

MODULE ONE: CORE APPLICATION GUIDELINES



GETTING STARTED

Welcome to the Guidelines for completing the Common Application Form for ethical review of research projects involving humans.

The application forms and guidelines are designed to help you provide the information that is used by a Human Research Ethics Committee (HREC) to determine whether your project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007).

Note that ethical review of a research project by an HREC is required under the *National Statement*. The *National Statement* is found on the NHMRC website at <http://www.nhmrc.gov.au>.

You need to read and understand both these guidelines and the *National Statement*. The *National Statement* not only sets out principles for the conduct of research involving humans, it also gives a clear indication of the issues that HRECs will consider in determining the scientific merit of, and ethical issues raised by, your project proposal. If you are familiar with the *National Statement*, you will understand the purpose of the questions in these application forms and will find it easier to provide appropriate answers. **You will be asked at the end of the application to sign a declaration that you have read the *National Statement*.**

In addition to meeting the requirements of the *National Statement*, there may be other conditions you will need to meet before your research can commence. For example, there are Commonwealth and State privacy laws that regulate how personal information is collected, used and disclosed. You may need to seek approval to access such information from the relevant body **before** you submit your project to an HREC.

Note that if your project is targeted to, or likely to include a significant proportion of, participants who are of Aboriginal and Torres Strait Islander origin, you should apply the NHMRC's *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*.

If your project also involves animal experimentation and/or gene technology, then you will need to submit your proposal to other review committees.

This application form applies only to those aspects of the project for which Human Research Ethics Committees have a designated responsibility as set out in the *National Statement*.

DO YOU NEED TO SUBMIT YOUR PROJECT FOR ETHICAL REVIEW?

The first step in deciding whether it is necessary to complete this form is for you to determine whether your project is research. The *National Statement* provides a broad definition of "research", which you may find helpful (see page 7 of the *National Statement*).

If you decide that your project is not research but is, instead, an audit or quality assurance activity, you may not need to submit it for ethical review by an HREC. However, if the proposed activity involves any potential breach of confidentiality or privacy, or raises ethical issues, then review by an HREC may be necessary.

For example, if the project involves identified (or potentially identifiable) information about an individual that is being collected, used or disclosed without that person's consent, then the activities must be approved by an HREC, whether they are for the purposes of **research or compilation or analysis of statistics**. The ethical review is required under Victorian privacy legislation (the *Health Records Act 2001*) and under Commonwealth privacy legislation (section 95A of the *Privacy Act 1988*).

In summary, the following types of projects must be submitted to an HREC for ethical review:

- All **research** projects;
- All projects involving the collection, use or disclosure of information for the purposes of **compilation or analysis of statistics**, where the information is identified (or potentially identifiable) and consent will not be obtained;
- All projects involving the collection of health information for the purposes of **management, funding or monitoring of a health service**, where the information is identified (or potentially identifiable) and consent will not be obtained, where the Privacy Principles set out in Section 95A of the Commonwealth *Privacy Act 1988* apply.

Other projects involving the collection, use or disclosure of information for the purposes of funding, management, planning, monitoring, improvement or evaluation may benefit from ethical review by an HREC, particularly if the activity raises any ethical issues.

USING THIS APPLICATION FORM

The application form and guidelines are modified and updated from time to time. Please ensure that you go back to the website each time you make a new application to ensure that you are using the latest version of the Modules.

These guidelines provide information and instructions on how to answer the questions in the Module One: Core Application Form. It is important to include all relevant information so that your application can be assessed for approval without unnecessary delay. It is also important that you write in **clear, everyday English** so that the members of the HREC who do not have a science or health industry background can easily understand your answers. Define all terminology and abbreviations. **All pages must be clearly numbered.**

The Checklist at the end of Module One assists you in ensuring that all relevant documents are included with your application. Include the completed checklist with your application.

To fill out check boxes on the Application Forms:

- View the document in Print Layout (or Page Layout) View
- Fill in boxes with a cross by double-clicking on the check box and selecting the "checked" option under the Default Value.

Note that text boxes for descriptive answers will expand to accommodate long answers and therefore the size of the box in the blank form is not indicative of how long your answer should or may be.

SECTION A: PROJECT OVERVIEW

1.1 Application date

Give the date of final preparation/submission of the application.

1.2 Full project title

Give the full technical or scientific project title.

If you are conducting a clinical trial, either the sponsor or the pharmaceutical company may have designated the project with a protocol number. Please include any such identifying number.

1.3 Brief lay summary of the project

This description of the project must be easily understood by HREC members with no scientific or health industry background. Your response to this question should be as brief as possible and **no more than one page in length**. In terms of complexity and language used, this summary should lie somewhere between a Participant Information sheet and a detailed protocol.

Provide a brief description of key aspects of the project, for example, who will be participating, what information will be collected and by what means (e.g. questionnaire, interview, focus groups, etc), what drugs will be tested (if any), types of analysis to be performed, etc. You should also identify and summarise key issues that the project raises.

- Do not cut and paste from other documents or from the detailed project plan – this is an overview summary description of the project and must be written in plain English.
- Do not include references
- Do not provide a detailed project plan. Complete details are required later in the application at Question 1.14 – Detailed Project Proposal (or in Module Two for clinical drug/device trials).

Researchers should be aware that the **summary of the research project will be made publicly available** (e.g. via the approving organisation's annual report or website) **if the requirement for consent is waived by the approving Committee in accordance with sections 2.3.6 and 2.3.7 of the *National Statement on Ethical Conduct in Human Research (2007)***. In research aiming to expose illegal activity, the research summary should only be made publicly available after the research has been completed (*National Statement 2.3.8*).

1.4 Relationship to other projects

Indicate whether the project is a new stand-alone project, a sub-component of a previously approved project, or related in some other way to a previously approved project.

A project that is a *sub-component* of another project will usually have been flagged in the original application. For example, the original application may have sought approval to conduct a file review and focus groups, with a further application to be made separately to conduct interviews. The subsequent application to conduct interviews would therefore be considered as a sub-component of the original application.

A *related* project is one that is a follow-up or extension of previous work and will usually not have been flagged in an earlier application. For example, the original application may have requested approval to follow-up participants in a drug trial or some other form of intervention for a period of two years. The new application may seek to follow-up those same participants five years after their participation in the earlier study. Note that a project that is similar to others that have previously been approved may not necessarily be related to the previous project(s).

If the current application is a sub-component of, or otherwise related to, another project, provide the application number of the original project and the identity of the approving HREC.

1.5 Broad category of research

This question is included to provide reporting information for HRECs. Indicate the category that best fits the application. If the project is a clinical drug trial, indicate whether it is a CTN or a CTX trial.

1.6 Project summary

Indicate Yes or No for each project component. **Do not leave blank to indicate that your project does not involve a particular component.** This list should serve as a prompt for those sections of Module One and other Modules that must be completed as part of your application. This list also assists the HREC (and its Secretariat) in determining whether the application is complete.

1.7 Multi-site projects

Indicate whether the project involves participants and/or data from more than one site. A *site* is an institution, organisation, agency or location. Examples of multi-site projects include:

- A clinical drug or device trial where participants will be recruited at a number of hospitals.
- A project in which participants will be recruited from a hospital and some community clinics.
- A project that involves children recruited from various schools or day-care centres.
- A project involving the clients of various disability service providers.
- A data collection project where information will be collected from the DHS, several hospitals and other data sources.

Projects involving more than one site may sit across multiple jurisdictions and may therefore need to be reviewed by more than one HREC. For example, most major hospitals have their own HREC, whereas smaller health service providers may fall under the jurisdiction of the Department of Human Services, especially if they are funded by the DHS. Researchers should identify which Australian HREC(s) have responsibility for the various sites involved in the project and indicate which sites are covered by each HREC. It is acceptable to provide collective information if individual sites are not known. For example, if a rolling strategy will be employed to engage a number of schools in the project, you may provide an answer such as:

HREC	Site	Status of application
<i>Dept of Education HREC</i>	<i>~ 50 public primary schools</i>	<i>Submitted</i>

This question satisfies *National Statement* section 5.3.4, which states that, at the time of submitting the research project, the principal researcher must inform the ethical review body that reviews and approves the research:

- of all other sites at which the research will be conducted, and of the name and location of any other body that will conduct an ethical review of the research; and
- of any previous decisions made about the research by other review bodies (in Australia or elsewhere).

If a proposal is being submitted to the Department of Human Services Human Research Ethics Committee (DHS HREC), researchers must ensure that one of the criteria for referral of research proposals to this Committee applies and should accurately indicate this in the relevant tick box.

The criteria are available at:

<http://www.health.vic.gov.au/ethics/single/criteria.htm>

SECTION B: RESEARCHERS AND CONTACT INFORMATION

1.8 Researchers

The *National Statement* stipulates that “[u]nless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable.[p.11] ... Research that has merit is conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research” (*National Statement*, 1.1(e)) The HREC is responsible for ensuring that the research proposal meets this requirement and all researchers directly involved in this project must have appropriate credentials and must be included in the list of researchers.

Complete one copy of the table for each researcher. **Note that the principal researcher is the person at this site with overall responsibility for the project.** In addition to name and contact information, indicate the responsibilities each researcher has in this project. For example, the researcher may be involved in recruitment of participants, data analysis, training of other researchers, supervision, etc. You are also asked to provide details of the qualifications and relevant research experience of each researcher concerning the proposed research. For phone numbers, provide the most direct contact phone number available. Do not provide the Institution’s central inquiry phone number. For any student researchers, specify the degree and Institution and whether this project also requires the approval of that Institution’s HREC.

Provide a **one-page resume** for researchers who are not known to HREC or who are new to this field of research. If possible, **please do not provide full Curriculum Vitae for any researchers and please do not include information that is not relevant (e.g. hobbies, marital status, etc).** Please enumerate publications and conference presentations (e.g. 27 papers in International refereed journals) rather than providing full listings.

If you are a researcher who is not on the Institution’s staff and you wish to conduct research at the Institution, you must:

- Contact the appropriate head of department to discuss the research proposal; and
- Obtain the involvement and cooperation of a researcher who is a senior member of staff at the Institution.

If you are a student researcher, your supervisor(s) must be a member of the research team and accept overall responsibility for the conduct of the project National

Statement 1.1(e). A senior staff member of the Institution where the project is being conducted must also be a member of the research team or must agree to be a sponsor for the project (see *National Statement* Glossary).

1.9 Training

Indicate whether any of the researchers require additional training to enable their participation in the project. Training may be required for any aspect of the project, for example, to use a piece of equipment, experimental methods, statistical methods, interview techniques, tissue collection, etc. For each researcher that requires training, indicate what training is required and who will provide the training.

1.10 Other personnel

1.10(a) Some hospital departments employ research coordinators to take charge of the day-to-day running of the department's research projects. These staff members may not be listed as a researcher on a particular project. However, they may have significant involvement with participant recruitment, data collection, reporting, etc. The Ethics Committee needs to be aware of who the research coordinator is, the extent of their role in the project, and their credentials.

1.10(b) Include contact details of the person to whom the HREC secretariat may direct correspondence concerning the project if this is not the Principal Researcher. HRECs will generally direct correspondence to the Principal Researcher, but there may be circumstances where another contact is appropriate to ensure that information is forwarded promptly to relevant researchers.

SECTION C: PROJECT DETAILS

1.11 Anticipated duration of project (in months)

State the number of months you expect it will take to complete this research project. In general, the duration of a project starts on the date of HREC approval and ends on the date of completion of data analysis. Since the analysis of data is considered to be part of the research project, the ongoing analysis of data requires ethics approval. Therefore, if the ethics approval expires before data analysis is complete, an extension for the approval will have to be sought from the HREC.

1.12 Anticipated commencement date at this site

State when you expect to start this research project at this site.

1.13 Anticipated Completion Date at this site

State when you expect to complete this research project at this site. Note that different institutions may vary in relation to the question of when the project is deemed to be completed (i.e. once data collection is completed versus once data analysis is completed). Researchers should therefore consult the HREC at the Institution about accepted practice at that Institution.

1.14 Detailed project proposal

If the project is a clinical drug or device trial, this question should not be completed. Instead, provide a detailed project proposal in Module 2. In such cases, go directly to Question 1.15.

Researchers should note that HRECs are specifically required by the *National Statement* to consider all aspects of the project, including the scientific and statistical validity and the overall methodology, in addition to any ethical issues and other relevant information (*National Statement* 1.1(b) and other sections of the Statement relevant to specific types of research)

(a) Project checklist

Complete the checklist to indicate where specific information may be found in the detailed protocol. If a particular element is not included because it is not applicable to the project, tick the “not applicable” box for that element.

This checklist serves two purposes. Firstly, it assists the researcher to ensure that all relevant aspects of the project protocol are included. Secondly, the checklist assists the HREC in finding particular aspects of the protocol, by listing the page or section number where that information is to be found.

(b) Project protocol

Provide a detailed research protocol. The following elements should be included:

- Literature review (an analysis of previous literature and studies, including references)
- Rationale of Project
 - Description of how your proposed research will complement or enhance or contribute to existing knowledge. Explain why this research is necessary given existing knowledge in this field. Note that replication of previous studies in the field is acceptable if, for example, the aim is to confirm or extend existing results, using more rigorous experimental criteria.
- Primary hypothesis and/or research questions – if applicable. Some projects may not have specific hypotheses.
- Aims – All projects should have aims, including those that do not have a specific research question or hypothesis.
- Methodology or Project design, including scientific description of experimental procedures, surveys and questionnaires, recruitment strategies and other relevant information.
 - Please provide sufficient detail to enable the HREC to determine the project’s methodological rigour. Indicate any limitations of the project design and any potential sources of bias and how these will be dealt with.
 - For questionnaires, check with the HREC about whether copies of these documents are needed. For well-established instruments, it may not be necessary to provide copies. For instruments that are not well-known, details of validation or other publications should be provided.
- Inclusion/exclusion criteria, if any
 - Include details of criteria for inclusion and/or exclusion of participants or data. Note that exclusion criteria should not be given as “anyone who does not meet the inclusion criteria”; only independent criteria for exclusion should be given. For example, the inclusion criteria may be “adults with late-onset diabetes” and the exclusion criteria might be “persons taking X medication”.

- Randomisation procedures
- Statistical or other analyses
 - To ensure rigorous research design, seek professional advice from a clinical epidemiologist or bio-statistician.

Please note that other questions in Module One request specific information about Research Involving Collection, Use or Disclosure of Information. This is to assist the HREC in assessing privacy considerations and other ethical issues involved in the project.

1.15 Registration and reporting

(a) Registration of clinical trials

Background

In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all clinical trials. The ICMJE proposed comprehensive trials registration as a means of solving the long-standing problems with selective reporting of clinical trials. As of 1 July 2005, all the 11 ICMJE member journals adopted a trials-registration policy. The ICMJE journals require, as a condition of consideration for publication, registration in a public trials registry. Since the September 2004 ICMJE editorial, an increasing number of medical journals have announced their adoption of the ICMJE trials-registration policy. This policy applies to any clinical trial that started recruitment on or after 1 July 2005. The goal of the ICMJE in introducing this policy was to foster a comprehensive, publicly available database of clinical trials.

Definition of a Clinical Trial

The ICMJE defines a clinical trial as: "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and health outcomes." This definition includes drugs, surgical procedures, devices, behavioural treatments, process-of-care changes, and the like. A trial must have at least one prospectively assigned concurrent control comparison group in order to trigger the requirement for registration.

The ICMJE wants to ensure public access to all "clinically directive trials" - trials that test clinical hypotheses about health outcomes. Excluded from the registration requirement are trials whose primary goal is to assess major unknown toxicity or determine pharmacokinetics (many phase 1 trials). Registration is required for all trials whose primary goal is to affect a clinical practice (phase 3 trials).

Which Registry?

The ICMJE does not advocate one particular registry, but its member journals require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge, it must be open to all prospective registrants and managed by a not-for-profit organisation. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable.

At a meeting of the World Health Organisation (WHO) advisory group in April 2004, attendees identified a minimal registration data set of 20 items. The ICMJE supports the WHO minimal data set and adopted it as the ICMJE's requirement - a trial will be considered for publication if the authors register it at inception by completing all 20 fields in the WHO minimal data set.

WHO Minimal Registration Data Set*

Item	Comment
1. Unique trial number	The unique trial number will be established by the primary registering entity (the registry).
2. Trial registration date	The date of registration will be established by the primary registering entity.
3. Secondary IDs	May be assigned by sponsors or other interested parties (there may be none).
4. Funding source(s)	Name of the organization(s) that provided funding for the study.
5. Primary sponsor	The main entity responsible for performing the research.
6. Secondary sponsor(s)	The secondary entities, if any, responsible for performing the research.
7. Responsible contact person	Public contact person for the trial, for patients interested in participating.
8. Research contact person	Person to contact for scientific inquiries about the trial.
9. Title of the study	Brief title chosen by the research group (can be omitted if the researchers wish).
10. Official scientific title of the study	This title must include the name of the intervention, the condition being studied, and the outcome (e.g., The International Study of Digoxin and Death from Congestive Heart Failure).
11. Research ethics review	Has the study at the time of registration received appropriate ethics committee approval (yes/no)? (It is assumed that all registered trials will be approved by an ethics board before commencing.)
12. Condition	The medical condition being studied (e.g., asthma, myocardial infarction, depression).
13. Intervention(s)	A description of the study and comparison/control intervention(s) (For a drug or other product registered for public sale anywhere in the world, this is the generic name; for an unregistered drug the generic name or company serial number is acceptable). The duration of the intervention(s) must be specified.
14. Key inclusion and exclusion criteria	Key patient characteristics that determine eligibility for participation in the study.
15. Study type	Database should provide drop-down lists for selection. This would include choices for randomized vs. non-randomized, type of masking (e.g., double-blind, single-blind), type of controls (e.g., placebo, active), and group assignment, (e.g., parallel, crossover, factorial).
16. Anticipated trial start date	Estimated enrolment date of the first participant.
17. Target sample size	The total number of subjects the investigators plan to enrol before closing the trial to new participants.
18. Recruitment status	Is this information available (yes/no) (If yes, link to information).
19. Primary outcome	The primary outcome that the study was designed to evaluate Description should include the time at which the outcome is measured (e.g., blood pressure at 12 months)

20. Key secondary outcomes	The secondary outcomes specified in the protocol. Description should include time of measurement (e.g., creatinine clearance at 6 months).
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* The data fields were specified at a meeting convened by the WHO in April 2004; the explanatory comments are largely from the ICMJE.

Registries that currently meet these criteria include:

Australian New Zealand Clinical Trials Registry (www.anzctr.org.au)

The registry sponsored by the US National Library of Medicine (www.clinicaltrials.gov)

The International Standard Randomised Controlled Trial Number Registry (www.ISRCTN.com)

The Netherlands Trials Register (www.trialregister.nl)

The Japan Clinical Trials Registry (www.umin.ac.jp/ctr/index/htm)

The Cochrane Renal Group Registry (www.cochrane-renal.org/trialsubmissionform.php)

The National (UK) Research Register (www.update-software.com/national/)

Australian New Zealand Clinical Trials Registry (ACTR)

The **Australian New Zealand Clinical Trials Registry** (ANZCTR) is an on-line register of clinical trials being undertaken in Australia and New Zealand. It is funded for 5 years by a National Health and Medical Research Council Enabling Grant. The ANZCTR includes information about:

Clinical trials into pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, rehabilitation strategies and complementary therapies; and

The ANZCTR allows researchers to identify unpublished and ongoing clinical trial research and is a resource for all those with an interest in health care research - including health care providers, consumers and funders.

The full ANZCTR has been phased in over several years and will be completely operational by 2008. However, a range of functions will come online earlier than this. Researchers can now register their trials with the ACTR and should visit the ACTR website for updates: www.anzctr.org.au

References and Further Information

The Australian Clinical Trials Registry – Frequently Asked Questions - <http://www.anzctr.org.au/faq.aspx> -

NHMRC Clinical Trials Centre - <http://www.ctc.usyd.edu.au/trials/registry/registry.htm> -

Is This Clinical Trial Fully Registered?: A Statement from the International Committee Of Medical Journal Editors - http://www.icmje.org/clin_trialup.htm -

De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. *Clinical trial registration: a statement from the International Committee of Medical Journal Editors*. Ann Int Med. 2004; 141:477-8. Epub 2004 Sep 8 [PMID:15355883]

International Committee of Medical Journal Editors - www.icmje.org -

(b) Indicate whether the researchers will be restricted in any way in terms of publication of results. If any type of limitation or restriction will occur, give details, e.g. who will impose the restriction, for how long the restriction will apply, etc.

(c) If a public report is to be made available at the end of the project, in what form will this report be and how will members of the public be able to access it? If a public report will not be made available, please justify. Refer to the *National Statement 1.3(d)*.

You should also identify any relevant research register that exists for projects in this field of research, for example, the Australian Clinical Trials Registry, Cochrane Collaboration Database. Indicate whether the project will be registered.

(d) Explain how the findings from the project will be made directly available to the participants and in what form*. Note that providing details of where participants can access the information in professional journals is not generally acceptable, as this information is unlikely to be presented in plain English for a lay audience.

If a final report is to be made available to participants, inform them of this at the start of the project. Also advise whether group or individual results (or both) will be reported. Include information in the Participant Information and Consent Form on how participants can gain access to the final report.

If the project outcome is expected to show that some participants need further clinical follow-up, the report needs to include details of access to this clinical follow-up.

At the end of the project, it is useful to give all participants a final report of meaningful group data. Providing a report can assist with recruitment and compliance, as many participants appreciate receiving feedback and are rewarded by knowing the results of their participation.

*This is not applicable in cases where the HREC is being asked to waive the need for participant consent and participants will not know that they were involved in the research.

1.16 Adverse or unforeseen events

Explain the monitoring, reporting and other procedures set up to manage serious adverse events and unforeseen events.

Adverse events include all adverse events that are related to or possibly related to a project. Adverse events may relate to the participants or to unintended events in relation to information. Examples of the latter include: collecting the wrong information about an individual or collecting information about the wrong individual or receiving individually identifiable information (or access codes for re-identifiable (coded) information) when the information was supposed to be received in a non-identifiable form. The principal researcher is responsible for reporting all adverse events, signing all correspondence regarding adverse events, and forwarding safety updates to the HREC.

For serious adverse events, the principal researcher must report to the HREC as soon as possible and, if practicable, within 24 hours of awareness of the event. For a definition of serious adverse events, refer to *National Statement Glossary*.

When reporting an adverse event, the principal researcher must give a written opinion as to whether:

- the project was or was not responsible;
- it is appropriate to continue or discontinue the project;

- the Participant Information and Consent Form should be changed. A copy of any changes must promptly be forwarded to the HREC.

SECTION D: RESEARCH INVOLVING PARTICIPANTS

For the purposes of this application, a **participant** is "anyone who is the subject of research in any of the ways set out [in the *National Statement*] on page 8 [as follows]:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

The term 'participants' is therefore used very broadly ... to include those who may not even know they are the subjects of research; for example, where the need for their consent for the use of their tissue or data has been waived by a Human Research Ethics Committee."

1.17 Participants - numbers

(a) Indicate the total number of participants that will be involved across all sites, regardless of whether some of those participants will be at sites for which this HREC is not responsible.

(b) See Question 1.7 for a definition of a *site*. If the project is being conducted at more than one site, list each site for which this HREC has responsibility and the number of participants anticipated at each site. For example:

Site	No. of participants
Royal Melbourne Hospital	75
Western Hospital	40

If this HREC only has responsibility for one site, list that site and the number of participants anticipated.

You may answer this question collectively; for example:

Site	No. of participants
20 day-care centres	10 participants per centre

(c) If the research involves more than one group, for example a test group and a control group or three different focus groups, indicate the number of participants in each group.

1.18 Participants - Details

(a) Indicate all categories of participants that are to be involved. This might be quite non-specific (e.g. "members of the general public") or it might be very specific (e.g. "Gay men who have become HIV positive in the last 12 months"). If control groups are to be involved, include this as one of the categories of participants.

(b) Indicate whether persons of Aboriginal or Torres Strait Islander origin will be specifically targeted for inclusion in the project, for example, because the project aims to study a particular health or social issue in an Aboriginal community or amongst Aboriginal people. For projects that are not specifically targeted to ATSI people, indicate whether ATSI people are likely to be highly represented in the cohort of people that are being studied. If the project is specifically targeted to, or likely to include significant numbers of, people of Aboriginal and Torres Strait Islander origin, researchers should ensure they consult the NHMRC's *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*.

(c) If researchers from this institution are conducting the research in another country and involving participants from that country, researchers must comply with Chapter 4.8 of the *National Statement* which requires that (i) details of any local ethics approval processes in that country are provided, and (ii) local cultural values have been acknowledged in the design of the research, including continuing consultation with the local participant population and the communities to which they belong.

(d) Indicate the range of ages of participants.

(e) In the detailed protocol (Question 1.14), you should have included information about inclusion and/or exclusion criteria. Discuss any ethical issues that these criteria could give rise to. For example, a project that will exclude participants who do not speak English fluently may raise issues of fairness, equity, bias in the results or sampling inadequacies. Please do not reproduce large amounts of technical information from the detailed protocol in answering this question, but refer to where this information may be found in the detailed protocol.

1.19 Recruitment of participants

(a – "No") In some research projects, the person will not be told about the research and their consent will not be obtained (e.g. a data linkage project where patient records are being accessed for certain information without the patient's consent). **If you will not be approaching individuals to recruit them as participants, do NOT complete Questions 1.19 to 1.22 (these questions may be deleted), and go directly to 1.23.**

(a – "Yes") Describe the recruitment procedure, including information about where participants will be sought (e.g. doctors' surgeries, out-patient departments, needle and syringe program sites, schools, etc) and how the recruitment will occur, including how information will be provided to potential participants. For example, the source of participants may be maternity ward patients of a particular hospital during a given period, or the general population, or people accessing particular disability services, etc. The recruitment process may be through general advertisement in the newspapers or targeted recruitment to clients of a particular service, etc. If relevant, indicate whether the clinician(s) responsible for the care of the participants have agreed to have their patients approached about the project. Provide samples of each form of recruitment material to be used. This may include printed advertisements, transcripts of radio or television advertisements and telephone calls, copies of photographs or other images to be used, posters and letters of invitation.

(b) Provide details any follow up procedures to be used to improve the response rate, such as telephone calls, additional mailout of information, further contact through case-worker of primary care physician, etc.

(c) This question concerns the possibility that participants may be recruited in situations where they are in some way dependent upon the person doing the recruiting. The *National Statement* indicates that the consent of a person to participate in research must not be subject to any coercion (*National Statement* 2.2.9). In the first part of the question, indicate the nature of the unequal or dependent relationship (e.g. doctor/patient, counsellor/client, etc). In the second part of the question, indicate how potential problems arising from unequal or dependent relationships between recruiters and participants will be handled. Refer also to Chapter 2.2 of the *National Statement*.

(d) This question deals with the possibility that the researcher may, in some instances, have more than one relationship with some or all of the participants in the research. For example, the researcher may also be a colleague of the research participants or may have responsibility for the program area being studied. This situation is referred to as a “dual relationship” and does not necessarily involve an unequal or dependent relationship, although it may. Dual relationships are often inevitable and the important thing is that they are acknowledged and managed. In the first part of this question, indicate the nature of any dual relationship (e.g. the researcher is a work colleague of the participants). In the second part of the question, indicate how potential problems arising from dual relationships will be managed. Some examples of ethical issues raised by dual relationships are their potential to:

- influence the voluntariness of participation (e.g. colleagues may feel obliged to participate)
- involve a conflict of interest (e.g. a head of department who is also a researcher could potentially favour his/the department’s research interests)
- give the researcher access to information about a colleague which they would not be party to in their usual relationship (e.g. the researcher may discover significant health information about a colleague, or information that could be professionally harmful)

(e) This question covers the issue of reimbursement, payment or other incentives to be made to participants. Note that participants may, in certain circumstances, be paid or reimbursed for their inconvenience and time. However, a payment should not be too large or it risks becoming an inducement to participate and potentially biasing the project’s results.

1.20 Information to participants

(a) This question concerns research involving deception of participants. This issue is discussed in Chapter 2.3 of the *National Statement*.

(b) Will information be given to participants in the form of a written Participant Information? It is stipulated by the *National Statement* that obtaining informed consent must involve provision to participants, at their level of comprehension and in ways suitable to them, of information about the research (*National Statement* Chapter 2.2 and 5.2.16). There may be circumstances where the use of a written Participant Information may not be suitable. If a written Participant Information will not be used, explain the reasons for this.

(c) Consent to participation in research must (i) be preceded by an appropriate and well-informed explanation of the proposed research and the implications of participating in it, and (ii) be voluntary. Often the Participant Information is not the only means of communicating information about the research, and potential participants may rely as much, or more, on a verbal explanation as a written one.

(i) It is important that the person providing information to the participant has sufficient understanding of the research to explain it fully and answer the participant's questions. The principal researcher is usually best placed to undertake this role; however in cases where it is delegated to another person, it is the principal researcher's responsibility to ensure that the delegate is suitably equipped to fulfil this function.

(ii) In some cases, researchers may wish to minimise the influence of an unequal or dual relationship by having an independent person obtain formal consent. This person may, therefore, not be the same as the person who explains the research to the participant.

Note: The Participant Information and Consent Form (PICF) should be included as an appendix to Module One. Additional information about the PICF is given in separate guidelines and PICF templates available on the DHS HREC website (www.health.vic.gov.au/ethics).

1.21 Consent

Before giving approval, the HREC must be satisfied as to how the researcher(s) will verify that a participant has given valid consent to participate in the project. HRECs generally require that written consent will be obtained from all participants and the signed Consent section of the PICF is evidence that valid consent has been obtained. In some circumstances, it may be ethical to rely on verbal or implied consent [*National Statement* 2.2.5]. Sometimes verbal consent may be valid and formal written consent may be unnecessary or even undesirable. In these cases, consent may be recorded by another means. Examples include video or audio taping or researcher's notes of a conversation, verbal consent given over the telephone before a telephone interview. Implied consent may be expressed by the completion and return of a questionnaire.

(a) Indicate whether any participants will have the capacity to give informed consent (*see below for a discussion about competence and capacity*). If "yes", that at least some of the participants will have capacity to give informed consent, indicate whether consent will be obtained from those participants in written form (using a Consent Form), verbally (for example, over the telephone), or in some implicit fashion (for example, the completion of an anonymous questionnaire may be taken as implicit consent to participate, where signing a form would negate the anonymity of the process). For verbal consent, explain how consent will be recorded.

(b) Indicate whether any participants will **not** have the capacity to give informed consent. If "yes", that at least some of the participants will **not** have capacity to give informed consent, indicate who will be asked to provide consent for those individuals.

For research that involves a "medical research procedure":

Note that if the participant(s) are not competent to give consent as the result of a disability and the research involves a "medical research procedure" as defined in the *Guardianship and Administration Act 1986* (Vic) then researchers must apply steps 1–4 as described in Sections 42Q, 42R, 42S and 42T of the *Guardianship and Administration (Further Amendment) Act 1986* (Vic). In summary, these steps are:

- Step 1 – Section 42Q – Approval of the research project by the relevant HREC
- Step 2 – Section 42R – Is the patient likely to recover within a reasonable time?
- Step 3 – Section 42S – Consent of person responsible
- Step 4 – Section 42T – Procedural authorisation

Section 42A: There may be rare cases where the medical research procedure comes under the provisions for “Medical Emergency”, when the proposed procedure is necessary as a matter of urgency to save life, prevent serious damage to health or prevent significant pain or distress. In such cases, consent does not need to be obtained from the patient or the person responsible.

It is the principal researcher’s responsibility to ensure that he/she and all members of the research team are fully conversant with the requirements of the *Guardianship and Administration Act 1986* (Vic) and, in particular, Division 6 of Part 4A of the Act which describes these steps in detail.

Essential Links:

Guardianship and Administration Act 1986 (Vic) –
http://www.austlii.edu.au/au/legis/vic/consol_act/gaaa1986304/

Guardianship and Administration (Further Amendment) Act 2006 (Vic) -
<http://www.findlaw.com.au/Legislation/docs/53962.doc>

Section 42T certificate

<http://publicadvocate.vic.gov.au/media/docs/Section-42T-Certificate-8682190d-5f47-4c81-8dec-d4cf30e2bb72.rtf>

For research that DOES NOT involve a “medical research procedure”:

Certain kinds of research may involve contact with participants but may not involve a medical research procedure, e.g. observational studies, non-obtrusive examinations, and collecting or using information.

Consent of next-of-kin

If you anticipate that participants will not be able to consent on their own behalf, and the project **does not** involve a medical research procedure as defined within the *Guardianship and Administration Act 1986* (Vic), Participant Information should be provided for consideration by a third party (e.g. next-of-kin/carer). Since next-of-kin/carer cannot legally give consent for participation, but can object to participation, the next-of-kin/carer of an incapacitated person should be asked to sign an Acknowledgment Form, acknowledging receipt of Participant Information and indicating that they do not object to participation of their relative. Next-of-Kin may include a participant’s spouse, nearest relative or legal guardian.

(c) Explain how the person who will recruit participants will determine the competence of individuals to give consent. This explanation should include information about how the decision will be made, who will make it, the criteria being used to make the determination. [NS 4.5.9 (a)-(c)] See the discussion below for general considerations in relation to competence. This issue is particularly important when potential participants are intellectually disabled, suffering from a mental illness or another disease that may reduce the individual’s ability to understand the research project.

(d) Within certain participant groups, the capacity to consent may fluctuate and may need to be reassessed during the progress of the research. [NS 4.5.9 (d)] In such cases, a reassessment of capacity should be designed into the research procedures.

(e) The Guardianship and Administration Act is quite specific about who the person responsible may be and researchers need to consider how the appropriate person will be identified. Careful consideration should be given to how the person responsible will be approached, bearing in mind that this may in some situations also be when the person responsible first learns of a relative's accident or health condition. In some cases, when the research is time-critical and the person responsible is not present, they may need to be informed and provide consent by telephone. Details of how this will be done and recorded should also be included, if relevant.

(f) Procedural Authorisation (in accordance with Section 42T of the *Guardianship and Administration Act 1986* (Vic)).

- The case for using procedural authorisation should be based on the criteria set out in Section 42T of the *Guardianship and Administration Act*.
- If the medical research procedure is to continue after a person responsible has been located or after the participant themselves regains the capacity to consent, 'continuing consent' must be obtained. If the procedure is already over, researchers should check whether their HREC requires information to be given to the person responsible and/or participant after the event.

Submitting a Section 42T Certificate

Before, or as soon as practicable after the research procedure is carried out, the practitioner supervising the conduct of the procedure must sign a Section 42T certificate ('Medical research procedure on a patient who is unable to consent and there is no person responsible to provide consent'). The certificate is available at <http://publicadvocate.vic.gov.au/media/docs/Section-42T-Certificate-8682190d-5f47-4c81-8dec-d4cf30e2bb72.rtf>. Copies of this certificate must be forwarded to both the Office of the Public Advocate and the relevant HREC within a maximum of 2 working days of the medical procedure being carried out. The original certificate should be filed in the patient's medical record. A separate Section 42T certificate must be submitted for each patient recruited under procedural authorisation. If the procedure extends over more than one month, and it is still not possible to obtain person responsible or participant consent, a further Section 42T certificate must be submitted (and resubmitted every month for the duration of the procedure) as above.

General considerations

What is consent and competence?

Consent must be:

- Given by a competent person;
- Given by a person who has been adequately informed of the risks and benefits for the participant of participation; and
- Given freely.

Competence involves:

- Comprehending and retaining information relevant to making the decision;
- Believing this information;
- Understanding any further implications of the decision; and

- Weighing the information in the balance and arriving at a decision.

A thorough assessment of a participant's competence and capacity to make a valid informed decision is necessary prior to their recruitment into the research project. The details of this assessment should be clearly documented in a patient's health record, where appropriate.

In those circumstances where participants have NO capacity to make a valid informed decision and the research project involves a medical research procedure, the provisions of the *Guardianship and Administration Act 1986* (Vic) will apply.

In those circumstances where participants have some capacity to understand and provide a valid informed consent, consideration should be given to the extent of that capacity in the context of the study contemplated; for example, the stress and anxiety of an accident and emergency room, the nature and seriousness of the participant's clinical condition. These factors may impact on the reality and capacity of a participant to peruse and digest a detailed participant information statement. In such cases, a more limited verbal process of informing participants of the proposed research may be more appropriate. In this event, accurate documentation must be included in the participant's health records. The more detailed Participant Information and Consent Form can be provided for further consideration at a later stage. This is in accordance with 4.4.5 of the *National Statement*.

Dependency and consent

If the research involves participants in a dependent relationship with the researcher, for example, employees, students etc., it should be considered whether an independent person should make the initial approach and/or seek consent [*National Statement* 4.4.12].

Normally any interpreter needs to be independent. However, with low-risk research, an English-speaking relative or friend may be acceptable.

Children and consent

In most States the legal age of majority is 18 years. For a person aged under 18 years, consent can be obtained if the person is competent. Youth does not necessarily indicate incompetence - this needs to be formally evaluated on a case by case basis and will vary according to the age of the child, their maturity and the nature of the research project and procedures involved.

The *National Statement* recommends that specific consent should be obtained from the child or young person wherever they are capable of deciding AND from a parent or guardian in most circumstances [NS 4.2.7]. Exceptions may be where there is "standing parental consent" for school-based research [NS 4.2.10-11] or where an HREC determines that it is appropriate for only the young person to consent [NS 4.2.8-9]. Where a child is assessed as NOT having the requisite capacity to provide a valid informed consent, parental/guardian consent MUST be obtained in all circumstances. In all cases, children need to be informed about the project so that they can understand what is going on and so that they are aware they are not required to participate if they do not want to.

In studies involving participants under the age of 18, two Participant Information and Consent Forms will usually be required: one for the participant and one for the parent/guardian. Researchers should ensure that the Participant Information and

Consent Form intended for the participant under 18 is written in language that will be understood by the age group.

For clinical trials and other relevant situations, clear documentation should be made in each participant's health record of an assessment as to their capacity to provide informed consent to participate in the study.

Note: The reference to "parent" includes a person with "parental responsibility".

Cognitive impairment, Intellectual disability or mental illness and issues of consent

For research involving people with cognitive impairment, intellectual disability or mental illness, researchers need to evaluate each participant's competence. If the participant is competent, researchers must obtain their valid consent. It would be wise to consult relatives or carers as part of the consent process. The HREC should be informed about how the evaluation of competence will be made, as outlined in 1.21(b) above and in the *National Statement* 4.5.9.

It is important to remember that the PICF for such individuals must be designed to facilitate adequate understanding of the research to which they are being invited to take part.

1.22 Consequences of participation

Based on the evidence available (including that from the systematic review of the literature) discuss the expected consequences of participation including:

(a) Potential or Actual Harms – What are the risks to participants compared to those people who do not participate? Include psychological and physical risks (such as invasive, uncomfortable or risky procedures). Include any risks to length or quality of life of participants or potential invasion of privacy. Give an indication of the severity of any risks, and of how likely or unlikely (e.g. probability) it is that these would occur.

(b) Indicate whether there is any possibility of discomfort to participants and describe any such discomfort.

(c) State whether it is necessary to offer any specific counselling of participants. Note that counselling may be needed before, during or after participation, depending upon the nature of the project. If counselling is required, describe the form it will take, state who will conduct the counselling and give details of their qualifications to provide this support. *Note:* Counselling should be conducted by a person independent of the project.

(d) Will participants be denied access to any other interventions (treatments or therapies) or services as a result of participating in this research? If yes, explain the consequences for participants and explain how the researchers will ensure that participants receive care or service equivalent to or better than current standard practice. If a placebo is proposed, demonstrate that participants are not being denied access to a proven treatment.

(e) Benefits – How might this project benefit participants in any way?

Note: Participants must be informed of the consequences of participation in the Participant Information and Consent Form.

1.23 Other ethical issues

Provide details of any other ethical issues not described above and how these issues will be addressed. Issues may include:

- Monitoring and reporting illegal activities (see *National Statement* Chapter 4.6);
- Indigenous or other special community or cultural groups (see *National Statement* Chapters 4.7 and 4.8);
- Risk to third parties. If the project presents risk to third parties (e.g., transmissible disease or illegal activity), explain how these risks will be addressed and how participants will be informed of risk minimisation procedures.

If your project does not involve the recruitment of participants, there may still be risks and ethical implications for participants even though they may not know they are included in the research. Risks may include issues such as:

- confidentiality being breached
- the discovery of health information of significance to the participant.

SECTION E: COLLECTION/USE/DISCLOSURE OF INFORMATION

This section covers those aspects of the project proposal to which the various pieces of State and Commonwealth privacy legislation relate. It is expected that all researchers will have to complete at least some of the questions in this section, since every project will involve the collection, use or disclosure of some piece of information.

It is hoped that the process of completing this section of the application form will be educative for researchers, as well as providing information that assists the HREC in assessing the project from the perspective of privacy issues. While privacy legislation may seem complex, the underlying principles are actually quite straightforward. Moreover, the principles are consistent between State and Commonwealth legislation, so if the project is compliant with the privacy principles in Victoria, in most cases, it will also be compliant with the Commonwealth legislation.

The first time researchers complete the questions in Section E, they will be faced with issues that they may not have considered in previous research projects. It is hoped that, once they are aware of the issues that must be addressed, researchers will take these issues into account when they are developing future research projects. Some of these issues include the source of the information and the purpose for which the information will be used and how this relates to the purpose for which the information was collected in the first instance. Researchers should also consider the nature of the information (see definitions below) and why the collection, use or disclosure of that information is justified.

The following is an overview of the State and Commonwealth privacy legislation that may impact upon a project. Note that Question 1.27(e) helps the researcher identify which pieces of legislation (and which Privacy Principles within that legislation) are relevant to the project.

Note: Most of the advice given in these Guidelines only relates to the Privacy Principles concerned with collection, use or disclosure of information, since these are the Privacy Principles to which the various sets of Statutory Guidelines apply. There are other Privacy Principles that deal with data quality, data security, access to data, identifiers, trans-

border data flows and other issues. **Researchers should review ALL Privacy Principles in the relevant legislation to ensure that their project is fully compliant with all aspects of the law.** Legislation and any relevant guidelines can be downloaded from the web sites listed below.

Researchers should be aware that HRECs have a statutory reporting requirement in relation to information that is provided in this section of the application. Failure by the researcher to provide all this information will delay the review of the application.

VICTORIAN LAW

(a) Health information – where the collection, use or disclosure is by an organisation in Victoria

The *Health Records Act 2001* (Victoria) applies to all health information (see definitions below) handled by the Victorian public sector and private sector. There are eleven Health Privacy Principles (HPPs). HPP 1 and 2 govern the collection, use and disclosure of health information, including for the purposes of research. This Act is administered by the Victorian Health Services Commissioner, who may issue or approve Guidelines in relation to the HPPs. The Guidelines in relation to research can be obtained from the Health Services Commissioner's website: www.health.vic.gov.au/hsc. Any researcher who considers that the HPPs might apply to their research should read these guidelines.

It is important to note that this Victorian Act applies generally to private sector organisations when they handle health information in Victoria. Unlike the Commonwealth Privacy Act (see below), it does not contain any exemptions for "small business".

(b) Other personal information - where the collection, use or disclosure is by the Victorian public sector or a contracted service provider to the public sector

The *Information Privacy Act 2000* (Victoria) sets out ten Information Privacy Principles (IPPs) that regulate the responsible collection and handling of personal information – which includes "sensitive information" but excludes health information (see definitions below) – by organisations in the Victorian public sector, including universities set up by state legislation. The IPPs also apply to agencies that provide services under contract to the Victorian Government. IPPs 1, 2 and 10 deal with the collection, use and disclosure of this information for the purposes of research. There are no separate Guidelines issued in relation to this Act. This Act is administered by the Victorian Privacy Commissioner: www.privacy.vic.gov.au.

Although the IPPs are very similar to the National Privacy Principles of the Commonwealth legislation (see below), the numbering of the principles is different.

(c) Other laws

Other more specific laws may apply to particular categories of research. For instance, section 60 of the *Cancer Act 1958* regulates the disclosure of information from registries established under that Act.

COMMONWEALTH LAW

(a) Personal information held by the Commonwealth public sector

The *Privacy Act 1988* (Commonwealth) applies to the Commonwealth public sector and has implications for medical research using information held by a Commonwealth agency. The *Privacy Act* sets out eleven Information Privacy Principles (IPPs) and these treat all

categories of personal information (including sensitive information and health information) in the same way. Section 95 of the *Privacy Act* permits the NHMRC to issue guidelines, such that medical research carried out in accordance with the guidelines will not be in breach of the IPPs.

Any researcher wishing to obtain information from a Commonwealth agency should read the Guidelines Under Section 95 of the *Privacy Act 1988*, issued by the NHMRC (see http://www.nhmrc.gov.au/publications/synopses/_files/e26.pdf).

(b) Personal information – where the collection, use or disclosure is by a “private sector organisation”

In 2000, the *Privacy Act 1988* was amended to incorporate the *Privacy Amendment (Private Sector) Act 2000* (Commonwealth), which extends the scope of that Act to include information held by organisations in the private sector. This amendment sets out ten National Privacy Principles (NPPs), but these apply only to businesses and bodies that fall within the definition of “organisation” as set out in the *Privacy Act 1988* (for a summary, refer to the definition below). Therefore, the NPPs will apply only in certain circumstances. Furthermore, the NPPs distinguish sensitive information and health information from other types of personal information. Section 95A permits the NHMRC to issue guidelines that form part of the compliance requirements under the NPPs and any researcher who considers that the NPPs might apply to their research should read the Guidelines approved under Section 95A of the *Privacy Act 1988*, issued by the NHMRC (see http://www.nhmrc.gov.au/publications/synopses/_files/e43.pdf).

GENERAL CONSIDERATIONS

All of the Guidelines described above provide very clear instructions as to the information that researchers must include in their application.

Researchers are responsible for identifying the relevant Act and guidelines under which an application for approval of a project is made.

If more than one Act (or set of guidelines) applies, all relevant legislative requirements will need to be met, including the obtaining of any necessary approvals from a Human Research Ethics Committee. The statutory guidelines referred to above are not identical, as they must reflect the various statutes under which they are made and any different requirements must be adhered to. There is nonetheless a high level of concordance in relation to the key requirements.

Researchers should note that this discussion about privacy laws is general information intended to provide a starting point to assist them in understanding how the legislative regimes may apply to their research activities. It does not constitute legal advice. If in doubt as to their legal obligations, researchers should seek their own advice, or contact the responsible Commissioner:

Health Records Act: Victorian Health Services Commissioner (1800 136 066);

Information Privacy Act: Victorian Privacy Commissioner (1300 666 444);

Privacy Act: Federal Privacy Commissioner (1300 363 992).

DEFINITIONS

Collection – an organisation or individual collects information if it gathers, acquires or obtains information from any source and by any means, whether that information has been requested or not. Questionnaires, surveys, interviews, focus groups and requests

for information held in databases, data sets or institutional records are all examples of how information may be collected.

Use – an organisation or individual uses information if it handles the information in any way. Use of information includes any form of quantitative or qualitative analysis and any inclusion of the information in any form of publication. Note that contacting a person based on contact details is considered to be use of that information.

Disclosure – an organisation or individual discloses information when it releases information to other organisations or individuals (that is, outside of those who collected the information in the first instance). Giving individuals information about themselves does not constitute disclosure.

Personal Information generally¹ means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Health Information under the Victorian *Health Records Act 2001* means:

- (a) information or an opinion about:
 - i. the physical, mental or psychological health or a disability (at any time) of an individual; or
 - ii. an individual's expressed wishes about the future provision of health, disability or aged care services to him or her; or
 - iii. a health, disability or aged care service provided, or to be provided, to an individual;
that is also personal information; or
- (b) other personal information collected to provide, or in providing, a health, disability or aged care service; or
- (c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or
- (d) personal information that is genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or any of his or her descendants.

Sensitive Information means information or an opinion about an individual's:

- racial or ethnic origin; or
- political opinions; or
- membership of a political association; or
- religious beliefs or affiliations; or
- philosophical beliefs; or
- membership of a professional or trade association; or
- membership of a trade union; or
- sexual preferences or practices; or
- criminal record;

that is also personal information; or (in the Commonwealth Privacy Act only): health information about an individual.

An **organisation** for the purposes of section 95A of the amended Privacy Act 1988 and the National Privacy Principles is generally a private sector organisation that:

- has a turnover of more than \$3 million, or

¹ The Victorian Health Records Act also expressly provides that "personal information" includes information about a person who has been dead for 30 years or less.

- is a health service provider, or
- undertakes the collection or sale of personal information for a profit, or
- provides a service to the Commonwealth, or
- is specifically prescribed by the Commonwealth Attorney-General under the Privacy Act-

EXCEPT political parties and State and Territory authorities, including universities set up under State legislation.²

OTHER RELEVANT INFORMATION

Other relevant Federal and State Government legislation includes:-

- The *Public Records Act 1973* and Amendments (Victoria)
- Disposal Schedule for Public Health Services Patient Information Records "PROS 99/94" the Health Services Act 1988 Victoria

Recommendations/Guidelines of national bodies include:

- The National Statement on Ethical Conduct in Human Research (2007), produced by the National Health and Medical Research Council (NHMRC) under the *National Health and Medical Research Council Act 1992*.
- *The Australian Code for the Responsible Conduct of Research* (2007)
- *Guidelines for the Protection of Privacy in the Conduct of Medical Research Aspects of Privacy in Medical Research* (1995)

Note: The National Health & Medical Research Council requires original data to be kept at least seven years for clinical research, 15 years for clinical trials and 23 years for clinical trials involving children.

GENERAL ADVICE FOR COMPLETION OF SECTION E

There may be projects that involve more than one set of information, with each set being collected, used or disclosed in a different manner. In these cases, researchers may find it difficult to answer questions in this section unambiguously.

It is recommended in these situations that researchers duplicate Section E and distinguish each repeated section with a number (e.g. Section E-Part I, Section E-Part II, etc) or title (e.g. Information from Case Workers, Information from DHS datasets, etc). In this way, it will be clear which answers apply to each set of information.

An example of circumstances when this approach might be useful is if one set of information is to be handled with the consent of the individual, while another set of information is to be individually identifiable (or re-identifiable) but handled without consent. Another example is when the researcher is handling more than one set of individually identifiable information without consent, but the reasons for needing identifiable information or for not obtaining consent are different for each set of information.

Individually identifiable, re-identifiable and non-identifiable information

The *National Statement* identifies three mutually exclusive forms of data identifiability, as follows [NS 3.2]:

² This information is general advice only. Precise information about the scope of the application of the Privacy Act can be obtained at www.privacy.gov.au.

Individually identifiable data where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;

Identifying information can include other information, if that information is unique in some way or highly specific. For example, "employee of the Victorian Department of Human Services" is not sufficient information to identify a person. However, "employee of organisation X" which only employs three people may be sufficient information to identify someone, particularly in conjunction with other information;

Re-identifiable data, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets;

Non-identifiable data, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.

Consider the situation where health information is disclosed to a researcher without information that could identify the individual, but coded so that it may be re-identified if necessary. If it would be impossible for the researcher to access the link, then the information collected and subsequently used by the researcher is **non-identifiable**. If the researcher is given the code, as well as the information, then the information is **re-identifiable**, as long as the code remains associated with the information. Potentially identifiable information is treated in the legislation in the same way as **identifiable** information.

1.24 Collection of participants' information

(a) If participants will not be aware of their inclusion in the research and are not being asked for consent, do not answer any other parts of this question and move directly to question 1.25. If the project does involve collection of information about individuals (either directly from the individual or from a source other than the individual) **with their knowledge and consent** indicate which categories of information will be collected in part (b).

(c) Indicate whether you are seeking consent from participants to use their data for this specific research project ('specific' consent), future research that is closely related to the original project or in the same general area of research e.g. cancer research ('extended' consent), or unspecified future research ('unspecified' consent). Refer to the *National Statement* 2.2.14 for further information about consent to future use of data.

(d) The *National Statement* defines databanks (which includes databases) as "[A] systematic collection of data, whether individually identifiable, re-identifiable or non-identifiable." (see *Glossary*). If data are being collected, aggregated and stored with a view to use for future related or as yet unspecified research, this may involve 'banking' the participants' data. For more information, refer to the *National Statement* Chapter 3.2.

(e) If information is being collected with the consent of the individual, the researcher is responsible for informing the participants about how the information will be used, disclosed, stored and published and how the individual may access the information concerning them. If the participants will not be informed about these matters in the Participant Information and Consent Form, give reasons why this is the case. Failure to

include this information is a breach of Privacy Principles IPP2, NPP1, HPP1 or VIPP1, depending on the relevant Act.

1.25 Do other questions in this section have to be completed?

(a) If the project does not involve the collection **or** use **or** disclosure of individually identifiable or re-identifiable (potentially identifiable) information (see definitions above), then you do not need to answer most of the questions in this section. Go directly to question 1.30 and do not answer questions 1.26(b), 1.26, 1.27, 1.28 or 1.29. Please remember that access to identifiable records for the purpose of extracting non-identifiable data constitutes 'use' and 'disclosure' of identifiable data, even if such data will not be 'collected' by the researcher. Therefore, the correct answer to this question is "yes" and further questions in this section must be answered. That is, the answer to part (a) is "yes" if **any one** of the possible activities (collection/use/disclosure) involves individually identifiable or re-identifiable information.

(b) If the project does not involve collection or use or disclosure of information without the consent of the person whose information it is, then you do not need to answer most of the questions in this section. Go directly to question 1.30 and do not answer questions 1.26, 1.27, 1.28 or 1.29. Please note that the answer to part (b) is "yes" if **any one** of the possible activities (collection/use/disclosure) will be conducted without consent.

1.26 Type of activity proposed

Indicate **all** types of activity for which this proposal is seeking approval. You may be seeking approval for more than one type of activity, for example, collection and use of information. Note that disclosure may occur in two directions: an organisation may disclose information to a researcher (which the researcher, in turn, collects from that organisation) and/or the researcher may disclose information to other organisations or in the form of a publication.

If you are collecting information about individuals from a third party (i.e. not directly from the individuals themselves), then you should consider whether this application for ethical approval is to cover the disclosure of the information from the third party, as well as the collection and use of the information by yourself and your colleagues. (Note: You will be asked about this issue specifically in Question 1.27c) There is no legal requirement for a separate application to be made by the disclosing organisation providing the application covers disclosure, if applicable. Therefore, it is important for the application to cover **disclosure, collection and use** of information. This issue is most relevant in cases where the disclosing organisation does not have its own HREC. In such situations, the disclosing organisation would probably prefer to have its disclosure activities reviewed as part of the application to collect and use the information.

Researchers who wish to collect information from data sets held by the Department of Human Services must obtain permission from the relevant DHS program area for the release of the data held by DHS prior to submission of the proposal to an HREC. A proposal must answer questions about all aspects of the project, not just those in relation to disclosure (see paragraphs 3.6 and 3.6 of the *Statutory Guidelines on Research issued for the purposes of Health Privacy principles 1.1 (e)iii and 2.2 (g)iii*).

DHS HREC approval for research involving access to DHS-held data is not required if:

- The Principal Researcher is external to DHS and will be seeking approval from the HREC of the organisation of which they are a member of staff (primary ethics committee). Please note that external researchers are required to submit to their ethics Committee and will not have access to the DHS Committee.

- The Principal Researcher is a DHS member of staff but has already been granted approval for the conduct of the research by another HREC (e.g. an HREC accessed via a Co-Researcher on the same research project).

DHS HREC approval for research involving access to DHS-held data is required if:

- The Principal Researcher is a DHS member of staff and does not have access to any other HREC.

1.27 Collection of information about individuals from a third party

The italicised instruction at the start of this question is a reminder to researchers that if they answered “no” to either part (a) or part (b) of question 1.25, then they should not be answering this question.

(a) Specify the source of the information that is to be collected. Check as many boxes as are relevant (i.e. if information will be collected from multiple sources).

In the case of health information, researchers should note that some organisations that are not health service providers (such as the YMCA or child care centres) do collect and hold health information. If such an organisation is the source of the health information to be used in the research project, researchers should check the box corresponding to “An organisation other than a health service provider”.

Carers are sometimes used as the source of information about an individual they are caring for. If the carer is a professional or is being professionally managed (whether as paid or unpaid workers), they are health service providers for the purposes of the *Health Records Act 2001*. If the carer is a family member or friend and is providing care in a private capacity, then the carer is not a health service provider and the researcher should check the box for “Others”.

Note: Definition of “Health Service Provider”:

For the purposes of the *Health Records Act 2001*, a health service provider means a person or an organisation that provides a health service in Victoria. A health service means an activity that is intended or claimed to assess, maintain or improve a person’s health, or to diagnose or treat illness, injury or disability, and includes a disability, palliative care or aged care service.

Note: Definition of “Commonwealth agency”:

For the purposes of the *Privacy Act 1988*, a Commonwealth agency is a minister, department, statutory corporation or other body established for a public purpose by Commonwealth legislation. This covers virtually all Commonwealth departments. The main exceptions are companies, incorporated societies, intelligence organisations and trade unions. Some of the organisations and government departments defined as Commonwealth record keepers are listed below. This list is a guide to the agencies most commonly approached by researchers (from the AHEC Report on Use of Section 95 Guidelines)

Aboriginal and Torres Strait Islander Commission (ATSIC)	Australian Electoral Commission (not State Electoral Offices)
Australian Archives	Australian National University
Australian Bureau of Statistics	Australian Sports Commission
Australian Institute of Health and Welfare	Health Insurance Commission

In the box at the end of part (a), list the categories of individuals or organisations from which information will be collected and clearly indicate precisely what information will be obtained from each source.

(b) Indicate whether the organisations from which you intend to collect information have agreed to provide that information. Please supply written evidence of the agreement to disclose information. If the agreement of the disclosing organisation has not yet been obtained, explain why not and how/when the agreement will be obtained.

(c) As discussed above in Question 1.26, indicate whether the organisation(s) from which information will be collected will be seeking separate HREC approval for disclosure of the information. All relevant privacy *Acts* allow that the disclosing organisation does not have to apply separately for HREC approval. If separate approval is sought, researchers should supply a copy of that approval when it is available. If separate approval will not be sought, then the researcher should supply a copy of this HRECs approval (and any conditions associated with it) to the organisation disclosing the information.

(d) Indicate whether the person collecting the information routinely has access to the information. An example would be a psychiatrist who routinely accesses the RAPID database (a DHS database) for clinical purposes, but wishes to use the database for a research purpose.

(e) If you are answering this question, it is because individually identifiable (or re-identifiable) information will be collected without the consent of the individual whose information it is. In this case, Guidelines may have to be applied, depending upon which Privacy Principles apply. This part of Question 1.27 assists researchers to identify which Privacy Principles apply to the collection of information. This will be determined by:

- The type of information being collected;
- The type of organisation that will be collecting the information (i.e. the researcher's organisation or institution).

Tick as many boxes as apply. For example, if health information and non-health personal information are being collected, tick both boxes. Remember that health information includes personal information (such as name, address, date of birth, Medicare number, etc) that is contained within the health record. Therefore, if health information is being collected, it is not necessary to tick "personal information" as well. "Personal Information" only needs to be ticked if personal information that is not part of a health record is being collected.

Then, within each category of information, tick the box next to the type of organisation that is collecting the information. For example, if the researcher is in the Victorian public sector, the "Victorian public sector" box should be ticked. (Note that the identity of the disclosing organisation will be considered in question 1.29a) The right-hand column for each row that has been ticked will identify the Privacy Principle(s) relevant to that situation. **Remember that these Privacy Principles only relate to the collection of information and other Privacy Principles in that Act may also apply.**

The relevant Guidelines are:

For Health Privacy Principles (HPPs) – *Statutory Guidelines on Research issued for the purposes of Health privacy principles 1.1 (e)(iii) & 2.2(g)(iii)*.

Download from the Health Services Commissioner's website:

<http://www.health.vic.gov.au/hsc/downloads/guideres.doc>

For Information Privacy Principles (IPPs) – *Guidelines Under Section 95 of the Privacy Act 1988*. Download from: http://www.nhmrc.gov.au/publications/synopses/_files/e26.pdf

For National Privacy Principles (NPPs) – *Guidelines Approved under Section 95A of the Privacy Act 1988*. Download from:
http://www.nhmrc.gov.au/publications/synopses/_files/e43.pdf

(f) Identifiable data may not be collected for deposit in a databank without participants' consent unless an HREC gives permission. By ticking the 'yes' box here, you are asking the HREC to waive the need to seek consent from participants to 'bank' their data for possible use in future research *National Statement 3.29 (c)(ii)*.

Parts **(g)**, **(h)** and **(i)** are key issues. The answers provided by the researcher to these questions will in large part determine whether the HREC comes to the conclusion that the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals.

In answering part (g), researchers are asked to explain why the information will not be collected in a non-identifiable form, e.g. because identifiers are required for data linkage, etc. This question is **not** requesting an explanation of why the information is considered to be individually identifiable or re-identifiable (e.g. because names and birth dates will be included). Similarly for part (h), the researcher should explain why consent will not be obtained, e.g. because the number of records is so large that obtaining consent is not practicable, or because not obtaining consent from all relevant individuals would impact on the scientific rigour of the research, or because of the negative impact that an attempt to obtain consent might have on individuals. This question is **not** seeking an explanation of why the researcher's actions constitute 'not seeking consent' (e.g. because the researcher won't be contacting the individuals).

1.28 Use of information about individuals

The italicised instruction at the start of this question is a reminder to researchers that if they answered "no" to either part (a) or part (b) of question 1.25, then they should not be answering this question.

If you are answering this question, it is because individually identifiable (or re-identifiable) information will be used without the consent of the individual whose information it is. In this case, Guidelines may have to be applied, depending upon which Privacy Principles apply. This part of Question 1.28 assists researchers to identify which Privacy Principles apply to the use of information. This will be determined by:

- The type of information being used;
- The type of organisation that is using the information.

Tick as many boxes as apply. For example, if health information and other non-health personal information are being used, tick both boxes. Then, within each category of information, tick the box next to the type of organisation that is using the information. For example, if the researcher using the information is in the Victorian public sector, the "Victorian public sector" box should be ticked. The right-hand column for each row that has been ticked will identify the Privacy Principle(s) relevant to that situation. **Remember that these Privacy Principles only relate to the use (and disclosure) of information and other Privacy Principles in that Act may also apply.**

The relevant Guidelines are as listed above for question 1.27(e).

(b) Specify how the information is to be used.

(c) If the information is to be used for a purpose (the “secondary purpose”) other than then primary purpose for which the information was collected, the secondary purpose may be directly related to the primary purpose and the individual might reasonably expect that their information would be used for that purpose. If this is the case, state how the secondary purpose is related to the primary purpose.

Parts **(d)**, **(e)** and **(f)** are key issues. The answers provided by the researcher to these questions will in large part determine whether the HREC comes to the conclusion that the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals. Please refer to Question 1.27 parts (f) and (g) for guidance about the information sought from researchers in response to these questions. Researchers who have already answered similar questions in Question 1.27 (f), (g) and (h) may refer to their earlier answers, if those answers are relevant.

1.29 Disclosure of information

The italicised instruction at the start of this question is a reminder to researchers that if they answered “no” to either part (a) or part (b) of question 1.25, then they should not be answering this question.

Question 1.29 examines “disclosure” from two different perspectives, since disclosure may occur at the start of the process (i.e. an organisation discloses information to the researcher) and/or at the end of the process (i.e. the researcher discloses information to another organisation), but does not include publication (which is considered to be a “use” of information, not a “disclosure”).

(a) If you answer “yes” to this question, it is because individually identifiable (or re-identifiable) information will be disclosed by an organisation to the researcher without the consent of the individual whose information it is. In this case, Guidelines may have to be applied, depending upon which Privacy Principles apply. This part of Question 1.29 assists researchers to identify which Privacy Principles apply to the disclosure of information. This will be determined by:

- The type of information being disclosed;
- The type of organisation that is disclosing the information.

Tick as many boxes as apply. For example, if health information and other non-health personal information are being disclosed, tick both boxes. Then, within each category of information, tick the box next to the type of organisation that is disclosing the information. For example, if the organisation disclosing the information is in the Victorian public sector, the “Victorian public sector” box should be ticked. The right-hand column for each row that has been ticked will identify the Privacy Principle(s) relevant to that situation. **Remember that these Privacy Principles only relate to the disclosure (and use) of information and other Privacy Principles in that Act may also apply.**

The relevant Guidelines are as listed above for question 1.27(e).

(b) If you answer “yes” to this question, it is because individually identifiable (or re-identifiable) information will be disclosed by the researcher to another organisation without the consent of the individual whose information it is. As for part (a) above, Guidelines may have to be applied, depending upon which Privacy Principles apply. This will be determined by:

- The type of information being disclosed;
- The type of organisation that is disclosing the information (i.e. the researcher's organisation).

Tick as many boxes as apply. For example, if health information and other non-health personal information are being disclosed, tick both boxes. Then, within each category of information, tick the box next to the type of organisation that is disclosing the information (i.e. the researcher's organisation or institution). For example, if the researcher is in the Victorian public sector, the "Victorian public sector" box should be ticked. The right-hand column for each row that has been ticked will identify the Privacy Principle(s) relevant to that situation. **Remember that these Privacy Principles only relate to the disclosure (and use) of information and other Privacy Principles in that Act may also apply.**

Identify the individuals or organisations to which the information will be disclosed, if applicable. List the organisations by name (or by category if there are a large number, e.g. "child care centres") and clearly indicate what information will be disclosed to each one.

Parts (c), (d) and (e) are key issues. The answers provided by the researcher to these questions will in large part determine whether the HREC comes to the conclusion that the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals. Please refer to the guidelines for Question 1.27 parts (f) and (g) for guidance about the information sought from researchers in response to these questions. Researchers who have already answered similar questions in Questions 1.27 or 1.28 may refer to their earlier answers, if those answers are relevant.

1.30 General issues

These questions assist the HREC to determine whether other Privacy Principles have been adhered to.

(a) Provide an indication of the number of records that will be collected, used or disclosed in this project. A record is a set of information about an individual. If the information is only to be collected directly from the person whose information it is, then the number of records will be equal to the number of participants given in answer to Question 1.17. If the information is to be collected from a hospital or a DHS-held dataset, then the number of records will be equal to the number of separate individuals, whether identifiable or non-identifiable, whose information is collected. If information is to be collected from participants and from datasets, then the number of records will be the sum total of the two. Provide approximate numbers if exact numbers are not known. Also specify the type of information that will be collected. Note that this question is part of the mandatory reporting requirement for HRECs.

(b) The use of unique identifiers and the adoption of identifiers assigned by another agency or organisation is dealt with in privacy legislation. Researchers should ensure that the use of identifiers is done in accordance with Privacy Principle dealing with Identifiers in any relevant privacy legislation (e.g. HPP 7 in the *Health Records Act 2001* (Vic), VIPP 7 in the *Information Privacy Act 2000* (Vic), NPP 7 in Section 95A of the *Privacy Act 1988* (Cth)).

(c) Trans-border data flow occurs if, for example, a researcher in Victoria sends data to a colleague interstate or overseas. Researchers should ensure that such data transfers of personal and/or health information are carried out in accordance with the Privacy Principle dealing with Trans-border Data Flows in any relevant privacy legislation (e.g.

HPP 9 in the *Health Records Act 2001* (Vic), VIPP 9 in the *Information Privacy Act 2000* (Vic), NPP 9 in Section 95A of the *Privacy Act 1988* (Cth)).

(d) Indicate the period of time for which the information will be retained. Note that the *Australian Code for the Responsible Conduct of Research* (2007) recommends that data should be retained for at least 5 years from the date of publication, but in the case of clinical research, 15 years may be more appropriate. (see *Australian Code* 2.1.1)

(e) Describe the security arrangements for storage of the information, including who will have access to the information.

(f) If the research data will be 'banked' in a databank for possible use in future research, this additional information about how data will be stored and made available for future use should be provided. Researchers should be familiar with the requirements in the *National Statement* - Chapter 3.2: Databanks.

(g) Explain how the publication of results from this project will be handled in terms of the privacy of the individuals whose information has been used.

1.31 Other ethical issues

Provide details of any other ethical issues (with respect to the collection, use or disclosure of information) not described above and how these issues will be addressed. Issues may include:

- Identification and reporting of illegal activities;
- Consequences of the findings of the project for indigenous or other special community or cultural groups (see *National Statement* Chapters 4.7 and 4.8).

SECTION F: FINANCIAL AND RELATED ISSUES

1.32 Potential conflict of interest

The *National Statement* (5.2.10, 5.2.11) requires a researcher to disclose to the HREC any affiliation or financial interest when proposing and when reporting the research.

Researchers need to satisfy HREC that:

- Payment in money or kind would not cause the researchers to apply influence or pressure on individuals to obtain their participation;
- Payment in money or kind would not influence the results of the research; and
- Relevant aspects of the budget will be disclosed to participants.

Specifically, researchers should indicate whether they have received any funds or gifts from pharmaceutical or device companies associated with the research and whether this information will be disclosed to participants.

1.33 Indirect costs

Researchers must satisfy the HREC that payment in money or kind could not influence the findings of the research (*National Statement* 5.2.10). Indicate any payments above the costs of running the project that will be received (for example, from a sponsor or another source) and provide justification for receipt of these payments.

1.34 Project budget

The HREC has a responsibility to examine, especially in the case of clinical trials, those aspects of the budget that may raise ethical issues (*National Statement 3.3.4*).

Researchers should provide a detailed project budget. Include all estimated costs associated with the entire project. For example, salaries, on-costs, administrative costs, consumables, participant reimbursement, HREC fees, departmental charges (Pharmacy, Pathology, Radiology, Interpreting, Medical Records). Include all estimated indirect costs over and above the project's direct costs, for example, travel and conference costs, recruitment incentives, equipment

If a detailed budget is not included, please give reasons.

1.35 Source of funding

A researcher must disclose to the HREC the amount and sources or potential sources of funding (*National Statement 5.2.10*). Researchers should include, for example, department funds, non-commercial funding body, National Health & Medical Research Council grant, Cancer Council grant, or commercial sponsor.

1.36 Funds coverage

There should be sufficient funding to conduct and complete the project, so that participants are not disadvantaged by premature cessation, particularly in clinical trials (*National Statement 3.3.5*). If a shortfall in funding is anticipated, explain how this will be made up or dealt with.

1.37 Claims through Medicare

Medicare does not cover medical services that are not clinically necessary. Patients in research who have any treatment over and above what they would normally receive in their usual clinical care cannot make a claim through Medicare. If a researcher has any doubt about what should or should not be claimed, he/she has an obligation to consult Medicare Australia and clarify or confirm a position. Contact the Provider Hotline on 132 150 or Public Enquiries on 132 011.

1.38 Declaration by researchers and research co-ordinators

Ensure all members of the research team sign and date this form. In addition to the dot-points that researchers are asked to agree to, researchers are also asked to declare that they have read the *National Statement on Ethical Conduct in Human Research (2007)*, published by the NHMRC. This document is available at:

<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>. Researchers are strongly advised against making a false declaration.

1.39 Certification by Principal Researcher and Head of Department

Ensure the principal researcher and relevant Head of Department complete this certification.

1.40 Declaration by Head of Supporting Department

Some Departments in an Institution may be providing support or services, but might not have any members on the research team. This declaration should be copied and completed by all such Departments, to provide evidence to the HREC that all relevant Departments are prepared to support the research project and have described the extent of their support.