Initial Application for Ethics Approval for Research Involving Humans
Guidelines for Applicants

1 SHORT TITLE OF PROJECT

The title will identify the essential point of the project. It should be succinct and in terms that an educated, but non-scientifically trained person can understand.

The title of the project, which appears on the Information Statement for participants, must be short, simple and in plain English, as the majority of human research seeks to recruit participants from the general community, rather than people who might be familiar with the focus of the research.

Investigators must advise the Committee if there is a change to the title of the project or any other modification.

2 APPROVAL FROM ANOTHER ETHICS COMMITTEE

If the project has received, or requires, the approval of another human research ethics committee, eg another university, hospital, health service, or government agency/department, then answer Yes.

Identify the committee, give details of the decision (approved, pending, rejected, yet to be submitted), the committee's application reference/approval number, and attach a copy of the committee's interim or final decision, or forward as soon as it becomes available.

3 CHIEF INVESTIGATOR *or* PROJECT SUPERVISOR

The first named Chief Investigator or Project Supervisor is responsible for the conduct of all aspects of the research project. This includes any necessary training or instruction of students or other members of the research team, equipment and environmental safety, and scientific and ethical conduct of those engaged on the research project.

If the Chief Investigator is not associated with a Uniting*Care* Health facility/service, at least one of the co-investigators should be.

4 CO-INVESTIGATORS *and/or* STUDENT RESEARCHERS

Please complete as applicable, listing all personnel who will be classified as an "investigator" or who will be an author on publications arising from the research.

5 STUDENT RESEARCH

Students are those enrolled in undergraduate, honours, certificate, diploma, and masters programs.

6 DURATION OF PROJECT

Provide the intended duration of the project where it is anticipated there will be contact with participants, their personal records, or human tissue samples.

7 FUNDING

Supply appropriate information. If the proposed project is awaiting the outcome of a grant application, will the study still be undertaken if funding is not successful?

For trials of drugs or devices that have an external sponsor, *e.g.* a drug company, submit **two originals** of **Medicines Australia *Form of Indemnity for Clinical Trials***, completed by the sponsor, indemnifying the Uniting Church in Australia Property Trust (Q), as appropriate. When signed, one original will be retained and one will be returned to the sponsor.

8 COMMONWEALTH PRIVACY LEGISLATION

If the proposed research involves access to personal information (*ie* information that can identify an individual) that is held by a Commonwealth department or agency, or an organisation in the private sector, **and** you want to access the information **without** the consent of the individual to whom the information relates, steps that comply with privacy principles established under Commonwealth Privacy legislation will need to be followed.

Information relating to these issues may be obtained from:

- Guidelines under Section 95 of the Privacy Act 1988 (for Commonwealth department or agency data); and
- Guidelines approved under Section 95A of the Privacy Act 1988 (for private sector data)

These are available at http://www.health.gov.au/nhmrc/publications/synopses/e26syn.htm;

If the answer is **Yes** to **both** parts of this question, the Ethics Committee requires the following information:

- Detail the type of data to be accessed/collected;
- The departments/agencies holding the information;
- Number of records involved.

The Ethics Committee must be provided with this information because it is obliged to report details to the Commonwealth Government where the privacy principles may be breached, *eg* accessing information without the prior consent of the individuals to whom the information relates.

9 AIMS AND VALUE OF PROJECT

This section should provide the background necessary to understand why the study is being done. It should include a review of current knowledge, with references provided. The explanations should be sufficiently clear that a reviewer, who may not be an expert in this area of research, will be convinced that the benefits of the proposed research to the participant or to the community at large will outweigh the risk.

- Why is this particular piece of research worth doing?
- If the results of this research were never produced, would the information be missed? Why?
- What special groups stand to benefit?
- What further avenues of research might be opened up by the results of this particular project?

For studies of therapies, procedures and interventions, the following must be explained clearly:

- What therapy or therapies and procedures represent the currently acceptable standard of care?
- What are the optional therapies?
- Why is the experimental therapy being proposed?

10 REPLICATION STUDIES

Has the same or a similar study been done elsewhere in Australia, or overseas? Reproducibility of important research is essential, but needless duplication is to be avoided. If this is a replication study, the Ethics Committee requires evidence that further work is justified.

11 SPECIFIC TYPES OF RESEARCH

Answer for each category and, where your answer is **Yes**, provide the required information, having reference to the relevant section of the *National Statement on Ethical Conduct in Human Research*.

12 CLINICAL TRIALS

A clinical trial is an experiment involving the testing of the effects of a diagnostic or treatment intervention on humans.

A clinical trial can involve testing a drug, surgical or other therapeutic or preventive procedure, or a therapeutic, preventive or diagnostic device or service. Any intervention, including "natural" therapies and other forms of complementary medicines, can be tested in this way. (Refer to section 3.3 of the *National Statement.*)

The ethical issues raised by clinical trials are not limited to medical and other health sciences. Social sciences and related disciplines may also conduct research that involves similar ethical considerations.

If **Yes** to this question, complete and attach Appendix A.

13 SAFETY IMPLICATIONS

If you answer **Yes** to any part of this question, provide details **and** contact Occupational Health and Safety Unit at Uniting*Care* Health, Tel 07 3511 4872 if you have any queries.

14 RESEARCH PLAN

This section should be sufficiently detailed to include all important aspects of the experimental procedure and design including:

- The type of study it is: qualitative versus quantitative; a particular type of study design, eg, a descriptive study, a randomized controlled trial, case control study, etc;
- Where the research study will be conducted;
- Method of assignment to experimental groups - which of the researchers will conduct important phases of the study, ie, who will obtain consent from the participants, perform the randomization?
- If "randomized", an explanation of randomization procedure;
- The research techniques and instruments that will be used to collect data, eg, record review, observation, intervention, tissue collection, psychological/physiological/surgical procedures, questionnaires, interviews, focus groups, audio/video recording;
- Whether research instruments are questionnaires/surveys, or standardised questionnaires. If they have been compiled specifically for your research, whether they have been tested/validated and how;
- Whether investigators will be "blinded";
- If "blinded", an explanation of blinding procedure;
- Frequency of subject visits and anticipated time commitment required;
- Laboratory testing;
- Medications and doses;
- The rationale for the determination of the proposed sample size. It is important to minimise the number of participants involved. However, too few participants may undermine the scientific value of the research through a failure to reduce measurement errors sufficiently. The Committee needs a simple statement of how these factors were reconciled;
- Information available to justify the measures to be used, (e.g., reliability and validity as appropriate);
- If more than one study design is being utilized, the different protocols should be clearly separated;
- The timetable for the research;
- The rules for stopping the study or withdrawing subjects from the study.

The research should be conducted in a location that is adequately resourced to enable the research to be conducted appropriately, *e.g.* the participants' privacy, comfort and safety is assured, the location is readily accessible, refreshments are easily available if participation requires lengthy sessions, medical personnel and equipment are on hand if required given the nature of the intervention/testing etc.

The agreement of the respective Uniting*Care* Health facilities/services to conduct the research is required. Your application will be sent to the relevant hospital's Director of Medical Services for agreement to accommodate the research.

If any equipment or resources (e.g. cardiac catheter laboratories or nursing staff) need to be utilized as part of the research protocol, then this needs to be explained and agreed to by the respective facility. Further, it needs to be made clear that the use of the equipment or personnel in the research will not disadvantage the usual clients of that particular service, and whether the service will be compensated for the use of the equipment, or the time the staff are expected to contribute to the research project.

Identify clearly the study population or participant group(s). That is, the specific characteristics that make the participants eligible for the study. They might be people of a particular age, gender, diagnosis, etc. Detail the inclusion and exclusion criteria.

If it is not obvious why a particular group is being recruited, and by default another group is being excluded, then this discrimination needs to be justified. In addition, there is to be a fair distribution of the benefits and burdens of participation in research and, for any research participant, a balance of burdens and benefits. Refer to s.1.5 of the *National Statement* for more detail on the issue of discrimination and distribution.

Are the participants in the research representative of the group(s) the research is intended to benefit?

If the potential participants belong to a potentially vulnerable group such as children and young people (see section 4 of the *National* Statement), people with an intellectual or mental impairment (section 5 of the *National Statement*), people highly dependent on medical care (s.6 of the *National Statement*), people in dependent or unequal relationships (section 7 of the *National Statement*) then:

- Justify why they have been selected; and
- Explain what measures will be taken to ensure their wellbeing and to ensure they do not feel obligated or pressured to participate.

How, by whom, and where will potential participants be selected and approached to receive the invitation to participate?

Respect for the autonomy and privacy of potential participants is of prime importance. Potential participants have the right to decide for themselves whether or not they want to be part of the research. They should be made aware of the research in a way that does not invade their privacy and does not make them feel obligated, pressured or coerced to consent to participate.

How?

Explain how potential participants will be selected and approached to receive an invitation to participate, *eg* patients of a particular doctor.

By whom and where?

Who will select potential participants and make the initial approach. Where this requires a personal approach, it should be undertaken by someone the potential participants can reasonably expect to interact with in the context. For example, if the person is a clinic patient they should be approached only by clinic staff to be given the written information/invitation for the project, either handed to them or posted to them. The patients could then be given the choice of either returning a consent form directly to the researchers, or to the clinic staff, if they wished to participate. The information/invitation would, of course, give them contact details of the researchers if they wanted more information before making a decision.

The person recruiting potential participants should, where possible, avoid any conflict of interest or confusion of their role in relation to potential participants. Particular care needs to be taken where a person's treating clinician invites them to participate in a trial in which s/he is the Chief Investigator or one of the co-investigators. It is preferable for research staff, for example the unit's clinical research nurse, to approach potential participants.

How much time will potential participants have to consider the invitation to participate?

Ideally the potential participants should be able to take the study Information Statement away with them and take as much time as they want to consider whether or not to participate.

If consent is required on the same day or in a shorter period, potential participants should be given some time to consider whether to participate. They should also be provided with the means for contacting relatives, friends or their GP (*eg* access to a phone) if they wish to consult with others before making a decision.

What is required of participants?

Provide details of everything that the participants are being asked to do or that will be done to them, how much time it will take, where they need to attend and number of visits if applicable.

15 ANALYSIS

Provide the information requested. The proposed statistical evaluation should be included here. The purpose of this section is to convince the reviewer that useable data will be forthcoming.

16 PROPOSED REVIEW OF PROGRESS, PARTICIPANT CARE, WINDING UP PROCEDURES

Using the following sub-headings, state simply and clearly what you are intending to do.

Review of progress of the project

There is no point in continuing with the research project if it is becoming clear that the intended aims of the research cannot be achieved. Also there is no point in subjecting participants to inconvenience, potential harm or risk that has been shown to be avoidable by initial experience gained in conducting the research. Hence it is very important to nominate specific stages at which the progress of the research will be reviewed to assess the value of continuing, and/or to modify the procedures in the light of experience.

Will there be interim analyses? If so, provide details of when and what will be considered.

Duty of care to participants and research staff

Response to harm What is the protocol for addressing any physical or psychological harm that participants might experience in the course of the research? This might be the response to harm caused during the course of procedures, or anxiety caused by recounting stressful or painful life events. The reporting of adverse events in clinical trials is covered in the next section.

Response to unexpected information In some cases the research may have the potential to reveal unexpected information such as the coincidental diagnosis of an abnormality. If such outcomes are at all possible in your research, provide details of how you will respond.

Welfare of research staff If the research protocol provides a potentially emotionally difficult or physically dangerous situation for the researchers, what protocols/procedures/arrangements are in place to ensure their well-being and safety?

Procedures for reporting adverse events

Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance, procedure, or method.

For Clinical Trials, serious adverse events from the local site should be reported to the Uniting*Care* Health Ethics Committee within 72 hours and reports from other sites as they are available. For a definition of what constitutes a serious adverse event, refer to Appendix 3 of the *National Statement* and the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*, available at http://www.health.gov.au:80/tga/docs/html/ich13595.htm.

For projects other than clinical trials, unforeseen or adverse events and complaints from participants in the research or about the research should be reported to the Ethics Committee as soon as possible. These are events that occur during the course of, or as a result of, the research and that result in physical, psychological, or psychosocial harm, or any other event that might affect the continued ethical acceptability of the project.

Premature cessation of project

State the conditions under which the research would be discontinued or prematurely ceased and how the participants would be made aware of the decision.

In the case of a Clinical Trial, will the participants be made aware of what will happen and/or what they will be asked to do if the trial ceases prematurely? What arrangements will be made for the participants' ongoing/further treatment?

Feedback of results to participants

What information will be made available to participants about the outcome of the research? Will they be made aware of the time lag between their involvement in the research and the availability of results?

Post trial follow-up

What, if any, counselling/advice will be offered to participants after the completion of a Clinical Trial?

For Clinical Drug Trials, it needs to be clear what access, if any, participants will have to the trial medication at the end of the trial and at what cost. If not, then what advice will be given to participants about the sudden cessation of the trial medication and their continued care? These important points are to be addressed in both the Application and the Information Statement for participants.

In the case of intervention studies, if the research produces evidence of effectiveness or superiority of a particular intervention, will it be offered to the control group, when and at what cost to participants? If not, why not?

17 WHO WILL PAY FOR INJURIES OR COMPLICATIONS SUSTAINED FROM THE STUDY

Please provide information on who will pay for injuries or complications sustained from the study or its procedures. It is not always appropriate in a Private Health care setting to anticipate Medicare funding or expect the patient to go to a public hospital.

18 SUMMARY OF ETHICAL CONSIDERATIONS

In every piece of research involving humans, there is a balance to be struck between the invasiveness of the research interaction or intervention for those participating (*eg* in terms of discomfort, inconvenience, health risk, loss of privacy, etc) and the value to be achieved by carrying out the research. The Ethics Committee must be in a position to clearly evaluate this aspect of the project. As far as possible, the benefits should outweigh the risks.

Using the following sub-headings, state simply and clearly what you are intending to do.

How will voluntary participation be ensured?

People have the right to decide whether or not to be involved in research. State how it will be ensured, as far as is possible, that their decision is informed and free of obligation or coercion, whether implied or overt.

Potential participants should be informed that participation in the research project is voluntary and entirely their choice, and, if they decide to participate, that they can withdraw at any time without having to give a reason. Further, they need to know that, if they decide not to participate or to withdraw from the project, their decision will not disadvantage them in any way. If they are being sought for a project due to their status as a patient, student, or employee of a particular company, they also need to be assured that their decision will not affect their access to medical services, their course assessments, or relationship with their employer, respectively.

For participants who decide to withdraw from the project, will they be able to withdraw their data, tissue samples, interview tapes/transcripts, images, etc? Are there any restrictions on the withdrawal of data etc? If so, why are there such restrictions and will the participants be made aware of them?

Is active consent being sought from all participants for all aspects of the research involving them? If No, why not?

The active written consent of participants is the standard. Generally, the Ethics Committee will require that written consent be obtained from all participants. The Consent Form is evidence that valid consent has been obtained.

Sometimes written consent may be unnecessary. Anonymous surveys or questionnaires do not require explicit written consent. The return of the questionnaire to the Investigators may be taken as evidence of consent to participate, however, the participant should be given a Participant Information Sheet for such research. If the personal details of participants are not required for the purposes of the research, then do not ask for them. The security of the research data is more easily preserved if the data are anonymous. However, a survey is not rendered anonymous simply by not asking for names. Care must be taken to ensure that other questions will not identify individuals, *eg* people with particular or rare characteristics.

In limited cases it may be acceptable to conduct certain types of research without obtaining consent from participants, *eg* the use of de-identified data in epidemiological research, observational research in public places. The reasons and justification for not obtaining consent must be provided to the Ethics Committee, having reference to the relevant sections of the *National Statement*, *eg* sections 14 to 17.

If written consent is not considered necessary or appropriate, explain why, referring to 1.7, 1.9 and 1.11 of the *National Statement*.

Consent and competence.

To be able to give voluntary informed consent, a person must be competent. People are competent to give consent if they are adults or "mature minors" **and** are able to understand what the research involves, comprehend the information provided to them and understand the implications of their decision.

Clearly, it may be difficult to assess competence and a number of things may affect a person's competence to give consent, either temporarily or permanently, *eg* illness, anxiety, or intellectual impairment. Refer to sections 5 and 6 of the *National Statement*, L13 and L39 of *The Human Research Handbook*.

If it is anticipated that participants may not be competent to consent for themselves, and the research project is not a clinical trial, it will be necessary to submit an Information Sheet and Consent Form for the person who has lawful authority to consent on behalf of the participant.

Consent and children

Refer to section 4 and Appendix 3 of the *National Statement* and E5 and L1 of *The Human Research Handbook* for detailed discussions concerning consent and children.

Generally the consent of a parent or guardian will be required for children under 18 years of age participating in research projects. However, children must at least assent or agree to their participation and can also give consent if competent.

Depending on the nature of the research, and the personal situation of the young people, it may be appropriate for teenagers to consent for themselves, with or without information being provided to their parents/guardians.

Justification will need to be provided to the Ethics Committee for any case where it is believed appropriate not to obtain parent/guardian consent.

Except for the very young child who does not have the skills to make a decision whether or not to participate in a project, the Information Sheet to parents/guardians must ask them to discuss the project with their child. Furthermore, they should be advised that where consent is given by parents/guardians, the final decision as to participation rests with the child.

For those children who have adequate literacy skills (age 8 and over as a guide), a simplified version of the Information Statement should be developed and included with your application to the Ethics Committee. There should also be a section on the Consent Form for the child to sign if they wish – it should be made clear on the form that this is optional.

Participants from a non-English speaking background

If the research is to involve participants who are not skilled in the English language, then it must be explained to the Ethics Committee how they will be catered for, *eg* interpreters, documents in their chosen language.

How will participants' privacy be protected during the recruitment process, or access to tissue samples, or access to records?

Briefly explain how the privacy of potential participants will be respected and protected.

In addition, researchers must ensure that their proposed research complies with all relevant privacy legislation. Refer to section 18 of the *National Statement*.

For access to personal data held by Commonwealth departments/agencies, or from private sector organizations, refer to Q8 in these Guidelines.

Refer to Appendix 2 of the *National Statement* for details of the Privacy Principles, particularly Privacy Principle 11. Although the *Privacy Act 1988* applies only to Commonwealth data, the spirit of these principles is applied to any research project involving personal information.

What are the benefits and risks to participants and how will risks be minimised?

What are the potential benefits, if any, for the participant? Wider benefits for the society/community, or the increase in knowledge, should be dealt with in the project's aims and value. What are the risks to participants compared to those people who do not participate? How will potential risks for participants be minimised?

Further discussion on this topic can be found in section 1 of the *National Statement* and E3 of *The Human Research Handbook*.

Are there any potential conflicts of interest for the researchers?

A conflict of interest can arise if the researchers have a financial/commercial interest in the project, or a relationship to the potential participants.

Relationship to participants Refer to section 7 of the *National Statement*.
Do any of the researchers have a relationship to the potential participants, *eg* personal, care provider/patient, student/teacher, employee/employer? If so, will the researcher(s) be directly involved in the recruitment process or conduct of the research? How will the conflict of interest be addressed from the point of view of the participant? If the research involves people in dependent or unequal relationships, it is important that the research plan includes steps to acknowledge, address and overcome as far as is possible, the conflict of interest.

Commercial/financial interest Do any of the researchers have a commercial or financial interest in proposing the research or in the outcome of the research? In accordance with 2.21 of the *National Statement,* identify all sources and amounts of funding for the project. The Ethics Committee must be satisfied that funding is sufficient to conduct and complete the project. Applications for funding are to be detailed at Q7 of the application. For clinical trials additional information is sought in Appendix A.

Will the research involve payments/rewards/inducements to participants?

Monetary payments to research participants can only take the form of fair and reasonable reimbursement for time, inconvenience and out of pocket expenses such as travel or parking fees. The amount of the reimbursement must be specified. It must not be considered excessive and will be contingent on the relevant aspects of the project, *eg* number and length of visits, location of the study centre. Any proposed reimbursement is to be clearly stated in the Information Statement for participants.

Inducement involves the offer of excessive or inappropriate reward in order to obtain compliance from potential research participants and so compromises the ability of potential participants to make a free choice regarding participation. Section 1.10 of the *National Statement* states that "the consent of a person to participate in research must not be subject to any coercion, or to any inducement or influence that could impair the voluntary character".

How will confidentiality/anonymity of information received be ensured?

Confidentiality is the obligation of researchers, to whom private or personal information has been given, not to use the information for any purpose other than that for which it was given. This includes not giving anyone other than those persons identified to the participants access to the information.

Anonymity is only possible where the information cannot identify the person to whom it refers by name, inference, association or other characteristic. Anonymity or de-identification can be irreversible if the identifiers have been removed permanently or the data have never been identified. These data are referred to as "de-identified". Where identifiers have been removed and replaced by a code, it is possible to use the code to re-identify the person to whom the information relates. In these cases, the data are referred to as "potentially identifiable" or "re-identifiable".

Audio and visual data (eg videotapes) carry greater potential for identification of individual participants, even when names are not recorded. Careful consideration should be given to the storage and disposal of such data.

Describe what form the data will take and what, if any, processes will be used to render the data de-identifiable or re-identifiable.

The information for participants must state clearly what form their data will take and where they are potentially identifiable, what information about them will be used in any report arising from the research.

Any other ethical issues specific to the research?

Although the Ethics Committee has a broad expert and community representation, the research applicant might have particular knowledge or insights into the ethical issues presented by the research that are not covered elsewhere in these Guidelines. These might arise as a result of the uniqueness of the research or particular cultural attributes of the people who are the focus of the research.

APPENDICES

Advertisements

Advertisements to be distributed to patients or the public (e.g., by mail, newspaper, bulletin boards, websites) should receive Human Research Ethics Committee review and approval before placement. A description of where the advertisements are to be placed, and for how long, should be provided with the proposed advertisement. The following guidelines should be followed in writing the text:

1 The information in the advertisement should match the approved protocol;
2 For clinical trials, use of the term "treatment" should be avoided;
3 Investigational or experimental drugs/devices/procedures should be clearly noted as such;
4 No statement of direct benefit should be made;
5 The availability of compensation (but not specific amount) can be noted;
6 The sponsor's name should be noted, if appropriate.

Such advertisements should not appear under the auspices of a Uniting*Care* Health facility/service unless formally approved by the facility/service. Generally this approval will not be given unless the study is being conducted by or has the active participating interest of the facility/service.