangements are likely to be appropriate (see 5.7).

A sheet about the external research review arrangements and the application form can be found on the [forms page of the University’s human research ethics pages](#).

Inset Three – Example projects that might qualify for review via the E2 pathway - Below are very short descriptions of three projects that might qualify for panel review via the E2 pathway. It is important to note that the specifics of individual projects will determine whether the E2 or full review by the GUHREC is appropriate. These projects correlate to the three E1 projects discussed in [Commentary 02](#), to highlight some of the triggers between E1 and E2.

**E2 EXAMPLE ONE – SURVEY**

Unlike the E1 survey, third parties may be able to associate comments/data with individual coaches/sports people (even if only because they are the colleague of the participant and can infer their identity), but potential participants were forewarned of this, consented to the possible identification, and they were provided with drafts of the relevant excerpts of the research output.

Factors that are likely to be determiners of whether review via the E2 pathway is appropriate include (but are not limited to): the risks associated with the research (and the sufficiency of the strategies to negate/minimise or manage those risks); …… the exposure of illegal behaviour; whether the participants can edit how their comments/data is reported (as as to further conceal their identity).

**E2 EXAMPLE TWO – FOCUS GROUP**

A researcher plans to conduct a focus group with current sworn officers from the Queensland police. The topic for discussion is the practical value of the criminology degree offered by four Queensland universities.

The data being collected does not relate to individual offices, cases or incidents. Even if the specifics of such matters are shared, the researcher will only make very general notes so that it can be used as illustrative example of where the degree had proven directly helpful, generally helpful, neither helpful nor unhelpful, generally unhelpful, or incorrect/dangerous.

Despite the above, the researcher is conscious of the professional, legal and social risks so is careful about de-identifying all the data collected (including considering the potential for identification by inference by peers and colleagues). He also includes in the focus group instructions to participants to not repeat to third parties any…… comments made within the focus group.

Without the precautions discussed above the project would probably require full review by the GUHREC.

Continued overleaf
6.0 The elements of ethical project design/the ‘life cycle’ of a project

As was discussed at 4.0, the 2018 update to Chapter 3.1 of the National Statement introduced the concept of the elements of a project (sometimes referred to as the ‘life cycle’ of a project).

The seven elements described by National Statement Chapter 3.1 are:

- Element 1: Research Scope, Aims, Themes, Questions and Methods
- Element 2: Recruitment
- Element 3: Consent
- Element 4: Collection, Use and Management of Data and Information
- Element 5: Communication of Research Findings or Results to Participants
- Element 6: Dissemination of Research Outputs and Outcomes
- Element 7: After the Project

These matters are discussed further in 8.0 of Booklet 1 of this Manual. The seven elements are introduced the ‘key questions’ are provided, reflection prompts for Griffith University researchers suggested, as well as a link to the relevant GUREM booklet that discusses considerations/University guidance in more detail.

7.0 Review outcomes and responding to review feedback

It is important for applicants to have a clear understanding of how review outcomes/feedback are communicated at Griffith University and also the preferred approach to responding to the reviewers.
The outcome of Griffith University research ethics reviews are sent by email to all the named researchers for the application (see Commentary Inset Four) - depending upon what the researchers specified when the application was submitted.

### 7.1 CATEGORIES OF REVIEW OUTCOMES

Review outcomes can be categorised as being either:

- **Full/final approval** – No changes, extra information or clarifications are required and the project can be immediately commenced.

- **Conditional approval** – Some textual or administrative changes/documentation is required (see Commentary Inset Five for some examples). The project can be immediately commenced on the strict understanding that the stipulated material is provided to the Office for Research for the file. Researchers should respond to the review feedback via an email that responds to each item of the feedback notification.

- **Provisional approval** – Even though the reviewers were supportive of the project some changes, clarifications, new documentation of other more substantive matters are required (see Commentary Inset Six for some examples). Researchers should respond to the review feedback via an email that responds to each item of the feedback notification. The project cannot be commenced until the researchers provide a response and the Office for Research provides the researchers with authorisation for the commencement of the project.

- **Resubmission** – The number and/or significance of the items requiring attention are such that the reviewers believe that the application must be revised and resubmitted for research ethics review.
**Application returned** – (Even though this is not strictly speaking a review outcome it is included here for completion.) The Office for Research has not distributed the application for ethics review because of the number/significance of the issues/omissions. Rather than the researchers waiting for the review decision (which is very likely to be a **Provisional**).

For **Application returned** or **Resubmission** outcomes the Office for Research will provide feedback on recommended changes to minimise delays or problems in the subsequent review.

### 7.2 EXAMPLES OF REVIEW FEEDBACK

The following provides some examples of the review feedback applicants may receive (this list is not intended to be exhaustive):

**i)** suggested amendments or changes to the research design, which would normally discuss the matter that the amendment/changes is intended to manage or address⁴;

**ii)** provision of, or amendments to the provided, consent materials (generally to include features discussed in Booklet 22 of the GUREM);

**iii)** the applicants sharing their reflections on a particular matter with regard to the research design and conduct of the project⁴;

**iv)** provision of documentation (such as the recruitment flyer/materials), external approvals (such as from a collaborating organisation) or other supporting document (such as a letter of support from someone/body that has agreed to assist with recruitment);

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⁴ If the feedback item does not provide a **National Statement** or **GUREM reference** this should be available if requested.
v) a statement of any limitations of the approval (e.g. the reviewers might decide to only approve the first stage of a project and request that the researchers come back with a report [such as the actual experience with regard to the risks] before the reviewers will authorise the subsequent stages of the project;

vi) a statement on any special factors that made it possible for the reviewers to grant the work ethical clearance (e.g. the involvement of a research team member who has a specific expertise – which might foreshadow a suspension of the clearance if that member leaves the team/isn’t available); and

vii) matters that are tagged as being “not a condition of ethical clearance” (for example the reviewers might note a particular methodological matter that was not considered significant enough to be an ethical concern [vis-a-vis the ethical principle of merit and integrity] but the reviewers felt it might be helpful to draw to the attention of the applicants

Inset Six – Examples of provisional approval items - As discussed at 7.1 provisional approval is a category of research ethics review outcome where there are matters that need to be clarified/changed before the project can be commenced. Below are some examples of provisional approval outcomes:

The response to question E1 does not provide sufficient information about why the research is being conducted, the objectives, and how a review of the literature/prior work has informed the design of the project.

The response to question E2 only discusses the relevant expertise of the HDR candidate but does not discuss the supervisor(s).

Clarification of who will be conducting specific elements of a project, their expertise, and/or the training they will receive.

Clarification of the degree to which consultation with the community has informed the design of the project, what community approvals have been received, agreements reached with regard to the flow of benefits, and future use of the collected data/publications arising from the work.

With regard to identification of possible personal distress/family difficulties arising from participation in the research, the applicants providing details of appropriate sources of counselling or other support where the researchers will refer participants.

Providing further clarification in regard to the recruitment mechanism (e.g. how will potential participants be identified, initially approached and then recruited).

Clarifying whether the employer will know the participatory status of individuals. This should be discussed in the consent (and possibly the recruitment) materials.

Clarifying whether the potential participant pool includes persons aged under 18. Applicants should consider the guidance material in Booklet 24 of the GUREM.

Describing how the potential participant pool will be screened, who will conduct the screening, and what interested potential participants will be told if they are screened/excluded.

Justifying why the selected consent process is the appropriate/respectful mechanism for seeking the voluntary and consent of the potential participants.

Explaining how the collected data will be analysed.

Describing how the results of individuals/groups will be returned to them.

Describing how the overall results will be provided in an appropriate e.g. lay language and timely manner to participants.

7.3 FURTHER INFORMATION, RESOURCES AND ASSISTANCE

The other booklets of this manual provide essential guidance and resources with regard to the ethical design of a human research project. The booklets also provide links to relevant internal and external resources and guidelines. It is useful practice for applicants to reference this material so as to clearly indicate that the available resource material has been consulted and thoughtfully applied to the planned project.
Most Griffith University schools/departments and many research centres have appointed at least one Research Ethics Adviser. The academic staff appointed a REAs for the Element are a local source of collegiate advice with regard to practical approaches to research challenges. After consulting the GUREM and resource material a REA can be a valuable source of advice/assistance. Student researchers should only contact/meet with a REA accompanied by a supervisor. **REAs are not an alternative to the role of a supervisor with regard to research ethics matters.** A list of the current REAs can be accessed from the University’s research ethics site.

### 8.0 Commencing a project

Recruitment and data collection/testing cannot be commenced until the research ethics review of the work has been completed and notification of Conditional Approval or Full Approval has been received (i.e. a project cannot commence while the ethical clearance of the project is still only Provisional Approval).

The conduct of research without prior ethical clearance and authorisation is a potential breach of the **Australian Code for the Responsible Conduct of Research** and may be considered research misconduct – which may have serious consequences for the researchers.

In practice this means that activities like recruitment and data collection should not occur until the researchers have received authorisation to commence the project. Commencing a project without authorisation may constitute a breach of the University’s research ethics arrangements ([see Booklet 7 of the GUREM](#)).

There are a few valid circumstances where it may be possible to commence elements of a project prior to the research ethics review of the project being complete. Such circumstances include:

i) situations where pilot testing may be required ([see 6.0 of Booklet 17 of the GUREM](#) for more about pilot testing and research ethics review);

ii) projects/designs where there is no point in submitting an application for research ethics review until the researchers are sure there are individuals/sites that are willing to participate ([see 8.1](#));

iii) situations where the opportunity to recruit participants will be sooner than the research ethics review of the project can be finalised ([see 8.2](#)); and

iv) situations where the work was originally considered to be ‘outside the scope’ ([see 5.1](#)) or exempt from research ethics review ([see 5.2](#)) but now that the researchers are ‘in the field’ it becomes clear that the work might be more appropriately considered to be human research so only at that point the work is being submitted for research ethics review.

In all circumstances where a researcher believes a project needs to commence prior to the finalisation of the review they should contact the Office for Research ([see Contacts](#)) for advice.

### 8.1 EXPLORATORY/FEASIBILITY DISCUSSIONS PRIOR TO ETHICAL CLEARANCE

Some research projects (especially those including qualitative elements) would be impractical unless the researcher knew in advance that there is a cohort of people interested in participating and/or a site willing to host the research. So it would be precipitous to submit an application for research ethics review without
knowing whether the cohort/site is available. Indeed trying to finalise the design of some such a project (e.g. action research) without the direct involvement of the participants would be completely improper. The operational dilemma is that recruitment should not start until the research ethics review has been finalised and the commencement of the research has been authorised.

An appropriate strategy that is commonly used is for researchers to discuss with the potential participant cohort whether individuals are interested in the research or whether the site is in principle willing to host the research, but in doing so making it clear that the work must be ethically reviewed before it can be conducted and perhaps the interest/agreement will then need to later be reconfirmed (e.g. a signed consent form).

This should be discussed in the application for research ethics review and a reminder included in subsequent consent materials/requests for confirmation of site agreements.

### 8.2 OPPORTUNITY TO RECRUIT PARTICIPANTS, OR COLLECT DATA, IS SOONER THAN ETHICAL CLEARANCE CAN BE FINALISED

Sometimes a researcher can have the unexpected opportunity for access to a potential participant cohort, which is time critical.

For example: The researcher learns of an international conference where a number of key practitioners and commentators will come together. The findings of the research project will be substantially enhanced by one-to-one interviews with selected individuals/a focus group session with the attendees. This could be done at a fraction of the cost that would be otherwise required. The work does require research ethics review, but the review is unlikely to be concluded in time for the conference.

Even though a specially expedited review to accommodate such an opportunity may be possible, an assessment will be made of the degree of prior warning about the event/opportunity (see Commentary Inset).

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Even the term ‘participant’ can be inappropriate for such designs because ‘co-investigator’ would be a more accurate description of the relative positions and roles.

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Inset Seven – Applications that are ‘late’ rather than urgent - The term, ‘late’ application, refers to situations where a researcher has left her/his application until just before the project needs to commence (e.g. just before the researcher flies overseas to conduct some fieldwork). Because the application is submitted late the researcher then seeks a very speedy review of the proposed project.

Even though every reasonable effort is made to accommodate the University’s researchers and urgent requests for the review of research ethics review applications, matters already under review and other urgent matters being dealt with, will sometimes mean that the Office for Research and the ethics reviewers cannot respond to a request as quickly as a researcher would like.

Researchers are asked to submit review applications in time for ordinary review. Urgent requests should be limited to circumstances where a researcher could not anticipate in advance the need for ethical clearance and/or there are genuine extenuating circumstances outside of her/his control.

Repeated ‘late’ review application requests, with an expectation they will be processed urgently, are not reasonable, are disrespectful to the reviewers, and will not be accommodated. Indeed, such behaviour may be regarded as demonstrating poor planning or a lack of respect for the importance of careful research ethics review.
Seven for more on urgency rather than ‘late’ situations). Even then the special review process may take longer than the available time.

Unexpected opportunities also includes situations where a researcher was not intending to collect data, and so has not sought ethical clearance, but an opportunity to collect valuable data emerges unexpectedly.

For example: The researcher is attending a meeting of professional practitioners who are discussing the implications of a State government’s new program. Even though it might be possible to later seek ethical clearance and then interview participants the informal group discussion is very interesting and worthy of academic analysis.

The above kind of situation can emerge during some ethnographic work or field-based work where spontaneous opportunities to collect valuable data might be impossible to predict.

### 8.2.1 Interim approval

One strategy for a genuinely urgent situation is to initially review the proposed work via a lower pathway (e.g. executive review of a project that would ordinarily be considered by an E2 panel). The interim approval granted by this initial review will generally come with the kind of caveat discussed at 8.2.4 of this Booklet. The interim approval would then need to be ratified by a review at the correct level.

### 8.2.2 Immediate commencement of a project with advice from or

There will be situations where a researcher needs to act very quickly. As long as the situation is genuinely urgent (see Commentary 7 sidebar) for more on urgency rather than ‘late’ situations, the Office for Research (see Contacts) will provide verbal or email advice on what, if any, action is required to ensure the modified research complies with University policy (as outlined by the Booklets of this Manual). Any approval will almost certainly need to apply the kind of caveats discussed in 8.2.4 of this booklet.

### 8.2.3 More urgent commencement

There are almost no circumstances where a research team could justifiably commence a research project without at least first consulting the Office for Research. As was noted at 8.0 the conduct of a project without prior ethical clearance and authorisation to commence is likely to be considered to be a breach of the Australian Code for the Responsible Conduct of Research.

### 8.2.4 Caveats on research projects that are commenced prior to research ethics review/authorisation

Generally, having accepted that there are valid grounds for the urgent processing of an application, the following conditions are likely to be attached to any interim approval/authorisation to commence the project:

#### 8.2.4.1 QUARANTINING the Data

The collected data must be set aside and not reviewed or analysed until the proposed project is later reviewed via one of the pathways described at 5.0 of this Booklet. Subsequently the data may have to be destroyed if the formal review does not approve the project or requires major changes to the varied project. No publication/report/other research output can be published until the substantive clearance and authorisation have been received. It is possible that when the substantive review is conducted the researchers will be instructed that no outputs be produced based on the data collected while the interim approval was in place. This is one of the reasons why interim approvals should only be used as a last resort.
8.2.4.2 CONSENT

Any consent obtained with regards to the project will need to make it clear that formal approval for the project is being sought and the researcher may need to update the information they are providing to participants. Consequently, when the approval is updated the researchers may have to seek updated or supplementary consent.

9.0 Variations

A useful way to think about the research ethics review process is that a specified research team receives ethical clearance and authorisation to conduct a particular research from a specified date and at a specified location(s)/context(s) for a specified period of time. If the research team, potential participant cohort (including the recruitment and consent mechanisms), the research design, the location/context or duration of a project changes, the clearance must be updated.

A change to the research team, the duration of a project, the funding arrangements for a project, or the manner in which the outcomes/results of the work are reported may require a variation to the ethical clearance.

Failure to keep a clearance up to date might invalidate that clearance and might constitute a breach of the University's human research ethics arrangements and so interalia of breach of the Australian University Code for the Responsible Conduct of Research.

It is relatively easy (and often expeditious) for researchers to update a clearance. Griffith University’s variation mechanism is explained by Booklet 6 of the GUREM. Researchers who are not sure whether a changes requires review as a variation should consult the Office for Research (see contacts)

The approach to alleged breaches of the University's human research ethics arrangements are discussed in Booklet 7 of the GUREM.

10.0 Researcher responsibilities

The responsibilities of researchers with regard to research ethics review, the ethical conduct of research, and the responsible reporting of results is articulated by the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

In summary these responsibilities include:

i) submitting human research projects for prior research ethics review;

ii) conducting projects in accordance with the ethical clearance provided by the ethics reviewers and abiding by any conditions affixed to that clearance;

iii) taking appropriate action with regard to:

a. any unexpected risks,

b. harms that are more serious than expected,

c. emergent ethical issues, and
d. the benefits of the work no longer justifying the risks/burdens.

iv) responding in a timely and respectful manner to any relevant requests from the ethics reviewers/Office for Research;

v) having due regard for the safety and welfare of participants and placing this regard ahead of the objectives of the research;

i) responsibly managing the project’s data and materials (especially if the data is personally identifiable);

ii) reporting the results of a project responsibly, with honesty and integrity; and

iii) treating collaborators with respect and appropriately acknowledging the contributions of others.

See Booklet 3 of the GUREM for more about the human research ethics responsibilities of researchers. See the Responsible Conduct of Research policy for more about the research integrity responsibilities of researchers.

11.0 Hints and tips: Avoiding common mistakes and delays

It is relatively easy for applicants to avoid some of the more common reasons for delays in a project receiving ethical clearance and/or authorisation to commence the work. Discussed below are some matters for applicants to check prior to submitting an application for research ethics review. These points are equally true, regardless of the level of research ethics review being undertaken.

Level of review – Apply for the right level of research ethics review. Under-applying can result in an application having to be reconsidered at a higher level of review. Over-applying can result in a longer processing time, or greater than required documentation. Even though the Research Ethics & Integrity team try to identify early whether an application should be redirected to a different review pathway it is prudent not to assume this will always occur.

Fully complete the application – Complete all sections of the application form. Leaving questions blank can raise the question, “Was this supposed to be answered N/A, or does the applicant not know/want to share the answer?”.

Answer questions completely the application – Before answering a question on the form, read the full question and help text. This can avoid incomplete or inappropriate answers.

Use appropriate lay language – The membership of the GUHREC (and the E2 panels) includes lay people and persons from a range of different disciplinary backgrounds. Consequently, applications for research ethics review should be written in non-technical language. Where there is no alternative but to use jargon or technical language, the terms must be explained in lay language.

Avoid relying upon attached research proposals or grant applications – In some cases documents (such as grant applicants) that describe a project may have been produced for another purpose. Even though the applicant might feel that the document might be relevant to her application for review, the applicant should avoid indicating that the response to a specific question on an ethics form, can be found in such an attached document. A large volume of applications for
ethical clearance are being reviewed at any one time, and it should not be necessary for the
reviewers to wade through additional documents to try to locate the answer to a specific question
from an ethics form. Furthermore research ethics reviewers are unlikely to possess the same level of
technical expertise as the readers of grant applications/research proposals (see above).

**Carefully consider before copying and pasting** – The ethics review process has quite a different
purpose and audience, from other University processes – such as confirmation of candidature or
peer review. Copying from documents created for other purposes may generate confusion and
frustration on the part of reviewers – especially externals or lay members of the GUHREC/E2 panels.

**Carefully consider N/A responses** – An applicant should consider carefully before answering any
question as "non-applicable" especially if the question relates to a key ethical issues such as the risks
associated with a planned project.

**Carefully consider before recycling** – Like many areas of public policy, human research ethics
continues to see rapid change and development. During the last 3 years there has been significant
changes to the national human research ethics arrangements and this has been reflected in changes
to the University's policies, procedures and resource material. Furthermore feedback from
researchers, incidents/concerns or other experiences may prompt a change in the University's
arrangements. Consequently, just because a project or particular approach was approved 3 years
earlier it does not necessarily mean that it would be considered acceptable in a new application.
Before recycling elements of a previous application, the applicant should check to see how the
relevant expectations may have changed.

**Who is the chief investigator?** – Current University policy is that HDR candidates (and other
students undertaking research) cannot be the listed chief investigator for a proposed human
research project. This is the case even if they are also a member of staff/it is their own research.
Instead, they should be listed in the ethical clearance application and the consent
material as the student researcher. It is appropriate (and common practice) for the candidate/student to be the
listed contact person for an application – so all correspondence about the ethical clearance is sent to
the candidate/student and copied to the principal supervisor.

**Signed and authorised forms** – In the case of applications for full review by the GUHREC applicants
should ensure that Office for Research promptly receives a signed copy of the application form, even
though the processing of their application will be commenced upon receipt of an electronic copy. If
some signatures are outstanding, this should be acknowledged in the application and an indication
provided of when the remaining signatures will be made available. Applications for research ethics
review for all the pathways except FR can be ‘signed electronically’ using the workflow functionality.

**Appropriate signatories** – A member of the research or supervisory team for a proposed protocol
cannot also sign off on the project as the authorising officer. If the potential authorising officer is also
a member of the research or supervisory team, a more senior member of University staff (e.g. dean
or pro-vice-chancellor) must sign off on the project as the authorising officer.

**Attachments** – Applicants should ensure that Office for Research promptly receives copies of all
attachments (including third party approvals) that correspond with the application. If some
attachments are outstanding, this should be acknowledged in the application and an indication
provided of when the remaining documents will be made available.
12.0 Sources of Advice

During the design, research ethics review and conduct of human research Griffith University researchers have access to a number of sources of advice. Experience suggests that the best way to mitigate delays, problems and frustrations is to seek early advice.

It is important to remember that researchers have primary responsibility for the ethical design and conduct of their research. Nevertheless, Griffith University supports the reflective practice of the University's researchers in the following ways:

**GUREM** – The [Griffith University Research Ethics Manual](#) provides guidance material on a wide range of research ethics issues, resources for researchers, as well as links to internal and external material. The Manual is organised into booklets relating to methods, potential participant pools, contexts, subject matter and contexts. The GUREM has a [searchable consolidated index](#).

**HDR Supervisors** – For HDR Candidates her/his supervisor(s) are the next source of advice.

**Research Ethics Advisors** – Most Griffith University schools/departments and many research centres have appointed a member of academic staff to serve as a source of collegiate advice on research ethics matters. REAs will expect that researchers will have consulted the GUREM before contacting them. In the case of HDR Candidates a REA will expect to be contacted by both the HDR Candidate and supervisor. A list of current REAs can be found here.

**Office for Research** – OR should generally only be contacted if the above sources of information have proven unhelpful or with regard to administrative/technical matters.

13.0 A learning institution approach

Griffith University has adopted a learning institution approach to the GUREM, research ethics review and the University's broader approach to human research ethics.

Such an approach welcomes all feedback, reflects on difficulties and treats continuous improvement as fundamental to the health and robustness of the University's human research ethics framework.

Consequently all researchers are encouraged to contact the Office for Research (see left) with feedback, ideas, frustration and/or suggestions of how Griffith University's arrangements, resources, policies and procedures could be improved.

In some instances (e.g. when a project design is unfamiliar/novel and the research ethics review of the project proves to be problematic) the reviewers, the GUHREC or the Office for Research may contact the researchers to elicit feedback.

14.0 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@griffith.edu.au

**Research Ethics Systems and Support Officer**

Tel: (07) 373 5 2069  
research-ethics@griffith.edu.au

On the ethics web site you will find:

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

(In the intranet section)

- 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

**15.0 References**


### 16.0 Other recommended reading

*Griffith University Research Ethics Manual* (Booklets 1, 2, 17, 21, 22 and 23 are recommended for all researchers).

17.0 Glossary

- **Conditional approval**
  - Review outcome where there are textual or very minor issues to address, but the work can be commenced on the understanding those matters will be addressed.

- **E1**
  - Expedited research ethics Review level 1.

- **E2**
  - Expedited research ethics Review level 2

- **FR**
  - Full research ethics Review

- **GUREM**
  - Griffith University Research Ethics Manual

- **HREC**
  - Human research ethics committee

- **National Statement**
  - National Statement on Ethical Conduct in Human Research

- **NR**
  - Negligible risk research ethics Review

- **PR**
  - Prior research ethics review

- **Provisional approval**
  - The reviewers need further information or changes to the project before authorisation to commence the research can be issued.

- **REA**
  - Research Ethics Adviser

- **Research ethics review**
  - Consideration of a proposed project by a HREC or delegated process, as per the National Statement

- **RIMS**
  - Research Information Management System - The system that underpins the University's online proportional review application form.

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