**REMOVE INFORMATION PAGES BEFORE SUBMITTING WITH APPLICATION**

Informed consent is required by all research participants. This means that a participant’s decision must be voluntary and based on adequate understanding of the research. The NHMRC National Statement on Ethical Conduct in Human Research paragraph 2.2 states: “Respect for human beings involves giving due scope to people’s capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as ‘the requirement for consent.”

However while informed consent is required by all research participants, there are many way to ensure participants are fully informed of the aims, requirements and risks involved in a study. There are also many ways to obtain consent. Consider the needs of **your** participants and how best to convey enough information about the study to allow informed consent (See Section 2.2 of the National Statement).

All participants must be clear on the aims of the study, what participation involves, risk and benefits of participation, how their data will be treated, and who they contact for complaints or questions. Keep this information simple and brief. Titles for projects should also be simple and easy for participants to understand.

This template is based on the requirements of the National Statement as well as the requirements of the ICH Harmonised Tripartite Guideline for Good Clinical Practice.

The Headings are to guide you for content that should be included. To ensure the information statement is easy to read we suggest you use the headings as they are in bold and provide the relevant information underneath. The Headings also help break up the text to make the information more readable and ensure all relevant points are included.

**In the template there are prompts for content in the dot points and suggested text in *blue italics*. Please address the dot points but it is not intended that they be answered as questions. Select the most appropriate suggested text in blue italics and format to standard type. Delete any blue italic statements that are not relevant to your project.**

**Carefully consider what is relevant and appropriate for YOUR project**

**The *red italics* are details you must enter relevant to your project. Delete the red italics prior to submission for review.**

Additionally please:

* Ensure you use plain language, short sentences and use “we” and “you”. It addresses the person directly, it is familiar and friendly and the tone is warmer.
* Use active rather than the passive voice
  + The active voice is more to the point and lively.
  + The passive voice makes your writing more long-winded.

|  |  |
| --- | --- |
| **🗸 ACTIVE** | **X PASSIVE** |
| We will send you a short report of the results | A summary of results will be sent to all study participants |
| We will take a small blood sample from your child | A small blood sample will be needed from your child |

Once you have finished please proof read your document. Get a friend or colleague to proof read as well to ensure consistency, spelling, simplicity and readability. Remember you need to aim your information sheet to a 13 year old reading level. The best guide is to get someone unfamiliar with your research to read it and make sure it can be easily understood.

**PARTICIPANT INFORMATION STATEMENT**

|  |  |
| --- | --- |
| **HREC Project Number:** | *The Ethics Office will advise you of this number after you have submitted your project* |
| **Project Title:** | *This must be in plain English and match the consent form title* |
| **Chief Investigator:** | *Insert the academic title, first name and surname, position of the principal researcher* |
| **Student researcher:** | *Only If appropriate to include* |
| **Version Number:** | *Must align with footer details* |
| **Version Date:** | *Must align with footer details* |

**What is the Project About?**

Briefly describe, in simple terms:

* The background to the research project (what you already know).
* Why you are doing it? (what earlier research hasn’t covered, what aspect your project will focus on).
* What your project aims to do? (how your project intends to fill the gap in knowledge).
* Why it is important? (how it may contribute to care, education, or research in the future).
* How many children, adolescents or adults will be taking part in the project?
* If it is a follow-up project or pilot project, state this.

**Who is doing the Research**?

* *The project is being conducted by {insert name}.*
* If the research will contribute to a higher educational qualification this must be stated.
* In accordance with the National Statement on Ethical Conduct in Human Research (2007) 2.2.6h you must state the sources of funding for this research project.

*This research project is funded by a grant from {insert}* ***or*** *the results of this research project will be used by {insert name} to obtain a Doctor of Philosophy at Curtin University and is funded by the University.*

* You must also state any costs of being involved in the project and any payment, such as:

*There will be no costs to you and you will not be paid for participating in this project.*

**Why am I being asked to take part and what will I have to do?**

* Explain why you are inviting this individual to take part. For example:

*We are looking for healthy volunteers OR you have been asked to take part because you have the condition we are researching.*

* Explain what their participation will involve

* Indicate the location of the study. If this is going to be determined later by appointment state:

*The study will take place at a mutually convenient location.*

* If you are using a questionnaire, give some information about the nature of the questions, for example

*We will ask you questions about {Insert text} such as how long you have had it and what makes it feel worse or feel better.*

* How often does the questionnaire need to be completed?
* How do they return a completed questionnaire? is it electronic, posted in, collected by hand
* How much time is required for each aspect associated with the project?
* Any additional costs or reimbursement must be stated, for example

*There will be no cost to you for taking part in this research and you will not be paid for taking part. We will give you up to {insert amount e.g. $25} to cover your car parking while you attend appointments*

* If participants are randomised to groups, explain how this will be done and what the differences are between groups .For example:

*We will put you in to one of 2 groups. Group 1 will (describe) and Group 2 will (describe). This will be done by chance, like tossing a coin. Neither you nor the researcher can choose which group you go in. (If it is a blinded study also state that for the length of the study neither you nor the researcher will know what group you are in)*

* If a participant needs to keep a diary or fill in a chart, explain this.
* If you are recording (video or audio) an interview, state this. For example:

*We will make a digital audio/video recording so we can concentrate on what you have to say and not distract ourselves with taking notes. After the interview/focus group we will make a full written copy of the recording.*

* If you are accessing medical records/ looking at data linkage/future research this will need to be explained and optional consent requested
  + Optional Consent: Access to Medical Records: *in this project we will collect and use health information that is in your medical records at (state location) for research purposes. The information we collect includes: (list).*
  + Optional Consent Data linkage: *in this project we would like your permission to let us link to other databases or organisations (give examples such as Midwives register/NAPLAN and Australian Early Development Index(AEDI)*
  + Optional Consent Future Research: *We would like you to consider allowing us to send you information about future research projects. Once you receive the information it is your choice if you decide to take part or not.* OR *We would like you to consider letting us share the information we collect during this research with other researchers working in this area.* Explain how the information will be shared (identified, re-identifiable or non-identifiable)

**Are there any benefits’ to being in the research project?**

* State if your project provides any benefits to the participant.
* If there are no direct benefits, this must be made clear to the participant. It is acceptable to state:

There may be no direct benefit to you from participating in this research.

* If your project gives people an opportunity to express an opinion or describe their feelings, condition or development, you might mention that:

*Sometimes, people appreciate the opportunity to discuss their opinions/ feelings/condition* (delete as applicable to your study).

* Explain how your project may benefit other people in the future e.g.,

*We hope the results of this research will allow us to:*

* + *develop education programs*
  + *prevent a condition*
  + *promote health*
  + *add to the knowledge we have about this condition*

**Are there any risks, side-effects, discomforts or inconveniences from being in the research project?**

* Describe all possible known risks, side-effects and/or discomforts. These can be physical and psychological/emotional. Do not sate that there are “no risks”. You can state:

*There are no foreseeable risks from this research project.*

* Explain how you will manage any risks or side-effects e.g.:

*Blood sampling can cause mild discomfort, bruising and sometimes light headedness; to minimise this, the sample will be collected by someone with training and expertise in the area and you will be able to sit/lie down during the procedure*.

* If the risk is psychological/emotional then state :

*We have been careful to make sure that the questions in the survey do not cause you any distress. But, if you feel anxious about any of the questions you do not need to answer them. If the questions cause any concerns or upset you, we can refer you to a counsellor.*

* If appropriate, include a sentence stating that there may be additional unforeseen or unknown risks. Tell participants how you will let them know about them for example:

*During the research project we may find out new information about the risks and benefits of this study. If this happens we will tell you the new information and what it means to you. It may be that this new information means that you can no longer be in the study or you may choose to keep going or to leave the study. You might be asked to sign a new consent form to let us know you understand any new information we have told you.*

* If your project is of a highly sensitive nature, consider including a telephone contact number of an appropriate agency in the event that a person does not participate yet may be unsettled by the invitation to participate. With a statement such as:

*Sometimes just thinking about {condition} can be upsetting. If you chose not to be in this research but feel distressed from considering it then please contact {insert Samaritans or Lifeline contact number)*

* Indicate what the inconveniences are including travel, time off school or work, time taken to fill in questionnaires etc. A statement such as :

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

* Mention any available compensation for time/travel, this should relate to re-imbursement such as for parking while attending research appointments.

**Who will have access to my information?**

**You need to explain**

* Whether the information is identifiable/re-identifiable or non-identifiable. Also consider at which stage of the project data might be identifiable, re-identifiable or non-identifiable (i.e., data collection, data use, data storage). Select from below standard statements as appropriate:
  + *The information collected in this research will be identifiable. This means that any information we collect that can identify you will stay on the information we collect and it will be treated as confidential and used only in the project unless otherwise stated. We can let others know this information only if you say so or if the law says we need to*

*All information will be stored securely (state where) at (state Curtin University or other institution)*

*The following people will have access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development*

* + *The information collected in this research will be re-identifiable (coded). This means that we will collect data that can identify you, but will then remove identifying information on any data or sample and replace it with a code when we analyse the data. Only the research team have access to the code to match your child’s name if it is necessary to do so. Any information we collect will be treated as confidential and used only in this project unless otherwise specified. The following people will have access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development*
  + *The information collected in this research will be non-identifiable (anonymous). This means that we do not need to collect individual names or information is anonymous and will not include a code number or name. No one, not even the research team will be able to identify your information. The following people will have access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development*
  + *We will ask for your name and email address when we collect the data, to allow us to contact you if you are the winner of our prize draw. This means the data we collect will be identifiable. However, after the prize draw we will remove all identifying information from the data. That means the data we analyse and the data we store will be non-identifiable, and we will have no way to identify your information.*
* How information will be stored? State that:

*Electronic data will be password-protected and hard copy data (including video or audio tapes) will be in locked storage.*

* How long the information will be stored and what happens at the end of the storage period? This needs to comply with the data management policy for WAUSDA, Curtin University and any collaborating institutions.

*The information we collect in this study will be kept under secure conditions at Curtin University for 7 years after the research is published and then it will be destroyed/kept indefinitely (select one).*

* Explain how you plan to discuss or publish the results e.g.:

*The results of this research may be presented at conferences or published in professional journals. You will not be identified in any results that are published or presented.*

* Include statement about focus groups if you are using them:

*Whilst all care will be taken to maintain privacy and confidentiality of any information shared at a focus group or group discussion, you should be aware that you may feel embarrassed or upset if one of the group members repeats things said in a confidential group meeting.*

**Will you tell me the results of the research?**

* A summary of the project’s overall results should be sent to participants and their families (if children).
* Let participants know if you are sending group results or individual results.
* If possible, state an approximate time when results will be sent.

*If you are interested in obtaining a summary of the results please contact the researchers after {insert approx. date results will be available} OR*

*We will write to you at the end of the research (in about X months) and let you know the results of the research. Results will not be individual but based on all the information we collect and review as part of the research.*

* Describe where else you may make the results available (e.g. publication, website, newsletter).

**Do I have to take part in the research project?**

* Must state the following:

*Taking part in a research project is voluntary. It is your choice to take part or not. You do not have to agree if you do not want to. If you decide to take part and then change your mind, that is okay, you can withdraw from the project. If you choose not to take part or start and then stop the study, it will not affect your relationship with the University, staff or colleagues.* (Particularly important if recruiting via Curtin University staff and/or students.)

Consider the limits on withdrawal as they apply to your study. For example, in an anonymous questionnaire participants can withdraw their *participation* prior to submitting their responses. They can do this by simply closing the browser. However, as data are anonymous they cannot withdraw their *data* after their responses have been submitted.

In interview studies, if transcripts are de-identified after member checking, you might say that:

*You are free to withdraw from the study prior to approving your transcript*

For trials you might add: *You do not have to give us a reason; just tell us that you want to stop. Please let us know you want to stop so we can make sure you are aware of any thing that needs to be done so you can withdraw safely.*

*With your permission, if you chose to leave the study we will use any information collected unless you tell us not to.*

Or one of the alternative sentences below:

* + *We will destroy any information we have collected from you*
  + *We will be unable to destroy your information because it has been collected in an anonymous way*
* If it is an interventional study and there is an alternative to participation which is just to receive the standard of care treatment this must be explained (for example if the project is an exercise intervention the alternative is to continue to receive whatever treatment your health care provider recommends)

**What happens next and who can I contact about the research?**

* Provide a title, first name and surname for the most appropriate researcher or contact person to obtain further information or answer questions.
* Give the most direct telephone number.
* Do not provide personal mobile numbers
* Describe how you will obtain their consent:

*If you decide to take part in this research we will ask you to sign the consent form. By signing it is telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the consent form to keep.*

* Note how participants can access the information and consent form if an online study
* If appropriate explain how they can indicate consent at the start of a questionnaire by ticking a box.

*At the start of the questionnaire, available via the link provided, there is a checkbox to indicate you have understood the information provided here in the information sheet.*

**The following statement must be included in every information sheet:**

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number XX/XXXX). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.