



Standard Operating Procedure

Griffith University Human Ethics Committee

V3.00 – 0711

The Griffith University Human Research Ethics Committee (HREC) is a University committee, which reports to the Research and Postgraduate Studies Committee. Many of the standard operating procedures for the committee is described by *Guide to Committee & Meeting Skills* (<http://www.gu.edu.au/ua/aa/ctte/skill/content/commskill.pdf>). However, this document outlines those operating procedures which are specific to the GU HREC.

1.0 Authority

Griffith University has established the HREC to advise the institution on human research ethics matters, to assist researchers in the design and conduct of high quality ethical research, and to facilitate the University's compliance with the various regulatory frameworks which relate to the governance¹ of human research ethics issues.

Griffith University's human research ethics arrangements comply with the *National Statement on Ethical Conduct in Human Research (2007)*. The constitution (see Attachment 1) and functioning of this committee is in accordance with the provisions of the National Statement. The Committee also plays a valuable advisory role in regards to the institution's approach to the *Australian Code for the Responsible Conduct of Research*.

In addition to the National Statement, the drafting of this document was informed by the framing of relevant leading international guidelines and commentaries (such as the *Institute Review Board Guidebook produced by the Office for Human Research Protection* and the *World Health Organisation Operational Guidelines for Ethics Committees that Review Biomedical Research*).

The HREC has no delegated authority in relation to budgetary or management issues, but does advise the University on matters which may have budgetary implications.

The HREC also has an important role in reviewing applications for ethical clearance via the full ethical review pathway.

2.0 Reporting

The HREC reports and makes recommendations to the Deputy Vice-Chancellor (Research). The Committee also provides an annual report to Council via the Research and Postgraduate Committee, as well as reports to the Australian Health Ethics Committee of the National Health and Medical Research Council (as required).

¹ The University has responsibilities and processes that extend beyond the work of the HREC. Where the HREC is not directly responsible for the discharge of these responsibilities, it does play an important advisory role.

3.0 Resourcing

The Office for Research has appointed a Manager, Research Ethics, a Senior Policy Officer, and a Research Ethics Systems and Support Officer to work with the GU HREC. The University allocates financial resources to the Chair and Deputy Chair of the Committee to facilitate their work on behalf of the Committee.

4.0 Membership

The “core” membership structure of a HREC is outlined by the *National Statement on Ethical Conduct in Human Research*. This structure should include a reasonable balance between internal and external members², a balance between male and female members, and there should also be a balance of expert and lay perspectives.

The diverse nature of research conducted within the University necessitates a membership structure that combines an appropriate breadth of expertise and ensures a wide engagement with the elements of the University. See 4.4 for further information in relation to how the membership of the HREC responds to this challenge.

Members of HREC serve a two-year term. Although members can be renominated to serve additional terms, the normal maximum duration of consecutive membership is four years. In considering whether to renew a term of membership or seek a new appointment, every effort is made to maintain a balance between continuity of expertise and renewal.

Where a member ceases to fulfil the criteria of their position (eg a nominee of an element ceases to be a staff member of that element), their membership immediately lapses.

Much of the membership of the Committee is appointed by Deputy Vice-Chancellor (Research) or by the Research and Postgraduate Studies Committee on the recommendation of the Deputy Vice-Chancellor (Research). One position is *ex officio* the Professor of Indigenous Policy.

The Deputy Vice-Chancellor (Research) may determine the method by which his / her recommendation for nominations are made – which could include calling for expressions of interest, followed by whatever selection method which the Deputy Vice-Chancellor (Research) deems appropriate. The final selection of a recommended nominee will be at the discretion of the Deputy Vice-Chancellor (Research) and will be based upon issues such as expertise, representation, potential contribution, and relevant University policy.

A recommendation in relation to the filling of casual vacancies will be made by the HREC, and a final determination made by the Deputy Vice-Chancellor (Research).

4.1 Chair

The Chair of the HREC is the Deputy Vice-Chancellor (Research), or nominee. In addition to those duties, authorities and responsibilities established by *Guide to Committee & Meeting Skills*, the Chairperson:

- considers applications for Expedited Ethical Review Level 1;
- serves as one of the executive members who considers applications for Expedited Ethical Review Level 2;
- (when determined to be required by the Committee or Expedited Ethical Review Panel) considers under executive powers responses in relation to conditional ethical clearances;

² At least one third of the HREC membership must be external to the University.

- considers (and may award interim approval to) requests for minor changes to ethical clearances / projects;
- approves the draft outcome report prepared by the Secretary following meetings of the Committee / flying minutes;
- chairs (or nominates the chairs) of the various Audit panels, and such other working groups established by the Committee.

The Chair has debate and voting rights for all matters before HREC – except in situations where a conflict of interest precludes them from exercising such rights.

4.2 Deputy Chair

The Deputy Chair of HREC is appointed by the Committee. The Deputy Chair undertakes the role of the Chair in her/his absence and serves as the other executive member who considers applications for Expedited Ethical Review Level 2.

The Deputy Chair has debate and voting rights as per their substantive position (eg if the Deputy Chairperson was a core member before being appointed the Deputy Chairperson they have all the voting rights of a core member).

4.3 Executive

The Chair and the Deputy Chair of HREC comprises the HREC Executive.

4.4 Core members

The National Statement specifies some categories of membership which must be present for the consideration of an application for ethical clearance. These categories of members constitute the “core” membership of the HREC. Core members have debate and voting rights for all matters before HREC.

4.5 Research Ethics Advisor nominees

Each element of the University has been encouraged to appoint a Research Ethics Advisor (REA). Groupings of elements have a nominee who serves of the HREC. Ten such members serve on the HREC. These nominees will normally be drawn from one of the element REAs of their grouping. All nominees have full voting rights for policy and administrative matters before the HREC.

To maintain the balance requirements articulated by the National Statement, only the REA from the relevant element group will have voting and debate rights on an ethics application from her/his group. However, at the discretion of the Chair³, all nominees will have rights of audience for all applications. As such, the relevant nominee is considered a core member for the consideration of an application from their element grouping, and are considered to be the member who brings experience / understanding relevant to the application being considered.

4.6 Alternate nominees and proxies

³ Normally the other REAs who are present at a meeting will be invited to contribute to the debate after the ‘assigned discussants’ have spoken (see 5.4). However, where there is considerable debate, the Chair may defer inviting the other REAs to join the discussion until after all of the core members have had an opportunity to speak.

To ensure that the Committee can conduct its business, and to facilitate a renewal of membership, the University will endeavour to appoint alternate members to each of the core membership categories. Such alternate members will attend a meeting and have full debate and voting rights, and will count for quorum (see 5.3), in the absence of the relevant ordinary member. Alternate members will attend at least two meetings per year, if only to observe a meeting.

Although the practice of using proxies is not encouraged, a member can nominate an appropriate proxy in a situation where neither the ordinary, nor alternate, member is available.

4.7 Additional attendance at meetings

The constitution of the HREC permits the Committee to invite the attendance and participation in debate of additional persons, as required to enable the Committee to appropriately and efficiently conduct its business.

A co-opted member / invited expert has audience rights, but cannot exercise a vote or participate in debate unless specifically invited to do so on a particular matter.

4.8 Policy and administrative support

The Director, Office for Research, will appoint a Secretary to the Committee who will have rights of audience and debate. The Secretary will normally be the Manager, Research Ethics. The Research Ethics Officer may also attend meetings and support the work of the Manager, Research Ethics.

The Research Ethics team will:

- receive and forward correspondence to Executive members, as appropriate, (such as the *GU Expedited Ethical Review Checklist*, applications for ethical clearance, applications for minor changes to ethical clearances / projects, etc);
- conduct the initial administrative review of projects that already have been approved by another HREC, as per Booklet 8 of the Griffith University Research Ethics Manual;
- conduct the administrative review of projects exempted from ethical review by the University's negligible risk framework, and provide feedback to the researchers, report to the HREC, or identify matters that require further ethical review;
- provide commentary and advice to assist in the consideration of matters before the HREC, Expedited Ethical Review Panel, and Executive of the HREC;
- receive progress reports and determines what, if any, further action is required;
- process applications for extensions of ethical clearance within the three year limit;
- maintain the University's register of ethical clearances;
- assist in the preparation of internal and external reports, submissions and other corporate documents;
- provide advice to other officers of the Office for Research and the Deputy Vice-Chancellor on the governance of human research ethics, regulatory requirements, and compliance issues;
- support the work of the REAs;
- provide advice and assistance directly to researchers and supervisors, where appropriate;

- initiate and progress the business and work of the Committee;
- directly handle requests for textual or administrative changes to active ethical clearances; and
- draft such reports, policies and documents as requested by the Chair or the Committee.

The officers of the Research Ethics Team are not members of the Committee.

5.0 Meeting Procedures

A meeting schedule for HREC is determined at the end of the preceding year. Generally, the HREC will meet at least 10 times a year.

5.1 Committee papers

There are standard agenda items, and proformas to assist the HREC in the consideration of the following matters:

- i). Reporting the actions taken on conditional ethical clearances and seeking the Committee's ratification, amendment or modification of these actions.
- ii) Reporting the decisions of the Expedited Ethical Review Panel and seeking the Committee's ratification, amendment or modification of the Panel's decisions.
- iii) Applications for full ethical clearance.
- iv) Reporting the decisions of the Chair and the Office for Research on requests for modifications to existing ethical clearances and seeking the Committee's ratification, amendment or modification of the Chair's decisions.
- v) Presenting for action any progress reports which are deemed to require the attention of the Committee.

5.2 Distribution of committee papers

To enable appropriate processing, any matters for consideration by the Committee (such as applications for full ethical clearance) must be received by the Secretary of the HREC at least two weeks prior to the meeting.

Committee papers are generally distributed between one and two weeks prior to the meeting date.

5.3 Quorum

The quorum provisions for the GU HREC are articulated in the constitution for the Committee. In addition to these quorum requirements, for the Committee to be able to consider applications for ethical clearance, all the core members (or their alternates) must be present at the meeting – or must have provided, or will provide, their comments to the Chair (via the Secretary).

5.4 Conduct of meetings

Meetings of the GU HREC follow the distributed agenda, and discussion and debate are directed through the Chair. Nevertheless, formal standing orders do not apply to the conduct of the meeting, and debate is largely conducted in an informal manner.

When reviewing applications, there will be at least two, but preferably three assigned discussants who will identify matters that require attention, before the debate is opened to the wider membership of the Committee. Generally, these members will be: an experienced member of the Committee and/or an external or other core member and the relevant Research Ethics Advisor.

5.5 Basis for the consideration of issues

Griffith University is committed to the principle that the review of proposed human research should be transparent, consistent, and promptly communicated to the applicants. This process should have the objective of working collaboratively with researchers to facilitate excellent and ethical research.

The deliberations of the HREC and other ethics reviewers must be based upon the provisions of the National Statement, the GU Research Ethics Manual and other regulatory issues which relate to the terms of reference articulated by the Committee's constitution. Members are asked to carefully consider proposed research, policy and other matters, with reference to the above guidelines, policies and regulations. Any review decision and/or advice must be based upon these documents.

5.6 Method for reaching a decision

In most cases, the GU HREC reaches decision by consensus, but this does not necessarily mean an unanimous view. In those circumstances where a consensus cannot be reached, the Chair will call for a vote. As noted previously, only core members may vote on an application for ethical clearance. Even if a majority of core members vote to grant a project ethical clearance, the Committee may elect not to grant clearance if a significant number members are opposed.

5.7 Communicating the outcomes

Good communication is an important foundation of a sound approach to research ethics. After each meeting of the GU HREC, the Secretary will:

- (normally within five working days of receiving an endorsed outcome of a review) email the outcomes of ethical clearance to the proponents;
- (upon receiving a response from the proponent, and if specified as required by the reviewers) provide a response with the full documentation to the Chair for action; and
- (normally within 10 days of the meeting) forward any recommendations from the Committee to the Deputy Vice-Chancellor and / or Research and Postgraduate Studies Committee.

In the interests of timeliness, efficiency and sustainability, the described communication processes make use of email and the internet. The *GU Research Ethics Manual* is a source of further information in relation to the processing of applications for ethical clearance, including guidance to assist in responding to requests / concerns from the HREC.

5.7 Observers

The attendance of observers at a meeting of the HREC is at the discretion of the Chair.

5.8 Invitations to researchers

Having decided that an application must be revised and resubmitted to a subsequent meeting, the HREC can elect to invite the proponents to attend the meeting to discuss their application with the Committee.

6.0 Format of submissions of applications for ethical clearance

To be considered for any level of ethical review, an application must conform to the minimum requirements in relation to having been submitted on the correct form, including the appropriate signatures and attachments.

Any incomplete application or an application made using the incorrect form may be returned unprocessed.

Unless the proponent presents a compelling argument for action to the contrary, applications submitted after the due date for the meeting will normally be considered at the Committee's next meeting. At the discretion of the Chair of HREC (on the advice of the Manager, Research Ethics), late applications may be considered outside of a meeting by flying minute.

8.0 Monitoring of research

As per s5.5.1 to 5.5.5 of the National Statement, the University has established a number of strategies to monitor approved research, these include:

- i) Researchers completing an annual, or upon completion of the project, ethical conduct reports. This is a self report. Completed reports are received and initially reviewed by the Secretary, who determines whether a matter from a report should be referred to a member of the HREC executive, to a panel of the HREC, or a HREC meeting. The Committee receives a summary of the reports received and processed since the Committee's last meeting.
- ii) The HREC randomly selects a number of projects each year for audit. This audit process is described in Information Sheet No 4 of the *Griffith University Human Research Ethics Information Sheet Series*.

The following additional strategies are used both to monitor approved research and to identify research that has not been submitted for review.

- iii) Each week External Relations provides Office for Research with a copy of the 'digest of news items' before they are issued, so any research that is mentioned in the releases can be checked for ethical clearance and potentially any other issues of concern. External Relations often also consults on individual media releases.
- iv) Finance and Business Services will not create an account for a human research project without either confirmation of ethical approval, or advice from Office for Research.
- v) Griffith Graduate School consults with Office for Research if it appears that a PhD candidate needs ethical clearance, and does not appear to have a clearance, at the time of confirmation.

Further information about the University's monitoring processes, including the handling of serious adverse events, can be found in Booklet 5 of the *Griffith University Research Ethics Manual*.

9.0 Confidentiality

Each member of the GU HREC signs an Agreement to Accept the Terms of Reference and Standard Operating Procedures of the Committee (copy attached) confirming that they will not disclose any confidential information to third parties.

This agreement means that, outside of a meeting, members should only discuss matters relating to the Committee's deliberations if they are discharging an official responsibility / role (eg a REA discussing with a head of an area a pattern of problems with applications submitted from their area).

Members must never compromise intellectual property, commercial-in-confidence, or participant confidentiality.

The Office for Research maintains hard copy and electronic records in relation to ethical clearance applications and related activity. Any access to these records is limited to members of the research team (including supervisors), members of the GU HREC, and authorised officers (eg the Deputy Vice-Chancellor (Research), relevant REA, or the relevant head of element).

10.0 Conflicts of interest

Each member of the GU HREC signs an Agreement to Accept the Terms of Reference and Standard Operating Procedures of the Committee (copy attached) to disclose any duality of interest, or potentially perceived conflict of interest (eg they are a member of the research team, they are a supervisor for a particular student proponent's project, they have a pecuniary interest in a project). The member must disclose an actual, or potentially perceived, conflict of interest at the beginning of the meeting. The Committee will consider whether to instruct the member to withdraw from the meeting for the consideration of that matter, whether to remain as an observer, or whether to remain with rights of audience and debate. Such a withdrawal of a member will be noted in the minutes.

11.0 University indemnification of members

In accordance with Australian requirements and international guidelines, the University provides indemnification to the members of the HREC on the basis of them being either:

- (i) students, staff, voluntary worker, foundation, institute, centre or other body, affiliated to or operating within the framework of the University and formed by or with the knowledge and consent of the University; or
- (ii) any person acting in an honorary (academic or otherwise) capacity for the University and includes honorary research fellows and voluntary workers who occupy a duly recognised position in the business of the University.

This indemnification covers activities that are officially approved and undertaken with the knowledge of the University or under the direction or control of, or at the request of, or which are activities relevant to that person's position with the University.

12.0 Handling of initial complaints and investigations

Institutions are required to have processes in relation to the handling of complaints in relation to the ethical conduct of their research. The expectations in relation to these processes are articulated in the *National Statement*.

The University has established mechanisms in relation to the following matters:

- concerns / complaints from research participants;
- alleged breaches of the University's research ethics arrangements; and
- requests for a review of a decision of HREC.

The details of these processes are outlined in Booklet 7 of the *GU Research Ethics Manual*, and specify that the Manager Research Ethics is the initial contact for any concerns in relation to the ethical conduct of the research and attempts to resolve these matters in liaison with the complainant, the respondent, and the Chair of the HREC. The Deputy Vice-Chancellor is responsible for handling formal complaints.

13.0 Fees

At the time of writing, the GU HREC does not apply any processing fee to the consideration of any application for ethical clearance.

14.0 External research

At the time of writing, the GU HREC does not process ethical clearance matters which do not relate to Griffith University research. Research conducted on Griffith University students and/or staff by a research team that is entirely external to the University qualifies for a special administrative review, as long as the research has previously been approved by another HREC.

15.0 Member training

Griffith University is committed to the training and ongoing development of the members of the HREC. Consequently, the University will support the attendance of a delegation of the Committee to the biannual national research ethics conference. The University will also, where possible, support and fund the attendance of members at other training, developmental and networking opportunities. New members of the HREC will be provided with a resource kit of materials. Each year the Office for Research will conduct an induction workshop / refresher workshop for the members of the HREC.