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| **Participant Information Statement - General**   * This is a **general** participant information statement template designed to suit most studies. There are also a series of templates for specific types of research (e.g. oral history, ethnography) on our website. Feel free to choose the one that best suits your project. * This document references the [**National Statement on Ethical Conduct in Human Research**](http://www.nhmrc.gov.au/guidelines/publications/e72) (NHMRC, 2007), referred to as “the National Statement” in brief. It is essential reading when planning and conducting your study. * **This template is a guide only** **and you should adapt it to your project**. You must include all the numbered sections, but within each section there are paragraphs that are mandatory and others that are only relevant to specific types of studies. Youmay need to decide whether a certain paragraph should be included, or choose between alternative wording options.You should **delete** any paragraphs that are not relevant to your study and remove all prompts and instructions from your final document. * In this template:   + The *red italics* are instructions outlining the general nature of the information you need to provide in each section.   + The black text provides standard phrases for you to use when providing this required information. It may be the totality of what is required for the section or you may need to add extra information, as indicated by the *instructions*.   + The *blue italics* are prompts for required/suggested content. All sections are mandatory, unless marked with *“if applicable to your study”.* * Try to write concisely; long forms can be difficult to read and understand. * The documents should be writtenin **lay language** that is readily understandable for participants. Avoid jargon and technical language. Write to, not about, the participant (i.e. “you will be asked to…” NOT “participants will be asked to”). * **Please proofread documents for spelling, grammatical and formatting errors, clarity and comprehensibility.** * Include the document **version number and date** in the footer of each page, and update them each time revisions are made. If more than one Participant Information Statement/Consent Form is required for your project (e.g. for separate participant groups or a pilot/sub-study), please label the different forms clearly. * **Participants must be provided with a copy of the Participant Information Statement and signed Consent Form, and you must retain a copy for your study records.** * Although a written consent form is provided on our website, in some cultural contexts/with certain participants **oral consent** may be more appropriate (as per section 2.2.5 of the National Statement). If this is the case, you should use the Participant Information Statement/Consent Form templates as a guide to create an oral consent script. In your ethics application, you should explain why oral consent is appropriate and how consent will be recorded (e.g. using an audio recording, written in field notes etc). See our [website](http://sydney.edu.au/research_support/ethics/human/guidelines/consent_limits.shtml) for more information. * If Participant Information Statements/Consent Forms in languages other than English are to be used, you need to supply these to the HREC once you have final versions in English that are approved by the HREC. The **translations** must be certified by a person who has no conflict of interest and is not associated with the research project. A signed and witnessed Statutory Declaration is sufficient if the person is not an official translator or a university staff member with appropriate expertise. See our [website](http://sydney.edu.au/research_support/ethics/human/guidelines/translation.shtml) for more information. |

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|  | **CHIEF INVESTIGATOR (SUPERVISOR) NAME**  *Chief Investigator (Supervisor) Title*  *[NB: this should not be a student researcher]* | | Room XXX  Building and code  The University of Sydney  NSW 2006 AUSTRALIA  Telephone: +61 2 xxxx xxxx  Facsimile: +61 2 xxxx xxxx  Email: xxxxxxx@sydney.edu.au  Web: <http://www.sydney.edu.au/> |

**[*INSERT* Title of Study]**

**PARTICIPANT INFORMATION STATEMENT**

1. **What is this study about?**

You are invited to take part in a research study about*[INSERT a brief description of the purpose, aims and significance of your study in lay terms, (i.e. in plain English).]*

You have been invited to participate in this study because *[INSERT the reason for the invitation].* This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don’t understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

* Understand what you have read.
* Agree to take part in the research study as outlined below.
* Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

1. **Who is running the study?**

The study is being carried out by the following researchers:

* [*INSERT* names, positions and organisational affiliations].

[*INSERT*, *if applicable to your study – STUDENT DECLARATION*]

[*INSERT* name of student] is conducting this study as the basis for the degree of [*INSERT* degree undertaken] at The University of Sydney. This will take place under the supervision of [*INSERT* name and position of supervisor].

[*INSERT*, *if applicable to your study – FUNDING DECLARATION*]

This study is being funded by [*INSERT* name of funding body/bodies].

[*INSERT*, *if applicable to your study, a description of any potential/actual CONFLICTS OF INTEREST for researchers, sponsors and/or institutions involved in the project.*]

[*INSERT*, *if applicable to your study, a description of any FINANCIAL BENEFITS to the researchers or institution that might arise from the conduct of the research. This description should include the nature of the potential financial benefits, which individuals/institutions are likely to receive these benefits, and a statement that participants will not personally receive any financial benefits as a result of these outcomes.*]

1. **What will the study involve for me?**

[Describe in lay terms **what the study will involve** **from the participant’s perspective**. The participant must be in a position to give fully informed consent. Remember to write to, not about, the participant (i.e. “you will be asked to…” not “participants will be asked to…”). If there are multiple participant groups, create a separate PIS/PCF for each group and tailor the information provided to explain exactly what is involved for that group. You may wish to use tables, diagrams or flow charts to make the information more accessible and easily comprehensible.

This includes information about the following, as applicable to your study.

* Any screening procedures that will be used to determine their eligibility for the study.
* The nature, location, and timing of their involvement in study activities (e.g. questionnaires, surveys, focus groups, interviews, observation, assessments, medical and other procedures).
* A detailed description of what study activities will involve for the participant (e.g. the types of questions asked in interviews, focus groups or questionnaires).
* Whether there will be any audio/video/other recording (e.g. photos) involved.
* Any access to participants’ personal information or records that is being requested, including specific details of which records/information will be accessed, how, and for what purpose they will be used. This could include medical records, academic records, personal letters and journals, photographs etc.
* Whether an interpreter will be involved.
* A description of any opportunity for participants to review information generated about them prior to publication (e.g. review of interview transcripts or publications). This is likely to be appropriate where participants will be identifiable in publications. Be sure to describe the nature of the review process, when and how it will take place. See Section 3.1.15 of the National Statement for more guidance.]

1. **How much of my time will the study take?**

*[Describe* ***how much time*** *this study will involve for the participant, including both the time required for each part of the study and the total time commitment.]*

1. **Who can take part in the study?**

[Describe the **population of interest** for the study and any **inclusion and exclusion criteria** with an explanation of the reasons for these criteria. Be specific; rather than simply stating broad categories you should also explain the specific criteria within those categories. Clearly outlining and justifying the exclusion and inclusion criteria for your study is an important part of conducting research in accordance with the ethical principle of justice; see Section 1.4 of the National Statement.]

1. **Do I have to be in the study? Can I withdraw from the study once I've started?**

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney [*INSERT, if applicable to your study,* any other individuals or organisations related to your study].

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by *[INSERT* a description of how to withdraw from the study]. [*INSERT, if applicable to your study,* a description of any consequences of withdrawing from the study].

[*INSERT, if applicable to your study – ONE OR MORE of the following statements about study data].*

*[For INTERVIEW]*

You are free to stop the interview at any time. Unless you say that you want us to keep them, any recordingswill be erased and the information you have provided will not be included in the study results. You may also refuse to answer any questions that you do not wish to answer during the interview.

*[For NON-ANONYMOUS questionnaire]*

Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses if you change your mind about having them included in the study, up to the point that we have analysed and published the results.

*[For ANONYMOUS questionnaire]*

Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses any time before you have submitted the questionnaire. Once you have submitted it, your responses cannot be withdrawn because they are anonymous and therefore we will not be able to tell which one is yours.

*[For FOCUS GROUP]*

If you take part in a focus group, you are free to stop participating at any stage or to refuse to answer any of the questions. However, it will not be possible to withdraw your individual comments from our records once the group has started, as it is a group discussion.

*[For OTHER data that CAN BE WITHDRAWN]*

If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results.

*[For OTHER data that CANNOT BE WITHDRAWN]*

If you decide to withdraw from the study, we will not collect any more information from you. Any information that we have already collected, however, will be kept in our study records and may be included in the study results.

1. **Are there any risks or costs associated with being in the study?**

[Under the ethical principle of beneficence, research must be designed and carried out in such a way that the likely benefit justifies any risks of harm or discomfort (see the National Statement sections 1.6-1.9). Further, participants should be made aware of any risks involved in the project at the point of consent. Chapter 2.1 of the National Statement provides further guidance on risk and benefit in research.

In this section you should use lay language to describe the **nature, likelihood and severity of any risks** to participants, as well as any measures that will be taken to **manage these risk**s.

Possible risks may include, but are not limited to:

* Physical harms e.g. injury, illness, pain.
* Psychological harms e.g. feelings of distress or anger, learning about the possibility of developing a genetic disease, diagnosis of previously unknown medical conditions.
* Devaluation of personal worth e.g. being humiliated or manipulated.
* Social harms e.g. damage to social networks or relationships, discrimination in access to benefits, services, employment or insurance.
* Economic harms e.g. direct or indirect costs.
* Legal harms e.g. discovery and prosecution of criminal conduct if the researcher is obliged to disclose information relating to criminal activity by participants.
* Discomfort e.g. minor physical side-effects or negative feelings.
* Inconvenience e.g. giving up time to participate in the research project.

You should also describe any financial/non-financial costs of study participation.]

If no risks aside from inconvenience are anticipated, INSERT the following statement:

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

1. **Are there any benefits associated with being in the study?**

*[If there is any* ***direct financial or non-financial benefit to participants****, describe the amount and nature. Financial benefits may include reimbursement/remuneration such as a voucher or money, whilst non-financial benefits include meals, refreshments, course credit, and small gifts. Remember to be realistic about the potential benefits, and to describe any conditions of receiving them (e.g. whether participants have to complete the whole study to receive the benefits, and what happens if they withdraw halfway through). If the benefit is course credit, explain the alternatives to participation that are available (e.g. assignments).*

*Next describe any potential* ***benefits to others*** *in the future or to the broader community, being careful to distinguish these from any potential benefits to the participant themselves. Again, remember to be realistic and not over-state the potential benefits of the study.]*

*If no direct benefits to participants are expected INSERT the following statement:*

We cannot guarantee that you will receive any direct benefits from being in the study.

1. **What will happen to information about me that is collected during the study?**

*[This section needs to outline the following, in* ***lay language****:*

* *What types of information about participants will be collected and used in the study.*
* *If there will be any recordings taken (e.g. video or audio), an explanation of how these will be used (i.e. for analysis only, or also in publications).*
* *Details of any third parties who will have access to participants’ information during or after the study (e.g. transcription services).*
* *For internet research: details of any external service providers involved in data collection (e.g. online survey hosts) and their limitations in terms of privacy/data security/data ownership, and details about what electronic information will be collected from participants (e.g. their IP addresses, cookies, online server logs).*
* *Whether personal information will be kept confidential, and any limits to confidentiality (e.g. mandatory reporting, court orders or subpoenas, for research that may uncover illegal activity).*
* *Whether (and how) participants may access their personal information from the study.*
* *How and where study results will be published (e.g. student theses, journal publications, conference presentations, other reports).*
* *Where electronic and hardcopy data will be stored during and after the study and who will have access to it. If cloud or network storage will be used, describe any associated privacy/data security/data ownership limitations.*
* *How long data will be retained after the study and what will happen at the end of the storage period. That is, will data be kept in perpetuity (indefinitely), destroyed or archived? If you will archive the data, you should include the name of the archive(s).*
* *Whether the data collected in this project is intended to be used for any other purpose (e.g. future research projects, establishment of a research register/database, submission to a data sharing resource). This should also be declared in your ethics application.]*

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

*[INSERT ONE OF THE FOLLOWING]*

*[OPTION 1: where participants will NOT BE IDENTIFIABLE in publications]:* Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications*.*

*[OPTION 2: where it is intended to protect participants’ identities but there is a RISK THEY WILL BE IDENTIFIABLE in publications e.g. studies that focus on a small and specific cohort]:* Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published. Although every effort will be made to protect your identity, there is a risk that you might be identifiable in publications due to the nature of the study and/or the results.

*[OPTION 3: where participants will be given the opportunity to CHOOSE WHETHER THEY ARE IDENTIFIED in publications]:* Your information will be stored securely and your identity/information will only be disclosed with your permission, except as required by law. Study findings may be published, but you will not be identified in these publications unless you agree to this using the tick box on the consent form*.*

*[OPTION 4: where PARTICIPANTS WILL BE IDENTIFIED in publications e.g. oral history]:* Your information will be stored securely and will only be disclosed with your permission, except as required by law. Study findings may be published, and you will be identified in these publications if you decide to participate in this study.

*[INSERT* explanation of other points outlined above.*]*

*[INSERT, if applicable to your study, an explanation of any secondary purpose for which the data will/may be used in future. Some examples of standard wording are provided below. You may need to write your own if your intended other purpose deviates from these examples.]*

*Where data will/may be retained and used in future projects:* We will keep the information we collect for this study, and we may use it in future projects. By providing your consent you are allowing us to use your information in future projects. We don’t know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

*Where non-identifiable data will/may be submitted to a data sharing resource:* We intend to submit the information from this project to a public database for research information, so that other researchers can access it and use it in their projects. Before we do so, we will take out all the identifying information so that the people we give it to won’t know whose information it is. They won’t know that you participated in the project and they won’t be able to link you to any of the information you provided.

*Where non-identifiable data will/may be given to third party researchers:* We intend to give the information from this project to other researchers so that they can use it in their projects. Before we do so, we will take out all the identifying information so that the people we give it to won’t know whose information it is. They won’t know that you participated in the project and they won’t be able to link you to any of the information you provided.

1. **Can I tell other people about the study?**

*[INSERT one of the following]:*

*OPTION 1: Where there is no reason for participants not to tell others about the study]:*

Yes, you are welcome to tell other people about the study.

*[OPTION 2: Where there is some reason for participants not to tell others about the study]:*

Please don’t talk to other people about the study, because *[INSERT* reason].

1. **What if I would like further information about the study?**

When you have read this information, *[INSERT* name of appropriate investigator(s) who will be available at the time of consent*]* will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact *[INSERT* names, positions, university emails and phone numbers of at least one investigator. For overseas research, please include at least one local contact*].*

1. **Will I be told the results of the study?**

[Giving participants feedback about the **overall study results** (in a manner appropriate to a lay audience e.g. a one page lay summary) is standard practice, and is a key part of ensuring there is a fair distribution of the benefits of research participation. Feedback should be provided wherever possible. Of course, there may be some situations where this is not practicable. If this is the case, you should explain this in your ethics application and in the space below.]

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by *[INSERT* a description of how participants can indicate they are interested in receiving feedback *e.g. ticking the relevant box on the consent form, answering the relevant question in an online questionnaire].* This feedback will be in the form of *[INSERT* a description of the feedback that participants will be provided with, ensuring it is appropriate for the audience *e.g. a one page lay summary].* You will receive this feedback after the study is finished.

[On the other hand, providing participants' with feedback about their **personal results** will only be appropriate for certain types of studies, such as where results are likely to be of significance to the health of the participant, their family or community. Where very sensitive information is concerned (e.g. genetic testing, psychiatric assessment), it may be most appropriate to deliver these personal results through a nominated clinician.]

*[INSERT, if applicable to your study, a statement about any PERSONALISED FEEDBACK that participants are entitled to receive concerning their individual results in the study (e.g. diagnostic procedures, clinical tests, intelligence or aptitude testing). Be sure to distinguish between this type of feedback and the general group-based results described above. Include any conditions associated with this feedback (e.g. that participants’ personal results will only be provided to them through a nominated clinician such as a GP or psychologist) and explain when and how it will be provided.]*

1. **What if I have a complaint or any concerns about the study?**

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney *[INSERT* protocol number once approval is obtained*].* As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

* + **Telephone:** +61 2 8627 8176
  + **Email:** [human.ethics@sydney.edu.au](mailto:human.ethics@sydney.edu.au)
  + **Fax:** +61 2 8627 8177 (Facsimile)

*[INSERT, if applicable to your study, an* ***independent*** *local complaints contact for RESEARCH TAKING PLACE OVERSEAS/with participants who are located overseas – see section 4.8.16 of the National Statement. This should include their name, position and relevant contact details].*

# This information sheet is for you to keep