Notes to assist in completing HREC Form 1

(We trust Section A is self-evident)

Section B Project particulars

B1. Title of project:


This statement will be read by a range of people and MUST be in language able to be understood by a layperson. Include the following sub headings:

- Research aim/s - significance of the project
- Background - basis in the literature
- Research Method - including a full explanation of what participants will be required to do and a full description of any procedure that is beyond already established and accepted techniques.
- End points
- Statistical aspects

The statement should normally not exceed two pages.

If standard tests and questionnaires are being used please attach copies. If the questionnaires are not yet in final form, a draft of the questions must be submitted and followed by the completed questionnaire when available.

If interviews are to be conducted a copy of the interview schedule should be attached.

Refer also Guidelines for describing research projects and, if relevant, Clinical trials.

If you plan to analyse data that has already been collected, rather than collect it directly from participants please note:

Under State and Commonwealth privacy legislation personal information about an individual whose identity is apparent or can reasonably be ascertained, that has been collected for a particular purpose, generally cannot be disclosed for a purpose other than the purpose for which it was collected except with the consent of each individual concerned (See section F of the application form). In some circumstances exceptions can be approved where research can be shown to be in the public interest. (See HREC Form 5 Special Privacy Module)

B3. Proposed commencement of project

Investigators are reminded that a project classified Level 3 may not proceed until approval has been received from the RMIT HREC. Projects classified Level 2 or 1 may commence once approval has been received from the appropriate Portfolio Human Research Ethics Sub-Committee. Refer to Classification of research projects for definitions of risk level.

B4. Proposed duration of project; proposed finish date.

B5. Source of funding (internal and/or external)

Please give details of any funding source, purpose and extent. Also give details of any help in kind. External support should be disclosed in the plain language statement.
Please note that it is necessary to fund any medical examinations that are solely for the purposes of research, from sources other than Medicare.

B6. Project grant title; proposed duration of grant (where applicable)

Section C: Details of participants

C1. Number, type, age range, any special characteristics of participants, and inclusion/exclusion criteria.

C2. Source of participants (attach written permission where appropriate)

Where another organisation has responsibility for prospective participants, permission has to be sought from that organisation. Further, where there is a fully constituted HREC in the other organisation (eg Hospitals, Department of Justice) and where it had a duty of care with respect to the participants, then that HREC’s decision is necessarily paramount.

In the case of research in schools, applications for access may be lodged parallel with the one to the RMIT HREC. The research may proceed only in an organisation prepared to grant access.

Details of application procedures for research in Government schools, including the application form, are available from:


or

Senior Policy Officer
School Community Links & Networks
Department of Education, Employment and Training
(Floor 2, 33 St Andrews Place)
GPO Box 4367
Melbourne Vic 3001

Those seeking to conduct research in Catholic Schools should seek permission from:

The Director of Catholic Education
Catholic Education Office
PO Box 3
East Melbourne Vic 3002

If your research involves the courts or prisons, you must obtain approval from the Department of Justice, Victoria, Research Ethics Committee. Information is available from:

http://www.justice.vic.gov.au
(use the search option and type in “research ethics”)

C3. Means by which participants are to be recruited

Details should be provided on who will be recruiting participants and how this will be done. If you intend to advertise for participants please attach a copy of your advertisement.

Lecturers must not directly recruit their own students to participate in a project.

The Committee considers the use of RMIT students as research participants to be an undesirable practice and that any use of students by students, or staff use of students should be considered carefully on a case-by-case basis. Selection of research participants should not be based around convenience but around the efficacy of the project.

C4. Are any of the participants “vulnerable” or in a dependent relationship with any of the investigators, particularly those involved in recruiting for or conducting the project?
If so attach a statement explaining the relationship and the steps taken by the investigators to ensure that participation is purely voluntary.

Some common examples of dependent relationships are: lecturer and student, teacher and pupil, doctor and patient, health care or other professional and client. Special care should be taken in recruiting participants who may be in a dependent relationship with any of the investigators, to ensure that those approached do not feel any undue obligation to participate in the project. It is recommended that consent forms be administered by someone other than the investigators.

Investigators are also asked to take particular care with participants who may not be strictly in a dependent position but who are otherwise vulnerable, such as children, the disabled, prisoners, the elderly, those who are mentally or physically ill. Again, the HREC will need reassurance from the investigator that measures have been taken to ensure that consent to participate has been both informed and freely given.

Investigators whose work may involve vulnerable participants or persons in dependent relationships should be familiar with the relevant section of the NH&MRC National Statement on Ethical Conduct in Human Research 2007 (see section 4).

C5 Are you seeking to recruit Aboriginal and Torres Straits Islanders to this investigation?

C6 If you replied “Yes” to C5, have you taken account of the requirements in NH&MRC, Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, June 2003. when designing your research? Describe how. Please follow carefully the guidelines and advice in this document.

Also note that according to the National Statement (2007) all level 2 and 3 applications involving ATSI participants must be reviewed and approved by the Human Research Ethics Committee rather than a Portfolio Ethics Sub Committee.

Section D: Risk classification and estimation of potential risks

D1. Please identify the risk classification for your project by assessing the level of risk to participants or (if any) to the researcher.

Refer to the documents Classification of research projects and Issues to consider when planning your research before completing this question.

D2. If you believe the project should be classified level 2 or level 1, please explain why you believe there are minimal risks to the participants.

OR

If you believe the project is classified level 3, please identify all potential risks to participants associated with the proposed research. Please explain how you intend to protect participants against or minimise these risks.

Potential risks to participants may be physical, social, psychological or legal. Breach of privacy, a common risk, could have both social and legal impact on a participant or researcher.

If you consider that participation in the research does not present any potential risks to participants above that which they might encounter in the normal course of the day please explain why you believe this to be so. If there are slight risks to participants please identify those risks and explain how you intend to minimise the possibility of physical, social, psychological or legal risk to participants, so that in effect there is little likelihood of risk to participants.

It is not acceptable to state that there is no risk because participants are volunteers. It is quite possible that participants may volunteer for a project where they may be exposed to risk or distress to themselves.
Invasive procedures: If the research involves administration of foreign substances, or invasive procedures, attach a statement showing that they will be carried out by a medical or paramedical practitioner with appropriate indemnity insurance.

Where investigators external to the University are involved in a project, evidence of appropriate registration and professional indemnity should be provided as a matter of course.

If there are any identifiable risks to the researcher/s, these also should be addressed.

D3. Please explain how the potential benefits to the participant or contributions to the general body of knowledge outweigh the risks.

This question must be answered if it is considered that there may be any risks to participants.

D4. Contingency planning: first aid / debriefing

Where you have identified particular risks to participants it is imperative that you establish procedures for assisting them if necessary and for preventing any escalation towards harmful consequences. You should arrange to have someone with appropriate first aid or medical qualifications on hand if physical distress is a risk. If you are asking questions which participants may find emotionally distressing you should arrange for someone to be available for debriefing or counselling.

D5 Please complete the checklist.

Where you have answered “yes” to any of the questions on the checklist, please give details and state what action you intend to take to ensure that no difficulties arise for your participants. Participants should be advised of all risks and their likelihood in the plain language statement.

**Section E: Informed consent**

E1. Attach to your application -

   (a) a copy of the letter to participants giving information in plain language about the research. This is called the Plain Language Statement. It should normally be on RMIT letterhead.

   (b) a copy of the appropriate prescribed consent form. If you do not intend to obtain consent in writing you must explain why.

For further information on preparing these, refer to [Plain language statements and obtaining informed consent of participants](#).

If you are gathering data from blogs or interactive web-sites, you must advise all contributors/participants of your research purpose. Please refer to [Guidelines for those planning to conduct research on the Web](#) for the generic statement to be included on such websites. Depending on the nature of your enquiry, additional information may also have to be supplied.

E2. Dissemination of results

State where you hope to publish the results of your investigation. Also, participants should normally be informed in the plain language statement that results from the study may appear in publications.

E3. Participants under 18 years
If you plan to recruit minors to your research, you must obtain the consent of their parents as well as the person involved. Refer to the National Statement Section 4.

E4 Persons subject to the Guardianship Act (Vic)

Where research is being conducted which involves “procedures” either:

- with people over 18 years, who have a permanent or long term disability which renders them incapable of giving informed consent,
- or
- with people over 18 years who have a permanent or long term disability and are incapable of communicating their consent,

consent must be sought from the Victorian Civil and Administrative Tribunal (Guardianship List) before the beginning of the project.

Contact the Executive Officer of the Human Research Ethics Committee for further details.

Section F: Privacy of records

We wish to acknowledge permission from the Department of Human Services, Vic on whose Common Application Form the information in this section has been based.

Protection of privacy in research is an important consideration for researchers when developing a research project. There are now several pieces of legislation (State and Commonwealth) that could apply to your project in one or all of the recruitment, recording, analysis or reporting phases of your research.

The questions in section F will assist you and the HREC in assessing the project proposal with respect to privacy legislation, and ensuring your plain language statement conforms to requirements.

Please note that if you propose to collect information about an individual from a source other than the individual, or to collect use or disclose information without the consent of the individual whose information it is, you will also have to complete the Special Privacy Module (Form No 5) as well as the questions below.

Under statutory guidelines a HREC may approve some research where the public interest outweighs considerations of privacy, however a researcher must make a special case for such approval. The Special Privacy Module is the starting point for preparing such a case.

Section F covers those aspects of the project proposal to which the various pieces of State and Commonwealth privacy legislation relate.

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 that which collected the information in the first instance). Giving individuals information about themselves does not constitute disclosure.
Personal Information generally 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
   • 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 (But note that the Victorian Privacy Act applies to Victorian universities.)

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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.
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.
QUESTIONS

F1 Does this section have to be completed?
If the project does not involve the collection, use or disclosure of personal, sensitive or health information (see definitions above), then you do not need to answer any further questions in this section.

F2 Type of Activity Proposed
Indicate all types of activity for which this proposal is seeking approval – collection, use and/or disclosure. You may be seeking approval for more than one type of activity, for example collection and use of information.

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. There are fuller notes on this matter accompanying the Special Privacy Form, which should be completed if information is to be collected/used/disclosed without the consent of the individual/s concerned.

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 the subsequent sections unambiguously. It is recommended in these situations that researchers duplicate the privacy questions and answer them for each data set. 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 identified (or potentially identifiable) but handled without consent. Another example is when the researcher is handling more than one set of identified information without consent, but the reasons for needing identified information or for not obtaining consent are different for each set of information.

F3 Collection of Information
Information collected directly from an individual will, by implication, only be collected with the consent of the individual. However, in such cases, the researcher is responsible for informing the participants about how the information will be used, 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 plain language statement, please give reasons why this is the case in part (c) of the question. Note that failure to include this information is a breach of various Privacy Principles (IPP2, NPP1, HPP1 or VIPP1, depending upon which Act applies). If you have not already done so, cross check this list with the content of your plain language statement and amend if any aspect has been missed.

F4 Use or Disclosure of Information About Individuals
If the answer to either part (a) or part (b) is “No”, then go directly to Question F5.

If the answer to F4(b) is “Yes” you must fill out the Special Privacy Form (HREC Form No 5) as well as this form, see Appendix ix in the RMIT HREC Information Package, Edition 9. Please note also that projects involving the access, use or disclosure of information without the consent of the person whose information it is, are classified as risk level 3 and must be reviewed by the RMIT Human Research Ethics Committee.

F5 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 to be collected directly from the person whose information it is, then the number of records will be equal to the number of participants. If the information is to be collected from a hospital or another dataset, then the number of records will be equal to the number of separate individuals, whether identified or de-identified, whose information is collected. Please 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) Indicate the period of time for which the information will be retained. Note that the Joint NHMRC/AVCC Statement and Guidelines on Research Practice recommend 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 (this information may be downloaded from: www.health.gov.au/nhmrc/research/general/nhmrcavc.htm).

(c) Describe the security arrangements for storage of the information, including who will have access to the information. Please note, research data should be stored in the relevant School/research unit at RMIT for the relevant period post-publication.

(d) 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.

(e) 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 (Cwlth)).

(f) The use of unique identifiers and the adoption of identifiers assigned by another agency or organisation (eg Medicare number) 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 (Cwlth)).

F6 Adverse Events

Describe the monitoring, reporting and other procedures established to manage serious adverse events and unforeseen events, in relation to the collection, use or disclosure of information.

Adverse events include all adverse events or unintended consequences that are related to or possibly related to a project approved by an HREC. Examples include: collecting the wrong information about an individual or collecting information about the wrong individual or receiving identified information (or access codes for coded information) when the information was supposed to be received in a de-identified form.

The principal researcher is responsible for reporting all adverse events and signing all correspondence regarding adverse events. 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 Appendix 3.

When reporting an adverse event, the principal researcher should note that the HREC within their institution might have established procedures or protocols for such reporting. The researcher should give a written opinion as to whether:

- the project was or was not responsible;
- it is appropriate to continue or discontinue the project;
• any other action is required.

F7 Other Ethical Issues Relating to Privacy

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 8 and 9).

Section G: Other issues

G1. Do you propose to pay participants? If so, how much and for what purpose.

While it is permissible to reimburse participants' expenses or compensate them for their time or inconvenience caused by participating in a project, payment must never be so great as to be an inducement to participate.

G2. Where will the project be conducted?

Research to be conducted at another institution:

If the project is to be carried out at another institution you must provide written permission from that institution for conduct of the project and, where relevant, for recruitment of participants.

The Committee recognises that ethical responsibility for registered patients of hospitals, or students or staff of other institutions, rests with the duly constituted authorities of these hospitals or institutions. University staff may undertake projects at an institution affiliated with the University, or another appropriate institution as determined by the Committee, provided written approval has been obtained for such research or experimentation from a duly authorised officer or committee of that institution.

Where the research project involves enrolled students of RMIT or members of RMIT staff, or any other participants for whom that hospital or other institution does not take responsibility, this must also be drawn to the attention of the RMIT HREC when seeking approval.

In some cases another participating institution may insist on their consent forms, plain language statements and letterhead being used. This is acceptable as long as they have been approved by a duly constituted Human Research Ethics Committee of the relevant participating institution, and the consent form contains largely what is specified in the RMIT guidelines.

If research is to be conducted abroad:

Research conducted by staff or students of RMIT in other countries must comply with these guidelines and be in accordance with the NH&MRC National Statement on Ethical Conduct in Human Research 2007. If local practice or standards vary from those of RMIT, the researcher should comply with whichever expectation is the higher. If you find it is difficult to adhere to your plan then you should contact your supervisor and seek advice from the Human Research Ethics Committee/Sub-Committee which approved your project.

G3. Is this project being submitted to another Human Research Ethics Committee, or has it been previously submitted to a Human Research Ethics Committee?

If YES please supply details.
G4. Are there any other issues of relevance?

If you answered “No” to question F1, please answer the following two questions:
(Applicants who have completed all of section F will already have answered these questions)

G5 For what period of time will the research data be retained? How will the information be disposed of at the end of this period?

Note that the Joint NHMRC/AVCC Statement and Guidelines on Research Practice 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 (this information may be downloaded from: www.health.gov.au/nhmrc/research/general/nhmrcavc.htm)

G6 Describe the security arrangements for storage of the information. Where will the information be stored? Who will have access to the information?

Please note research data should be stored in the relevant School/research unit at RMIT for the required period post publication.

Don’t forget to attach your plain language statement and consent form to the application.