



Research Services Office

Human Research Ethics Guidelines for the Completion of the Application Form

1. Introduction

1.1 National Statement on Ethical Conduct in Research involving Humans

Investigators should become familiar with the guidelines contained in the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* (2007) prior to completing an application for research with human subjects.

Further detailed commentary on the *National Statement* can be found in the NHMRC's Human Research Ethics Handbook.

1.2 Information Privacy Legislation

Investigators must become familiar with all information privacy legislation and associated guidelines that may be relevant to their application for ethics approval. Information privacy legislation, including the Health Records Act, serves to protect individuals' personal information and to give them control as to how their personal information is collected, used and disclosed. Information privacy legislation and guidelines that may be relevant to investigators are detailed on the [Human Ethics](#) web site.

2. Specific Guidelines for Investigators

Note: The item numbers that are used in this section correspond to those that appear on the UHEC/FHEC Application Form for Research with Human Subjects.

Item 1 Project Title

Choose a short, simple and self-explanatory title that will identify for research participants and ethics committee members the essential point of the project. The application title should be the same as that which appears on all documentation provided to participants about the project. If a different title has been used for

funding purposes, as in a grant application, please ensure that the alternative title is given in section 6.

Item 2 Chief Investigator

Chief Investigators must be a current La Trobe staff member, either academic, including those in adjunct and emeritus positions or general staff. All fields in this section are required and must be completed before the application is submitted.

Item 3 Project Duration

Specify the intended project duration. Note that all proposals must be approved as ethically acceptable before the research can commence and before full funding for the research is released. The human ethics committee does not give retrospective approval for a research project where recruitment of participants, data collection and access to participant records has already commenced or has been completed.

The period specified should not include preparatory research activities such as the literature review. In general, the start date specified should be at least **30 working days** after submission of the ethics application. Note that your ethics approval will be active only until the completion date that you specify. If it becomes evident that the project is likely to continue beyond the approved period, a [Modification to Project](#) request will be required.

For the purposes of ethics approval, project completion means that all data are collected and analysed and all project documentation is stored as per UHEC requirements. Completion does not mean that all reports; theses and journal papers have been published.

Item 4 Project

Item 4a) Lay summary of the project

Provide a two-sentence summary in lay terms of what this research involves with particular reference to what participants are being asked to do. This summary should be 50 words or less to allow for use in annual reporting.

Item 4b) Type of project

Identify if the proposal is for research by academic staff member; supervised higher degree research, contract research or supervised undergraduate research.

Item 4c) Is this project part of a larger project?

If this application is for a study that is part of a larger project then details about the larger project are required so that the time taken by the ethics committee to consider the application will be minimised. Circumstances where this applies can be when the research is an Honours or postgraduate student project that is a sub-study of a larger project conducted by La Trobe staff and/or staff of an external agency.

Details of the larger project that should be provided include the project title; the name, title and affiliation of the Chief Investigator; the name of the ethics committee/s that has approved the larger project; and the ethics approval number/s.

Where the proposal is for a sub-study of a larger project conducted by staff of an external agency, a copy of the ethics application and all support documents submitted to that agency must be included in the proposal to La Trobe along with a copy of the approval notification from the agency. In addition, the application submitted to the external agency and/or the approval notification from that agency must clearly identify the relevant La Trobe University student/s and staff.

Item 4d) Does this project involve multi-centre research?

If the research project is being conducted at more than one institution; involves a researcher who has joint affiliations; or involves a student whose external supervisor is the chief investigator, then please consult the [Guidelines for Multi-Centre Research involving La Trobe University Students and Staff](#) and, if appropriate, the [UHEC Guidelines for DHS Applicants](#).

Item 5 Period during which activities requiring ethics approval will occur

Please see **Item 3 Project Duration** for information

Item 6 Funding

Information about funding from sources external to the University is requested in order to verify that ethics approval has been obtained as outlined in the conditions of grant of the funding body. Please note that student scholarships are not considered to constitute external research funding.

Item 7 Description of project

State clearly and simply the aims and/or hypotheses of the project, what type of research design will be used, what you are intending to do, who the participants will be, how the data will be analysed and why this particular project has merit.

The ethics committee needs to form a clear understanding of the aims and value of the project so that it can weigh the potential benefits of the proposed research against the burden placed on participants involved in the study. Burden for the participants can include discomfort in any form, inconvenience, risk to psychological or physical health, social, legal and/or economic disadvantage and loss of privacy.

Outline your project briefly in this section, using lay language as much as possible. Note that you will be asked to provide further details of the actual research procedures in item 13.

Item 8 Participant details

Specific details of the participants are required to assess whether the principle of justice has been considered in the design of the project. Investigators should recognise the potential for injustice if the benefits or burdens of research are restricted to a particular gender or age group because of factors such as convenience for investigators. It is also important to consider whether particular participants may have diminished ability to provide informed consent and/or there is an increased risk of being harmed or coerced to participate because of an impairment or disability.

Item 8a) Number of participants

If precise numbers of participants have not been established, indicate that the numbers are approximate.

Investigators should provide justification for their sample size, including statistical power analysis results where relevant. This information assists the ethics committee in determining whether the research is likely to contribute to knowledge and in establishing whether any risks of discomfort or harm to participants are balanced by the likely benefits of the research.

Item 8b) Age range

Be as precise as possible about the age range of participants. At the very least, use broad categories, for example, 'infants', 'pre-adolescent children', 'adolescents', 'young adults', 'older adults'. For projects involving participants under the age of 18 years, please also note item 8(g) below.

Item 8c) Will any participants be ill or frail?

If any participants in the study have a psychological, cognitive or physical impairment or disability, tick 'Yes' and state clearly the nature of the impairment or disability.

Item 8d) Inclusion and exclusion criteria

If there are any criteria that will determine whether participants are included in, or excluded from, the research then please specify all the criteria you will use and explain why each criterion is important to the purpose of the research. Inclusion/exclusion criteria may contain, but are not limited to, factors based on a person's race, age, sex, health status, disability, religion, culture, political beliefs, educational background, socio-economic group and place of residence.

Item 8e) Recruitment method

Explain clearly how you will gain access to participants and their data for the project. Examples of recruitment sources include:

- Agencies/organisations asked to identify possible participants and/or data
- Public records, such as a phone book
- Non-public records, such as government files, hospital records, mailing lists of professional associations
- Friends, family, patients, students, employees, professional colleagues or associates approached by investigators
- Advertisement in publications or public media/notice boards

Include details of how you will gain access to confidential data and/or names and contact details for participants; clarify who will make the first contact with potential participants to ask if they would like to participate in the project; and explain how that first contact will be made. Will it be by letter, phone call or a personal approach?

If recruitment is to be through advertisement, please identify the publications or media to be used and provide a copy of the text or script for the advertisement.

Note that all recruitment documentation must specify the relevant La Trobe University human research ethics application reference number, the investigators' affiliations with La Trobe University and, where relevant, indicate the name of the course of study for which the research is being conducted.

Where it is intended to recruit students from the University's Schools/Centres, a letter from the Head of School/Centre authorising approval to recruit the students should be obtained. In addition, where it is intended to recruit students through lectures or other University classes, prior approval from the lecturer or other relevant staff member must be obtained. For projects involving students from the University's Schools / Centres, please also note item 8(h) below.

Item 8f) Compensation to participants

The *National Statement* maintains that payment should not encourage participants to take risks (N. S. section 2.2.10-11), and if compensation is to be provided to participants, it should not be so large as to create inducement to participate. It is acceptable, however, to provide appropriate compensation for costs such as travel and parking.

Item 8g) Involvement of special groups

This section must be completed if the research involves people who are:

- Prisoners, parolees or wards of the state
- Unable to provide informed consent because of an intellectual disability, mental illness or cognitive impairment
- Not legally competent to give informed consent
- Highly dependent on medical care
- Pregnant women
- Children or young people under the age of 18*
- Aboriginal or Torres Strait Islanders**
- Living in other countries

***Children or young people under the age of 18** - In accordance with chapter 4.2 of the *National Statement*, researchers are asked to justify studies involving young children and demonstrate that it does not involve undue risks to these potential participants. The researcher is also required to demonstrate whether the young person would be capable of providing informed consent and understanding the full implications of their participation. The recruitment of participants under the age of consent should also seek parental consent in addition to the consent of the prospective participant. For participants aged 17 to 18 years, their single consent may only be required in particular circumstances, although the fact of participation should also be conveyed to parents/guardians in most cases. However, it is acknowledged that there are some circumstances where gaining parental/guardian consent would be detrimental or inappropriate and the researcher would need to demonstrate the “exceptional circumstances” to allow for waiver of parental consent.

****If Aboriginal people and or Torres Strait Islanders** are potentially to participate in a project, researchers are also advised to familiarize themselves with the [**NHMRC Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research \(2006\)**](#). Proposals for ethics approval should detail the consultations that have been undertaken with relevant community groups, committees and agencies.

When a project involves participants from special groups, as listed above and outlined in chapter 4 of the *National Statement*, the researcher must provide the following information:

- The nature of the special group
- Justification for the inclusion of people from this special group
- Details as to how the rights and welfare of participants from the special group will be protected in your research
- The persons and/or agencies from whom permission will be sought for these groups to participate in the research

Item 8h) Participation of La Trobe University students

The *National Statement* maintains that an ethics committee should take special care in the review of applications involving people in dependent or unequal power relationships and thus applications for research involving the participation of La Trobe University students must satisfy the ethics committee that their inclusion in the study is justified, that the rights and welfare of students will be protected, and that the students' consent is both adequately informed and voluntary. In addition, the researcher must provide an assurance that refusal to participate in, or withdrawal from the research, will not result in any discrimination or other penalties for the students.

Item 8i) Participants in dependent or unequal power relationships with the investigators

Researchers and the ethics committee must take special care if any participants in a study are in a previously existing dependent or unequal power relationship with any of the researchers. Participants who might be considered to be in a dependent relationship with the researchers include:

- People under the care of a health professional or carer who is also a researcher
- People under the care of a health professional or carer who will assist in recruiting participants
- People whose superiors in their place of employment will assist in recruiting participants
- University students whose teachers or supervisors will assist in recruiting participants
- School students whose teachers or school principal will assist in recruiting participants
- People who are clients of an investigator or of any professional who will assist in recruiting participants

Applications for research involving the participation of people in dependent or unequal power relationships must satisfy the ethics committee that inclusion of people in this situation is justified, that the rights and welfare of participants will be protected, and that the person's consent is both adequately informed and voluntary. In addition, the applicants must give an assurance that refusal to participate in, or withdrawal from the research, will not result in any discrimination, reduction in the level of care, or other penalties for the participant.

Item 8j) Requirement to have a *Working with Children* Check

Does this project require the researchers to have a *Working with Children* Check? Information about such requirements is available on the [Working with Children web site](#).

Item 9 Research using existing databases

Where the researcher intends to use existing records that may identify individuals and which are not normally available to the public, particular care must be taken to comply with all relevant privacy legislation - see [Summary on Privacy Legislation](#). In addition, the applicant must provide evidence that the relevant agency / organisation has agreed to provide or allow access to the existing records.

Secondary use of data

Where the investigator plans to undertake analysis of data collected in a previous research project, including re-analysis of data the investigator has collected previously and regardless of whether that data is written, electronic, audio/video, specimens or samples, the investigator must indicate the sources of the data and specify which of the following categories of personal information will be accessed and used:

- Identified - data that allows the identification of a specific individual/collectivity
- Potentially identifiable - data which have had identifiers removed and replaced by a code so that the process of de-identification is reversible
- De-identified - anonymous data and data for which the de-identification procedure is irreversible

In cases where the data are de-identified, and provided that all Commonwealth and State/Territory legislation and policies dealing with the privacy and confidentiality of data are complied with, secondary use of the data is permissible. If special groups are involved, please refer to item 8(g) of the ethics application form then specific permissions or consultations may be required.

In all cases where the data are identified or potentially identifiable, consent of participants should be obtained. However, the ethics committee may approve access to such data without obtaining consent, if the committee can be satisfied that the research complies with all applicable Commonwealth and State / Territory privacy legislation and Guidelines - see [Summary on Privacy Legislation](#).

Item 10 Location of study

Identify where the research will take place, such as where questionnaires will be distributed, experiments conducted, or focus groups and interviews will take place. Include the name and address of locations external to the University. Please also identify whether any aspect of the research will take place in the participant's home or workplace. If the research is to take place in a clinic of the University or at an external organisation or centre, investigators must provide written evidence of permission to use those facilities.

Item 11 External approvals

Regardless of whether approval has been obtained, state under this section whether any institution, ethics committee, authority, guardian or next of kin approvals are required. If approval is required but has not yet been sought, then explain why this has not occurred. If approval has been sought but not yet obtained, then specify when the approval is likely to be obtained. Please note that copies of approvals must be provided to the ethics committee at the time of application lodgment or made available as soon as possible thereafter. Final approval from the human ethics committees cannot be given until all relevant approvals have been provided.

Ensure that external approvals are on an institution's or organisation's letterhead and that the approvals are specific as to the title of the project, the names of all researchers, and exactly what approval is given for. Note that a general statement of permission to conduct project 'x' is not sufficient. Ensure that you have sought approval from relevant external ethics committees when required.

Note that researchers wishing to conduct studies in schools of the Department of Education and Early Childhood Development (DEECD) and / or the Catholic Education Office (CEO) in Victoria must comply with the research approval requirements of DEECD and / or the CEO. Information is available on their web sites. Investigators wishing to conduct research in schools outside of Victoria should contact relevant departments of education for approval requirements.

Item 12 Informed consent

Persons who are asked to participate in a research project must be properly informed as to what they are being asked to do and the likely consequences for them if they choose to participate. Researchers are required to provide potential participants with an information statement describing the project and its associated benefits, harms and risks so that they may make an informed choice as to whether or not they will participate. Researchers need to prepare a statement developed from the participant's point of view, in simple non-technical language, of the essential points, which any reasonable person would wish to know before agreeing to participate in a research project. Potential participants should be given reflective

time to consider the proposal and to obtain further advice if they so wish prior to consenting to participate. The choice to participate must be made in the absence of any coercion.

Normally written consent of participants is required. For this reason, investigators are required to prepare a written Participant Information Statement (PIS) and Consent Form (see below). Exceptions to the requirement for a written PIS and Consent Form will be considered and will include situations of implied consent as defined below. In studies where a written PIS and Consent Form is not to be used, or where signed consent is not to be obtained, needs to be justified in the application for ethics approval.

Along with a PIS and Consent Form, a Withdrawal of Consent Form should also be provided to potential participants at recruitment stage - see [Withdrawal of Consent Draft Form](#). There will be exceptions where a Withdrawal of Consent Form will not be appropriate and researchers are requested to justify in their application when this is the case.

Participants must be provided with their own copy of the PIS and Consent Form to keep. An outline of the required components of a PIS and Consent Form is available on the human research ethics web site - see [Guidelines for the Participant Information Statement](#). If the Consent Form is provided as a separate document for participants, the title of the project and the names of the investigators must appear at the top of the form. Investigators are required to retain the Consent Forms separately from the data for a minimum period of **7 years**. Research data, conversely, must be retained for at least **5 years** for non-clinical trial data and **15 years** for clinical trial data following publication/completion of the project.

If the research is conducted in an **overseas country**, then written PIS and Consent Forms are usually expected to be translated into the language of that country or the most appropriate language for the participants being recruited. If the researcher is not a native speaker of the language, then translated copies should be verified as being equivalent to the English versions by a LTU staff member or, for studies posing high risks to participants, the translated copies should be professionally certified.

For projects involving participants who are **under 18 years of age**, it is the responsibility of the investigator, in all but exceptional circumstances, to ensure that each child or young person has parental/guardian consent prior to them participating in the project. In addition, it is the responsibility of the investigator to ensure that the child or young person is willing to participate. Investigators should not assume a child's agreement to participate just because their parent or guardian has given consent. Where signed consent is not to be obtained from parents or guardians for participants under 18, justification for this must be included in the application for ethics approval.

If a research project involves procedures for the purposes of medical research and -

- the procedure is to be conducted on participants 18 years and over
- the participants have a disability
- the participants are incapable of giving consent to the procedure

then the consent of the Victorian Civil and Administrative Tribunal (VCAT) may be required before the research may commence. For these purposes, a disability is defined as having an intellectual impairment, mental disorder, brain injury, physical disability or dementia.

For these purposes, medical research includes clinical trials, observational studies, human tissue studies, human genetic research, physiotherapy studies, behavioural science projects and epidemiological studies. However, VCAT has advised that an application to VCAT is unnecessary where the project involves simple forms of measurement of height, weight, blood pressure or vision; routine diagnostic measurements such as ECGs and MRIs; where there is minimal risk of harm to the patient; the collection of body tissue by non-invasive means, such as collection of urine samples, provided that the collection is not for the purposes of genetic or other controversial research; observation of a person's activities without significant compromise of privacy; gathering information in the course of routine medical treatment and talking to or questioning a person, whether by formal questionnaire, personal interview or focus group; and where the consequences of participation are not detrimental to the person's interests. In these instances, consent may be obtained from the next-of-kin.

Consent for research in schools

In all but exceptional circumstances, researchers must ensure that parental consent is obtained for children or adolescents participating in research at their school by one of the following methods:

- the participant hands the signed consent form directly to the investigator at the time of commencing the first stage of the research activity
or
- the participants respond to a roll call conducted by the investigator, reading directly from the consent forms

Normally, no student may take part in research unless parental approval is demonstrated by one of these means.

See also item 11 above for information on Department of Education and Early Childhood Development and Catholic Education Office requirements for research in schools in Victoria.

Implied consent

The ethics committee accepts that a questionnaire completed and returned by a participant may constitute implied consent. A signed agreement to participate is not required if the project only necessitates the return of a questionnaire that does not contain information identifying the participant, for example, an anonymous survey. It may be sufficient to provide participants with a Participant Information Statement as a cover page to the questionnaire. In this case, the cover page must include all of the information required in a standard PIS and Consent Form with the exception of the signature block at the end of the form. Please note, however, that where an anonymous questionnaire is to be administered to children in schools, parental consent is normally required.

If the project includes any methodology other than an anonymous questionnaire, a signed agreement must be included, with provision for both participant and investigator to sign the form, unless the ethics committee has approved an alternative.

Item 13 Description of procedures

This section asks for a detailed description of every procedure to be undertaken, including those that may have adverse consequences. Examples of procedures that should be specified here include:

- completion of a written questionnaire
- face-to-face interview
- telephone interview
- focus group
- audio-taping or video-taping
- photography
- writing a personal journal
- being observed by the investigator
- tests of physical, cognitive or emotional status
- experimental procedures
- web-based data collection methods

Copies of any questionnaires, including commercially available questionnaires, to be used in the project must be submitted with the application. For studies using interview and focus group formats, a list of questions likely to be asked and/or issues to be canvassed must be provided. In the case of unstructured interviews, an interview schedule or agenda should be provided.

Mail surveys

If mail surveys are to be used in data collection, the Participant Information Statement should include an explanation of where the names of potential participants were obtained and, if appropriate, that non-respondents will receive

follow-up reminders to complete surveys and that coded envelopes will be used for the purpose of following up non-respondents. Envelopes to be used in mail surveys should have no identifying School or Centre stamp. The investigator may also need to inform the University's mail room of the originating School or Centre by other means.

Research involving deception

In nearly all cases, research which is covert or deceptive is unethical and should not be undertaken. It is acknowledged however that there may be experimental procedures which would be defeated if the participants knew in advance what the research aims and procedures were. In such cases, participants should not be subjected to any procedure which is likely to result in harm or undue risks and participants must be fully informed at the close of the experiment, through a debriefing process, about the true nature and aims of the research. Projects involving deception are usually considered to be above-low risk studies. Where a participant wishes to withdraw consent immediately following debriefing, investigators are required to destroy, in a secure manner, the participant's data arising from their participation. The participant should be provided with a [Withdrawal of Consent Form](#).

Item 14 Research using existing tissue/fluid samples

If your research involves access to human pathology or diagnostic specimens provided by an agency external to the University, you must provide evidence that the relevant agency has agreed to provide the samples. In addition, investigators are required to state the source(s) and number of samples to be used; whether the samples are de-identified, potentially identifiable, or identified; and whether the original donors gave permission for their samples to be used for research. In cases where the samples identify or could potentially identify individuals or groups, particular care must be taken to comply with all applicable privacy legislation. Please refer to [Information Privacy Act website](#). If special groups are involved then refer to item 8 (g) above, as special permissions or consultations may also be required.

Items 15 – 16 Administration or withdrawal of substances and Sampling of body tissues or fluids

Projects that involve any administration of substances, withdrawal of substances or sampling of body fluids or tissues should normally be reviewed as above-low risk studies. In this instance, the term 'substances' refer to any chemical compounds, drugs, medications or biological agents. Both pharmaceutical and non-pharmaceutical medications are included as substances. Researchers are required to provide precise details about the names of the substances or samples involved; total amounts, dosages and frequency of administration or samplings; anticipated

effects of administration or withdrawal; storage and disposal of samples; and the qualifications of persons taking samples.

Item 17 Risk and indemnity

This section asks you to outline any physical, emotional, social, legal or financial harm or risks of harm to the participants. Applicants are required to explain how those risks will be minimised and state what procedures will be in place to ensure the well-being of participants, should the risk events occur. If the research involves possible physical risks, details of arrangements for provision of first aid must also be provided.

For clinical drug trials, the NHMRC recommends that a 'no fault' liability, or an admitted liability insurance be purchased. Under this class of insurance, in the event of a subject/participant being injured or otherwise harmed, liability is admitted, and the only matter for negotiation is in relation to financial compensation.

This section also asks for details of any form of deception, concealment or covert observation that may be involved in the research. Applicants should refer to item 13 above and provide details about the type of deception, justification for the deception, debriefing procedures and all debriefing documentation for participants.

Duty of care

Researchers have a 'duty of care' responsibility to their human participants and this requires researchers to carefully consider the potential impact of their procedures and findings on the rights and welfare of participants and identify strategies for managing any consequences. These may include possible psychological or physical harm to participants, or that the investigator holds diagnostic information related to a medical condition of a participant. It is important that investigators have sufficient training to recognise such situations and respond appropriately.

It may be that your research protocol uses a questionnaire about mental health and that scores in a particular range are considered indicative of a possible diagnosis of depression or suicidal intent, or that a blood sample is taken for specific testing and a disorder is discovered. Depending on whether individuals are or are not able to be identified, researchers should consider methods of informing participants of the findings in an appropriate manner.

Other examples of studies where researchers need to carefully consider the impact of their study or the need to act on their findings include:

- where research may reveal information about illegal activities
- where there is the potential for procedures to result in either physical or psychological harm

Privacy of individuals must also be respected in accordance with both State and Commonwealth law. Studies involving the collection of data from individuals or collectivities should avoid identifying others who have not consented to participate in their own right, regardless of the type of data collected.

Investigators should also be aware that where they hold identifying information, neither anonymity nor confidentiality can be guaranteed to participants, as investigators are not legally protected against testifying in court, or against the mandatory reporting provisions of the *Children and Young Persons Act 1989*, if this is relevant to the field of work. In any conflict of requirements between this Act and privacy legislation, the mandatory reporting requirements take precedence. If investigators are unclear about their obligations they should seek advice from the ethics committees

Item 18 Safety procedures

This section of the application asks researchers to address all safety issues associated with projects involving any of the following:

- general equipment or machinery
- equipment connected to or powered by an electricity supply
- exposure to electrical or magnetic stimulation
- exposure to external irradiation or ionising radiation
- noise exposure

If participants will come into contact with any equipment that uses an electrical supply in any form, other than common and unmodified equipment such as a tape recorder or computer, a statement of safety for that equipment must be obtained from the Occupational Health and Safety (OHS) Office.

The OHS Office requires that any requests for safety assessments be accompanied by a memorandum from the Chief Investigator or the Supervisor in the case of a student project, which verifies that the safety assessment is for the purposes of an ethics application; that it is for a specific project; and include details of how the equipment is to be used in the project. This will assist the OHS office in providing appropriate testing and advice. Links to relevant occupational health and safety manuals and web sites can be found at the La Trobe University OHS web site.

Please note that the University's OHS office must be consulted for all projects involving safety issues, whether the project is conducted at the University or in external agencies.

When seeking evidence of the electrical safety of equipment from outside agencies, written approval must be obtained from the Head of the relevant department

advising that the equipment has undergone regular safety checks and noting the date of the latest safety check and reference number on the piece of equipment.

Ionising radiation

All research projects involving the use of ionising radiation require written approval from a relevant Radiation Safety Committee. In Victoria, approval is required from the Department of Human Services, Radiation Safety Unit and the Victorian Radiation Advisory Committee. To obtain approval, researchers are required to clarify the benefits of the research, to justify the use of radiation, including an explanation of why alternatives to radiation cannot be used, and to demonstrate that the dosage of radiation to be applied is safe relative to everyday risks.

Item 19 Potential benefits

Item 19a) To the participant

Explain how individual participants will benefit from taking part in the study. If there is no benefit to participants, then state that this is the case.

Item 19b) To humanity in general

How will the anticipated outcomes of the research benefit a population subgroup or the community in general? Your answer to this question is particularly important because it will assist the ethics committee in weighing the possible benefits of the proposed research against the burden for participants involved in the project.

Item 20 Recording and security of project documentation

Item 20a) How will data be recorded?

State the form in which data will be maintained - computer records, written records, photographic records, or audio/visual recordings. Please note that data collected for research purposes which allow for identification of individuals cannot be used for teaching purposes unless participants provide explicit permission to do so.

Data must be kept in a medium that will be accessible for up to 5 years for non-clinical trial data and 15 years for clinical trial data following completion of the project, as detailed in Item 20 (c) below.

Item 20b) Will confidentiality of results be maintained?

Clarify how your data collection and recording procedures will preserve the participants' confidentiality. Confidentiality can be maintained by:

- not recording participant names or any other identifying information
- using participant codes for identification
- keeping and storing results separately from the lists of names and codes
- ensuring that no individual can be identified in any reports and publication arising from the research

Particular care should be taken when conducting focus groups in which sensitive information may be revealed. At the beginning of a focus group, the facilitator should provide clear guidance about confidentiality practices that are to be observed by all group members. In addition, the facilitator should intervene whenever these practices are not followed by any group member, including the termination of the group discussion if necessary.

Item 20c) Security of data

Project documentation should be stored in secure, lockable locations. Computer files should be password protected. Data, de-identified where appropriate, and Participant Consent Forms should normally be kept for a period consistent with the requirements of the Public Records Office of Victoria Standard (PROS02/01), normally at least 5 years for non-clinical trial data and 15 years for clinical trial data, following publication/completion of the project. Please note that for certain types of research and for projects conducted in association with external agencies such as hospitals, data and consent forms may be required to be kept for longer periods than normally required by the University.

Additional advice on the storage of research records may be obtained from the University Records Manager.

(i) During the study

Specify the precise location of the storage place and explain who will have access to the data. Give details such as the storage medium, for example a locked filing cabinet or password-protected computer files and include precise location details, such as the room number, School and campus of the University or department in a specified external institution. It is not usually acceptable for data to be stored in an investigator's home but where this is the case, researchers should explain how the data will be kept secure and when it will be transferred to the University.

(ii) Following completion of the study

In virtually all cases, data must be stored at the University following completion of the study. Researchers are to specify the precise location of the storage place, as outlined above, and explain who will have access to the data. Note that it is not acceptable for original data to be stored in an investigator's home. Researchers are also to state the date and stage at which raw data, such as personal participant

identifiers, interview notes, returned questionnaires and audio/video tapes will be disposed of and the method of disposal.

Item 20d) Preserving data for possible future use

Where the investigator plans to preserve data, including samples and specimens collected for possible future use in another research project, the investigator must specify:

- the nature of the data to be preserved
- when the data might be used in another project
- how that data might be used and for what purpose it might be used
- who might be given access to the data for another project

Note that any further use of the data is subject to a specific separate ethics approval at the time it is to be used. The intention to preserve data for future use must be included in the Participant Information Statement and Consent Form. If this is the case, it is advised to not include in the PIS and Consent Form the specific names of personnel who will access the data in the future because then the data will be restricted to only allowing for access and use by those named individuals.

Item 21 Dissemination of results

Item 21a) Publications

If results of the study will appear in any hard copy or electronic publication - journals, conference papers, thesis, reports, state this here. Include this information on the Participant Information Statement and Consent Form. If you intend to include transcripts of interviews or written narratives prepared by participants in a thesis or in any publications, this should also be stated here and included on the PIS and Consent Form. In most cases, investigators should provide participants with copies of the transcripts or narratives to approve prior to inclusion in the thesis or publication. It is also advisable to ask participants to provide a secure address for sending such documents to so that the risk of confidential material being accessed by unauthorised persons is avoided, as an example, where workplace mail is routinely opened by persons other than the participant.

Permission to publish

The ethics committee appreciates that the results of research are normally published or presented in situations where peer review will occur. However, the investigator must also consider the rights of participants who are providing the research data, particularly with regard to extended written responses to questionnaires or surveys that may give rise to issues of copyright ownership.

An example of this might be a response supplied to an open-ended question that has the potential to be presented as a narrative. Having prepared the response, the participant may wish to publish or otherwise claim copyright ownership over it. Alternatively, the response may have been prepared for a different reason unrelated to the survey or questionnaire, but supplied because it coincidentally fits with the information required by the investigator. In any event, where questions of copyright may arise they should be addressed prior to informed consent being given by the participant.

The ethics committee suggests that due consideration be given to the nature of the data and from whom it will be collected with respect to any potential copyright issues. Researchers may wish to incorporate the following as checklist items in the consent form, presented as a 'Yes' / 'No' tick box option:

- I agree to my responses to this survey/questionnaire being published by La Trobe University in any format.
- My responses to this survey/questionnaire are original and I am the sole author.

Further advice concerning copyright issues may be obtained from the La Trobe University Copyright Officer or LTU Legal Services.

Item 21b) Availability of results to participants

In many cases, it is appropriate to provide participants with a summary of the results of the research. If relevant, this information should be included in the Participant Information Statement and Consent Form.

Item 21c) Availability of personal data to participants

Information Privacy legislation at Commonwealth and State levels require that an organisation provides an individual with access to personal information it holds about them upon request, except in specified circumstances. The Victorian Privacy Legislation is subject to the Freedom of Information Act 1982 (Vic.) which provides that individuals have the right to access documents held by an organisation covered by the Act, except where specified exemptions apply. Investigators are therefore advised to inform participants that personal information about the individual collected in the course of a research study will generally be provided to the individual if requested, unless exceptions under the privacy legislation or the Freedom of Information Act apply. This should be stated in the PIS and Consent Form.

Item 22 Ethical issues

Carefully assess whether any of the listed ethical issues apply to your project and tick "Yes" if there is any possibility that the item applies. If you have ticked "Yes" for

any item, you must then provide details of how the issue is relevant to the study and justify the need for that item. Note that if three or more items are ticked "Yes", then the application must be considered as an above low risk study.

Item 23 Details of investigators

For data base purposes, all details in this section, including staff or student numbers, must be current. Please ensure that the details of all investigators' affiliations external to La Trobe University are included. This information assists the ethics committee in determining whether the investigators have appropriate experience to conduct the research and to ensure that conflicts of interest do not impede the research. Please also note that any change of investigator or supervisor on the project must be notified immediately to the relevant ethics committee.

La Trobe University staff, students and external investigators involved in the project must sign the form. There is no necessity for research assistants to sign the ethics application form, as the principal researcher is responsible for the overall conduct of the study and the 'Casual Employment Form and Authority to Engage Casual Staff' states the condition that staff must adhere to University regulations and code of conduct.

Item 24 Checklist

Please make sure that all the appropriate boxes are selected.