1. This form is to be used by Masters, PhD, Professional Doctorate candidates and staff undertaking research in the ‘Risk level 1’ and ‘Risk level 2’ categories as described in the accompanying guidelines. All applications must be completed by filling out this form in its electronic version and printing it out. ‘Risk level 3’ applications must be completed on the RMIT Human Research Ethics Committee form available at www.rmit.edu.au/rd/hrec_apply.

2. This form is available at www.rmit.edu.au/bus/research/ethics.

3. Candidates should submit applications early and allow at least **30 working days** for assessment and approval.

### Section A: Approvals and Declarations

1. **Project Title:**

<table>
<thead>
<tr>
<th>Research Degree</th>
<th>Staff Research Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete this column if you are undertaking research for a <strong>research degree</strong> at RMIT or another university (Masters of Business by Research/PhD/Professional Doctorate)</td>
<td>Complete this column if your research is not for any degree.</td>
</tr>
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<table>
<thead>
<tr>
<th>Investigator</th>
<th>Principal investigator</th>
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<tbody>
<tr>
<td>Name:</td>
<td>Name:</td>
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<tr>
<td>Student No:</td>
<td>Qualifications:</td>
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<tr>
<td>Qualifications</td>
<td>School:</td>
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<td>School:</td>
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<td>Email:</td>
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| Degree for which Research is being undertaken: |

<table>
<thead>
<tr>
<th>Senior Supervisor</th>
<th>Other investigator/s</th>
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<tbody>
<tr>
<td>Name:</td>
<td>Name/s:</td>
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<tr>
<td>Qualifications:</td>
<td>Qualifications:</td>
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<td>School:</td>
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<td>Phone:</td>
<td>Phone:</td>
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<td>Email:</td>
<td>Email:</td>
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</tbody>
</table>

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2. Declaration by the investigator(s)

I/We, the undersigned, accept responsibility for the ethical conduct of the research detailed below. I/We have read the current NH & MRC National Statement on Ethical Conduct in Research Involving Humans 1999 (in particular, see Principles of Ethical Conduct pp.11-14), and accept responsibility for the conduct of the research in this application in accordance with the principles contained in the National Statement and any other condition laid down by the RMIT Human Research Ethics Committee.

Signed: ___________________________ Date: ___________________________
(Signature of investigator)

Signed: ___________________________ Date: ___________________________
(Signature of other investigators if applicable)

3. Declaration by the Supervisor (if not an investigator)

I have informed the student of their responsibility to undertake this research in a manner that conforms with the NH&MRC National Statement on Ethical Conduct in Research Involving Humans 1999, and any conditions of approval of this research by the RMIT Human Research Ethics Sub-Committee.

Signed: ___________________________ Date: ___________________________
(Signature of senior supervisor if applicable)

4. Declaration by the Head of School/Centre

The research project set out in the attached application, including the adequacy of its research design and compliance with recognised ethical standards, has the approval of the School. I certify that I am prepared to have this project undertaken in my School/Centre/Unit.

Signed: ___________________________ Date: ___________________________
(Signature of Head of School or approved delegate)

Comments:

School/Centre: ___________________________ Extn: ___________________________
Section B: Project Particulars

NB: The numbered bolded headings in this form must remain in your completed application for ethics approval. Please leave these headings and the detailed guidelines as you go through and complete the form. If a heading is not relevant write ‘Not applicable’ underneath it.

1. Title of Project

2. Project Description: for Human Research Ethics Sub-Committee assessment of ethical issues

This description of the proposed study, which a range of people will read, must be in language able to be understood by a layperson. Use the dot points below as sub-headings in this section:

- aims and significance of the research
- the research question
- proposed methodology
- the research methods
- what participants will be required to do

This description should normally be no more than two pages long. Research degree students can cut and paste relevant parts of their ‘Application for Candidature’. Remember its purpose is to get a quick and clear idea of what the research is about in relation to the involvement of human participants and what you will actually do.

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.

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 Appendix IX of the HREC Information Package)

If you are gathering data from blogs or interactive web-sites, you must advise all contributors/participants of your research purpose. Please refer to Appendix X of the HREC Information Package for the statement to be included on such websites. Depending on the nature of your enquiry, additional information may also have to be supplied.

3. Research timetable

Include a brief set of timelines for the proposed research activity for which approval is being sought, including the commencement and finishing date.

Projects classified Category ‘Risk level 1’ or ‘Risk level 2’ may commence once approval has been received from the Business Portfolio Human Research Ethics Sub-Committee.
Investigators are reminded that projects classified ‘Level 3’ must be completed on the RMIT Human Research Ethics Committee (HREC) form and may not proceed until approval has been received from the (HREC).

Please refer to www.rmit.edu.au/rd/hrec_apply

4. Research funding

Include here any details of funding for this activity including internal/external, source, and duration.

Section C: Details of Participants

NB: The numbered bolded headings in this form must remain in your completed application for ethics approval. Please leave these headings and the detailed guidelines as you go through and complete the form. If a heading is not relevant write ‘Not applicable’.

1. Number, type, age range, and any special characteristics of participants

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

If your research involves participants recruited through other organisations, (particularly schools, correctional facilities, health and community services) additional approvals in accordance with their ethics procedures may be necessary. You must list the other organizations here that you have or will be applying to for approval of this application. For research with Indigenous people the National Health and Medical Research Council has guidelines that must be followed.


3. 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 a written document/ email other than the Plain Language Statement is to be given to potential participants this should be attached.

4. 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?

This is a very important question. It is here that you signal whether the people you are studying are in any way vulnerable and if there is attendant ethical risk in your research. If you answer yes to this question you must explain the relationship and the steps taken by the investigators to ensure that the participants' involvement in your research is purely voluntary.

Special care should be taken in recruiting participants who may be in a dependent relationship with any of the investigators to ensure that consent to participate in the research has been freely given. Some common examples of dependent relationships are: lecturer and student (or teacher/pupil), doctor and patient, health care/criminal justice/other professional and client, manager and subordinate.

Investigators are also asked to take particular care in recruiting participants who may not be strictly in a dependent position but who potentially may be vulnerable, such as children, people with disabilities, prisoners, the elderly, and those who are mentally or physically ill.
Investigators whose work may involve vulnerable participants or persons in dependent relationships should be familiar with the guidelines provided in chapters 4 to 7 of the NH&MRC National Statement on Ethical Conduct in Research Involving Humans 1999.

Section D: Estimation of Potential Risk to Participants & Project Classification

NB: The numbered bolded headings in this form must remain in your completed application for ethics approval. Please leave these headings and the detailed guidelines as you go through and complete the form. If a heading is not relevant write ‘Not applicable’ underneath it.

Please refer to:  
www.rmit.edu.au/rd/hrec_apply  

1. Please identify the project classification by assessing the level of risk to participants

You need to nominate your own classification of the risk involved. The Ethics sub-committee can change this if it considers you have underestimated the risk. You should classify your research using the Risk Classification of Research Projects guidelines which can be found at www.rmit.edu.au/rd/hrec_apply

2. If you believe the project should be classified category ‘Risk level 1’ or category ‘Risk level 2’ please explain why you believe there are no risks or minimal to the participants.

It is not enough to simply say people have volunteered to participate. You have to also assure the Ethics sub-committee that the participant’s interaction with you through the research process is ethical and that their rights as described in the application and Plain Language Statement, (e.g. confidentiality and anonymity) are protected. It is quite possible that participants may volunteer for a project where they may be exposed to risk or distress to themselves.

If there is a minimal risk to participants please identify the risk and explain how you intend to minimise the possibility of social, psychological or legal risk, so that in effect there is little likelihood of risk to participants. Please describe any remedial actions that have been put in place to deal with any situation where a participant experiences distress or discomfort (e.g. access to counselling)

If you are conducting interviews/ focus groups/ administering a questionnaire etc please attach a list of your interview questions/themes or a copy of the questionnaire so that the Ethics sub-committee can identify the level of potential risk to participants and the project classification.

3. Please detail any other ethical issues which may be particularly associated with this project.

Where you have marked ‘YES’ to any of the tabled questions, please give details in the table stating what action you intend to take to ensure that no difficulties arise for your participants.

Cross X in the appropriate boxes (Do not delete any questions in this section).
<p>| | |</p>
<table>
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<tbody>
<tr>
<td>a)</td>
<td>Does the data collection process involve access to confidential data without the prior consent of participants?</td>
</tr>
<tr>
<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>b)</td>
<td>Will participants have pictures taken of them e.g. photographs or videos?</td>
</tr>
<tr>
<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>c)</td>
<td>If interviews are to be conducted will they be tape-recorded?</td>
</tr>
<tr>
<td></td>
<td>NB if interviews are being conducted please attach a list of proposed interview questions/themes to this application.</td>
</tr>
<tr>
<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>d)</td>
<td>Are the participants in a dependent relationship with the investigator/s?</td>
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<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>e)</td>
<td>Is deception to be used?</td>
</tr>
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<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>f)</td>
<td>Do you plan to use an interpreter?</td>
</tr>
<tr>
<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>g)</td>
<td>Does the research involve any tasks or processes which participants may experience as stressful or unpleasant during or after the data collection?</td>
</tr>
<tr>
<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
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<tr>
<td>Yes</td>
<td>No</td>
</tr>
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<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>i)</td>
<td>Are there in your opinion any other ethical issues involved in the research eg is it possible that you will be collecting/disclosing information about a third party not involved in the research?</td>
</tr>
<tr>
<td></td>
<td>If ‘Yes’ please give details of any actions you will take to ensure that participants are not compromised by this:</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Section E: Informed Consent

NB: The numbered bolded headings in this form must remain in your completed application for ethics approval. Please leave these headings and the detailed guidelines as you go through and complete the form. If a heading is not relevant write ‘Not applicable’ underneath it.

1. Attach to your application

   (a) a copy of the letter to participants providing plain language information about the research. This will often be the letter inviting people’s participation. This should normally be on RMIT letterhead. (see attached guideline for the Plain Language Statement (PLS) at Appendix 3)

   (b) a copy of the Consent form (see Appendix 1) for research participants. If you are not obtaining consent in writing or not using a standard consent form, please explain why.

2. Dissemination of results

   Participants should be informed that results from the study may appear in publications. This information is to be included in the information given in the Plain Language Statement prior to obtaining informed consent.

Section F: Research Involving Collection, Use or Disclosure of Information

Please note that if you propose to collect information about an individual from a source other than the individual, or to use or disclose information without the consent of the individual whose information it is, you will also have to complete the HREC Form 5: Special Privacy Form (as well as the questions below).

Download the HREC Form 5: Special Privacy Form from: www.rmit.edu.au/rd/hrec_apply

Also see “Notes to assist in the completion of the Special Privacy Form No. 5” titled “Special Privacy Module” at the aforementioned web address.

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 HREC Form 5: Special Privacy Form is the starting point for preparing such a case.

For a more detailed guidance and definitions for each of the questions below, see Section F of “Notes to assist in completing HREC Form 1” at www.rmit.edu.au/rd/hrec_apply

1 Does this Section have to be completed?

   Does the project involve the collection, use or disclosure of personal information (includes names & contact details), health information including genetic information, or sensitive information? (see Section F of “Notes to assist in completing HREC Form 1” at www.rmit.edu.au/rd/hrec_apply)

   □ No – you do not have to answer any questions in this section. Go to Section G
   □ Yes – you must answer questions in this section. Go to Question F2.

2 Type of activity proposed

   Are you seeking approval from this HREC for:
   (a) collection of information?

       □ Yes – start at Question F3
       □ No – start at Question F4

   (b) use of information?

       □ Yes □ No
3 Collection of Information

(a) Does the project involve collection of information directly from individuals about themselves?
   - No – (i.e. collected from a third party/existing records) you must fill out the Special Privacy Form HREC Form 5 at www.rmit.edu.au/rd/hrec_apply
   - Yes – answer the following questions:

(b) What type of information will be collected? (Tick as many as apply)
   - Personal information (e.g. name, contact details etc)
   - Sensitive information (e.g. affiliations, income, values, attitudes etc)
   - Health information

(c) Does the plain language statement explain the following:
   - The identity of the organisation collecting the information and how to contact it?  
     Yes □ No □
   - The purposes for which the information is being collected?  
     Yes □ No □
   - The period for which the records relating to the participant will be kept?  
     Yes □ No □
   - The steps taken to ensure confidentiality and secure storage of data?  
     Yes □ No □
   - How privacy will be protected in any publication of the information (i.e. how is anonymity of participants guaranteed)?  
     Yes □ No □
   - The fact that the individual may access that information?  
     Yes □ No □

If you answered “No” to any of these questions, give the reasons why this information has not been included in the plain language statement:

4 Use or Disclosure of Information about Individuals

(a) Does the project involve the use or disclosure of identified or potentially identifiable information?
   - No – go Section G.
   - Yes, answer the following questions.

(b) Does the project involve use or disclosure of information without the consent of the individual whose information it is?
   - No - go Section G.
   - Yes, you must fill out the Special Privacy Form HREC Form 5 as well as this form. (download the Special Privacy Form from www.rmit.edu.au/rd/hrec_apply).
Section G: Other Issues

NB: The numbered bolded headings in this form must remain in your completed application for ethics approval. Please leave these headings and the detailed guidelines as you go through and complete the form. If a heading is not relevant write ‘Not applicable’ underneath it.

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

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

2. Where will the project be conducted?

If the project is to be carried out at another institution you should give details of that institution and you must provide written permission from that institution for conduct of the project and, where relevant, for recruitment of participants. Otherwise just give details of the location where your interaction with human research participants will occur.

The Committee recognises that ethical responsibility for staff, members, or students at 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 other appropriate institution as determined by the Ethics sub-committee, provided written approval has been obtained for such research and experimentation from a duly authorised officer or committee of that institution.

Where the research project involves enrolled students or members of University staff, or any other participants for whom the other institution does not take responsibility, approval must be obtained from the RMIT Ethics sub-committee before proceeding.

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 a duly constituted Human Research Ethics Committee of the relevant participating institution has approved them and they are consistent with the Plain Language Statement and Consent Form requirements used at RMIT. Please note RMIT Ethics approval is still required.

3. Is this project being submitted to another human research ethics committee, or has it been previously submitted to a human research ethics committee?

If approval has already been received from another ethics committee, attach evidence of that approval.

4. General Issues

(a) How many records will be collected, used or disclosed? Specify the information that will be collected, used or disclosed (e.g. date of birth, medical history, number of convictions, etc)

<table>
<thead>
<tr>
<th>Number of records:</th>
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<tbody>
<tr>
<td>Type of information:</td>
</tr>
</tbody>
</table>

(b) For what period of time will the information be retained? How will the information be disposed of at the end of this period?

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

(d) How will the privacy of individuals be respected in any publication arising from this project?

(e) Does the project involve trans-border (i.e. interstate or overseas) data flow?

☐ Yes  ☐ No

If Yes, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP 9, VIPP 9 or NPP 9).
(f) Does the project involve the adoption of unique identifiers assigned to individuals by other agencies or organisations?

☐ Yes ☐ No

If yes, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP 7, VIPP 7 or NPP 7).

5 Adverse Events

Are procedures in place to manage, monitor and report adverse and/or unforeseen events relating to the collection, use or disclosure of information?

☐ Yes ☐ No

Give details.

6 Other Ethical Issues

Discuss any other ethical issues relevant to the collection, use or disclosure of information proposed in this project. Explain how these issues have been addressed.

END OF FORM

NOTE: Consent form Appendix 1

A consent form is required for Persons Participating In Research Projects Involving Interviews, Questionnaires, Focus Groups or Disclosure of Personal Information. However if anonymous postal/email surveys do not need a consent form as return of the form constitutes consent. The Plain language Statement should include this information.
RMIT HUMAN RESEARCH ETHICS COMMITTEE
Prescribed Consent Form for Persons Participating In Research Projects Involving Interviews, Questionnaires, Focus Groups or Disclosure of Personal Information

PORTFOLIO OF
SCHOOL/CENTRE OF

Name of Participant:

Project Title:

Name(s) of Investigators:        (1) Phone:        
                              (2) Phone:        

1. I have received a statement explaining the interview/questionnaire involved in this project.

2. I consent to participate in the above project, the particulars of which - including details of the interviews or questionnaires - have been explained to me.

3. I authorise the investigator or his or her assistant to interview me or administer a questionnaire.

4. I give my permission to be audio taped: ☐ Yes ☐ No

5. I give my permission for my name or identity to be used: ☐ Yes ☐ No

6. I acknowledge that:

   (a) Having read the Plain Language Statement, I agree to the general purpose, methods and demands of the study.
   (b) I have been informed that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied.
   (c) The project is for the purpose of research and/or teaching. It may not be of direct benefit to me.
   (d) The privacy of the information I provide will be safeguarded. However should information of a private nature need to be disclosed for moral, clinical or legal reasons, I will be given an opportunity to negotiate the terms of this disclosure.
   If I participate in a focus group I understand that whilst all participants will be asked to keep the conversation confidential, the researcher cannot guarantee that other participants will do this.
   (e) The security of the research data is assured during and after completion of the study. The data collected during the study may be published, and a report of the project outcomes will be provided to _________ (researcher to specify). Any information which may be used to identify me will not be used unless I have given my permission (see point 5).

Participants should be given a photocopy of this consent form after it has been signed.

Any complaints about your participation in this project may be directed to the Executive Officer, RMIT Human Research Ethics Committee, Research & Innovation, RMIT, GPO Box 2476V, Melbourne, 3001. Details of the complaints procedure are available at: http://www.rmit.edu.au/rd/hrec_complaints

Any complaints about your participation in this project may be directed to the Chair, Portfolio Human Research Ethics Sub-Committee, Business Portfolio, GPO Box 2476V, Melbourne, 3001. The telephone number is (03) 9925 5594 or email address rdu@rmit.edu.au. Details of the complaints procedure are available from: http://www.rmit.edu.au/rd/hrec_complaints

Participant’s Consent

Name: ____________________________    Date: ____________________________
     (Participant)

Name: ____________________________    Date: ____________________________
     (Witness to signature)

Where participant is under 18 years of age:

I consent to the participation of ____________________________ in the above project.

Signature: (1) ____________________________    (2) ____________________________    Date: ____________________________
         (Signatures of parents or guardians)

Name: ____________________________    Date: ____________________________
     (Witness to signature)
Plain Language Statement to be used in a research project involving human participation. It must be printed on RMIT letterhead and be written in language appropriate to the audience and any technical terms need to be explained.

(This letter must be given to participants on appropriate letterhead)

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT
PROJECT INFORMATION STATEMENT

Project Title:
- What’s the Secret of the Universe?

Investigators:
- Mr Joe Blow (Psychology Masters degree student)
- Dr John Smith (Project Supervisor: Senior Lecturer, Psychology, RMIT University, john.smith@rmit.edu.au, 9925-5555)

Check that the information above gives clear details on the student’s course of study. The supervisor’s affiliation and their full contact details should also be provided. If there are other investigators, they should also be listed, along with their affiliation. Note that the student’s contact details have not been provided. For undergraduate and Honours-level research the supervisor should serve as the first point of contact. Where the student researcher has a suitable level of professional experience and/or training, it might be appropriate to provide contact details for both the student researcher and the supervisor. In either instance, the supervisor’s contact details must be provided. A landline office number must be provided; a mobile phone number cannot be the sole contact number.

The opening paragraph should be along the following lines unless there is a particular reason to alter it:
Dear …

You are invited to participate in a research project being conducted by RMIT University [include the names of any other organisations or bodies that might be involved in the conduct of the research here]. This information sheet describes the project in straightforward language, or ‘plain English’. Please read this sheet carefully and be confident that you understand its contents before deciding whether to participate. If you have any questions about the project, please ask one of the investigators.

Feel free to add other sub-headings if you believe they will add to the clarity of the information.

**Who is involved in this research project? Why is it being conducted?**
In this section, you should:
- Clearly describe who the researchers are, including any outside (i.e., non-RMIT) parties. Make sure the researcher’s roles are clear. For example, if the research is a student project, the supervisor should be clearly identified as such and named. If there is an outside consultant, he/she should be clearly identified.
- If the research is being conducted as part of a degree, state this and provide the name of degree.
- State that the project has been approved by the RMIT Human Research Ethics Committee and any other bodies that may have scrutinised it. Also, if outside bodies (e.g., businesses, companies, organisations) have given approval or support for the research, this should be mentioned here.
- If the research is being funded by an outside body, this should be stated here. For example, “This study is partly funded by the Acme Widget Company”.

**Why have you been approached?**
In this section, you should:
- Clearly explain why the participant has been approached with this invitation. If he/she has been selected at random, then say so. If they have been selected through some other process, then explain that process. If their contact details have been obtained, then explain how and, possibly, who gave permission for this. If their name has been passed on by someone else, explain how this took place. If participants have not been approached randomly, they have a right to know why and how they have been approached.

**What is the project about? What are the questions being addressed?**
In this section, you should:
- Give a brief description of the project in plain English. As part of this description, state the primary research questions, in plain English.
- State how many people you expect will participate.

**If I agree to participate, what will I be required to do?**
In this section, you should:
- Explain in plain English what a participant will be required to do if they agree to participate. You need to provide the participant with enough information so that they can make a truly informed decision about whether they want to participate. Make sure you describe the time commitments involved with participation. If the study involves completing questionnaires, some example questions can be helpful. You should extend an invitation for the participant to examine the test materials before deciding whether they want to participate. Any unpleasant or inconvenient aspects of taking part should be fairly described. You want to avoid any possibility of a participant saying to you, “If I had known that the project required me to do X I would never have agreed to participate”.

- 13 - Version #3: 10/12/2007
What are the risks or disadvantages associated with participation?
In this section, you should:
- Give an honest assessment of any risks associated with participation. If there are no perceived risks outside the participants normal day-to-day activities, then say so. If you can quantify the risks (eg “one in x thousand chance of happening”) that is usually helpful.
- This is also the relevant section in which to include information for participants in the event that they are concerned about their involvement in the study. For example, in a questionnaire study that includes questions pertaining to clinical conditions (depression, anxiety, stress, gambling, drug and/or alcohol use, attitudes, etc.) there is the possibility, however slight, that participants may be concerned or upset about their responses. It is an ethical requirement that you have a clear protocol in place in case this occurs. Further, in your plain language statement, you need to let potential participants know that there is an avenue they can pursue if they feel the need, for example:

“If you are unduly concerned about your responses to any of the questionnaire items or if you find participation in the project distressing, you should contact [insert name of appropriate person] as soon as convenient. (Named person) will discuss your concerns with you confidentially and suggest appropriate follow-up, if necessary”

You and your supervisor should have a clear protocol in place if this occurs. You should also consider providing the contact details of other appropriate services that might be of assistance.
- In the case of a placebo controlled trial it would be right to explain that some participants may not receive the substance being appraised.
- If you anticipate that your investigation may reveal data which it is in a participants interest to know, you must include in the plain language statement advice that, if any serious risk is revealed by the study, the participant may be contacted and referred to someone who can be of assistance.
- If you are planning a clinical trial your plain language statement must conform to all requirements listed in the ICH Note for Guidance on Good Clinical Practice.

What are the benefits associated with participation?
In this section, you should:
- Give an honest assessment of any benefits that may accrue to the participant as a result of their participation. If there is no direct benefit to the participant as a result of their participation, then say so.

What will happen to the information I provide?
In this section, you should:
- Explain the safeguards for participants data. Remember, confidentiality and anonymity are not one in the same thing. Anonymous means that the participant cannot be identified at any stage of the research. Confidential means that identified data will be seen by a small number of people (you should clearly state who these are). If your participants need to be identified in your research records, you need to clearly explain why this is necessary.
- State that, “Any information that you provide can be disclosed only if (1) it is to protect you or others from harm, (2) a court order is produced, or (3) you provide the researchers with written permission”. This should be written verbatim.
- Explain how the results will be disseminated (e.g., in a student report, paper for publication, conference, etc.) and that data will be aggregated or you plan to use pseudonyms. Explain that the research data will be kept securely at RMIT for a period of 5 years before being destroyed.
If you are not obtaining informed consent, this should be stated here and justified. For example, “Because of the nature of data collection, we are not obtaining written informed consent from you. Instead, we assume that you have given consent by your completion and return of the materials (i.e., survey, questionnaires, etc.).”

**What are my rights as a participant?**

In this section, you should:

- Explain participants’ rights, which include:
  - The right to withdraw their participation at any time, without prejudice.
  - The right to have any unprocessed data withdrawn and destroyed, provided it can be reliably identified, and provided that so doing does not increase the risk for the participant.
  - The right to have any questions answered at any time.

**Whom should I contact if I have any questions?**

- This should be self-evident. As a general rule, undergraduates should NOT provide their personal phone numbers, either land-line or mobile, instead, the supervisor should serve as the first point of contact in the event of query. If you do not think this is appropriate, then you need to justify a deviation from this policy in Section E1 of the application pro-forma. Post-graduate students should discuss contact arrangements with their supervisor. It is advisable to give an office rather than a private number.

**What other issues should I be aware of before deciding whether to participate?**

In this section, you should:

- Give an honest assessment of any other ethical issues that you think a potential participant should be aware of before deciding whether they want to participate.

Yours Sincerely

The plain language statement must be signed by all researchers, with his/her qualification/s listed below each name.

The version number and date should form part of the footer. The boxed information below must appear on both the plain language information sheet and the informed consent form.

The plain language information sheet is often the only “public face” of the research. It should look professional. It must be free of typographical errors and obvious errors in expression and presentation. Take time to format the plain language statement so that it has a polished appearance. A poorly prepared plain language statement reflects badly on all concerned.

Any complaints about your participation in this project may be directed to the Secretary, Portfolio Human Research Ethics Sub Committee, Business Portfolio, RMIT, GPO Box 2476V, Melbourne, 3001. The telephone number is (03) 9925 5594 or email address rdu@rmit.edu.au. Details of the complaints procedure are available from http://www.rmit.edu.au/rd/hrec_complaints

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