

## 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;*

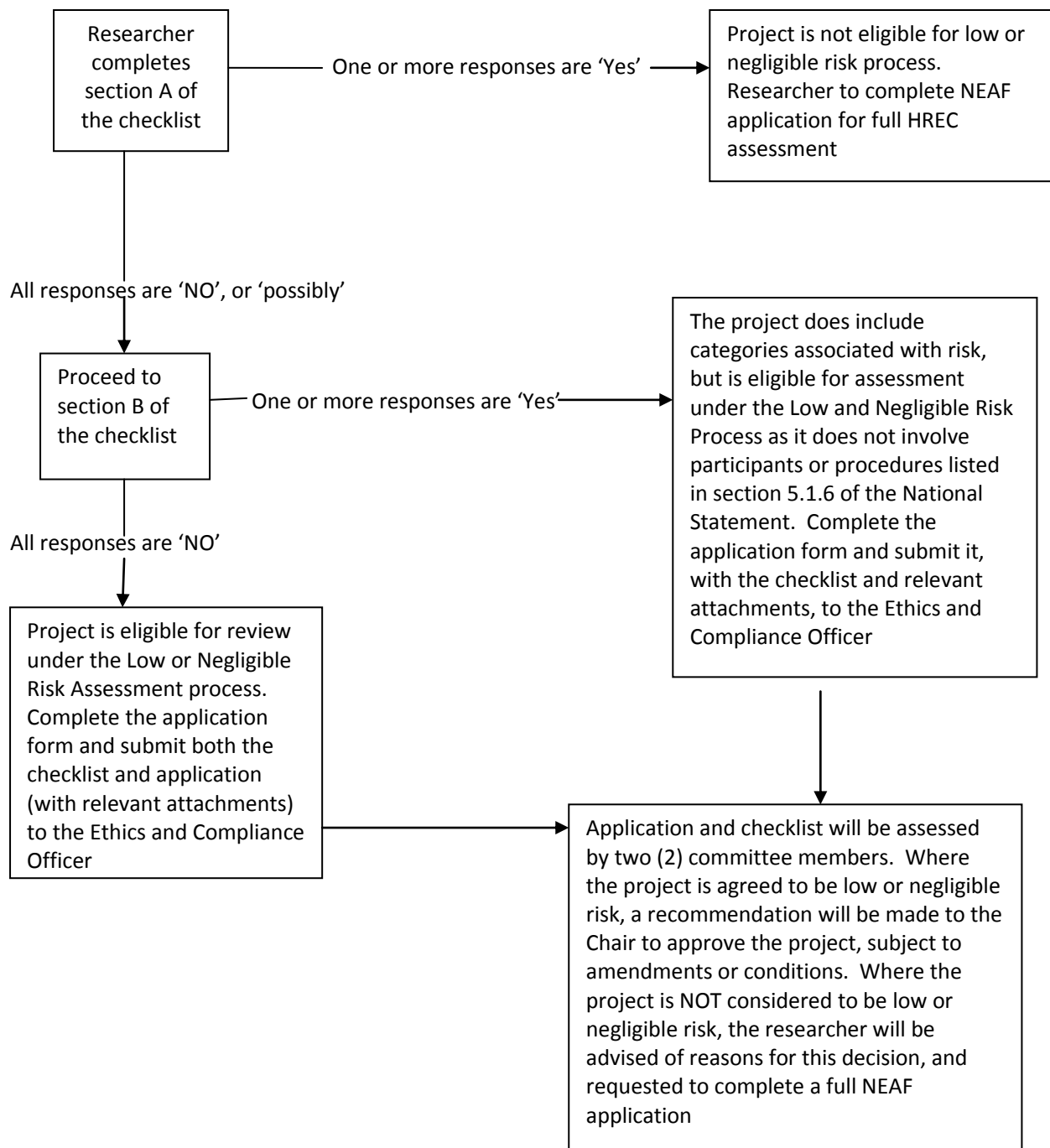
*2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk'*

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  Participants are identifiable or re-identifiable
- YES  NO  Some form of deception is involved
- YES  NO  The procedure involves experimental manipulation or includes the presentation of any stimulus other than question-asking
- YES  NO  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  Participants are aged less than 18 years
- YES  Possibly  NO  Participants are cognitively or emotionally impaired, or are highly dependent on medical care
- YES  Possibly  NO  Participants belong to the Aboriginal or Torres Strait Islander People,
- YES  Possibly  NO  Female participants who are pregnant and/or the human foetus
- YES  Possibly  NO  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 /In infliction of pain
- YES  NO  X  Administration of drugs /Administration of other substances or devices
- YES  NO  X  Exposure to ionising radiation

- YES  NO  Tissue sampling or blood for pathological or genetic testing
- YES  NO  Collecting body fluid (eg saliva)
- YES  NO  Use of medical records where participants can be identified or linked

**Other Risks:**

- YES  NO  Are there risks to the researcher? (Eg research conducted in unsafe environments or trouble spots)
- YES  NO  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  Suffers from a psychiatric or psychological disorder
- YES  NO  Suffering a physical disability or medical condition
- YES  NO  Children and/or young people without parental or guardian consent
- YES  NO  Resident of a custodial institution
- YES  NO  Unable to give freely an informed consent because of difficulties in understanding information provided (eg language difficulties, NESB)
- YES  NO  Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities
- YES  NO  Participants are identifiable in final report when specific consent for release has not been given
- YES  NO  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	<a href="mailto:w.hillman@cqu.edu.au">w.hillman@cqu.edu.au</a>
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 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		Title	
Name		Name	
Telephone		Telephone	
Facsimile		Facsimile	
Email		Email	
Qualifications		Qualifications	
Research experience		Research experience	
Role (supervisor, 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	
Name	
Telephone	
Facsimile	
Email	
Position in organisation	

## **PART 2 Project Details**

### **2.1 Project Title**

Health Precautions of English Speaking Travellers to Nepal: Travel Health Advice and Information Received from GPs and/or other Health Providers

### **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 amount and types of health travel advice travellers to Nepal receive in their home country from their General Practitioner or other health provider before departure for Nepal. To date, there has been very little data collection concerning this area of health concern. Other studies specifically target travellers from host countries where there is a certain amount of pre-travel literature available before departure to a foreign destination. Many travellers also glean their information about health in specific countries from travel agents and/or travel guides or brochures. However, a cross-cultural comparison of English speaking travellers to Nepal from various international points of departure has not previously been undertaken. The participant group will consist of 15-20 international English speaking travellers in Nepal. The methods utilised will be in-depth semi-structured interviews. The interviews will be recorded in the field. Later, the interviews will be transcribed and imported into Nvivo, where they will be coded using a hierarchical, thematic coding structure. The open ended questions will be about health advice and/or instruction about travel to Nepal received from the traveller's General Practitioner (GP), or other health provider, before departing from their country of origin. Some possible outcomes from this research include, but are not limited to: the frequency of pre-travel information sought from travellers by GPs; the frequency of advice concerning travel vaccinations, STDs, travel insurance, safety, local diseases, safe sexual practices, first aid knowledge, jet lag; and, types of written information made available to travellers before departure to Nepal.



**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 'Health Precautions of English Speaking Travellers to Nepal'. Participants will be asked to complete a 45minute interview, which will be recorded in situ. The data will be 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 English speaking international travellers to Nepal access information about health concerns and needs prior to the commencement of their journeys. Other researchers have expressed concern that many travellers do not access appropriate and timely information from their GPs and other health service providers. This research will assist in understanding how to address this perceived deficiency.

## 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 researcher. The participants are unknown to the researcher 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.

Please indicate the potential benefits of the research

The benefit of this research will be to provide data about how individuals access travel and health information before their departure for Nepal from their home country. This data and subsequent outcomes will form the basis for a larger project on this area of concern.

To whom the benefits are likely to accrue

International travellers and the travel industry.

## 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

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

Self-funded

YES  NO

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

YES  NO  If yes, please provide details:

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

YES  NO  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 

**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**

The research project has previously been approved by CQUniversity HREC on 15 October 2010. This research is an extension of that previously approved project, as the CI has the opportunity to return to Nepal again in 2011. There were minor amendments involved with the initial application in 2010, but these were all addressed and final approval was given.

**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  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 international English speaking travellers to Nepal will be recruited for the research project. The age range will be from 18-65 years. Potential participants will be approached through common travel arrangement and on-site tours conducted in and around Kathmandu, Nepal. English speaking tourists holidaying at the same time as the researcher, in Nepal, will be approached and asked to take part in the project.

## 5.2 What is the proposed method of recruitment of participants?

English speaking tourists holidaying at the same time as the researcher, in Nepal, will be approached and asked to take part in the project.

## 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  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 researcher in case they wish to contact either the university or the researcher at a later date, regarding this research.

## 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 recorded, which will be in the possession the researcher 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  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 a journal article and one or two conference papers. Participants will not be provided with information on the findings or outcomes of the project as they

do not reside in Australia. Therefore, provision of copies of the findings will not be undertaken due to costs of printing and postage. The researcher also does not wish to appear as if she is invading their privacy any more than necessary, by asking for addresses etc and more personal information beyond the usual demographic data of age and country of origin etc.

## 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
  - Unforeseen 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

30 August 2010

Print Name	Signature	Date
Print Name	Signature	Date
Print Name	Signature	Date
Print Name	Signature	Date