BOOKLET 17

Griffith University Research Ethics Manual

Scope of Griffith University's research ethics review arrangements

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Contents

1.0 Introduction

This booklet of the Griffith University Research Ethics Manual has been produced to assist researchers to determine whether or not a planned activity requires prior University research ethics review.

An introduction to the University's human research ethics arrangements can be found in Booklet 1 of the Griffith University-REM. An overview of the process for seeking research ethics review can be found in Booklet 2.

Griffith University defines some research activities as not being human research (so falling outside the scope of the University's human research ethics arrangements) and some other activities, which may have the characteristics of human research, as being exempt from research ethics review.

Rather than classifying certain types or work as all being outside the scope or exempt from review, the University has also established some strict criteria, against which individual projects should be assessed.

An activity that is deemed to be not human research or exempt does not need to be submitted for any level of research ethics review. However, the persons undertaking and otherwise responsible for such activities must comply with the relevant University and national ethical standards (see 8.0 of this booklet), and the activity may still be subject to other approvals (such as a health and safety clearance).

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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. In the Preamble the *National Statement* articulates the historical context of research ethics review. This is elaborated further (including defining human research) in the 'Purpose, scope and limits of this document' section.

Paragraph 5.1.6 and chapter 2.1 of the *National Statement* define the research that must be reviewed by a human research ethics committee (HREC) and the work that can be reviewed by other delegated bodies. Chapter 5.2 of the *National Statement* discusses the responsibilities of research ethics reviewers.

Also *see* *Ethical Considerations in Quality Assurance and Evaluation Activities, NHMRC 2014* for guidance around activities that might fall outside of the Griffith University ethics review arrangements.

This Booklet describes Griffith University's implementation of these guidelines, standards and responsibilities. Further information about Griffith University's approach to risks can be found in Booklet 9 of the Griffith University-REM.

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3.0 Scope of Griffith University's human research ethics arrangements

The question of what requires prior University ethics clearance is at first glance straightforward. The National Statement *at p.7* direct that all human research must be submitted for prior research ethics review. In the 'Purpose, scope and limits of this document' section of the *National Statement* there is direction that this applies to all human research conducted under the auspices of an institution that receives either ARC or NHMRC funding (i.e. not only the projects in direct receipt of funding). However in practice the question of what constitutes human research can sometimes be problematic.

As the *National Statement* provides, any research activity that involves participation of humans, including completion of questionnaires, interviews, focus groups, conduct of tests, observations of behaviour etc. is human research. Furthermore, access to identified personal information that is not already on the public record must also be considered human research. Access to online material (such as postings on a social media site) may also be considered human research. Consequently, the scope of what is considered to be human research is very broad and can include research in most disciplines.

Griffith University has defined some activities, that possess some characteristics in common with human research, as being outside the scope of

Commentary Inset 1 – Research while on practicum

Students in a Business School course will spend 4 weeks on professional placement with hotels based in the South West. A component of this practical experience is producing a report for the host business based upon data collected from the hotel's employees.

The experience will obviously be of direct academic and professional value for the students. The students will also produce a reflective paper, which coupled with the employers' report on the students' performance/research, will be a significant component of their grades for the semester.

However, the nature of the activity will direct whether the students' research falls within the scope of Griffith University's human research ethics arrangements. In this example:

1. *The work will be conducted under the auspices of the host hotels;*
2. *The material supplied to employees of the host hotel will describe the work as a research project of the hotel not Griffith University research;*
3. *The collected data will belong to the host hotels and the data (neither the original nor a copy) cannot be sent to the University;*
4. *There will not be a research output (e.g. journal article or journal presentation) arising from that research.*

Based on the above, we can determine that the students in that course will not need to submit an application for research ethics review for the collection of data for the report to the host hotel. The students must however conduct themselves ethically, with integrity and honestly. See 8.0 of this booklet for more.

In the event the host hotel needed any change to the four matters above (e.g. if they wanted the data collection to be described as Griffith University research) or the student/course convenor wants to produce a research output based on the data) then the work falls with the scope of the University's human research ethics arrangements and may need to be submitted for research ethics review. Refer to 3.0 and 4.0 to confirm whether the work is otherwise outside the scope or exempt from review.

the University's human research ethics arrangements. These are discussed below, as well as any qualifying criteria. See 5.0 of this Booklet for information about the research use of data arising from such activities. The University's expectations with regard to the ethical conduct of such activities are discussed at 8.0 of this Booklet.

3.1 Evaluation of a Griffith University course or service

If the primary purpose of the data collection is to evaluate a course or teaching, or to evaluate/improve a University service, the work is not treated as human research. This is the case even if the work may contain some elements in common with human research (e.g. surveys).

The relevant Head of School, or nominee, must approve the conduct of such work.

In some cases, an academic staff member may conclude that there could be academic interest in the findings of a course evaluation and may wish to produce a research output (e.g. journal article). As was noted above, 5.0 of this Booklet discusses such situations.

3.2 Work conducted while on practicum

Many Griffith University courses include students undertaking one or more professional practicums with external industry/professional/community partners for a period of time. While they are on that practicum the students may be asked to conduct research for the partner body (see Commentary Inset 1 for an example). Even though such an activity might meet the definition of human research, or perhaps include some components generally considered to be human research, they may not be considered within the scope of Griffith University human research ethics arrangements.

Whether individual human research practicum projects should be considered to be Griffith University human research can be determined by answering the following questions.

3.2.1 IS THE WORK TO BE CONDUCTED UNDER THE AUSPICES OF AN INDUSTRY, PROFESSIONAL, COMMUNITY PARTNER?

IF YES GO TO 3.2.2 IF NO GO TO 3.2.5

A consideration in determining whether the planned work is within the scope of the University's human research ethics arrangements is whether the work is to be conducted under the auspices of, on the one hand, the professional/community partner or, on the other, the University.

3.2.2 WILL THE WORK BE DESCRIBED TO POTENTIAL PARTICIPANTS AS A GRIFFITH UNIVERSITY RESEARCH PROJECT?

IF YES GO TO 3.2.5 IF NO GO TO 3.2.3

Even if the work is to be conducted under the auspices of the professional/community partner (see Q3.2.1) will it be described to potential participants as a Griffith University project? If so it may require Griffith University research ethics review.

3.2.3 WILL THE INDUSTRY, PROFESSIONAL, COMMUNITY PARTNER OWN THE DATA?

IF YES GO TO 3.2.4 IF NO GO TO 3.2.5

Another factor in deciding whether the work requires Griffith University research ethics review is whether the professional/community partners own the data, or whether it will be owned by the researcher/Griffith University.

3.2.4 WILL THERE BE A RESEARCH OUTPUT (E.G. PUBLICATION) THAT CAN BE CLAIMED AS GRIFFITH UNIVERSITY RESEARCH ACTIVITY?

IF YES GO TO 3.2.5 IF NO GO TO 3.2.6

The final consideration in determining whether the work requires Griffith University research ethics review is if a research output (e.g. publication that can be claimed as Griffith University research activity) will result from the work.

3.2.5 TEST FOR EXEMPTION

The work appears to fall within the scope of Griffith University human research. It should be tested to see whether it is exempt from research ethics review (see 4.0 of this booklet).

3.2.6 OUTSIDE THE SCOPE

The work appears to be outside the scope of the University's human research ethics arrangements. Even though the student does not need to submit an application for research ethics review for the project he/she must still conduct the work in an ethical and responsible manner (see 8.0).

3.3 Teaching and learning activity

Some teaching and learning activities can have characteristics that are very similar to human research (see Commentary Inset 2 for some examples). Even though such an activity might meet the definition of human research, or perhaps include some components generally considered to be human research, they still may not be considered to be within the scope of Griffith University human research ethics arrangements.

The responses to following questions will determine whether that work needs

Commentary Inset 2 – Teaching and learning activity

This sidebar provides examples of some activities for teaching and learning purposes, which have some characteristics/elements in common with human research, but are considered to be outside the scope of the University's human research ethics arrangements (so don't require research ethics review).

PRACTICAL EXERCISE OR TEST CONDUCTED FOR TEACHING PURPOSES

A member of staff will administer a standardised personality test to a tutorial group, to demonstrate the testing process and the evaluation of the collected data.

There is no intent to produce a research output based upon the data.

The work may be outside the scope of the University's human research ethics arrangements as long as:

i) the collected data is not personally sensitive;

ii) either individual participants will not be identifiable (including identification by inference by their peers) or any identification could not be problematic (e.g. humiliate participants or expose them to risks – such as social or legal risks).

DEMONSTRATION OF A PROCEDURE FOR EDUCATIONAL PURPOSES

A member of academic staff will collect blood from a healthy volunteer with voluntary consent of the volunteer. The staff member possesses the appropriate expertise. Standard safety arrangements will be observed.

The purpose of the activity is to either demonstrate the extraction technique or to demonstrate a test on the collected blood.

WORK/DATA COLLECTION BY STUDENTS FOR TEACHING/LEARNING PURPOSES

Following a few weeks studying the design of effective structured interviews the students will design an interview protocol and interview members of their family or friends.

This work will be evaluated in terms of how individual students have appropriately applied the concepts studied and analysed the data collected.

The purpose of this activity is not to produce a research output/make a contribution to body of scientific knowledge.

The work may be outside the scope of the University's human research ethics arrangements as long as:

i) the collected data is not personally sensitive; and

ii) either individual participants will not be identifiable (including identification by inference by their peers) or any identification could not be problematic (e.g. humiliate participants or expose them to risks – such as social or legal risks).

to be submitted for research ethics review via the Griffith University human research ethics arrangements or whether other ethical considerations apply.

Q3.3.1 IS THE WORK A PRACTICAL EXERCISE OR TEST CONDUCTED FOR TEACHING PURPOSES?

IF YES GO TO 3.3.4 IF NO GO TO 3.3.2

If the work involves educational tests (cognitive, diagnostic, aptitude or achievement), survey procedures, interview procedures or observation of public behaviour), conducted for the purposes of teaching/learning (i.e. there is no intention to collect data and use it in a research output), the work is outside the scope of the University's human research ethics arrangements and so does not require research ethics review.

Q3.3.2 IS THE WORK A ROUTINE EXPERIMENT OR PROCEDURE CONDUCTED FOR TEACHING/LEARNING PURPOSES?

IF YES GO TO 3.3.5 IF NO GO TO 3.3.3

If the work involves routine procedures (such as the collection of a blood sample) conducted by a person with necessary expertise and only for the purposes of teaching/learning, the work is outside the scope of the University's human research ethics arrangements and so does not require research ethics review.

Q3.3.3 IS THE WORK/DATA COLLECTION CONDUCTED BY A STUDENT FOR TEACHING/LEARNING PURPOSES?

IF YES GO TO 3.3.3.1 OTHERWISE GO TO 3.3.7

Data collection conducted by students purely for the purposes of teaching/learning (e.g. to enhance their understanding of an issue) may be outside the scope of the University's human research ethics arrangements.

q3.3.3.1 Will the results only be published/presented for academic assessment purposes?

IF YES GO TO 3.3.6 OTHERWISE GO TO 3.3.7

If the outcomes of the student's work will be disseminated beyond the assignment/paper/presentation for internal academic purposes, the proposed work will need to be ethically reviewed further.

3.3.4 OUTSIDE SCOPE – PRACTICAL EXERCISE OR TEST

The practical exercise or test, conducted for a teaching/learning purpose is outside the scope of the University's human research ethics arrangements. Consequently, it does not require research ethics review. The following ethical considerations should however be considered and the design/conduct of the work may need to be modified accordingly (to either remove them from the work or to address any harms that could arise).

a. If the information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to individuals, could that identification be considered problematic or a cause for concern by the participants (e.g. because it could be humiliating or because it might affect their future grades).

b. Will the collected data be published/reported beyond the University?

c. The information obtained is recorded in such a manner that any disclosure of the participants' responses/results outside the research team could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation; or

d. The research deals with sensitive aspects of the participants' own behaviour, such as sexual preference, illegal conduct, use of alcohol, drug use, or includes information about health status.

3.3.5 OUTSIDE SCOPE – ROUTINE EXPERIMENT OR PROCEDURE

The routine experiment or procedure, conducted for a teaching/learning purpose is outside the scope of the University's human research ethics arrangements. Consequently, it does not require research ethics review. The following ethical considerations should however be considered and the design/conduct of the work may need to be modified accordingly (to either remove them from the work or to address any harms that could arise):

a. The activity will be conducted by an appropriately qualified/experienced/accredited person;

b. The activity is covered by an appropriate biosafety clearance (if required);

c. If the information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to individuals, could that identification be considered problematic or a cause for concern by the participants (e.g. because it could be humiliating);

d. The information obtained is recorded in such a manner that any disclosure of the participants' responses/results outside the research team could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation; and

e. The activity deals with sensitive aspects of the participants' own behaviour, such as sexual preference, illegal conduct, use of alcohol, drug use, or includes information about health status.

3.3.6 OUTSIDE SCOPE – STUDENT WORK

Student work, conducted for a teaching/learning purpose may be outside the scope of the University's human research ethics arrangements. As long as the outcome of this work will not be disseminated/reported/published outside of the academic assessment item (e.g. the student's assignment), the student work does not require research ethics review. The following ethical considerations should however be considered and the design/conduct of the work may need to be modified accordingly (to either remove them from the work or to address any harms that could arise):

a. The participant group can be characterised as vulnerable.

b. The information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to the subjects, and that identification is likely to be considered problematic or a cause for concern by the participants.

c. The information obtained is recorded in such a manner that any disclosure of the participants' responses/results outside the research team could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation.

d. The work deals with sensitive aspects of the participants' own behaviour, such as sexual preference, illegal conduct, use of alcohol, drug use, or includes information about health status.

3.3.7 TEST FOR EXEMPTION

The work appears to fall within the scope of Griffith University human research. It should be tested to see whether it is exempt from research ethics review (see 4.0 of this booklet).

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4.0 Exempt from research ethics review at Griffith University

As was noted at 1.0 of this booklet, the University exempts some human research activities from research ethics review, though this is still dependent upon individual projects meeting specific design criteria and still requires that design and conduct of a project adhere to Griffith University's research ethics arrangements (see 8.0 of this booklet).

In summary, these activities are:

1. work only with existing data;
2. work involves only 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);
5. output of the research will be journalistic (e.g. a news story or a documentary); and
6. human ethics review of human biological biospecimens (including cell lines).

The qualifying criteria for above categories of activities are outlined below.

See 5.0 of this Booklet for information about the research use of data arising from such activities. The University's expectations with regard to the ethical conduct of such activities are discussed at 8.0 of this Booklet.

4.1 Does the project only involve work with existing data?

IF YES GO TO 4.1.1 IF NO GO TO 4.2

Some research involves work with existing data (e.g. data collected for an earlier research project). When there will be no primary data collection (e.g. interviews, surveys or observation) this work may be exempt from research ethics review.

The responses to the following questions will determine whether that work needs to be submitted for research ethics review via the Griffith University human research ethics arrangements.

Q4.1.1 WILL THE DATA BE ACCESSED IN A DE-IDENTIFIED FORM?

IF YES GO TO 4.1.2 IF NO GO TO 4.1.1.1

Even if the researcher will follow steps to protect the confidentiality of participants, if the existing data is accessed in an identified form, the question of whether the work is exempt from research ethics review needs to be tested further.

q4.1.1.1 Is the data already in the public domain?

IF YES GO TO 4.1.2 IF NO GO TO 4.1.1.1.1

Even though the researchers will be accessing the existing data in an identified form, the work may still be exempt if the data is already in the public domain.

Q4.1.1.1.1 Was Consent Obtained for the Potential Reuse of the Data?

IF NO GO TO 4.8 IF YES GO TO 4.1.2

Even though the researchers will be accessing the existing data in an identified form, the work may still be exempt if, at the time when the original data was collected or at some point since, consent was obtained that anticipated such a re-use.

Q4.1.2 DOES THE RESEARCH INVOLVE ONLY NEGLIGIBLE RISK?

IF YES GO TO 4.7 IF NO GO TO 4.2

Negligible risk is defined by the ***National Statement*** as involving no more than inconvenience. To be exempt from research ethics review, work with existing data can involve no more than negligible risk. Further information about the assessment of the severity of risks can be found in Booklet 09 of the Griffith University-REM.

Q4.2 Will the work involve only the analysis of existing documents?

IF YES GO TO 4.2.1 IF NO GO TO 4.3

Some research will involve the analysis of existing documents (e.g. policies and other organisational documents, minutes, correspondence, books). When work will involve only archival research and there will be no human research activities (e.g. interviews) that work may be exempt from research ethics review.

q4.2.1 Are the documents available to the public?

IF YES GO TO 4.2.2 IF NO GO TO 4.2.1.1

Are the documents to be utilised in this research all publically available? If all of the documents are publically available, then that work may be exempt from research ethics review. Where approval is required for access to the documents, there are additional matters that need to be checked to see whether the work is exempt.

Q4.2.1.1 IS SOME FORM OF APPROVAL REQUIRED BEFORE A PERSON CAN ACCESS THE DOCUMENTS?

IF YES GO TO 4.2.1.1.1 IF NO GO TO 4.2.2

Is organisational approval or other authorisation required for access to any of the documents? If organisational approval is required for access to the documents, there are additional matters that need to be checked to see whether the work is exempt.

Q4.2.1.1.1 Has approval already been obtained, or will it be obtained?

IF YES GO TO 4.2.2 IF NO GO TO 4.3

Where the researchers have already, or will, obtain the approval of the organisation or other authorisation, the work may be exempt from research ethics review. In many cases, organisations will not grant such approval before the work has either been ethically reviewed or confirmed to be exempt. If the researchers intend to obtain the documents without organisational approval or other authorisation (e.g. via a whistle-blower) this work definitely must be submitted for research ethics review.

Q4.2.2 DOES THE RESEARCH INVOLVE MORE THAN NEGLIGIBLE RISK?

IF NO GO TO 4.7 IF YES GO TO 4.3

Negligible risk is defined by the ***National Statement*** as involving no more than inconvenience. To be exempt from research ethics review, archival work can involve no more than negligible risk. Further information about the assessment of the severity of risks can be found in Booklet 09 of the Griffith University-REM.

Q4.3 Should the work be characterised as evaluative practice, quality assurance or an audit?

IF YES GO TO 4.3.1 IF NO GO TO 4.4

Work that is evaluative practice, quality assurance or an audit may be exempt from research ethics review, subject to the answers to some further questions.

Q4.3.1 HAS/WILL THE WORK BEEN/BE APPROVED BY THE ORGANISATION RESPONSIBLE FOR THE AREA/TEAM/ACTIVITY THAT IS SUBJECT TO THE EVALUATIVE PRACTICE, QUALITY ASSURANCE OR AUDIT?

IF YES GO TO 4.3.2 IF NO GO TO 4.8

Where the researchers have already, or will, obtain the approval of the organisation or other authorisation for the quality assurance or audit, the work may be exempt from research ethics review. If the researchers intend to conduct the work without organisational approval this work must definitely be submitted for research ethics review.

Q4.3.2 IS IT PREDICTABLE THAT AN ACADEMIC PUBLICATION OF OTHER RESEARCH OUTPUT WILL ARISE FROM THE WORK?

IF YES GO TO 4.8 IF NO GO TO 4.3.3

In addition to any report back to the organisation on the outcomes of the quality assurance or audit, if there will be any research outputs (e.g. journal publication, conference paper, public report/book) this work will need to be submitted for research ethics review.

Q4.3.3 DOES THE RESEARCH INVOLVE ONLY NEGLIGIBLE RISK?

IF YES GO TO 4.9 IF NO GO TO 4.4

If there is a more than a negligible risk to participants, or known third parties (e.g. employees, clients), where they could suffer a harm (e.g. economic, professional or social) it will require research ethics review. Further information about the assessment of the severity of risks can be found in Booklet 09 of the Griffith University-REM.

Q4.4 Will the final output of the research be creative (e.g. photographic exhibition, theatrical or music performance, novel)?

IF YES GO TO 4.4.1 IF NO GO TO 4.5

Research that results in a creative output (e.g. photographic exhibition, theatrical or musical performance, or a novel) may, subject to some criteria and requirements, be exempt from further research ethics review.

Q4.4.1 WILL THE WORK INCLUDE INTERVIEWS, SURVEYS OR FOCUS GROUPS?

IF YES GO TO 4.8 IF NO GO TO 4.4.2

Creative research is not exempt from research ethics review if it includes interviews, surveys or focus groups.

Q4.4.2 WILL THE CONSENT OF PARTICIPANTS BE OBTAINED?

IF YES GO TO 4.7 IF NO GO TO 4.4.3

When the consent of participants in the creative research is not sought, that work will be subject to research ethics review (i.e. to determine whether a waiver of the consent requirement can be approved). Where consent will be sought, qualification for exemption from review needs to be tested further.

Q4.4.3 COULD PARTICIPANTS BE IDENTIFIED BY THIRD PARTIES (INCLUDING OTHER PARTICIPANTS)?

IF YES GO TO 4.4.3.1 IF NO GO TO 4.4.4

A consideration in determining whether a creative research project is exempt is whether participants will be identifiable by third parties. The possibility of identification does not mean that a project is ethically problematic, but it does mean that whether the work is exempt from review needs to be tested further.

q4.4.3.1 Will participants consent to being identifiable?

IF YES GO TO 4.4.4 IF NO GO TO 4.8

As long as the consent process (see Q2.4.1) anticipates that all participants will be identifiable, or seeks individual consent for the identification, the work may still be exempt from research ethics review.

Q4.4.4 IS THERE MORE THAN A NEGLIGIBLE RISK OF HARMS (PHYSICAL, PSYCHOLOGICAL, SOCIAL, ECONOMIC, LEGAL ETC.) TO PARTICIPANTS, THE RESEARCHERS OR KNOWN THIRD PARTIES?

IF YES GO TO 4.5 IF NO GO TO 4.7

If there is a more than a negligible risk that participants, or known third parties (e.g. employees, clients), could suffer a harm (e.g. economic, professional or social) or if a creative research project involves more than negligible risk, it will require research ethics review. Further information about the assessment of the severity of risks can be found in the Help notes for Part 4 of this checklist and in Booklet 09 of the Griffith University Research Ethics Manual.

Q4.5 Will the final output of the research be journalistic (e.g. a news story or a documentary)?

IF YES GO TO 4.5.1 IF NO GO TO 4.8

Research that results in a journalistic output (e.g. news story or documentary) may, subject to some criteria and requirements, be exempt from further research ethics review.

Q4.5.1 WILL THE CONSENT OF PARTICIPANTS BE OBTAINED?

IF YES GO TO 4.7 IF NO GO TO 4.5.2

When the consent of participants in the journalistic research is not sought, that work will be subject to research ethics review (i.e. to determine whether a waiver of the consent requirement can be approved). Where consent will be sought, qualification for exemption from review needs to be tested further.

Q4.5.2 COULD PARTICIPANTS BE IDENTIFIED BY THIRD PARTIES (INCLUDING OTHER PARTICIPANTS)?

IF YES GO TO 4.5.2.1 IF NO GO TO 4.7

A consideration in determining whether a creative research project is exempt is whether participants will be identifiable by third parties. The possibility of identification does not mean that a project is ethically problematic, but it does mean that whether the work is exempt from review needs to be tested further.

q4.5.2.1 Will participants consent to being identifiable?

IF YES GO TO 4.7 IF NO GO TO 4.8

As long as the consent process (see Q4.5.1) anticipates that all participants will be identifiable, or seeks individual consent for the identification, the work may still be exempt from research ethics review.

Q4.6 Will the research involve work with human biospecimens, including cell lines?

IF YES GO TO 4.6.1 IF NO GO TO 4.8

Research that involves human biospecimens (including cell lines) may, subject to some criteria and requirements, be exempt from further research ethics review. See 11 of this Booklet for further information.

Q4.6.1 DOES THE WORK INVOLVE PROSPECTIVE COLLECTION?

IF YES GO TO 4.8 IF NO GO TO 4.6.2

Work that involves the prospective collection of human biospecimens (e.g. cells, tissues, or blood) will require research ethics review.

Q4.6.2 PURCHASE OR USE OF HUMAN-DERIVED CELL LINES FROM COMMERCIAL BIOBANKS

IF NO GO TO 4.8 IF YES GO TO 4.6.2.1

Work that involves the purchase or use of human-derived cell lines from commercial biobanks may be exempt from research ethics review.

q4.6.2.1 Is the activity registered in GSafe?

IF YES GO TO 4.7 IF NO GO TO 4.8

Where the activity is registered in GSafe, it is exempt from further research ethics review.

4.7 Exempt from research ethics review

Based upon the responses to the questions above this work is exempt from research ethics review. It is still however human research and subject to the national guidelines and University policy with regard to the

ethical design and conduct of such work. The following is a list of some of the key ethical considerations that need to be considered and addressed. Please refer to the other relevant booklets the Griffith University-REM for further guidance on these and other ethical considerations:

a. The design of the work needs to be based upon a sound understanding of the literature, previous research or practical experience – in terms of the research questions/objectives, the design, and the strategies to address risks and/or ethical issues.

b. The design of the research must be respectful of participants with due regard for their welfare, rights, beliefs and culture. This respect and due regard must take precedence over the objectives and needs of the research. See Booklet 26 of the Griffith University-REM for guidance on these matters.

c. The inclusion and exclusion criteria for participation must be fair, based upon ethical and legal standards, and must have a sound basis in the variables of interest/research questions. Exclusions from a participant pool may need to be disclosed in the reporting of the results (e.g. as a potential limitation to the findings). See Booklet 21 of the Griffith University-REM for guidance on these matters.

d. The recruitment mechanism must not breach ethical and regulatory privacy standards. See Booklet 23 of the Griffith University-REM for guidance on these matters.

e. The risks associated with the research must be justified by the benefits of the work. See Booklet 09 of the Griffith University-REM for guidance on these matters.

f. Consent must be obtained from all participants, including full disclosure about the research and the standard information and assurances outlined by Booklet 22 of the Griffith University-REM.

g. Any assurance provided to participants with regards to anonymity of confidentiality must be honoured. See Booklet 23 of the Griffith University-REM for guidance on these matters.

h. Participants should be provided with an appropriate and timely summary of the results of the work. Where individuals are to be debriefed about their own results, especially when those results are likely to be of concern, the results should be communicated by someone with appropriate expertise and knowledge.

4.8 Not exempt from research ethics review

Based upon the responses to the questions earlier in this section this work does require research ethics review. However, if it has already been reviewed by another research ethics committee it may qualify for the University's special prior review arrangements (see Booklet 8 of the Griffith University-REM). Depending upon the presence of risks and ethical sensitivities the work may qualify for review by a Griffith University E1 pathway. All other research must be submitted for review by a meeting of the Griffith University Human Research Ethics Committee. See Booklet 2 of this Manual for more about the University's proportional research ethics review pathways.

4.9 Potentially exempt from research ethics review

Based upon the responses to the questions earlier in this section this work **may** be exempt from research ethics review. Send an email to research-ethics@griffith.edu.au with a succinct summary of the work and your response to the questions in Part Two. The Research Ethics and Integrity team will conduct an administrative review and promptly advise whether the work is exempt from further review (see 4.7) or needs to be reviewed via one of the University's ethics review pathways (see Booklet 2 of this Manual for more about the University's proportional research ethics review pathways).

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5.0 Research use (including publication) of data from exempt purposes

Some work is considered to be outside the scope of the University's human research ethics arrangements (see 3.0) and some human research is, subject to qualifying criteria (see 4.0), exempt from research ethics review. Later there may be an interest in producing a research output from such activities (e.g. a conference paper from a quality assurance activity).

Despite the fact that the original data collection was for non-human research or an exempt purpose, there can be a genuine and valuable academic or professional interest in the results of such exercises. This interest could result in a potential research use for such data (e.g. academic publication). This raises the question of whether ethics clearance is required for such a research use.

Commentary Inset 3 – Example of the use of pilot testing

The researchers have created a web-based memory test, which tracks short-term and medium-term memory over time. The intention is to utilise it in conjunction with trialling a new intervention for people with early stage dementia.

The trial protocol will compare the performance of a trial cohort against a control cohort over a six-month period.

Prior to the main study the researchers want to conduct a pilot study to assess whether the tasks are age appropriate, how easily persons of a comparative age understand and complete the tasks, whether the immediate positive reinforcement is effective, and how much instruction the users need.

The pilot study will be briefly discussed in the research output – as part of discussing the validity of the protocol. The researchers do not anticipate using the pilot study data beyond refining the tasks and the instructions being provided to the participants.

Such a pilot test would need to be submitted for research ethics review (either separately or combined with the main study) and a modified version of the consent materials from the main study should be used (explaining that this is a study to refine the tests prior to their use in the main study).

5.1 Is/was the research use predictable?

If the researcher can predict the research use of the data, then the question of whether the research use requires ethics clearance will depend upon the following. The research use will not require research ethics review as long as:

i. either no individual's data will be used (e.g. the research use is actually reflective on the process by the practitioner) **or** the data from the original exempt purpose has been aggregated/otherwise de-identified prior to the research use (i.e. so the researcher cannot identify individual respondents in their research use of the data);

ii. the participant group should not be characterised as vulnerable;

iii. the recruitment of participants for the original exempt purpose was in accordance with Booklet 21 of the Griffith University Research Ethics Manual;

iv. the consent of participants for the original exempt purpose, was obtained in accordance with Booklet 22 of the Griffith University-REM, and an element of this consent was seeking permission for the research use of the information;

v. the conduct of the original exempt purpose was otherwise in accordance with principles articulated by the booklets of the Griffith University-REM; and

vi. the results of the original exempt purpose, if known beyond the practitioner who conducted the data collection, could not expose participants to risks greater than a low risk of harm (see Booklet 9 of the Griffith University-REM for more about risks).

Otherwise, the research use must be submitted for prior review, and it is likely that fresh consent may need to be sought from participants. One option to obtaining consent would be the opt-out approach (see 18.0 of Booklet 21 of the Griffith University-REM). If obtaining project-specific consent is not possible e.g. because the original data collection did not collect personal identifiers, so the data is anonymous, the researcher will need to seek a waiver of the consent requirement (see 07.0 of Booklet 33 of the Griffith University-REM). Depending upon the circumstances, the GUHREC may decide that, in the absence of project-specific consent, the research use of the data cannot be authorised.

Commentary Inset 4 – Pilot testing that does not require research ethics review

As a general principle, pilot testing that involves human research must be submitted for research ethics review. 6.1.1 lists the three criteria that can be used to determine whether a pilot test requires research ethics review.

EXAMPLE ONE – A researcher wants to check how long it takes to complete a survey instrument, so they intend to ask some students and HDR candidates to complete the survey and report the amount of time it took them. The data/answers will not be retained/analysed/reported, the potential participant cohort is not vulnerable and the activity involves no more than negligible risk. Consequently, this pilot test is exempt from research ethics review.

EXAMPLE TWO – A research team wants to confirm that an interview protocol used in the US context is relevant/useful in the Australian context. They have already identified and modified popular culture references and spelling, but want to ensure the collected data isn't undermined by participant reactions to discordant statements/concepts. They plan to conduct a focus group discussion with a small number of individuals from the community who are similar to the participant group they will be interviewing. No comments/observations from the focus group will be retained/analysed/reported, except to refine the interview protocol, the potential participant cohort is not vulnerable and the activity involves no more than negligible risk. Consequently, this pilot test is exempt from research ethics review.

With regard to the two examples above the pilot testing would require prior research ethics review if one or more of the following applied:

i) the data from the pilot testing was to be incorporated or otherwise used for the main study (e.g. the data set from the pilot study would be added to the data from the main study and then the combined data analysed);

ii) the pilot testing participant pool includes persons who should be considered vulnerable; or

iii) the work involves more than negligible risk.

5.2 Was the research use unforeseen?

If the research use was unforeseen, but the test outlined in 5.1 of this Booklet can still be met, the research use of the data can still occur without research ethics review and without additional project-specific consent. One of the practical difficulties for such work is that the original consent is unlikely to address the requirements with regard to consent (see 5.1 item iv). In the event this test cannot be met, the proposed research use of the data must be submitted for research ethics review and the issue of consent will need to be explored (see the discussion at the end of 5.1).

5.3 Prior collections that are not exempt

If a researcher wishes to make research use of data previously collected for another purpose, that is not exempt (see 2.0 of this Booklet) and was not covered by an appropriate ethics clearance, they will definitely need to submit that research use for research ethics review.

The GUHREC is likely to apply the test outlined in 5.1 of this Booklet to inform its decision whether to allow the research use, and whether project specific consent would now need to be sought from the participants. **As a general principle, the GUHREC will not approve the research use of data that was collected under circumstances that are contrary to the University and national policies on ethical conduct in research.** Furthermore, given that the data collection will have already occurred, the Griffith University research ethics reviewers (e.g. the GUHREC) will be unable to work with the researchers to resolve any ethical issues, so the research use of the data may not be possible. Indeed, the situation may constitute a breach of the Griffith University Framework for the Responsible Conduct of Research – because the earlier work was conducted without ethics clearance.

If in fact the earlier work received Griffith University ethics clearance refer to Booklet 42 of the Griffith University-REM for guidance with regard to research ethics review and consent for the reuse of the data from that earlier work.

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6.0 Pilot testing

Pilot testing can often be a valuable component of human research and can be essential for the successful, respectful and (in some cases the safe) conduct of a project.

Reasons for conducting pilot work can include, but are not limited to, the following (a more detailed pilot testing case study can be found in Commentary Inset 3):

i) fine tuning the topics or questions for an instrument (e.g. a semi-structured interview design;

ii) testing how long it takes to complete an instrument (e.g. a survey); and

iii) determining whether a research design (e.g. a program to help young people improve their resilience to emotional stress) used in another country needs to be modified for the Australian context.

Commentary Inset 5 – Ethics reviewer directed pilot test: Recruitment/consent

The reviewers may direct that a particular group are recruited for the pilot testing (e.g. if the reviewers were concerned that the potential participants might not understand the terminology used in the project's instrument they might direct the researchers to directly administer the instrument to a small number of comparable persons and for the researchers to explore how well those individuals understand the terminology). The reviewers may also direct the number of participants required for the pilot test and how those participants are to be recruited.

In most cases the instructions to the researchers will direct whether the consent mechanism from the primary project should be used, whether additional information should be provided, or whether a pilot-test-specific mechanism is required. In most cases participants in the pilot test should be provided with information about:

i) the fact this this is a pilot test, what a pilot test is and why the pilot test is being conducted;

ii) an indication of whether their information/data will be recorded in a personally identified form, whether it will be combined with the primary project's data, and who will have access to any personally identified data; and

iii) what risks and benefits are applicable to the pilot test (which may be different from the primary project).

Ideally the participants in the pilot test should be offered access to a lay summary of the results of the primary project and perhaps a brief statement on how the pilot testing refined the design of the final version of the primary project.

Pilot testing can also be used as an important component of the risk management strategies for a project, including conducting the research procedures with a smaller group to:

i) assess the likelihood of a risk and the associated harm;

ii) evaluate the effectiveness of strategies to minimise, manage or otherwise mitigate the risks;

iii) identify necessary exclusionary criteria for the screening of the potential participant pool; and

iv) assist with the beneficence reflections for the project (the degree to which the benefits of the project do genuinely justify the risks).

The need for pilot testing might be identified by a researcher or by the research ethics review body (e.g. the Griffith University HREC).

6.1 Need for pilot testing identified by a researcher

Generally, such testing will be to fine-tune an element of a project deign to maximise the likelihood the project will achieve its objective, to improve the efficiency of the design, to minimise the burden on participants, or otherwise improve the project.

If this work is not outside the scope of the University's human research ethics arrangements (see 3.0 of this Booklet) or exempt from research ethics review (see 4.0) it must be submitted for prior research ethics review. In practice this means that, in making an application for clearance for an entire protocol that involves some pilot testing, the best approach is to:

- outline the nature of the pilot testing, the purpose of the pilot testing, and whether any special arrangements (e.g. in terms of recruitment) will apply to that pilot work; and
- outline how the pilot testing will inform, or potentially impact upon the subsequent phases of the research, and the degree to which the details provided of the subsequent phases should be considered contingent upon the outcomes of the pilot work.

Commentary Inset 6 – Ethics reviewer directed pilot test: Endpoints

Typically, when ethics reviewers direct that a pilot test is required for a project (e.g. to assess the effectiveness of a risk management strategy) they will indicate end points for the pilot test.

Endpoints refer to triggers to cease the participation of individuals and to conclude the pilot test.

> *EXAMPLE – The reviewers might direct that the participation of an individual be terminated as soon as a risk/harm is detected. The reviewers might also direct that the pilot test be stopped early if >20% of participants tested thus far are affected by the risk or if 3 consecutive participants are affected by the risk.*

Depending upon the nature of the project the researchers may wish to consult a statistician and propose amended endpoints that are. more practicable, appropriate and/or useful.

When the approved endpoints are reached work should be suspended and a report sent to the ethics reviewers. This report should discuss whether the pilot test results indicate that a modification to the project is required (e.g. additional screening of potential participants) or if the project should be abandoned (e.g. because the risks associated with the work are no longer justified by the benefits).

Ethics reviewers can sometimes direct a pilot test where there is uncertainty about significant risks and where, in the absence of more information, the reviewers might otherwise elect not to provide the main study with ethical clearance.

Where there is limited previous/work about a research design with significant risks, researchers are encouraged to consider incorporating a limited pilot test into the design. Such an approach is likely to be considered favourably by the ethics reviewers.

See Booklet 9 of the Griffith University REM for more about Risks, Booklet 6 for more about variations to projects and Booklet 3 for more about the responsibilities of researchers.

In reviewing the application for ethics clearance, the reviewers (e.g. an expedited review panel) is likely to adopt one of two positions:

1) That only a limited number of phases of the proposed project are approved (e.g. just the pilot testing), and the researchers will need to resubmit once the final details for the later stages has become clearer. This is most likely in situations where the research involves significant risks or ethical issues, and/or the contingent nature of the later stages are such that they warrant close scrutiny (informed by the experience during the pilot phase).

2) The protocol is approved, as presented. If the pilot work results in required changes to this project, those changes are to be handled as per the University's mechanism for the handling of variations (see Booklet 06 of this Manual).

6.1.1 PILOT TESTING THAT DOES NOT REQUIRE RESEARCH ETHICS REVIEW

In very limited circumstances (see Commentary Inset 4 for some examples), it may not be necessary to submit a pilot test for prior research ethics review. This special exemption from research ethics review must only be used where:

i) no data from the pilot test will be analysed/used for the main study;

ii) the potential participants are not vulnerable; and

iii) the work involves no more than negligible risk.

6.2 Need for pilot testing identified by ethics reviewers

Ethics reviewers (such as the Chair of the Griffith University HREC) may require researchers to conduct a pilot test to confirm a statement in the consent materials (such as the estimated time it will take to complete a questionnaire) or to provide more information to support the beneficence assessment of the proposed project (e.g. whether the screening test is sufficient).

Generally, reviewers will specify the requirements in terms of:

i) how long the pilot test should last/how many participants will be required;

ii) recruitment and/or consent (see Commentary Inset 5);

iii) any endpoints for the pilot test (see Commentary Inset 6);

iv) monitoring; and

v) reporting during and at the end of the pilot test.

Commentary Inset 7 – Examples of ethics reviewer directed pilot testing

EXAMPLE ONE: TIME REQUIRED TO COMPLETE A SURVEY – The application for research ethics review and the consent material states that participants will be able to complete the survey in under 15 minutes. The potential participant pool is parents who are refugees from non-English speaking countries.

The ethics reviewers believe that the 15-minute estimate is too low. An underestimation of time is an ethical concern because: a) it is disrespectful to the participants; and b) could result in potential participants making a decision about participation based upon inaccurate information and in weighing the burden of the research against its benefits the reviewers are basing this upon skewed information.

When queried on the time estimate the applicants indicate that this is based upon the researchers and colleagues doing dummy completions, and experience with other surveys. Of course the problem is that the comparative language competence of the researchers/colleagues and the potential participant pool may be very different.

Ultimately the decision of how significant an issue is likely to be is proportional to the risks and ethical sensitivity of the research. In many cases the ethics reviewers will only suggest the researchers adjust the estimate of time to minimise any discontent participants might feel about being misinformed. In some instances, the reviewers will direct the researchers to: pilot test the survey with persons more like the potential participant pool; then report back; and update the consent material accordingly.

EXAMPLE TWO: RECOVERY TIME AFTER TESTING – A project will involve healthy volunteers engaging in sub-maximal exercise on a treadmill and then completing a rapid sequence of scored fine motor tasks.

An experienced physiotherapist will supervise the activity.

The researchers have arranged a recovery room where participants will be urged to remain for 15 minutes.

The ethics reviewers wonder whether this is sufficient (e.g. for participants safely travelling home). They require the researchers to initially conduct a small pilot test involving conducting standard clinical observations (e.g. pulse rate, estimation of haemoglobin-oxygen saturation, and level of consciousness) by a registered nurse at the 15, 30, 60 and 90 minute mark to determine whether participants must be required to remain in the recovery room. Following the pilot test the researchers will be required to report back to the ethics reviewers and potentially modify the project.

See Commentary Inset 7 for two examples of ethics reviewer-required pilot tests. See Booklet 2 of the Griffith University-REM for more about research ethics review, Booklet 9 for more about beneficence and Booklet 3 about the responsibilities of researchers.

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7.0 Practicum and industry placement

Subject to qualifying criteria (see 3.2 of this booklet) research that is conducted while a Griffith University student/candidate is on a professional/vocational practicum or on an industry placement is considered to be outside the scope of the University's human research ethics arrangements – so in most cases does not need to be submitted for research ethics review at Griffith University.

This is the case even if the research activity otherwise has the characteristics of human research (such as conducting interviews with a view to writing a report for the host institution). The qualifying criteria distinguishes between activity, data and outputs for Griffith University research purposes and activity where there may be an educational/vocational benefit for the student but the research activity/output is for the host institution. Even if the activity is considered to be outside the scope of Griffith University's human research ethics arrangements, students must still conduct themselves ethically, with integrity and honesty. See 8.0 of this Booklet for more guidance on this.

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Commentary Inset 8 – Managing changes to an 'outside the scope'/exempt project: Two case studies

EXAMPLE ONE: A student is working with a community choral group and other musicians on a musical performance for an upcoming community festival.

The work with the community and the performance is a research output and is a component of the student's masters. However the work meets the creative output test (see 4.4) and is exempt from research ethics review.

During the process the student and her supervisors realise that there might be a credible conference paper/journal article about the creative process and community engagement. Data collection would be in the form of interviews during creative/community engagement process, an audience survey at the end of the performance and a focus group interview after the festival with the community choral group.

The addition of these data collection methods means that the project is no longer exempt so must be submitted for research ethics review.

Instead of the possible research output being identified early this might evolve more organically during the process (e.g. the student might decide the creative process could be improved by interviews with key informants at the community group that is organising the festival). So the value of the other data collection methods and the possible papers might not become apparent until the student starts conducting the interviews.

As soon as possible the student and supervisor should contact the Research Ethics Office (see Contacts) for guidance. It is likely that the following will occur:

i) the data already collected will be 'quarantined' and so not used for research purposes until the matter is resolved;

ii) there will be an assessment of whether the 'reviewable' human research to date has otherwise adhered to the University's research ethics policies; and

iii) consent for the research use of their comments must be sought from the persons already interviewed.

As long as the student and supervisor have acted in good faith the circumstances should not initiate breach proceedings (see Booklet 7 of the Griffith University-REM). The situation would be considerably more difficult if the audience survey had been completed before ethical clearance was sought or if the research to that point in some way didn't adhere to the University's human research ethics policies.

Griffith University researchers whose work has been assessed as exempt from ethics review must remain mindful that changes/additions to the project may alter the exempt status of the project. Furthermore exempt projects must still be designed, conducted and its results reported in a manner that adheres to the University's human research ethics policies.

CONTINUED OVERLEAF

8.0 Acting ethically, with integrity and honesty

Even if work falls outside the scope of the University's human research ethics arrangements (see 3.0 of this Booklet) or it exempt from research ethics review (see 4.0) it must still be designed and conducted ethically, with integrity and honesty.

8.1 Ethical design and conduct

The following is a list of some of the key ethical considerations that need to be considered and addressed for work that has been assessed to be 'outside the scope' or exempt from Griffith University research ethics review. Please refer to the *Griffith University Human Research Ethics Manual* for further guidance on these and other ethical considerations.

a. The design of the work needs to be based upon a sound understanding of the literature, previous research or practical experience – in terms of the research questions/objectives, the design, and the strategies to address risks and/or ethical issues. See Booklet 38 of the Griffith University-REM for more on these matters.

b. The design of the research must be respectful of participants with due regard for their welfare, rights, beliefs and culture. This respect and due regard must take precedence over the objectives and needs of the research. See Booklet 26 of the Griffith University-REM for guidance on these matters.

c. The inclusion and exclusion criteria for participation must be fair, based upon ethical and legal standards, and must have a sound basis in the variables of interest/research questions. Exclusions from a participant pool may need to be disclosed in the reporting of the results (e.g. as a potential limitation to the findings). See Booklet 21 of the Griffith University-REM for guidance on these matters.

d. The recruitment mechanism must not breach ethical and regulatory privacy standards. See Booklet 23 of the Griffith University-REM for guidance on these matters.

e. The risks associated with the research must be justified by the benefits of the work. See Booklet 09 of the Griffith University-REM for guidance on these matters.

Commentary Inset 8 – Managing changes to an 'outside the scope'/exempt project: Two case studies
CONTINUED FROM PREVIOUS

EXAMPLE TWO: An evaluation of the use of social media in a Griffith University course.

Social media has recently been incorporated into an existing course – as a collaborative tool for group work and for participation in weekly discussion topics.

Initially the course convenor and some of the teaching staff decided to survey students using a Unit Teaching and Evaluation Instrument (UTEI) in the first semester in which social media was utilised.

The evaluation met the test at 3.1 and initially would meet the test at 5.1 for the production of a research output based upon the course evaluation. Consequently, the relevant Head of School can approve the activity. The design and conduct of the work must adhere to the University's human research ethics arrangements (e.g. with regard to voluntary participation, consent and privacy) and the activity must involve no more than negligible risk.

However when she is writing the article the course convenor wishes to include some illustrative comments from the students' social media posts. Even if the students are not referred to by name or student number the use of their phraseology/any description of their demographics means that the students may be identifiable by inference, if only by their peers and perhaps other members of academic staff in the School.

This would mean that the test at 5.1 could no longer be met and possibly an application for research ethics review is now required and the consent of the quoted students must be sought.

f. Consent must be obtained from all participants, including full disclosure about the research and the standard information and assurances outlined by Booklet 22 of the Griffith University-REM.

g. Any assurance provided to participants with regards to anonymity of confidentiality must be honoured. See Booklet 23 of the Griffith University-REM for guidance on these matters.

h. Participants should be provided with an appropriate and timely summary of the results of the work. Where individuals are to be debriefed about their own results, especially when those results are likely to be of concern, the de-brief should be communicated by someone with appropriate expertise and knowledge.

i. Booklet 3 of the Griffith University-REM provides further guidance with regard to the ethical responsibilities of researchers.

8.2 Acting with integrity and honesty

All Griffith University researchers must adhere to the principles of research integrity and honesty, as articulated by the *Griffith University Framework for the Responsible Conduct of Research*.

The Griffith University Code covers:

i) publication ethics;
ii) authorship;
iii) responsible storage of data;
iv) honesty and integrity in the reporting of research results;
v) the responsibilities of students/candidates and supervisors;
vi) collaborative research;
vii) peer review; and
viii) conflicts of interest.

These principles apply irrespective of whether a project is human research, whether it requires research ethics review, the discipline/methodology, the funding source (if any), the research output, or the experience of the researcher(s).

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9.0 Unanticipated changes in status

In the event a project changes from being 'outside the scope' (see 3.0) or exempt from research ethics review (see 4.0), to requiring review, the chief investigator must promptly contact the Office of Research Ethics and Integrity (see Contacts) to discuss what should be done.

Typically an application for research ethics review will be required. See Commentary Inset 8 for two examples.

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10.0 Academic publication

Prior to accepting/publishing an article many academic publications require confirmation that the work has been ethically reviewed.

It is possible that work that has been deemed to be 'outside the scope' (see 3.0) or exempt from research ethics review (see 4.0) may form the basis of an academic publication. **Care should be taken to ensure that such a research output doesn't change the scope/exempt status for the work (see 5.0).**

As long as the status of the work has not changed the Research Ethics and Integrity team (see Contacts) can provide formal confirmation that the work was considered 'outside the scope' or exempt from research ethics review – so there is no ethical impediment to academic publication.

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11.0 Human ethics review of human biological biospecimens (including cell lines)

The National Statement on Ethical Conduct in Human Research (2007, Updated 2018) directs that both the prospective collection of human biological biospecimens and the access/use of existing, stored biospecimens require ethics review-approval. However, Griffith University recognises that different ethical considerations are involved in the prospective collection of human biospecimens (for example, blood, urine, cells and tissues) compared with the routine use of immortalised cell lines of human origin from commercial providers or research collaborators.

Consequently, the University has put in place a streamlined ethics review process for research involving only stored or purchased human cell lines that is concordant with the ethical considerations for negligible risk, routine scientific use of commercially available human cell lines in research. All other prospective research activities using human biospecimens require submission of a human research ethics application.

The ethics review process for widely available or commercial human cell lines takes advantage of the existing registration and approval processes in place for research with genetically modified organisms (GMOs) or other biological activities in the University's GSafe system, which is administered by the Health, Safety and Wellbeing team.

The University's differing approaches to the ethics review of research involving prospective collection of human biospecimens versus stored or purchased human biospecimens from commercial biobanks or research collaborators are outlined below:

1) Prospective collection from consented research participants

Research involving the prospective collection of biospecimens (e.g. cells, tissues, or blood) from research participants will require human ethics review for each individual project. An approved consent process must be in place for the collection and research use of biospecimens (including cell lines) from study participants. A human ethics application must be submitted using the RIMS online platform.

2) Purchase or use of human-derived cell lines from commercial biobanks

As an alternative to a human research ethics application, research involving only commercially available cell lines cultured *in vitro*, such as those obtained from commercial biobanks (e.g. ATCC) can be registered in the online system GSafe, the University's Health and Safety management system (https://www.griffith.edu.au/health-safety-wellbeing).

The three registration types which include a human ethics declaration include OBD (Other Biological Dealing) registration which covers non-GMO biological research, ED (Exempt Dealing), or NLRD (Notifiable Low Risk Dealing) registration which covers research with Genetically Modified Organisms (GMOs). For more information, please see the 'Activity Register" document entitled "Creating an Activity Application". This document is located on the Biosafety, Chemical and Radiation Section of the HSW website (https://www.griffith.edu.au/health-safety-wellbeing/biosafety-chemicals-radiation) under 'Working with Biological Materials Chemicals or Radiation'.

If the cell lines being used are included in one or more of these activity registrations in GSafe, investigators are now asked to make an additional declaration and abide by approval conditions relating to the National Statement. No further ethics review is required if this human ethics declaration has been completed in GSafe.

These registrations in GSafe will permit the University to register the research activity, storage location of samples, persons who will be using the samples, and any associated risk assessments. The Ethics and Integrity team will receive notifications about registration of human lines in the GSafe system and will make enquiries if there is any further information that needs to be provided about the activity.

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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 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

Griffith University is commercialising the GUREM through licenses to other universities and research institutions. Consequently, Griffith University staff are asked not to send copies of any booklet to persons external to Griffith. For further information please contact the Office for Research (see above).