

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 you do not need a consent form as return of the form constitutes consent. The Plain language Statement should include this information.

Appendix 1

RMIT BUSINESS COLLEGE HUMAN ETHICS ADVISORY NETWORK

Prescribed Consent Form for Persons Participating In Research Projects Involving Interviews, Questionnaires, Focus Groups or Disclosure of Personal Information

COLLEGE 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).

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)

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 Chair, Business College Human Ethics Advisory Network, College of Business, RMIT, GPO Box 2476V, Melbourne, 3001. The telephone number is (03) 9925 5598 or email address rdu@rmit.edu.au. Details of the complaints procedure are available from <http://www.rmit.edu.au/browse:ID=2jqrn7hnpyo>



University

College of Business

School of

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 Business College Human Ethics Advisory Network 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".*

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 upon completion of the project 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.*
 - ✓ *The right to request that audio recording be terminated at any stage during the interview (if you are conducting interviews and they are to be audio recorded this statement must be included)*

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 Chair, Business College Human Ethics Advisory Network, College of Business, RMIT, GPO Box 2476V, Melbourne, 3001. The telephone number is (03) 9925 5598 or email address rdu@rmit.edu.au. Details of the complaints procedure are available from <http://www.rmit.edu.au/browse:ID=2jqmb7hnpyo>

As a footer:

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