GUIDELINES
FOR COMPLETING THE INITIAL APPLICATION FOR APPROVAL TO
UNDETERMINE
RESEARCH INVOLVING HUMAN PARTICIPANTS

A copy of the application form without the instructions can be downloaded from

A. GENERAL INFORMATION

1. Descriptive Title of Project:

   * Please use a short, descriptive title of your project.

2. 7 line summary of project aims:

   * Explain in non-technical language what you hope to achieve in your project. When reviewing an application the HREC must assess whether the achievability and significance of the aims justify the potential risks/burdens for participants.

3. Participating Researchers

   Summarise the qualifications and experience of all personnel who will be participating in the project.

   NB: For student research, a Supervisor must be the Principal Investigator.

   * The Principal Investigator has primary responsibility for ensuring that the information given in the application form is accurate and for ensuring that the project, if approved, is conducted in accordance with the project proposal and any conditions imposed by the Committee.

   * The qualifications and/or experience of researchers are relevant to the ethical conduct of the research. Please indicate the relevant skills or qualifications of researchers or the steps that will be taken to train them.

<table>
<thead>
<tr>
<th>Principal Investigator/Supervisor</th>
<th>Title</th>
<th>First Name</th>
<th>Family Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Guidelines for Completing Standard Application - Vs Mar 2014

Office Use Only
HE

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Position</th>
<th>Role in project, relevant research experience (if no experience, describe how relevant experience will be obtained)</th>
</tr>
</thead>
</table>

Second Investigator (in absence of PI)

<table>
<thead>
<tr>
<th>Title</th>
<th>First Name</th>
<th>Family Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Position</th>
<th>Role in project, relevant research experience (if no experience, describe how relevant experience will be obtained)</th>
</tr>
</thead>
</table>

Co-Investigator/Student

<table>
<thead>
<tr>
<th>Title</th>
<th>First Name</th>
<th>Family Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Position</th>
<th>Role in project, relevant research experience (if no experience, describe how relevant experience will be obtained)</th>
</tr>
</thead>
</table>

Please add extra boxes for additional researchers

4. Contact details for correspondence

Name:

Postal Address:
5. **Expected duration of Research** (Please specify as near as possible 'start' and 'finish' dates for the conduct of research):

   FROM:  
   TO: 

6. **Purpose of Project**
   Indicate whether the research is one or more of the following:
   
   * Staff Research (University of Wollongong)
   * Staff Research (ISLHD)
   * Student Research - specify:
     - Course undertaken:
     - Unit/Faculty/Department:
     - Supervisor/s:
   * Other (Please specify)

7. **Has this research project been reviewed by any other Institutional Ethics Committee?**
   
   YES *  NO *

   If no, go to Section B. If YES:
   7.a What committees has the application been submitted to?

   7.b What is the current status of these applications? Please include copies of all correspondence between the sponsor or researcher and the other Ethics Committee(s) to this point.
B. FINANCIAL SUPPORT FOR RESEARCH

* The National Statement requires that researchers disclose to the HREC the amount and sources or potential sources of funding for the research (S5.2.10) and also declare any financial interest when reporting the research (S5.2.11). The HREC should be satisfied that funding is sufficient to conduct and complete the trial as designed.

* The National Statement requires that researchers inform the HREC of any business, financial or other similar association between a researcher and the supplier of a drug or surgical or other device to be used in the trial, any other possible conflicts of interest, and any restrictions of publication (S3.3.4)

8. What is the source and amount of funding from all sources for this research?

<table>
<thead>
<tr>
<th>Source (Name of Organisation / Funding Scheme)</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For sponsored research please include the budget for the trial including information about capitation fees, payments to researchers, institutions or organisations involved in the research, current and consequential costs and costs which may be incurred by participants.

If the research is sponsored:
8.a Is there any affiliation/association or financial interest between the researcher(s) associated with this research and the sponsor/funding body/supplier of a drug, surgical device or other therapeutic device to be used in the study?

YES * NO *

If Yes, Please detail.

8.b Are there any conditions placed on this research by the funding body?

YES * NO *

If YES, please provide details and provide a copy of the contract/letter of agreement with the funding organisation detailing the terms on which the research is being supported.

* The Committee needs to verify that the terms on which researchers obtain consent from participants (including confidentiality undertakings) are consistent with any
contractual agreements with sponsoring organisations. The contractual obligations must be consistent with researchers’ obligations under the *National Statement* (NHMRC, 2007) and the *National Code for Responsible Conduct of Research* (NHMRC, 2007).

* Please indicate any conditions placed on the research by the funding body or sponsor and/ or any benefits from the research which the sponsor expects to receive. For example, a manufacturer might support research into a new therapeutic device with the expectation that a report on the efficacy of the device will be supplied to the manufacturer; similarly a local council or community group might support research and provide access to participants with the express aim of receiving a report on the research at its completion.

* If there are any conditions regarding the publication of research findings (eg veto rights over publication) please provide details. Any conditions on publication must be consistent with the *National Code for Responsible Conduct of Research* (NHMRC, 2007).

* If there are any conditions regarding the confidentiality of participants’ information, please provide details.

8.c Is a copy of the HREC approval to be forwarded to the Granting Body?

YES * NO *

If YES, please advise of any deadlines.

C. RESEARCH METHODS

9. Research Categories

Please mark the research categories relevant to this research proposal. At least one category should be marked for each grouping. You should mark as many categories as are relevant to the proposed research. For "Other", please specify.

A Research procedures used

* Anonymous questionnaires/ surveys
* Coded (potentially identifiable) questionnaires/ surveys
* Identifiable questionnaires/ surveys
* Examination of student work, journals etc
* Examination of medical, educational, personnel or other confidential records
* Observation (overt)
* Observation (covert)
* Interviews (structured or unstructured)
* Telephone interviews
* Procedures involving physical experiments (e.g. exercise, reacting to computer images)
Office Use Only
HE

* Procedures involving administration of substances (e.g. drugs, alcohol, food)
* Physical examination of participants (including eg. blood glucose, blood pressure and temperature monitoring)
* Collection of body tissues or fluid samples
* Surgical procedures
* Other:

B Research areas

* Qualitative research
* Social Science research
* Humanities research
* Educational research
* Health research
* Psychological research
* Comparison or evaluation of drugs or surgical or other therapeutic devices
* Comparison or evaluation of clinical procedures
* Comparison or evaluation of counselling or training methods
* Investigation of the effects of an agent (drug or other substance)
* Investigation of bio-mechanical processes
* Biomedical research
* Epidemiology
* Genetic research
* Other:

10. Does the project involve: the use of drugs, a surgical device, a therapeutic intervention, or a physiological trial?

   YES * NO *

If no, go to Q11. If YES:

10.a Please give details of the type of intervention and provide evidence that appropriate indemnity and compensation arrangements are in place to ensure adequate compensation to participants for any injury suffered as a result of participation in the trial (Indemnification forms and, if the research is being undertaken in a private practice, evidence of adequate and appropriate insurance coverage).

* As part of the HREC’s role in the protection of the welfare and rights of participants in research, the HREC must be satisfied that for clinical research ‘the indemnity or insurance and compensation arrangements required by CPMP/ICH Note for guidance on Good Clinical Practice, the ISO 14155 Clinical Investigation of Medical Devices and the TGA (National Statement S3.3.24) are in place.

* UOW insurance arrangements for clinical/physiological research require UOW research projects to be individually evaluated to determine whether they are covered by existing insurance or require additional insurance to be obtained. This process is managed by the Financial Services Unit.
The HREC requires:

i. **For ISLHD research**: a copy of the indemnification agreement entered into by the research sponsor;

ii. **For research within a private practice**: a copy of the indemnification agreement entered into by the research sponsor and evidence of adequate insurance to cover injuries that may be suffered by participants as part of the research in circumstances not covered by the indemnification agreement (for example, injuries sustained as the result of negligence or injuries sustained while travelling to or from the research site).

iii. **For UOW research**: a copy of the ‘Clinical Trial Insurance Requirements’ form. This form can be downloaded from [http://staff.uow.edu.au/finance/insurance/policy/clinical/index.html](http://staff.uow.edu.au/finance/insurance/policy/clinical/index.html) and must also be submitted to the Financial Services Unit.

10.b Is the research registered:

- As a CTN Trial with the TGA
- As a CTX Trial with the TGA
- On any national or international clinical trial registers
- Other (Please detail)

11. **Research design and justification**

Describe what you want participants to do and justify the design. Please provide an explanation in terms understandable by a non-expert reader. A flow chart or other diagram illustrating the sequence of research activities should be included if possible. For research involving a treatment or physical intervention (e.g., clinical studies, physiological trials, mental health interventions) a protocol should be provided.

- In order to assess the ethical acceptability of a research proposal the HREC needs to consider a number of features of the research methodology and procedures. These include:
  - whether the research question is one likely to advance understanding or knowledge;
  - whether the research methodology used to address the question is likely to achieve the stated aims;
  - whether the value of the research justifies the risks, discomforts, inconvenience or intrusion of privacy that may be experienced by research participants.

- If the research involves specific communities, when describing the research design you should mention whether you have discussed (or will discuss) the proposal with members of the community and whether community members will be involved in oversight of the project – such discussions are **required** for research involving...
Aboriginal people and Torres Strait Islanders (see the NHMRC *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*). It is also helpful to indicate whether some members of the research team have particular skills or experience which may make them more sensitive to the ethical issues which may come up in the research, or better able to identify and respond to potential problems.

For guidelines/policies regarding specific research areas please refer to the Ethics webpage.

12. **Statistical design**

Any research project that involves the collection of data should be designed so that it is capable of providing information that can be analysed to achieve the aims of the project. Usually, although not always, this will involve various important statistical issues. It is important that the design and analysis be properly planned in the early stages of the project. You should seek statistical advice. The University of Wollongong has a Statistical Consulting Service that provides such advice to research students and staff undertaking research.

**Are statistical issues relevant to this project?**

YES * NO *

If no, go to Q13. If YES:

12.a **Have you discussed this project with the Statistical Consulting Service or any other statistical advisor?**

YES * NO *

If NO, please explain why not.

12.b **Provide the calculations used to determine the appropriate sample size. If no power calculations have been done please explain the reason for choosing the sample size.**

* Applicants should be aware that the quality of research, which is an important element in the justification for the involvement of human participants in research, will often depend on the statistical design of the research project. The HREC is obliged to take the statistical adequacy of a proposal into account in assessing whether the likelihood of establishing useful results is sufficient to merit the risks and intrusions posed to participants.

D. **ETHICAL CONSIDERATIONS**

13. **What are the ethical considerations relevant to the proposed research, specifically in relation to the participants’ welfare, rights, beliefs, perceptions, customs and cultural**
heritage? How has the research design addressed these considerations? Consideration should be at both individual and collective level.

* The National Statement requires that “In each research proposal the researcher/s should demonstrate that the research has merit and reflects the ethical values of justice, beneficence and respect for humans” (S5.2). These ethical concepts are described in the National Statement in Chapter 1 ‘Values and Principles of Ethical Conduct’. Within this statement of ethical considerations you should briefly identify and explain the potential harms and burdens for participants associated with this research, and the measures put in place to address them. These issues should be fully addressed in the following questions.

E. RISKS AND BENEFITS

* The Committee will weigh the harms/burdens relative to the potential benefits of the research, the nature of the agreement to participate in the project, and any protections for participants put in place by the research team. The possibility or existence of harm or burden resulting from participation does not mean that a project cannot be approved. Most research involving human participants involves some risks and burdens. Participants who are adequately advised of the nature (including the risks and burdens) of the research and who are sufficiently free to make the decision to participate of to refuse to participate may well be prepared to take on those risks and burdens.

14. Does the project involve the risk of emotional distress or physical harm, or the use of invasive procedures (e.g. blood sampling)?

YES * NO *

If YES
14.a What are the risks?

* Please detail the risks or burdens participants may experience as a result of participating in this project; participants must be informed of the risks of all aspects of the research in the participant information sheet.

* Examples of harms or burdens which may result from participation in research include: physical pain, discomfort or injury in the course of physically invasive research; illness, exacerbated medical conditions and injurious side-effects in drug trials; embarrassment or emotional upset in the course of interviews; intrusion on privacy in observational research; inconvenience and expenditure of time.

* Harms may also arise as a result of a breach of confidentiality or if information obtained in research is disseminated in a manner prejudicial to the interests of participants. Further, identifiable information about a person may be subject to court subpoena, requiring that a researcher’s tapes, notes, or other data be included in
evidence in legal proceedings. You should be able to identify whether the research may give rise to such harms.

14.b Explain how the risks of harm or distress will be minimised. In the case of risks of emotional distress, what provisions have been made for an exit interview or the necessity of counselling?

* Please detail any precautions taken to reduce any risks associated with the research. This might include whether and how debriefing may occur, whether support services will be notified about the research, and whether participants will be given information on obtaining counselling or other support if they experience distress as a result of their participation.

15. Is information about criminal activity likely to be revealed during the study?

YES * NO *

If YES, have you included a caution regarding any relevant mandatory reporting requirements in the Participant Information package?

16. Detail the expected benefits of the study to the participants and/or the wider community.

* Participation in research may have direct and indirect benefits to participants eg awareness that one is participating in a worthwhile project; benefits associated with talking about an issue of concern for the participant; close monitoring of health during a study; having access to the results of the research project; practical assistance (e.g. research on learning difficulties may take the form of a novel program to overcome the difficulty).

* Where participation in a research project will not directly benefit participants researchers should state this clearly.

* A study may be justified by its potential benefits to the wider community, even where there are no benefits to the individual. If this is the case these potential benefits should be stated.

* Benefits should be proportional to the risks/burdens for the participants. For example the main benefit from a student project may be the training of the student in research methods. This is appropriate if the risks/burdens are very small.

F. PARTICIPANTS
17. Mark the categories relevant to this proposal.

* Healthy members of the community
* University students
* Employees of a specific company/organisation
* Members of a specific community group, club or association
* Clients of a service provider
* Health Service clients (e.g. users/clients of a health service)
* School children
* Hospital in-patients
* Clinical clients (e.g. patients)
* Aboriginal/Torres Strait Islander people
* Members of socially disadvantaged groups
* Cadavers/ cadaveric organs
* Other (please specify):

18. Expected age(s) of participants – please mark one or more

* Children (under 14)
* Young people (14-18)
* Adults (> 18)

19. What is the rationale for selecting participants from this/these group/s?

* Participants who have limited capacity to decide or refuse consent to participate (including those living in institutions) should not be targeted for recruitment simply because doing so is convenient for the researcher.

G. RECRUITMENT

* If the research involves an institution other than the University or the SESIAHS such as a school, business, etc then include in your application a letter from the appropriate authority indicating permission for the research to be conducted.

* For research being conducted within the UOW evidence of authorisation from the appropriate Head of Unit is normally indicated by appropriate sign off of the application form. If the research involves an area of the UOW other than the one the researcher is located in, evidence of approval from the appropriate unit head must be included.

* For research being conducted within the SESIAHS head of unit approval is reviewed by the SESIAHS as part of the governance approval process, and does not need to be included in this application.

20. How will potential participants be approached initially and informed about the project? e.g. direct approach to people on the street, mail-out to potential participants
Office Use Only

Guidelines for Completing Standard Application - V3 Mar 2014

through an organisation, posters or newspaper advertisements, etc. Please explain in detail and include copies of any letters, advertisements or other recruitment information.

* Where access to potential participants depends on the cooperation of a practitioner, agency, institution or organisation, then the initial contact with potential participants should be made through that other person, agency or organisation. The researcher should not obtain or be given personal information (including names, addresses or telephone numbers) concerning potential participants by those who hold the records without the consent of the individual concerned.

* Potential participants should be told how they were identified by the researcher as someone to be approached to participate in the research. For example, if they were approached because they are members of a particular social club or organisation, then they should be informed of this; or if they were approached because of a particular condition they have which is recorded in their medical records, then they should be told this.

21. Where will potential participants be approached by the researchers to seek their participation in the research, and where will research activities involving participants be conducted?

* Explain where approaches to potential participants and where research procedures involving participants will occur. For example: “recruitment via the Psychology Notice Board, and activities to be conducted in the Psychology Department Labs”, “or “recruitment through GPs’ surgeries, and procedures to be done in the University’s Biomedical labs”, or “recruitment through ISLHD outpatient clinics, and interviews to be conducted in participants’ homes”.

22. How many participants in total do you anticipate will be involved in the project? If the research has several stages and/or groups of participants, please provide the total number of participants expected as well as the number and participant group involved in each stage.

H. CONSENT PROCESS

Generally the consent of participants must be obtained prior to conducting research. If you do not intend to seek people’s permission to use information about them which may be identifying, you may need an exemption from State and Federal Privacy requirements. This is addressed in Section I.
Attach copies of any letters of invitation, information packages, consent forms, proxy/substitute consent forms, debriefing information, identification cards, contact detail cards, etc.

* In research that involves obtaining information from individual participants over an extended period of time you should indicate how you will check for the continued agreement of the participant and how you will ensure that the participant is aware of the freedom to discontinue at anytime.

23. Will consent for participation be obtained from participants or their legal guardians?

   YES *  NO *

   If NO, go to Q31.

24. How will consent for participation be obtained?

   * in writing
   * verbally
   * tacit (eg indicated by completion and return of survey)
   * other (please specify)
   * consent not being sought

   Please explain why the method chosen is the most appropriate and ethical.

   * You should show that the method of negotiating agreement which you propose is appropriate to the research topic and population.

   * If you do not intend to seek the agreement of people to participate in your project (eg for covert research) you must explain why this is necessary or appropriate. The HREC will determine whether the reasons given justify covert or deceptive research.

   * In low risk research which does not collect demographic or other identifying information it can be preferable not to obtain documented consent, to avoid unnecessary collection of personal information. Participants should be informed that participation is taken as having given tacit consent.

   * If you intend to negotiate agreement orally (e. g. over the phone) or in some other way, explain fully how this will take place, and provide a transcript of what will be said to the potential participant.

   * You should note that, unless permission has been gained from participants for subsequent use of their information, information obtained in the course of one research project should not be used for another research project. Ordinarily secondary or subsequent analysis of data beyond that agreed to by participants requires the specific permission of participants. Subsequent use of non-identifying data which is obtained anonymously may be permissible.
25. Is it anticipated that all participants will have the capacity to consent to their participation in the research?

YES * NO *

If NO, please explain why not (e.g. children, incompetent participants, etc.) and explain how proxy or substitute consent will be obtained from the person with legal authority to consent on behalf of the participant.

* Some research projects need to involve people who are not fully able to understand a research project or to make a decision concerning participation. Where it is not clear that potential participants are able to make decisions for themselves other people who know them well should be involved in negotiating agreements (e.g. parents, legal guardians, carers, etc). If the people who you wish to recruit as participants refuse to participate then you must respect that decision, even if their guardians or close friends believe that their participation is acceptable or beneficial.

* Where a researcher wishes to involve participants who clearly lack the capacity to consent for themselves, then the research must obtain consent from the person’s legal guardian. In NSW, the Guardianship Board has authority for determining whether people who fall within the scope of the Guardianship Act can participate in research.

26. For participants who have the capacity to consent, how does the process ensure that informed consent is freely obtained from the participant?

* You should explain the process by which you will convey the nature and aims of the project to potential participants, what information you will give them and what evidence you will obtain to indicate that a participant has made a considered decision to participate. This information may be written (leaflets, advertisements, Participant Information Sheet and Consent Form) or verbal. All written documents should be submitted for HREC approval. If it is a verbal process you should include a transcript of what will be said.

* You should explain how you will establish that the potential participant has understood the project, ie that the decision to participate is based on an accurate understanding and is free from misunderstanding.

27. Are any participants in a dependant relationship with the researcher, the institution, or the funding body (for example the researcher’s clinical clients or students; employees of the institution; recipients of services provided by the funding body)? If so, what steps will be taken to ensure that participants are free to participate or refuse to participate in the research?

* People in dependant situations (eg. researcher’s patients, clients or students; residents of nursing homes, psychiatric patients, recipients of government benefits or services, employees of a funding body, prison inmates, parolees, students etc) may feel less
able to refuse to participate in institutionally sanctioned research, or may feel less able to respond frankly to questions asked of them. Researchers who provide services to potential participants should be particularly aware of the formal and informal power they may have over potential participants and demonstrate how they will protect against undue influence.

* If the population of participants you wish to recruit includes people in dependant relationships, you should identify the steps you will take to preserve their right to refuse participation. This may include:
  i. explaining to the participant exactly what your relationship is with the institution (or other body) on which the person is dependent;
  ii. giving the person opportunities to refuse to participate or to withdraw participation.

28. **How does the project address the participants’ freedom to discontinue participation?**

Will there be any adverse effects on participants if they withdraw their consent and will they be able to withdraw data concerning themselves if they withdraw their consent?

* Researchers must protect each participant’s voluntary choice to participate by providing opportunities for participants to express their wish to discontinue participation while the research is being undertaken, and respecting those decisions.

* Please explain what mechanisms are present to enable participants to withdraw consent at various stages of the research and if/how such withdrawal will affect participants’ health, welfare and rights.

29. **Does the project involve withholding relevant information from participants or deceiving them about some aspect of the research?**

   YES * NO *

If YES, what is the justification for this withholding or deception and what steps will be taken to protect the participants’ interest in having full information about their participation?

* Withholding information about an aspect of the project relevant to a participant’s decision to participate is not ordinarily ethically acceptable (e. g. the primary researcher’s identity or institutional affiliation, the funding body of the research, the general nature of the project or the form in which the research findings will be produced).

* If *withholding information* is a necessary part of the research, you must explain why it is necessary, what information will be withheld, and what arrangements will be made for debriefing.
If the research project involves deceiving participants you must explain why such deception is necessary and justified in the case of your project. Explain clearly what the nature of the deception is (e.g. will people be deceived into participating, or will the deceptive aspect of the project arise only after an agreement to participate is made?). Detail any debriefing you intend to offer.

30. Will participants be paid or offered any form of reward or benefit (monetary or otherwise) for participation in the research? If so, please detail and provide a justification for the payment, reward or benefit.

* It is sometimes desirable to acknowledge the assistance that participants give researchers by recompensing participants for their time, travel costs and inconvenience. Any payment/reward should not be significant enough to cause people to take risks or accept burdens they would otherwise avoid.

* Payment of participants or rewarding participation requires justification, and researchers proposing to pay or reward participants (in any way) need to establish that the research project involves little personal risk, that the participant is aware that the payment does not depend on continued participation (freedom to withdraw consent is preserved) and that the reward for participation is not likely to make the participant dependent on the researcher.

I. CONFIDENTIALITY AND PRIVACY

31. How will the privacy of individual subjects be protected when recording and analysing the data?

* Ordinarily, people agree to participate in research on the understanding that any information provided will be treated confidentially. Specify who will have access to the information obtained from participants (questionnaires, surveys, interview notes or tapes, photographs etc) and whether it will be collected in a manner which reveals the identity of the participants. If third parties such as transcribers, translators, or data analysts are involved please include a copy of the Confidentiality Agreement being used.

* In focus groups and research involving the interview or observation of several people at once, preservation of confidentiality becomes more difficult. You should indicate whether a group of participants will know the names of the other participants, or whether they will know the other participants only by appearance and voice, etc. Participants should be informed who will have access to the information and for what purpose.
32. Will information collected from data or interview be published or reported?

   YES * NO *

   If YES, what form this will take? All uses of data must be explicitly consented to.

   * Give details of the form in which you anticipate that your findings will be published or reported (eg journal article, thesis, conference presentation, training materials).

   * Explain whether you will take steps to offer participants feedback on the research (and if so, in what form) and whether you anticipate a risk that the findings may be misused.

   * Explain whether you intend to obtain the participants’ permission to identify them in publications, and if not how their confidentiality and privacy will be preserved in the publication of your research findings.

33. Will any part of the research activities be placed on a visual or audio recording (eg audiotape, photograph or video-tape)?

   YES * NO *

   If YES,

33.a What will the recording be used for?

33.b Who will see/hear the recording?

   * If you are making a visual or audio recording of participants you need to explain the use to which the recorded images/voice will be used and who the audience will be. Participants must be advised of what will happen to the tapes or recorded images after completion of the study. If participants will be identifiable then they must be told this on the participant information sheet.

34. Data (including questionnaires, surveys, computer data, tapes, transcripts and specimens) must be securely stored at all times. Where will the data be held and who will have access to it:

   a. during the project?

   b. on completion of the project?

   * Primary data must be retained for a period of at least five years after completion of the study to conform to the University’s Code of Practice—Research and the
Australian Code for Responsible Conduct of Research (NHMRC 2007). Data must be retained in a secure place, this means secure storage at the research institution, not in the researcher's home. After 5 years (15 years for clinical trials), the data must be securely destroyed. Please explain why the storage place chosen is secure.

35. Data should be held securely for a minimum of 5 years (15 years for clinical research) after completion of the research. How long will the data be stored for? If it is not being stored, please provide an ethical justification for this.

* In some cases retention of primary data can pose a threat to the safety of participants. In these cases data may be destroyed rather than stored – in such cases, please explain to the HREC why this is necessary for the protection of the welfare of participants.

36. Does this project involve obtaining identifiable information (e.g. data) from a third party without prior consent from the participant?

   YES * NO *

   If NO: You have completed the questionnaire. Please ensure that the form has all the appropriate signatures and attachments (see checklist) before submission.

   If YES: go to question 37.

37. Who will be providing the information? Please include copies of any correspondence regarding permission to access this information from a responsible officer of the Agency.

38. Will the information be deidentified during collection use or disclosure?

   YES * NO *

   If NO: You must apply for an exemption to the State and Federal Privacy Acts. Please complete the Privacy Exemption Application Form available from the ‘Forms’ section of the Ethics webpage.

   If YES:

   38.a Who will be deidentifying the information? Is this a person who would normally have access to the information?

   38.b How and when will the data be deidentified?
J. DECLARATION BY INVESTIGATORS

Principal Investigator:

- I certify that I am the Principal Investigator named on the front page of this application form.

- I undertake to conduct this project in accordance with all the applicable legal requirements and ethical responsibilities associated with its carrying out. I also undertake to take all reasonable steps to ensure that all persons under my supervision involved in this project will also conduct the research in accordance with all such applicable legal requirements and ethical responsibilities.

- I certify that adequate indemnity insurance has been obtained to cover the personnel working on this project.

- I have read the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Research*. I declare that I and all researchers participating in this project will abide by the terms of these documents.

- I make this application on the basis that it and the information it contains are confidential and that the Human Research Ethics Committee of The University of Wollongong/SESIAHS will keep all information concerning this application and the matters it deals with in strict confidence.

<table>
<thead>
<tr>
<th>Name (please print)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

**Signature/s of other researcher/s:** The first named researcher will assume responsibility for the project in the absence of the Chief Investigator. All investigators must sign the application.

<table>
<thead>
<tr>
<th>Name (please print)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Include additional lines if necessary.

K. APPROVAL BY HEAD OF UNIT
This person must not be a member of the research team.

I am aware of the content of this application. I am satisfied that:

* All appropriate safety measures have been taken;
* The research is in accordance with UOW/SESIAHS Policy;

and approve the conduct of the project within this unit.

______________________________

Name (please print)       Signature       Date

NOTE: RESEARCH MUST NOT COMMENCE UNTIL THE APPLICATION HAS BEEN APPROVED BY THE HREC.
CHECKLIST (for applicants use)

Applications should be sent to:  Ethics Unit  
Research Services Office  
University of Wollongong  
Wollongong NSW 2522

Applications for the full HREC require 17 copies plus the original. Applications to the Executive Committee of the HREC (expedited review) only require the original.

* Original Ethics Application plus appropriate number of copies (See Web)
* Participant Information Sheet/Package
* Consent Form(s)
* Copies of Questionnaire(s)/Survey(s) or Interview/Focus Group Questions
* Copies of all material used to inform potential participants about the research, including advertisements and letters of invitation.
* Evidence of permission to conduct research from site managers
* Evidence of approval/rejection by other HREC(s), including comments and requested alterations to the protocol
* Copies of Confidentiality Agreement templates for any third parties involved in the research
* Copy of Research Contract for sponsored/contract research
* Copy of ‘Clinical Trial Insurance Requirements’ Form (UOW researchers answering Yes to Q10 only)
* Privacy Exemption Application (researchers answering No to Q38 only)

For Clinical Trials you should also include:

* Protocol (17 copies)
* Summary Sheet (17 copies)
* Budget (17 copies)
* Investigator’s Brochure (6 copies)
* Indemnity Form/s (3 copies)
* CTN or CTX Form (1 original copy)
* Insurance information (1 copy)
Office Use Only
HE

* Clinical Trial Agreement (1 copy)