HREC Guidelines for Application Form

This document provides general guidelines regarding ethical approval, and instructions for each question on the HREC Application Form.

Approved by: Human Research Ethics Committee
Date: 15 September 2014

Why do I need ethical approval?

The National Health and Medical Research Council (NHMRC) mandates that all research projects involving human participants - including surveys, interviews, qualitative research, and observation - are to be reviewed. The National Statement on Ethical Conduct in Human Research (2007) (National Statement) applies to ‘any researcher conducting research with human participants; any member of an ethical review body reviewing that research; those involved in research governance; and potential research participants’.

The National Statement is available on the NHMRC website. You should consult the Statement when completing the University of Divinity Application for Ethical Approval of a Research Project: it sets out the general principles on which your application will be considered. These centre on the duty of care which you as a researcher owe to yourself and to all those involved – their privacy, dignity, reputation, well-being (including its faith dimensions), rights and relationships.

You should also consult the Australian Code for the Responsible Conduct of Research.

The University of Divinity is required to have an active Human Research Ethics Committee (HREC). The Terms of Reference of the HREC are governed by Regulation 1.

These guidelines apply to all research conducted by University of Divinity staff and students, including honorary researchers.

HREC must be notified of all research involving humans, and applicants must receive clearance from HREC before commencing research.

The purpose of gaining ethical clearance is to minimise the risk of physical, mental and spiritual harm, danger and discomfort from research and its procedures. It aims to protect your welfare and the rights of the researcher to carry out legitimate, justifiable investigation. It provides preventative mechanisms to minimise the potential for any claims of negligence made against the researcher, or the University.

Research projects that do not need HREC clearance

Not all research projects need to be cleared by HREC. Such projects include:

1. Undergraduate projects with an education, training, or a practical experience focus do not normally require approval. Student coursework, assignments and essays are also exempt.
2. Use of information freely available in the public domain.
3. Research about a living individual involved in the public arena based exclusively on publicly available information, documents, records, works, performances, public archives or third-party interviews.
4. Studies of public behaviour that are purely observational (non-invasive and non-interactive), such as standing in a public place and noting the actions of passers-by. Ethics review is required if the disclosure of recorded observations identifies individuals (names,
photographs) and places them at risk of harm, stigma or prosecution.

5. Purely observational studies (with no element of intervention) in established educational settings, involving normal educational practices, researching current instructional strategies; or research on the effectiveness of instructional techniques, curricula, or classroom management.

6. Testing within normal educational requirements and in accordance with a host institution’s normal practices and approvals.

7. Quality assurance/audit projects that do not involve access to or collection of private, sensitive or health data.

8. Education, training and practical classes among students, which do not involve students learning through testing procedures on each other.

**Research projects needing HREC clearance**

‘Human research’ has a broad definition and includes research conducted with or about people, or their data or tissue. You need ethics approval if you are a University staff member or a postgraduate student and want to conduct certain research activities involving humans. These include, but are not restricted to:

1. Gathering information about human beings (and organisations) through interviewing, surveying, questionnaires, observation of human behaviour, audio/video taping, administering tests or stimuli, collecting or using human tissue/bone/blood or other body fluids.

2. Where the research is being funded by an organisation external to the University, or where such funding has been sought.

3. Where there is a risk of physical, mental, social, spiritual or other harm.

   Such risks may arise if the project involves surveys, interviews, or focus groups which could reasonably result in placing a subject at risk of criminal or civil liability, damage to his/her financial, reputation or social standing and employability, or cause emotional or other distress.

   All research involving humans must proceed on the basis of their **informed consent**. Every person involved in such research needs to be provided with all the relevant information they need to make an informed decision whether or not to participate, without coercion or inducement. If a research project involves children, people in special groups such as prisoners, or people of diminished capacity, informed consent must be obtained from a parent or guardian.

4. Where the research involves possible breaches of legislative confidentiality.

   Clearance by HREC is required by law for any research project which involves access to existing records of personal information about subject(s) held by a public or private organisation, agency or individual, where:

   a) the information is not publicly available

   b) the data has been recorded in such a way that subject(s) can be identified directly or through identifiers linked to the subject(s) and

   c) the disclosure of which requires obtaining the consent of the subject(s).

5. Study or research in illegal activities.
All research proposals must be designed to ensure that any risks of discomfort or harm to participants are balanced by the likely benefit to be gained. You must suspend or modify any research in which the risks to participants are found to be disproportionate to the benefits, and stop any involvement of any participant if continuation of the research may be harmful to that person.

**Further Advice**

Any researcher who is uncertain whether their research project requires clearance from the HREC must seek advice from the University’s Director of Research.

**Application Procedure**

Every research project that is submitted to HREC must first have been endorsed by an approved peer-review process, such as an approval or confirmation panel, or a College-based peer-review.

1. Complete the Application for Ethical Approval of a Research Project form on the University website. Keep to word limits, use jargon-free language, and answer each question in accordance with these guidelines. Each application must be signed the researcher, the supervisor (where appropriate), and must include all necessary attachments.

2. Submit the signed original copy to the Research Services Officer (c/- 29 College Crescent, Parkville, 3052). The application must be lodged no later than 3 weeks prior to the HREC meeting. Meeting dates are available on the University calendar. Late applications will not be accepted.

3. An application in which ethical clearance is sought for a proposed research project is assessed by all HREC members. The HREC makes one of the following decisions:
   a) to exempt the project from requiring ethical clearance
   b) to grant ethical clearance
   c) to grant ethical clearance subject to minor changes or clarification
   d) not to approve the application, but require that it be revised and resubmitted to HREC
   e) to reject the application.

   Where changes and/or a resubmission are required, the Director of Research communicates the nature and extent of the changes to be made.

   Enquiries about the outcome of an HREC meeting must be made only through the University administration.

**Complaints and Appeals**

Researchers who wish to lodge an appeal against the outcome of an application for ethical clearance, or who believe that the conditions imposed upon the research project by the HREC, or who have a grievance about the process of assessment, should refer to the University Appeals Policy.

**Privacy Legislation**

1. The Privacy Act 1988 (Commonwealth) (the Act) regulates the handling of personal information (that is, information about an individual whose identity is apparent, or can reasonably be ascertained) by Australian government agencies and some private sector
organisations. The Act, as amended by the Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Commonwealth), requires those agencies and organisations, known as ‘APP entities’, to comply with thirteen Australian Privacy Principles (APPs) regarding the use, collection, storage and disclosure of personal, sensitive and health information. The Act applies to organisations with an annual turnover of over $3 million, and to all health service providers. The University of Divinity comes under the former provision, and all University of Divinity researchers must abide by the APPs, which are given effect through the Victorian Act (see below).

Information about the Privacy Act can be found at the Office of the Australian Information Commissioner’s website, www.oaic.gov.au

2. The Information Privacy Act 2000 (Victoria) (IP Act) establishes a structure for the responsible collection and handling of personal information by Victorian public sector organisations and bodies established for a public purpose, including all universities.

‘Personal information’ is essentially the same as under the Privacy Act.

Central to the IP Act are the Information Privacy Principles (IPPs), which prescribe how personal information is to be collected, used, disclosed and stored. All University of Divinity researchers must comply with the IPPs in carrying out their research. Principles 2.1 and 10.2 are of particular relevance to research where it is not proposed to obtain any participant’s consent to the use, disclosure or collection of personal information:

IPP 2.1(c) provides that an organisation may use or disclose personal information about an individual for a secondary purpose without that individual’s consent if:

a) the use or disclosure is necessary for research, or the compilation or analysis of statistics, in the public interest, other than for publication in a form that identifies any individual, and:

b) it is impracticable for the organisation to seek the individual’s consent; and

c) in the case of disclosure, the organisation reasonably believes that the recipient of the information will not disclose the information.

IPP 10.2 provides that an organisation may collect sensitive information about an individual without that individual’s consent if:

a) the collection is necessary for research, or the compilation or analysis of statistics, relevant to government funded targeted welfare or educational services; and

b) there is no reasonably practicable alternative to collecting the information for that purpose; and

c) it is impracticable to seek the individual’s consent to the collection.

‘Sensitive information’ is defined as personal information that is information or an opinion about an individual’s racial or ethnic origin, political opinions, membership of a political association, religious beliefs or affiliations, philosophical beliefs, membership of a professional or trade association or trade union, sexual preferences or practices, or criminal record.

The above situations will be rare. The consent of each participant to the collection, use or disclosure of personal information is always to be obtained unless HREC gives written permission.

Further information about the IP Act and the IPPs can be found on the Victorian Privacy Commissioner’s website at www.privacy.vic.gov.au.
Informed Consent

‘Informed consent’ is a fundamental concept affecting all human research. Anyone asked to participate in a research project must be properly informed as to what they are being requested to do, and the likely consequences for them if they choose to participate.

In almost all cases, written consent of participants is required. For this reason, researchers are required to prepare a written Participant’s Information and Consent Form (PICF). Exceptions must be justified.

The PICF is to be directed to the participants, in plain, non-technical language and in the language in which they are fluent. It must summarise the major points of the research project – with its associated benefits, harms and risks – and must provide information that any reasonable person would want to know before agreeing to participate.

Each potential participant must be given time to consider the request to participate, and be able to obtain further advice before consenting. There must be no coercion, direct or indirect, affecting each person’s choice to participate or not.

Each participant must be given a Form of Consent to sign. This must contain the title of the research project, and the names of every researcher. The signed forms must be retained by the researcher or by the University of Divinity for at least five years.

Implied consent

HREC accepts that a questionnaire completed and returned anonymously by a participant may constitute ‘implied consent’. A signed agreement to participate is not required if the research project only requires the return of a questionnaire that does not contain information identifying the participant (i.e., it is anonymous). Every researcher must, however, provide participants with a PICF as a cover page to the questionnaire.

Where an anonymous questionnaire is to be administered to children in schools, parental consent is normally required.

Research with special groups

Researchers must be particularly careful in constructing consent processes where potential participants are in any of the following special groups:

1. children and young people
2. people in dependent or unequal relationships
3. people highly dependent on medical care who may be unable to give consent
4. people with a cognitive impairment, an intellectual disability, or a mental illness
5. people who may be involved in illegal activities
6. Aboriginal and Torres Strait Islander people
7. people in other countries.

If a research project involves participants from these special groups, the application for ethical clearance must detail the consultations that have been undertaken with relevant community groups, committees and/or agencies. The following information is also to be supplied:

1. the nature of the special group
2. justification for the inclusion of people from this special group
3. details as to how their rights and welfare will be protected in your research project
4. the persons and/or agencies from whom permission will be sought for the group to participate.

If Aboriginal people and/or Torres Strait Islander people will be participants in the research, the NHMRC Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research should be consulted.

For research involving school children the (Victorian) Department of Education and Training, and the Catholic Education Office requirements for research in schools in Victoria also apply.

What if Something Goes Wrong?

The National Statement requires the researcher to contact the University of Divinity if any of the following situations arise or are likely to arise:

1. substantial changes to the research project, questionnaire, or interview outline.
2. unforeseen events that might affect the continued ethical acceptability of the research project. In such circumstances, the researcher must postpone any further research until the HREC has determined the most appropriate way of addressing the situation.
3. participants have their well-being affected in any harmful way. In such circumstances, the researcher must immediately cease the research until the HREC has determined the most appropriate way of addressing the situation.

Complaints from Participants

Complaints from participants in a research project are to be made in writing to the Director of Research.

Completing the HREC Application Form

ALL questions must be answered unless directed otherwise.

In the application form, the following requirements apply:

1. For YES/NO/PENDING boxes, type an ‘X’ in your answer (choose one only).
2. For boxes requiring a sentence response, type or paste your response in the grey-shaded box directly below the question concerned. For example,

   My research project examines the effectiveness of HREC procedures in giving actual protection to participants in research projects involving humans ...

   The grey-shaded boxes will expand vertically as you type.
   NB: TAB moves you to the next box – to insert a tab stop within a box, press CTRL + TAB together.
3. If you need to add tables or pictures to your application, append them as part of an accompanying Word document, and indicate this in the response box.
   A paperclip icon beside a question is a reminder for you to include an attachment.
4. Read the final checklist (Question 20) to ensure that all relevant documentation is attached to your Application Form.

Incomplete information will mean that the processing of your application is likely to take more than one HREC meeting, thus delaying your research project by weeks or even months.
5. Print out and sign the completed application form.
6. Mail or hand-deliver the signed original form to:

   Human Research Ethics Committee
   University of Divinity
   29 College Crescent,
   Parkville VIC 3052

**Deadlines**

HREC application deadlines are published on the Research page of the University’s website.

**NOTES ON QUESTIONS**

Page 2: This Summary should only be filled in *once you have completed your application form.*

Question 1: Include a comment on how the anticipated outcomes of your research may benefit a population subgroup or the community in general, and/or how participants will benefit from participation in your project. If there is no benefit, state that this is the case. You should also refer to the *National Statement, p. 7-8, for a definition of research.*

Question 2: Note that it is an *ethical* issue as to whether your research project has a clearly defined aim: aimless research is ethically questionable.

Question 3: How this question will be answered depends upon the project. Your answer should be closely related to your stated aims.

Question 4a) Answer as specifically as possible: e.g. “by reading primary and secondary literature about …”; “by one focus group in each of two UCA inner-city congregations …”; “an initial questionnaire followed by structured hour-long interviews with respondents”.

Question 4b) If no human participants are involved respond with “No research with human participants is involved in this project”.

‘Who’ is involved does not mean that you list names, but the groups or categories of people involved: e.g. “Defence Force chaplains who have served overseas”; “Roman Catholics who have been through a catechumenal process between 1995 and 2000” etc.

*NB: 4b) should be answered briefly at this stage: fuller details are sought at Questions 11 and 14.*

Question 4c) Even where your research project does not involve human beings, you still need to indicate how you intend to analyse your data.

Question 5: Two ethical aspects arise here. First, as with Question 4c), to engage in research without overall planning is itself ethically questionable, and may place unexpected burdens on any human participants involved. Second, it is important that HREC know the time period during which you will be actively conducting human research (especially the time the research is to conclude). The active research period includes your recruiting of and contact with participants, and when you will be accessing records not in the public domain. **Ethical clearance applies only to the HREC-approved time period of your human research.**
Question 6: These questions are straightforward; their purpose is to ensure that any external funding will not influence the outcome of your research, or affect the well-being (in the widest sense) of any person.

Question 7: This is a key question, and you must not answer ‘NO’ without good reason.

If you are in doubt about the response to make, seek the opinion of your Supervisor, and/or the Director of Research before submitting your Application. If still in doubt, answer ‘YES’ and proceed with the remainder of the Application.

Where your answer is ‘NO’, ensure that page 4 contains the required signatures, complete the Summary Index, and submit pages 1-4 of the Application Form (discard the rest).

Do not assume HREC approval until informed by the Chair in writing. If a situation arises later where ethical clearance may be necessary, you must inform HREC in writing, and not proceed with any research involving human participants until clearance is given.

Where your answer is ‘YES’, continue with the remaining questions.

Question 8: Another straightforward question – the point is to ensure that all institutions potentially affected by your research are aware of it, and have given appropriate consent.

Question 9a-d) When research involves one or more organisations (e.g. church communities, parishes, schools, hospitals, universities, companies) permission may be required prior to obtaining access to the participant population, particularly where minors, vulnerable individuals or sensitive information (including cultural myths or stories) may be involved.

While church registers, minute books or the like are generally not regarded as ‘confidential’, they are not in the public domain, and written permission to use them is required. Attach the original or a certified copy of this permission together with your Application Form – provisions for ‘pending’ permission are stated on the Form.

Question 9e-g) The identification of particular individuals from records does not invalidate your research – it does mean that you need to take particular care to protect their well-being. Nor does the inability or inadvisability of your obtaining their consent exclude your research – it merely means that you need to justify this to HREC.

NB: unless HREC gives written permission, any copies or notes of records which include identifiable personal information from data not in the public domain must be destroyed when your research is concluded. The only grounds for the retention of such records is their potential for further research, raising the ethical issue of ‘secondary’ data usage.

Question 10: See the section on Privacy Legislation for information. The organisations themselves should be able to tell you whether they are covered by privacy legislation and, if so, what the limits are on any disclosure of information to you.

Question 11a) How many participants (i.e. ‘sample size’) you intend to involve in the research also needs to be justified. Where ‘qualitative’ methods are used, half a dozen people may suffice, but stating exact numbers is generally best avoided, because
the ‘cut-off’ number for qualitative research is difficult to establish before doing the research.

**Question 11b)** Selection of participants refers to the method of sampling or choice used. Your criteria for including or excluding participants must be specific and transparent.

**Question 11c)** Recruitment concerns the way you will implement your selection criteria. It is essential that you explain both your recruitment method and its justification. Why are you using your recruitment method? How does it relate to your aims and hypotheses?

For participation to be genuinely voluntary, you are not permitted to ‘follow-up’ individual potential participants who have not responded to an initial invitation – this may be perceived as coercive.

If recruitment is to be through any form of advertisement, identify the publications or media to be used and attach a copy of the advertisement, poster or similar material.

All recruitment documentation must specify your affiliation with the University.

**Question 11d)** Be as precise as possible about the age range of participants, and at the very least use broad categories, e.g., ‘infants’, ‘pre-adolescent children’, ‘adolescents’, ‘young adults’, ‘older adults’ etc.

For research projects involving minors (participants under the age of 18 years), additional information will be needed at Question 12d) below.

**Question 11e)** The ethical issues involved here concern both any unreasonable demands which may be placed on participants, and also whether such a time factor may render questionable the outcome of your research.

**Question 11f)** Any form of inducement may not only place your research outcomes in jeopardy, but also result in unfair or unjust treatment of participants.

If expenses are to be offered to participants, be as specific as possible in both setting them out, and in justifying them.

**Questions 12a-c)** If you have read the sections on Informed Consent and Preparing a PICF, these questions should be straightforward.

It is good practice to inform all participants that they have access to all the relevant data that refers to them. The best way to do this is in your PICF. Note, however, that privacy legislation requires an organisation to provide an individual with access to personal information it holds if they request it, except in specified circumstances. The Victorian Privacy Act (see Privacy Legislation earlier in these Guidelines) is subject to the Freedom of Information Act 1982, which provides that individuals have the right to access documents held by an organisation covered by the Act, except where specified exemptions apply.

- If a PICF is not to be provided for potential participants, your justification for this must be part of the response to Question 12a).
- If informed consent is not to be sought from all potential participants, your justification for this must be part of the response to Question 12b).
• If any group listed in the section on Informed Consent are to be included in your research project, and/or the consent of a parent/guardian for the participation of a minor is not to be sought, you must justify this in your response to Question 12c).

NB: 

a) A person may refuse to participate in a research project and need give no reasons nor justification for that decision.

b) A participant must be free at any time to withdraw consent to further involvement in your research project, provided that – in order to protect you the researcher – this right is exercised within the terms agreed at the time of signing the Form of Consent. If any consequences may arise from such withdrawal, advice must be given to potential participants about these before consent to involvement in your research project is given.

Question 12d) An ‘independent’ witness means someone not associated with your research project.

Such a witness may be needed where there is:

• any question about a potential participant’s capacity to decide about participation,

• a dependent or unequal relationship between yourself and the participant

• potential exposure to any level of risk beyond that normally encountered in everyday life.

Question 12f) Participants are entitled to withdraw from the research at any stage. However, participants should be informed about any consequences of such withdrawal. For example, you may wish to specify that, unless the participant withdraws within a specified time, e.g., 1-4 weeks after data collection, the data will be retained.

Question 13 You have a ‘duty of care’ to all participants in your research project, including yourself. You must carefully consider the potential impact of all your procedures and findings on the rights and welfare of all participants, and identify strategies for dealing with any adverse consequences.

The various parts of this question ask you to outline any risks of harm to participants. You must explain how such risks will be minimised, and what procedures will be in place to ensure the well-being of participants should risk events occur.

Question 13a) Dependent relationships always exist when one person seeks to glean information from others. Typically they include those between a minister/parishioner, spiritual director/directee, supervisor/student, pastoral associate/parishioner, counsellor/client, teacher/student, parent/child, doctor/patient and the like.

The existence of such a relationship does not necessarily constitute a barrier to your research – but it must be recognized and allowed for, to protect the quality of your research as well as protecting all participants. are aware of what it involves.
Question 13b-c) Such risks include physical, spiritual, psychological stress, any harm or discomfort, possible loss of reputation, unduly challenging approaches to a participant’s faith etc.

Question 13d-g) It is difficult to specify these, since each research project is distinctive. Not all may apply to your Application – if so, give a brief explanation as to why not.

Where there is potential for a participant to become distressed during your research, you must specify the details pertaining to a qualified person(s) to whom referral can be made quickly, and without cost to the participant.

See also the Guidelines section, “What if something goes wrong?”.

Question 13h) The risk here involves possible consequences when your research outcomes disclose potential risks to a participant or others, for which some response is needed. For example, you could uncover illegal activities, or a relationship which could affect family or congregational members’ perceptions of others.

Question 13i) Possible issues here include detection of depression, anxiety, suicidal tendencies, stress-related conditions, engaging in aggressive behaviour, etc. If there is any possibility of this, you must consult the Health Commissioner’s Statutory Guidelines on Research.

Question 13j) Such findings could include revelation of child abuse, drug dealing, fraudulent behaviour or other illegal activities. For example, a study investigating drug use in secondary schools may reveal to the researcher the identity of individuals dealing in illicit drugs.

Where you hold identifying information about participants for whom mandatory reporting needs to be made, where mandatory reporting is required for your profession their anonymity or confidentiality cannot be guaranteed, because such investigators are not legally protected against testifying in court, or against the mandatory reporting provisions of the Children and Young Persons Act 1989. Where there is a conflict of requirements between this latter Act and privacy legislation, the mandatory reporting requirements take precedence.

If you are unclear about your possible mandatory reporting obligations, seek advice from the relevant authority.

Question 13 k) The National Statement (2007) clearly sets out some of the potential risks to participants when research is being conducted in other countries. Read this chapter (4.8, p.73-75) and provide a comprehensive summary of how you will protect both yourself, the participants and their communities from any harm, and how the specific cultural context will be respected.

Question 14a) Data includes all information gathered from interviews (in person, taped or by phone), observation, questionnaires, personal correspondence etc. that is not on the public record.

You need to state how your data collection and recording procedures will maintain participants’ confidentiality. Confidentiality can be maintained by:

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

Focus groups:

Focus groups call for particular care, because sensitive information may be revealed. You may choose to have another person facilitate the group, and you need to consider whether or not you should be present. Audio-taping of a group needs to be justified, but is generally the least intrusive method of record-keeping, and best protects confidentiality. Video-taping of such groups needs definite justification, since confidentiality is much harder to preserve, and the selection of camera angle raises both research and ethical issues.

At the beginning of a focus group, the facilitator must provide clear guidance about confidentiality practices that must 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 group discussion if necessary.

Attach a copy of any questionnaire, survey, interview outline or the like: these are examined closely by HREC because they can affect participants’ well-being.

Questions 14b-c) The reasons for these questions are clear; your responses should also be clear.

Question 14d) The proper securing of data collected about human beings is extremely important. You must be careful not to leave completed surveys on your desk while at lunch, for example. Particular care must be taken with electronic records, including emails.

Adequate responses could include your data being locked in a filing cabinet with key/security code kept separately; deposited in a bank vault to which only you have access; held on a password-protected removable computer disk and stored securely etc.

It is not usually acceptable for data to be stored in your home, but where this is the case, you should explain how the data will be kept secure.

Questions 15a-b) Your research outcomes should normally be published in ways which both allow scrutiny, and also contribute to public knowledge. As well as the bound copies lodged with the University, journal articles, a monograph or CDROM/web publication are encouraged.

Participants could be informed by a letter or email advising them that your thesis is complete and can be accessed at the University or a particular library.

Question 15c) Your research conclusions should be reported using summaries of data wherever possible. Where a sample group or subset is small enough for participants to be identified, such data should not be reported, but general descriptive conclusions made.

If you intend to include, in your thesis or publications, transcripts of interviews or written narratives prepared by participants, this should be stated, and included on your PICF. In such cases you should consider providing participants with copies of the transcripts or narratives to approve, prior to their (unidentified) inclusion. NB: it is advisable to ask participants to provide a secure address for sending such
documents, to avoid the risk of confidential material being accessed by unauthorised persons (e.g. where mail in a workplace is routinely opened by persons other than the participant).

As noted above, organisational roles rather than personal names are normally to be used.

**Question 16**

All original data must be retained for five years: the reason for this is not academic, but so that any queries raised about the confidentiality or use of the data can be addressed.

The easiest way to store such data is electronically, on CDROM. All signed documents, however, including Forms of Consent, must either be kept securely for five years by yourself, and then destroyed, or passed to the University Research Office for safe-keeping and eventual destruction.

NB: it is not acceptable for original data to be stored in your home.

**Question 17**

If you believe that there may be other ethical issues raised, you have an obligation both to the potential participants, yourself and the University to raise these here.

Pragmatically, it is far better that such issues be considered at the pre-research stage than later, when your research might be halted as a result of not raising them. This is one of the many issues which may be clarified in the face-to-face discussion with members of the HREC.

**Question 18**

If you have answered YES to Question 10, the Privacy Act will almost certainly apply.

**Question 19**

You are advised to have two copies signed, retaining one for your own records.

**Question 20**

The checklist is for your own convenience, but should be attached with your Application.

When you have completed Questions 1-20, turn back to page 2, and fill in the Summary Index.

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**PREPARING YOUR PARTICIPANT’S INFORMATION AND CONSENT FORM (PICF)**

The information to be included in your PICF is outlined in point form below. The format and content should not normally vary greatly from this – apart from directing the information to the participant.

You need to have two copies signed – one for you to keep, the other for the participant (or authorised representative) to keep. If an independent witness is needed, s/he must be given a (third) signed copy.

1. The University of Divinity letterhead must appear at the top of the page. **You must contact your College and obtain the University co-branded letterhead that has been approved for your College.**
2. The title of your research project (exactly as approved) is placed just below the letterhead.

3. Your name and convenient contact details come next, with similar details for any others involved as investigators for your research project. This can be phrased informally – ‘My name is Kim Lee, and I’m conducting some research on … Thanks for being willing to work through this form which explains what is required by your involvement in the research. . .’

NB: the inclusion of personal details may lead to inappropriate contact with you from participants.

4. Describe in ‘lay’ jargon-free language the aims of your research project, how participants have been selected and recruited, and what benefits you hope the research will yield to the participant (or lack thereof) and to society in general.

5. If any non-University of Divinity bodies (especially commercial companies) have provided funding or sponsorship for your research project, this must be stated.

6. Describe how you are conducting your research, the time commitment expected of participants, and the information you are seeking, for example:
   - Each participant will be interviewed by myself for a maximum of 25 minutes
   - The interview will be audio-taped and then transcribed by myself or …
   - Participants will be asked to complete a questionnaire asking about…
   - The research programme will run for a period of ….. weeks
   - Participants may be asked to make themselves available for a further interview
   - The total time needed from each participants will be no more than two hours
   - Participants will be asked to use a computer to …
   - Participants will allow me to have access to records about their involvement in (name the organization)

   If ignorance of some part of your procedures could cause serious harm to a potential participant, this should be highlighted in some way, and the participant asked to indicate that they are aware of this, e.g. by checking a box, or including a statement setting out the possible risk (see next section).

7. You must explain, in a straightforward manner, any risks, possible discomfort or harm which may result from participation in the project, and how these will be minimised. If a person or institution is available in case they need support, included their contact details.

8. Indicate how you intend to use the information which participants will provide, in enough detail for them to be able to give informed consent to the use of the data you gather. You need to explain:
   a) procedures which will ensure the security and confidentiality of the information you gather
   b) any circumstances under which the confidentiality of the participant cannot be guaranteed (e.g., where disclosure of information is required by law)
   c) how and in what format (e.g., hard copy and/or electronic) information you gather will be used in reporting and/or publications, including the possible publication of interview transcripts or written narratives prepared by participants
d) that the participant may request a copy of personal information about them which is collected in the course of your research project

e) that each participant will be provided with an opportunity to review transcript(s) of any interview(s) prior to the submission of your thesis or publication

f) that participants will be provided with a summary of the results of your research

g) when, how, and for what purpose information gathered might be preserved for possible future use in another project, and who might be given access to this data

h) when and how the original information you gather – transcripts, questionnaires, recordings etc. – will be disposed of

9. In the case of mail surveys, explain any confidentiality and follow-up procedures (e.g., use of coded envelopes/questionnaires, reminders to complete questionnaires).

10. State that participants can decline to participate in your project, or withdraw, without any disadvantages, penalties or adverse consequences – this is especially important where participants are dependent on you or your professional colleagues for continuing care, or where participants are your students.

It is wise to set a limit to the time when a participant can withdraw permission for their data to be used (see further 13 below): e.g.,

Once you have been interviewed, you have up to ten days to withdraw your permission for the interview to be used in the research project.

11. An offer to answer any questions the participant has regarding the project must be included, as follows:

Any questions regarding this project may be directed to the University administration, (03) 9853 3177.

12. A statement indicating how complaints may be lodged needs to be included, as follows:

If you have any complaints or queries that the researcher has not been able to answer to your satisfaction, you may contact the University’s Director of Research: phone 03 9340 8820, e-mail rso@divinity.edu.au

13. Include a statement that the participant is free to withdraw consent and to discontinue participation in your research project. However, HREC acknowledges that in some cases it is appropriate to distinguish between the right of a participant to withdraw from active participation in a project, and the right to demand that no information arising from their participation is used. In such cases, HREC will consider your use of Forms of Consent that include a time limit on requests for the withdrawal of data (ie. a ‘sunset clause’), provided the time limit is not less than four weeks following the completion of data collection. An example of the suggested wording of such a clause is:

You have the right to withdraw from active participation in this research project at any time prior to your giving information.

You can also insist that information arising from your participation is not used in the research project, provided you exercise this right within N [maximum four] weeks of completing your participation in the project.
The information section of your PICF should be confined to one or two pages, with the Form of Consent on a new page. This can be convenient when using questionnaires, for which a Form of Consent is not needed, because this is implicit when a person fills it in and returns it.

14. A signed statement of agreement to participate, as follows:

I (the participant) have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction.

I agree to participate in the research project, realising that I may withdraw without prejudice.

I agree that information provided by me or with my permission during the research project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.”

Or, if a ‘sunset clause’ is to be used for the use of your research data:

I (the participant) have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction.

I agree to participate in the research project, realising that I may withdraw from the data collection part of the study at any time, and may also request that no information arising from my participation is used, up to N [maximum four] weeks following the completion of my participation in the project.

I agree that information provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.

Where an authorised representative (e.g. a parent or guardian) signs the PICF, the authorised representative will return one signed PICF to you and retain the second for their records. The following statement is to be included in the PICF:

I, the authorised representative of ______ (name of participant) have read and understood the information above, and any questions I have asked have been answered to my satisfaction.

I agree that ______ (name of participant) may participate in the research project, realising that s/he may withdraw at any time at either his/her request or mine.

I agree that information provided by ______ (name of participant) during the research project may be included in a thesis, presented at conferences and published in journals on the condition that neither his/her name nor any other identifying information is used.

15. End with provision for the following signatures:

Your name (in block letters):
Signature: ______________________________ Date: ___ / ___ / ___

Name of participant (in block letters):
Signature: ______________________________ Date: ___ / ___ / ___

Where an authorised representative gives consent, the following must also be included:
Name of participant (in block letters):

Participant’s age (if a minor):

Name of authorised representative (in block letters):

Relationship of authorised representative to participant:

Signature: ___________________________ Date: __ / __ / ____

Where an independent person bears witness to a participant’s consent being voluntary and informed, the following must also be included:

I believe that the above participant understands the above research project sufficiently,
and gives her/his consent voluntarily.

Name of independent witness (in block letters):

Address:

Phone contact:

Signature: ___________________________ Date: __ / __ / ____