Office of Research

CQUniversity AUSTRALIA

Human Research Ethics Committee
Negligible and Low Risk Review Process and Application Form

The National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research', 2007 (the National Statement') recognises that human research involves a wide range of activities that have variable risks and potential benefits. The National Statement establishes different levels of ethical review, based on the degree of risk involved.

There are three levels of risk:

- Harm;
- Discomfort; and
- Inconvenience

Researchers and HRECs are required to determine the existence, likelihood and severity of these risks based on the research methodology and design, participant population and research activity. The National Statement, sections 2.1.6-2.1.7 holds that:

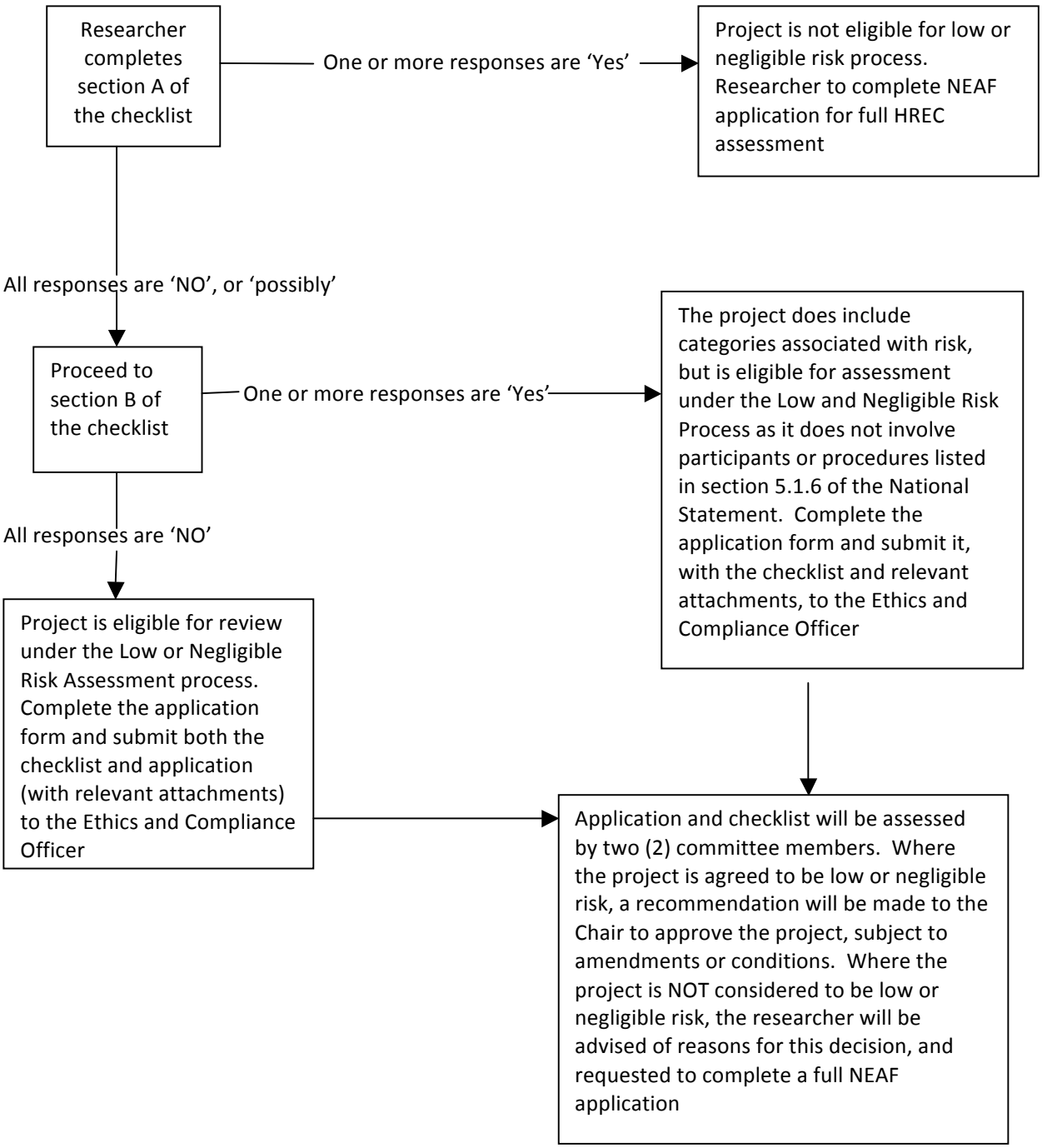
> *2.1.6 Research is 'Low Risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk;*
>
> *2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk'*

Research that involves the risk of harm or the likelihood of harm must be reviewed by a fully constituted HREC. For research involving only the risk of inconvenience, or discomfort (i.e. low or negligible risk', Institutions may establish alternative ethical review process. CQUniversity has resolved to proceed with such an alternative process.

It should be noted that research involving certain groups, methodologies or procedures, regardless of the level of risk, must be reviewed by a full HREC (Clause 5.1.6 of the National Statement).

There are a range of resources available to researchers on the Human research Ethics Committee webpage (http://content.cqu.edu.au/FCWViewer/view.do?page=10945), including sample information sheets, consent forms and an example of a completed Low Risk Application form. Researchers are encouraged to complete the checklist first and consult with the Ethics and Compliance Officer to gain an assessment of whether the project satisfies the criteria for alternative review. Time constraint is NOT an acceptable reason for seeking review through this process.

Process Flowchart



Low or Negligible Risk Assessment Process Checklist

SECTION A

Please indicate whether your project involves any of the following:

YES ☐ NO X☐	Participants are identifiable or re-identifiable
YES ☐ NO X☐	Some form of deception is involved
YES ☐ NO X☐	The procedure involves experimental manipulation or includes the presentation of any stimulus other than question-asking
YES ☐ NO X☐	The project involves interventions and/or therapies, including clinical and non-clinical trials and innovations, human genetics or human stem cells

Please indicate whether your project is actively seeking to recruit participants meeting the criteria below. Note - if it is possible that participants may meet one or more of these criteria as a result of being part of the general population, you should tick the 'possibly' box.

YES ☐	Possibly ☐	NO X☐	Participants are aged less than 18 years
YES ☐	Possibly ☐	NO X☐	Participants are cognitively or emotionally impaired, or are highly dependent on medical care
YES ☐	Possibly ☐	NO x☐	Participants belong to the Aboriginal or Torres Strait Islander People,
YES ☐	Possibly x☐	NO ☐	Female participants who are pregnant and/or the human foetus
YES ☐	Possibly ☐	NO X☐	Participants who may be involved in illegal activities, where the research is intended to study or expose illegal activity

IF you have answered YES to any of the above, your project CANNOT be considered under the Low or Negligible Risk Assessment Process, and you must lodge a NEAF application to the Human Research Ethics Committee.

If you have answered either 'NO' or 'Possibly' to all of the above, please proceed to Section B

SECTION B

Are any of the following topics covered in part or in whole?

YES ☐ NO X☐ Research about parenting issues

YES ☐ NO X☐ Research investigating sensitive personal or cultural issues

YES ☐ NO X☐ Explorations of grief, death or serious/traumatic loss

YES ☐ NO X☐ Mental disorders eg Depression, mood states, anxiety

YES ☐ NO X☐ Gambling

YES ☐ NO X☐ Eating Disorders

YES ☐ NO X☐ Illicit drug use / Substance abuse (prescription or over the counter)

YES ☐ NO X☐ Self report of criminal behaviour

YES ☐ NO X☐ Any psychological disorder

YES ☐ NO X☐ Suicide risks /anger management

YES ☐ NO X☐ Gender identity / Sexuality

YES ☐ NO X☐ Race or ethnic identity

YES ☐ NO X☐ Any disease or health problem

YES ☐ NO X☐ Fertility / Termination of pregnancy

Are any of the following procedures to be employed?

YES ☐ NO X☐ Use of personal data obtained from Commonwealth or State Government Department/Agency with participant consent

YES ☐ NO X☐ Deception of participants or concealing the purposes of the research

YES ☐ NO X☐ Covert observation (or minimal disclosure)

YES ☐ NO X☐ Audio or visual recording without consent

YES ☐ NO X☐ Recruitment of a third party or agency (asking participants to provide information about another person)

YES ☐ NO X☐ Withholding from one group specific treatments or methods of learning from which they may 'benefit' (eg in medicine or teaching)

YES ☐ NO X☐ Psychological interventions or treatments

YES ☐ NO X☐ Application of physical stimulus /Invasive physical procedures /Infliction of pain

YES ☐ NO X☐ Administration of drugs /Administration of other substances or devices

YES ☐ NO X☐ Exposure to ionising radiation

YES ☐ NO X☐ Tissue sampling or blood for pathological or genetic testing

YES ☐ NO X☐ Collecting body fluid (eg saliva)

YES ☐ NO X☐ Use of medical records where participants can be identified or linked

Other Risks:

YES ☐ NO X☐ Are there risks to the researcher? (Eg research conducted in unsafe environments or trouble spots)

YES ☐ NO X☐ Are there risks to non participants in the research, such as participant's family members and social community? (Eg effects of biography on family and friends or infectious disease risk to the community)

Select the categories of people that are targeted or likely to be targeted as participants in this research project

YES ☐ NO X☐ Suffers from a psychiatric or psychological disorder

YES ☐ NO X☐ Suffering a physical disability or medical condition

YES ☐ NO X☐ Children and/or young people without parental or guardian consent

YES ☐ NO X☐ Resident of a custodial institution

YES ☐ NO X☐ Unable to give freely an informed consent because of difficulties in understanding information provided (eg language difficulties, NESB)

YES ☐ NO X ☐ Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities

YES ☐ NO X☐ Participants are identifiable in final report when specific consent for release has not been given

YES ☐ NO X☐ Those in a dependent relationship with the researchers (eg lecturer/student, doctor/patient, teacher/pupil and professional/client)

If 'NO' has been selected for all questions in sections A and B, the project IS eligible for review under the Low or Negligible Risk Assessment process. Please complete the Application Form which follows and submit this entire document, together with a copy of the Information Sheet, Consent form and research instrument to the Ethics and Compliance Officer.

If you have selected 'YES" to any of the items in Section B, the project MAY STILL BE ELIGIBLE for assessment under the Low or Negligible Risk Assessment Process. Please complete the Application Form which follows and submit this entire document, together with a copy of the Information Sheet, Consent form and research instrument to the Ethics and Compliance Officer.

LOW OR NEGLIGIBLE RISK ASSESSMENT PROCESS
APPLICATION FORM

This form is to be completed for research involving no more than low or negligible risk, as identified by completion of the checklist on the preceding pages.

If you are a staff member seeking to survey students enrolled in courses that you have responsibility for, please ensure that in section 2.7 of the form, you acknowledge that there is a power differential between the researcher and participant, and address how you will minimise the potential for students to feel obligated to participate.

Please ensure that:

- You have attached the completed checklist
- All signatures have been obtained
- You have included copies of Information Sheets, Consent Forms, Research Instruments (survey, interview questions etc) and approvals from participating organisations (as appropriate)
- You do not commence data collection until written approval has been received from the Chair of the Human Research Ethics Committee

Please send the application to:

Ethics and Compliance Officer
Office of Research
CQUniversity
Building 32
Rockhampton Campus
CQ Mail Centre QLD 4702

PART 1 RESEARCHERS

Principal Researcher:

Title	Dr
Name	Wendy Hillman
Telephone	(07) 4930 9289
Facsimile	(07) 4930 6460
Email	w.hillman@cqu.edu.au
Current Qualifications	PhD, GCE(TT), MSocSc, BA(Hons)
Research experience	6 years research experience post PhD. Involved in five (5) research projects (1 external competitive grant, 4 internal funded grants and 1 consultancy). Three of these projects as Principal researcher. Topics ranged from national and international tourism to environmentalism, and social inclusion. Publications include 1 co-authored book, 3 book chapters, 6 refereed journal articles (1 other currently in press), and 16 conference papers.
If CI is a student, specify program	

Other Researchers (if you are a student, please include your supervisor details):

Title	Mr	Title	
Name	XXXXX	Name	
Telephone	(07) XXXXX	Telephone	
Facsimile	(07) XXXX	Facsimile	
Email	XXXXX	Email	
Qualifications	BSc, MSc	Qualifications	
Research experience	Currently undertaking PhD – data collection based in Nepal – supervisor – Dr Wendy Hillman (details as above)	Research experience	
Role (supervisor, co-researcher)	Co-researcher	Role (supervisor, co-researcher)	

Title		Title	
Name		Name	

Telephone		Telephone	
Facsimile		Facsimile	
Email		Email	
Qualification		Qualifications	
Research experience		Research experience	
Role (supervisor, co-researcher)		Role (supervisor, co-researcher)	

Authorisation from external organisations (if research is not conducted at CQUniversity locations)

Title	Mrs
Name	XXXXX
Telephone	XXXXX
Facsimile	XXXXX
Email	XXXXX
Position in organisation	Managing Director XXXXX

PART 2 Project Details

2.1 Project Title

Status of urban poor women in Nepal

2.2 Layperson Description:

Briefly outline in simple terms the project's aim(s), justification, participant group(s), method and possible outcomes

The aim of this project is to ascertain the conditions under which women training and working in a supported environment in Nepal came to the capital, Kathmandu, and how they are attempting to overcome their poverty and marginalisation. Many Nepali citizens were displaced during the insurgencies and uprisings of 1995-2005. To date, there has been very little data collection concerning this area of Nepali women's emancipation and empowerment. Other studies specifically target Nepali women's involvement in the insurgencies, and address issues of gender equality in the political system and in the grab for power and control. Many rural village women were left to fend for themselves throughout the insurgency and many men left or disappeared. Thus, the women who are the object of this research took a chance and travelled to Kathmandu enduring great hardship, until they found various training groups and enterprises to help them overcome their adversity. The participant group will consist of 15-20 female Nepali women living and working in a female friendly work training enterprise in Kathmandu. The methods utilised will be in-depth semi-structured interviews. The interviews will be recorded in the field. Later, the interviews will be transcribed, translated and imported into Nvivo, where they will be coded using a hierarchical, thematic coding structure. The open ended questions will be about the women's experiences before

and during their journey to Kathmandu, and also how they have overcome their destitution and poverty. Some possible outcomes from this research include, but are not limited to: the positive outcomes for impoverished women who travelled to Kathmandu during and after the insurgencies of 1995-2005; and, how the women gained skills and expertise in a trade that has enabled them to gain control of their lives and feel supported in their quest to become financially secure.

2.3 Data collection dates:

Start	10 October 2011	16 November 2011

2.4 Data Collection methods: (Please tick methods as appropriate)

Interviews	X	☐	Focus Groups	☐
Hard Copy Survey		☐	Online Survey	☐

Other (please specify) _____

_____

2.5 Research Methodology:

Outline the proposed method, including data collection techniques, tasks participants will be asked to complete, estimated time commitment required of them; and how data will be analysed. Give a justification of your proposed sample size, including details of statistical power of the sample where appropriate

The project will use semi-structured in-depth interviews to interview 15-20 participants on the topic of the 'Status of urban poor women in Nepal'. Participants will be asked to be involved in a 60 minute interview, which will be recorded in situ. The interviews will be undertaken by the co-researcher, who is a native-born speaker of the Nepali language. The data will be translated into English before it is imported into NVivo where it will be coded using a hierarchical, thematic coding structure approach. It is hoped that the maximum number of participants will be interviewed during the time period.

2.6 Research Aims and Significance

State the aims, research objectives, key research questions, and significance of the project. Where relevant, state the specific hypothesis to be tested. Also please provide a brief description of the relevance of your proposed project to current research, a justification as to why your research should proceed and an explanation of any expected benefits to the community or its potential to contribute to existing knowledge.

The researcher aims to show how impoverished women from rural and outlying areas of Nepal travel to Kathmandu to secure training and then gainful employment for themselves in Kathmandu.

Other researchers have expressed concern for rural women in Nepal, particularly after the insurgencies of 1995-2005, but have not specifically targeted their struggle to obtain gainful employment and ways to find a suitable income. This research will assist in understanding how Nepali women have overcome their adversity and become empowered.

2.7 Risk

Please outline the likelihood and severity of the risks to participants/others

There are no perceived risks to the participants or to the researchers. The participants are unknown to the researchers and will in no way be obliged to take part in the research.

Please identify who (participants and/or others) the risk may affect

participants

Please outline the mechanisms taken to minimise the risk

To minimise any risk, participants will be reassured at the outset that they will encounter no adverse affects from non-participation in the project. All interviews and conversations will be conducted in the Nepalese language by the co-researcher, as he is a native-born speaker of Nepali. If the participants appear to experience any distress or visible signs of anguish, they will be directed to an appropriate not-for-profit agency in Kathmandu (such as Care - https://my.care.org/site/Donation2?9463.donation=landing&df_id=9463 , Jagriti - http://www.jagriti-international.org/organizations.asp?Country=Nepal , or Tiny Hands International http://www.tinyhandsinternational.org/index.php?option=com_content&task=view&id=25&Itemid=27) that can help them deal with their anxiety.

Please indicate the potential benefits of the research

The benefit of this research will be to provide data about how impoverished women from rural areas in Nepal make their way to the capital city of Kathmandu and find access to training and then subsequent employment for themselves, and thus gain empowerment. The data and consequent

outcomes will form the basis for a larger project on this area of concern.

To whom the benefits are likely to accrue

Nepal Grhini Udyog, NGOs, women's empowerment groups, the Nepali government.

PART 3 Funding and Finance

Researchers should include any source of funding (eg departmental, commercial, non-commercial, government) – National Statement on Ethical Conduct in Human Research 2007, Chapter 5.4.

3.1 Has this protocol received research funding or is this submission being made as part of an application for research funding?

YES ☐ NO ☐X

3.2 What is the source of funding and has the funding been approved?

Self-funded

YES ☐X NO ☐

3.3 Will the researcher receive any remuneration and/or in kind funding to perform this research?

YES ☐ NO ☐X If yes, please provide details:

3.4 Will participants receive any payment or expenses for participation in the research?

YES ☐ NO ☒X If Yes, please provide details:

PART 4 OTHER APPROVALS

The principal researcher is responsible for informing each HREC of all other Australian sites at which the research is being proposed or conducted, at the time of submission of the research project; of any previous decisions regarding the research made by another HREC; and informing each HREC of whether the protocol is presently before another HREC (National Statement, Chapter 5.3)

4.1 Is this protocol being submitted or has it been previously submitted to another ethics committee?

YES ☐ NO ☒X

4.2 If yes, give details of other centres involved; the approval status of the study at each centre; and details of any required amendments

4.3 Other external approvals/reviews?

If your research has undergone peer review, review from a funding body or involves participants from other organisations, copies of letters of approval or reviews must be attached to this application (if pending at the time the application is submitted, forward to Ethics and Compliance Officer when available). In some cases, institutions/authorities may decline to provide approval letters until ethics approval has been granted. In such cases, you should submit your application to the HREC for provisional approval pending receipt of the documentation.

4.4 Has the research undergone peer review, review from a funding body or does it involve participants from other organisations?

YES ☐ NO ☒X If yes, specify from whom and attach a copy:

PART 5 RECRUITMENT OF PARTICIPANTS

5.1 Provide number, age range and source of participants. This explanation should also include how potential participants will be identified and how initial contact will be made. For CQUniversity staff recruiting students as participants, please note that approval to access students from either the Executive Dean of the faculty, or from the Executive Director (Corporate Services), depending on whether you are involving students from one faculty, or from across all faculties .

Approximately 15-20 Nepali women working in the clothing industry in Kathmandu will be recruited for the research project. The age range will be from 18-65 years. Potential participants will be approached via the female owner of a small clothing industry manufacturing company in Kathmandu, Nepal.

5.2 What is the proposed method of recruitment of participants?

All women training and working in the clothing enterprise will be approached to participate.

PART 6 CONSENT

*The potential participants must be provided with information **at their level of comprehension** about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research (including the likelihood and form of publication of research results)*

Informing participants: Participants Information Sheet and Consent Form

6.1 Will the research involve informed consent of participants?

YES ☒X NO ☐

6.2 If yes, how will informed consent be obtained/recorded? If no, please justify why consent will not be obtained.

Participants will each be presented with an information sheet, and an informed consent form. Each participant will be asked to read the information sheet, and then asked to participate in the research project. Upon acceptance, each participant will be given an informed consent form to read and sign. This will be taken as consent by the participant to be involved in the research. Additionally, each participant will be provided with a business card from the researchers in case they wish to contact either the university or the researchers at a later date, regarding this research. The details of both researchers will also be visible on the Informed Consent Form.

All paperwork will be translated into Nepali, and all interviews will be conducted in Nepali, as the co-

researcher, Mr XXXXX, is a native-born speaker of Nepal.

PART 7 INFORMATION PROTECTION (Confidentiality, data storage, security and disposal)

Confidentiality

7.1 Explain what methods will be used to guarantee confidentiality/anonymity of participant data

All collected data will be de-identified and no names or other identifying information will appear in the final report. All participants will be given a pseudonym to protect both their anonymity and confidentiality.

Data Storage and security

7.2 Explain how and where data will be held, including any arrangements for data security during the project?

In the field, data will be collected on an electronic voice recorder, which will be in the possession of the researchers at all times.
Upon return, data will be stored electronically on a password protected server.

7.3 Please outline how long the data will be kept?

Data will be kept for five years, in accordance with the CQUniversity Code of Conduct for research.

7.4 Will the data be disposed of at some point?

YES ☐X NO ☐

7.5 If yes, how will the data be disposed of? If no, why is the data to be retained, and how/where will it be stored.

All data and electronic documents will be deleted from the server.

PART 8 DISSEMINATION OF RESULTS

8.1 Explain when, how, where and to whom results will be disseminated, including whether participants will be provided with information on the findings or outcomes of the project.

The results will be disseminated in the form of journal articles and conference papers. Participants will be able to access information on the findings or outcomes of the project through contact with either of the researchers via the CQUniversity email system, or website. Therefore, provision of copies of the findings will be available to each participant on request.

PART 9 DECLARATIONS

Signatures and undertakings:

Applicant/Principal Researchers (including students and supervisors where appropriate)

I/We certify that:

- All information is correct and complete as possible;
- I/We have had access to and read the NHMRC 'National Statement on Ethical Conduct in Human Research', (2007);
- The research will be conducted in accordance with the National Statement;
- I/We have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these;
- I/We will immediately report to the HREC anything that might warrant review of the ethical approval of the research including:
    - Serious or unexpected adverse effects on participants
    - Proposed changes in the protocol; and
    - Unforseen events that might affect continued ethical acceptability of the project;
- I/We have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my/our obligations and the rights of participants;
- I/We will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the HREC, including:
    - Conditions of approval stipulated by the HREC; and
    - Cooperate with monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC
- I/We have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise;

Wendy Hillman		12 September 2011
Print Name	Signature	Date
XXXXX		12 September 2011
Print Name	Signature	Date
Print Name	Signature	Date
Print Name	Signature	Date