School of Health and Rehabilitation Sciences
Recommended procedure to obtain Ethical Approval of Staff and Student research

INFORMATION FOR STAFF MEMBERS AND STUDENTS

SHRS Research and Postgraduate Studies Committee recommends the following procedure to obtain ethical approval for new studies. The procedure differs depending on the role of the lead investigator;

Staff member: Application must be submitted to a central ethics committee (MREC or BSERC). This may be as a full application. However, it is recommended that the staff member consider whether it is more appropriate to submit an amendment to an existing approved application or to apply for a “program type” application for ethical approval that covers a broader series of studies within a theme rather than a single or small number of studies.

Student (Honours/GEMS/MPhil/PhD/coursework Masters): If the study involves even minimal risk or a vulnerable group an application must be considered by a central ethics committee. If there is very low risk (e.g. audit, simple measurement, no deception) and the procedures are considered routine within the student’s profession the application can be considered by a school based review process. This is not to be considered a faster or easier alternative to full review. It is recommended that student projects be included as an amendment to an existing approved protocol or inclusion in a program type ethics.

Non-SHRS researcher: If the study is lead by a non-SHRS staff member in collaboration with an SHRS staff member the study requires full review by a central ethics committee.

Procedure
1. New application - Full submission to MREC or BREC. Is student submission a cover letter is required to defend why it requires full review (risk of procedure or inclusion of vulnerable group). Consider whether an amendment to an existing approved protocol or inclusion in a broad “program type” application for ethical approval would be better options to minimize workload for the researcher and the ethical committee. It is recommended that applications with students as the lead investigator should be submitted with a cover letter highlighting why the application requires full review rather than consideration by a school-based committee (e.g. identify that risk is greater than very low, that a vulnerable group is involved, etc)

2. Amendment - Submission of amendment for expedited review by MREC/BSERC. Amendment can be for addition of new participant group, greater number of participants, additional methods to an existing approved protocol that falls within the same theme as the approved protocol and can be more than just small adjustments to the protocol. There is an option to provide new Participant Information Sheets and Consent Forms to describe the new amended protocol. The amendment is provided a new approval number, can run concurrently with the original approved protocol and undergoes a separate
annual review by the ethics committee. There is no limit to the number of amendments that can run concurrently.

3. “Program type” ethical approval - Consider submission of application for ethical approval for a broad program of research rather than single or small group of studies(s). There is no separate form or process for this type of application for ethical approval. The only difference from a conventional application for ethical approval is that it is clearly stated in the application that it is for a “series of studies” and the breadth of the studies are detailed. The requirement for adequate explanation of the procedures, risks and benefits remains the same. The application should clearly state that not all participants are the same nor do they have the same methods applied. The application can include multiple Participant Information Sheets and Consent Forms or a “tick box” form on which all potential participant groups and measures are listed and identified by a “tick” by the experimenter for the individual study. Explanations of the background and aims are necessarily broader than that used in an application for a single study.

4. School based review – This is only to be used for studies with very low risk undertaken with a student as the lead investigator. The study cannot involve a vulnerable group. The application for ethical clearance must:
   - Be submitted on the current UQ application for ethical clearance form (download this new each time to ensure you use the most recent version) with all sections completed;
   - Be submitted to the Research Administrative Officer in SHRS;
   - The ethical clearance paragraph in the Patient Information Sheet must include a statement regarding the nature of the ethics committee and this differs from the statement used on forms that are approved by MREC or BSERC.

“This project has been cleared in accordance with the ethical review guidelines and processes of the University of Queensland. These guidelines are endorsed by the University’s principal human ethics committee, the Human Experimentation Ethical Review Committee and registered with the Australian Health Ethics Committee as complying with the National Statement. You are free to discuss your participation in this study with project staff listed on this document. If you would like to speak to an officer of the University not involved in the study, you may contact the Chair of the Research and Postgraduate Studies Committee, School of Health and Rehabilitation Sciences through the Secretary on (07) 3365 7123.”
Recommended procedure to obtain Ethical Approval of Staff and Student research

INFORMATION FOR DIVISIONAL ETHICS REPRESENTATIVE

When you review an application for ethical approval as part of the school based ethical approval scheme it is recommended that you consider the following points.

1. You are not accepting legal responsibility for the study, you are indicating whether the protocol abides by ethical principles and you can only be delegated to do this if the project is very low risk.

2. If the study involves risk that you deem to be greater than very low, involves vulnerable groups, involves measures/methods that are not commonly regarded as within the scope of professional practice then you should recommend that the application is submitted for full review by a central ethics committee with a letter indicating the reasons. As a general rule if you are in any doubt regarding the risks or the appropriateness of the school-based review for a specific application then either discuss the issue with other senior and experienced colleagues within SHRS before consulting the Ethics Officer or recommend that the application be sent on to a central committee.

3. Check that all items on the “checklist” that is included at the back of the application form.

4. Ensure that the ethical clearance statement in the Participant Information Sheet includes a statement such as the following:

   “This project has been cleared in accordance with the ethical review guidelines and processes of the University of Queensland. These guidelines are endorsed by the University’s principal human ethics committee, the Human Experimentation Ethical Review Committee and registered with the Australian Health Ethics Committee as complying with the National Statement. You are free to discuss your participation in this study with project staff listed on this document. If you would like to speak to an officer of the University not involved in the study, you may contact the Chair of the Research and Postgraduate Studies Committee, School of Health and Rehabilitation Sciences through the Secretary on (07) 3365 7123.”

5. Check that all gatekeeper letters are provided.

6. Assign an approval number to the application in the following format;

   <Year>SHR-<Division><Approval number> (e.g. 2010SHR-PHTY001)

7. Record the approval on the centrally collated record of Ethical Approvals (need to include details of where this is located)

8. Write a letter on letterhead to the applicant stating the approval number and any recommendations;

   Dear XXX,
   Re: Ethics application approval #2010SHR-XXX001
   I am pleased to advise that your project ‘XXX’ (#2010SHRS-XXX001) has been approved with the following conditions:
   XXX
   Yours sincerely,
   XXX
School of Health and Rehabilitation Sciences

Recommended procedure to obtain Ethical Approval of Staff and Student research

Is the lead investigator an SHRS staff member or student?

No

Submit to MREC or BSERC as new proposal or amendment to existing approved protocol

Yes

Bias? (Edited)

Is the lead investigator an SHRS staff member?

Yes

Submit to MREC or BSERC as new proposal or amendment to existing approved protocol

No

Does the proposal involve vulnerable groups or procedures that involve even minimal risk or are not considered part of professional practice?

Yes

Submit to MREC or BSERC as new proposal or amendment to existing approved protocol

No

Preferred option:
Submit to MREC or BSERC as either:
1. Amendment to existing protocol
2. Inclusion in application for ethical approval of broad program of research

Alternative option:
Submit proposal for school-based review for studies that have very low risk (e.g. audit, Measurement with no risk, no deception).

NOTES:

1. New application - Full submission to MREC or BREC. Is student submission a cover letter is required to defend why it requires full review (risk of procedure or inclusion of vulnerable group). Consider whether amendment would be better options.

2. Amendment - Submission of amendment for expedited review by MREC/BSERC. Amendment can be for addition of new participant group, greater number of participants, additional methods to an existing approved protocol that falls within the same theme as the approved protocol. Can provide new Participant Information Sheet and Consent Form.

3. Program type ethical approval - Consider submission of application for ethical approval for a broad program of research rather than single or small group of studies(s). Can include multiple consent forms or tick box form on which measures are listed and identified by the experimenter for the individual study. Explanations of the background and aims are necessarily broader than that used in an application for a single study.

4. School based review - Only to be used for studies with very low risk. Patient information sheet must include a statement regarding the nature of the ethics committee that differs from the statement used on forms that are approved by MREC or BSERC.