CLEARANCE NOº (office use only)

THE UNIVERSITY OF QUEENSLAND

Application Form for Ethical Clearance for Research Involving Human Participants

For review by: **Medical Research Ethics Committee (MREC)**
Behavioural & Social Sciences Ethical Review Committee (BSSERC)
For Staff and Student Research
Refer to last page for website and other information, including mailing address

Please tick boxes:

MREC		**BSSERC**	
Full Review		**Expedited Review**	

Project Title:
Ensure that this is the same title as on the Participant Information Sheet.

Principal Investigator:	Student's name
Staff Noº/Student Noº: (cross out if not relevant)	Student number

Co Investigator/s:	
Project Co-ordinator (or authorised contact)	

Supervisor/s: (if applicable)	Research Degree supervisor

Schools/Departments:	

	Telephone	**Fax**	**Email**
Contact details of Principal Investigator			
Contact details of Project Co-ordinator or authorised contact			

Degree Enrolled (if student):	
Funding Body:	
If Project Funded - What year? **- Reference no. if available**	

Project Location:	It is important to be clear about where (country, state, organisation) the project will be conducted.	**Project Duration:**	

A. Is this submission identical or very similar to a previously approved protocol? **YES/NO** (circle)

If **YES**, please provide clearance no[º] **and** indicate whether identical or very similar):_____

B. Does this submission hold other ethical clearance? **YES/NO** (circle)

Note: Copies from other **AHEC** fully registered ethics committees must be attached.

C. Are you applying for Expedited Review? **YES/NO** (circle)

Note: Please see UQ Guidelines page 9 for the conditions necessary to qualify for Expedited Review.

D. Is the project a Clinical Trial (eg, a trial of a drug, device, therapy, intervention, treatment, etc) ? **YES/NO** (circle)

If **YES**, please specify:

PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS:

1) Who are the participants or informants?: eg, Children, University students, or other persons.

Note: Details of approximate **number**, age range, and male/female ratios are required.

2) Vulnerable Groups

The NHMRC has identified certain social groups as vulnerable and requires all researchers to take special care to protect the interests of these groups if they are in any way involved in the project. Those groups include: **children** (Section 4); **intellectually disabled** (Section 5); **those people highly dependent on medical care** (Section 6); **those people in dependent relationships** (Section 7); and **collectivities with their own social structures linked by a common identity and or common customs** (Part 8). Separate guidelines have been developed for **Aboriginal and Torres Strait Islander Peoples** (Part 9).

In preparing your research project and application for ethical clearance, you should investigate thoroughly, through consultation with supervisors, colleagues in your school and other professional groups/organizations, how these vulnerable groups may or may not be represented in your research.

Note: If participation of vulnerable groups is a focus of the research, the protocol can not qualify for expedited review (unless other current HREC clearance is held and a copy provided).

2a) Aboriginal and Torres Strait Islanders Group

Specify how this proposal accommodates / addresses the needs and interests of any Indigenous Australians who may be involved (as part of a sample, as volunteers or as the specific focus of the research). [For further assistance on indigenous cultural issues, please contact the UQ Aboriginal and Torres Strait Islander Studies Unit.]

no participation likely	some participation likely	a focus of the research
□	□	□

Provide a careful and considered rationale for your response: [Reasoning for the exclusion or inclusion of strategies to focus on this group must be clearly stated in your application for ethical clearance. All three possible responses require a considered statement, detailing your rationale]

If you do not plan to involve Aboriginal and Islander people you need to explain why. If you do involve

Aboriginal and Islander people you need to explain how you will do so in a culturally appropriate way.

2b) Other Vulnerable Groups

Specify how this proposal accommodates / addresses the needs and interests of any of the above groups that may be involved (as part of a sample, as volunteers, or as the specific focus of the research). – Specify the groups.

no participation likely	some participation likely	a focus of the research
□	□	□

Provide a careful and considered rationale for your response: [Reasoning for the exclusion or inclusion of strategies to focus on any of these groups must be clearly stated in your application for ethical clearance. All three possible responses require a considered statement, detailing your rationale]

You must explain your assessment of the likelihood of a vulnerable group participating in your study. Even if you indicate that participation is unlikely, you need to indicate why you consider this to be the case. Ensure that you have followed NHMRC guidelines.

3) Participant recruitment details: Please provide exact details of contact.

We need a detailed, step by step plan about the recruitment process will occur. More detail is best. We especially need to know how third parties who might assist you with the recruitment are involved in the process of recruitment and the privacy of the participants (and those who refuse to participate) is maintained. If you are involving an organisation in your recruitment process, you must supply a gatekeeper letter from that organisation.

4) In EVERY-DAY or LAY LANGUAGE please provide a summary of the project – including aims and benefit: This section MUST be completed in LAY LANGUAGE.

5) Give details of the research plan:

Note: The committee needs sufficient information to put into context the ethical considerations listed in later questions.

Note: This section should be completed in LAY LANGUAGE *as much as possible* so that it can be understood and appreciated by all Committee Members, including Lay Members.

Note: For application to the MREC – please keep response to a MAXIMUM of 2 pages.

We need you to set out, in detail, how the research will be done, including details of when and how data will be collected and how that data will be analysed. Give particular consideration to points at which there might be ethical issues raised, such as, issues of participants or potential participants' confidentiality and right to refuse involvement.

6) Give details of the ethical considerations attached to the proposed project:

List these and make sure that these issues are addressed in your participant information statement. For example, you may think that participants' may need an interpreter to understand the study, then, make sure that your participant information sheet includes reference to access to interpreter services. As another example, you may consider that the topic is potentially distressing to participants, in which case, your subject information sheet should include reference to where the participants can gain assistance in the event of distress.

7) How will informed consent be obtained from participants or informants?

You should outline the written and spoken communication that will occur in relation to consent. If

people with impaired capacity are to be included, please note how their involvement will be facilitated; if they are to be excluded, please note how the assessment of their impairment will be made.

8) Provide details of procedures for establishing confidentiality and protecting privacy of participants or informants:

This section should be linked to recruitment processes discussed earlier. It is important that you give consideration to how participants will be able to maintain confidentiality at each stage of the recruitment. Prior to involvement in the study, how will participants who do not want to participate maintain their confidentiality from you as the researcher? Once participants are involved, how will you ensure that others cannot identify them? Some ideas that have been presented include: use of pseudonyms; changing of identifying details.

9) Provide details of data security and storage:
Refer to the NHMRC National Statement, Section 14.

We need to understand where the data will be stored exactly (eg. A locked filing cabinet in the university office of the student's supervisor) and we need to know the security arrangements – such as how the data will be stored (such as with identifying information stored separately).

http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf

10) In what form will the data be collected:
Note: Tick the most appropriate box:

(i) Identified ☐ **(ii) Potentially Identifiable** ☐ **(iii) De-Identified** ☐

11) In what form will the data be stored and/or accessed:
Note: Tick the most appropriate box:

(i) Identified ☐ **(ii) Potentially Identifiable** ☐ **(iii) De-Identified** ☐

12) Give details of how feedback will be available to participants or informants:

It is important that you provide participants with an opportunity to learn of the findings of your research.

Simply providing transcripts is not an example of feedback, by contrast, access to a project summary at the completion of each research phase is. It is important also to consider how participants can access your research findings, so, for example, it is not usually enough to provide 'electronic' access via a website or similar as this excludes those with limited computer access.

13) Does the project involve any of the following possibilities? If YES, Give Details

a) The use of drugs.

b) Any invasive procedures (eg, blood sampling)

c) The trial of any intervention, therapy, or treatment (whether medical, behavioural, physical, or other)

d) The trial of any device

e) Any diagnostic scans carried-out for the purposes of the project (including, *but not limited to*: MRI, NMR, CT/CAT, X-Rays, etc).

1. If YES, please list.

2. Does your project involve the use of MRI? YES/NO

NOTE: If using MRI at a hospital site (i.e. a facility with emergency services available on site during testing), you MUST have at least one staff who has current CPR certification and must have undertaken an emergency evacuation drill at least once a year.

If using MRI at non-hospital sites, (e.g. UQ St Lucia Campus), you MUST have 2 staff who both have current CPR certification and they must have undertaken an emergency evacuation drill at least once a year.

Does your project fulfil these mandatory conditions? YES/NO

If NO, outline reasons for submitting your application without these conditions in place.

3. Does your project involve exposure to ionising radiation? YES/NO

NOTE: If YES, the protocol MUST comply with the Queensland *Radiation Safety Act (1999)* and *Radiation Safety Regulation (1999)*. The legislation requires compliance with the Australian Radiation Protection and Nuclear Safety Agency's *Code of Practice for the Exposure of Humans to Ionising Radiation for research Purposes (ARPANSA 2005)* (http://www.arpansa.gov.au/pubs/rps/rps8.pdf) and you MUST consult with the University Radiation Protection Adviser before submission.

Does your project meet the guidelines of the Code of Practice? YES/NO

Has the project been reviewed by the University Radiation Protection Adviser before ethics submission? YES/NO

f) The possibility of physical stress/distress, or discomfort

1. to the participants:
We need details of this.

2. to the researchers/data collectors:

g) The possibility of psychological/mental stress/distress, or discomfort

1. to the participants:

We need details of this. It is important that you think through the potential for emotional distress and how you will respond to it.

2. to the researchers/data collectors:

h) Deception of/or withholding information from, participant at **ANY** stage of the project

i) Access to data held by a Commonwealth Department or Agency (Please also specify the number of records to be accessed)

j) Access to data by bodies or people other than the investigators (eg, Medical Records)

14) Please Indicate What You Think Is The Level Of Risk For Prospective Participants Against The Scale Below: *Tick the most appropriate box. (Refer to the UQ Guidelines)*

- ☐ **Extreme Risk**
- ☐ **High Risk**
- ☐ **Some Risk**
- ☐ **Minimal Risk The School Ethics Committee will not normally consider applications that involve levels of risk higher than minimal risk.**
- ☐ **No Foreseeable Added Risk Above the Risks of Everyday Living**

15) Please provide details to assist the committee as to why you indicated the level of risk to prospective participants or informants in the question above (Question 14):

It is very important that your assessment of risk is credible and shows that you have thought through the potential for your research project to distress participants or to change their relationship with you (if you have a pre-existing relationship or another relationship with them, such as some sort of professional role in the organisation where the research will take place). We need detailed strategies for how you manage the risk and we prefer that there are a number of strategies available, such as contacting you or another resource in the event that the research process is distressing to them.

16) How has the possibility of withdrawal from the project been addressed?: **Note:** Ensure that details and effects of withdrawal without prejudice AT ANY TIME have been considered and explained. Refer to the NHMRC National Statement section 1.12.
Need to discuss how the participants will be informed of their right to withdraw and how this will be managed in the research process. For example, what will happen if a person does not complete an interview – will the interview data as a whole be destroyed?

17) Please note that this section must be completed for funded research or the application will not be processed.

17 a) Is this project receiving financial support to conduct the research? **YES/NO** (circle)
If your research is part of a project receiving external funding you need to complete this section.
17 b) If Yes, from what source(s)?
17 c) Who will be administering the budget?
17 d) Please provide details of the budget distribution. (Or attach a copy of the budget statement.)
17 e) Provide details of any other "in kind" support for the project or direct or indirect payment to any investigator:
17 f) Please provide details of participant reimbursement for their involvement in the Project, if any: **Note:** This could be cash payment, food vouchers, free services, or movie passes, etc.
Eg. honorariums

18) In undertaking this research do any "conflict of interest" issues arise?

If YES, please provide details.

Note: Conflict of Interest may arise, for example, because a researcher, or someone close to the researcher, stands to benefit financially from the research or the carrying out of the project or because inconsistent or incompatible obligations exist.

Refer to Sections 2.20-2.21, & 12.5-12.6 of the NHMRC National Statement:

This can be an issue if the research is taking place in an organisation where the researcher has a role, such as a volunteer or paid employee.

19) Is the project a multi-centre or site project?

If YES, provide the name of the principal ethics committee. Please provide copies of any conditions or requirements placed by other AHEC registered Human Ethics Committees:

Note: The Principal Ethics Committee is the Institutional Ethics Committee where the budget is to be administered.

UQ is likely to be the principal ethics committee, but you should name any other ethics committee's who may review your application or require UQ ethical approval as a condition of proceeding with the research.

20a) Some projects may involve permits from National Parks & Wildlife in relation to collection of data and Native Title issues. How have you addressed this issue?: (Refer to the UQ Guidelines)

20b) Does the project require biosafety clearance? **YES/NO** (circle)

ATTACHMENTS:

1) Participant Consent Form **Yes/No**
Note: for examples of what should be included in a consent form, please consult page 12 of the UQ Guidelines for Ethical Review of Research Involving Humans. Also refer to "Checklist" below.

2) Participant Information Sheet **Yes/No**
Note: for External Use - forms should be released on letterhead and contain University Ethical Paragraph.
Refer to UQ Guidelines and Ethics website, and "Checklist" below.

3) Questionnaire (if applicable) **Yes/No**

4) Indemnity Agreement (primarily for clinical trials and contract work) **Yes/No**

5) CTN (Clinical Trial Notification Form) (primarily for clinical trials) **Yes/No**

6) Gatekeepers or Permission-Givers **Yes/No**
Note: A 'gatekeeper' or 'permission-giver' is a person authorised to write a letter of Authority and Recognition from an organisation of any type involved with the research, which gives permission to the researcher for access to the population under the gatekeeper's or 'permission-giver's' authority.

7) Bibliographic References (not usually necessary at SWAHS level app). Yes/No

8) Other - please specify_____

_____

You will definitely require gatekeeper letters if you are involving an organisation in the recruitment of the participants or if you are in any way involving an external organisation in the research process.
_____

_____

DECLARATION

We/I, the undersigned researcher(s) have read the University of Queensland's Guidelines for Ethical Review of Research Involving Humans - 2000 and agree to abide by them in the conduct of this research. It is understood that this includes the reporting and monitoring roles associated with the approval by the University of Queensland.

Signature of Principal Investigator:_____

Date: / /

Signature of Supervisor (if applicable)**:**_____

Date: / /

An original plus 12 copies should be submitted to the:

Ethics Officer
The Office of Research and Postgraduate Studies
Cumbrae-Stewart Bldg (72)
THE UNIVERSITY OF QUEENSLAND QLD 4072

Ph: (07) 3365 3924
Fax: (07) 3365 4455

Email: humanethics@research.uq.edu.au

ADDITIONAL INFORMATION

Application information, including the UQ Guidelines, can be found on our website:
http://www.uq.edu.au/research/orps/?id=5064

The NHMRC National Statement can be found on the following website:
http://www.health.gov.au/nhmrc/publications/synopses/e35syn.htm

Information regarding biosafety can be found on the following website:
http://www.uq.edu.au/research/orps/?id=5257&pid=5256

Aboriginal and Torres Strait Islander Studies Unit website: http://www.uq.edu.au/atsis/ (which includes links to sites including the Australian Institute of Aboriginal and Torres Strait Islander Studies Unit under Cool Sites). Enquiries to the Aboriginal and Torres Strait Islander Studies Unit can be made on: 3365 6714 (ext 56714).

Full Review of applications may take a minimum of eight weeks from the time of submission. Expedited Review and Amendments may take a minimum of three weeks.

NHMRC: National Health and Medical Research Council

AHEC: Australian Human Ethics Committee

HREC: Human Research Ethics Committee and, for the purposes of this application, means an AHEC registered committee

Applications to MREC

Please note that medical research includes epidemiological research (Privacy Act 1988).

Audits

Please note that the Committee reserves the right to visit the research site and view materials at any time, and to conduct a full audit of the project.

Last Update 21/05/2007

Submission of Research Protocols for Human Ethical Clearance
APPLICATION CHECKLIST

This checklist is supplied for use as an additional means of ensuring all aspects of the proposed study have been considered and adequately detailed before submission to a reviewing Committee. A copy may be attached to the original application form for the reviewing Committee to support your submission.

Project Title:
Principal Investigator:

Participant Information Sheet (PIS)

	YES	NO	IF NO, WHY?
1. Version for each participant group *(if applicable)*			
2. On letter-headed paper *(if applicable)*			
3. Full title of project			
4. Lay title of project *(if applicable)*			
5. Names, positions & affiliations of all investigators			
6. Clear purpose of study			
7. Non-technical language			
8. Details of participation/ procedures			
9. Duration of participation			
10. Location for participation			
11. Risks outlined *(% explanation needed?)*			
12 Benefits to participants			
13 What support if something goes wrong			
14. Freedom to withdraw without penalty			
15. Assurance of confidentiality			
16. Access to results			
17. Debriefing			
18. Reimbursement to participants			
19. Need for Witnesses			
20. Contact details for further questions			
21. Ethical clearance statement			

Participant Consent Form (PCF)

	YES	NO	IF NO, WHY?
1. Version for each participant group *(if applicable)*			
2. Full title of project			
3. Lay title of project *(if applicable)*			
4. Names, positions & affiliations of all investigators			
5. Provision of space for full name of participant			
6. Written declaration of informed consent, eg, "I have read/"I understand…"			
7. Freedom to withdraw without penalty			
8. Assurance of confidentiality			
9. No benefit for participation			
10. Provision for signature of participant			
11. Provision for signature of witness and date			
12 Provision for signature of guardian, relationship to participant and date			