Participant Information Form

This template is based on the requirements of the National Health and Medical Research Council National Statement of Ethical Conduct in Human Research.

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.

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 project to read it and make sure it can be easily understood.

Refer to the example information forms provided on the SiREN website, these will give you a sense of how they can be formatted and designed (although design is not a requirement).

This template has been adapted from: Curtin University. Good research practice guidelines: Participant information form template. Perth, Western Australia: Curtin University 2017 [Available from: http://research.curtin.edu.au/ethics-integrity/human/guides-help/.

Template for Participant Information Form

PARTICIPANT INFORMATION STATEMENT

What is the project about?

Briefly describe, in simple terms:

- The background to the project.
- Why you are doing it?
- What your project aims to do?
- Why it is important?
- How many children, adolescents or adults will be taking part in the project?

Who is doing the project?

- *The project is being conducted by (insert name).*
- You must 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.
- Explain what their participation will involve.
- Indicate the location of the project. 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 or 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 project 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 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.*

Are there any benefits' to being in the 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 project.*
- Explain how your project may benefit other people in the future e.g.,
  We hope the results of this project 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 project?

- Describe all possible known risks, side-effects and/or discomforts. These can be physical and psychological/emotional. Do not state that there are "no risks". You can state: *There are no foreseeable risks from this 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 or 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 they do not need to answer them. If the questions cause any concerns or upset you, we can refer you to a counsellor.*
- 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 project 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 project appointments.

Who will have access to my information?

You need to explain

- Whether the information is identifiable/re-identifiable or non-identifiable. Select from below standard statements as appropriate:
  - *The information collected in this project 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. All information will be stored securely (state where) at (state agency or other institution). The following people will have access to the information we collect in this project: (state who).*
  - *The information collected in this project will be re-identifiable (coded). This means that the stored information will be re-identifiable which means we will remove identifying information on any data or sample and replace it with a code. 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 project: the (state who).*
  - *The information collected in this project 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 project team will be able to identify your information. Any information we collect and use during this project will be treated as confidential. The following people will have access to the information we collect in this project: the (state who).*

- How information will be stored? For example: *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?
- Explain how you plan to discuss or publish the results e.g.: *The results of this project will be written up into a report.*
- 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 project?

- Let participants know if you are providing them with the results of the project.
- Describe where else you may make the results available (e.g. publication, website, newsletter).

Do I have to take part in the project?

- Must state the following: *Taking part in the 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. 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. If you choose not to take part or start and then stop the study, it will not affect your relationship with the organisation. 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.*

What happens next and who can I contact about the project?

- Provide a title, first name and surname for the most appropriate contact person to obtain further information or answer questions.
- Give the most direct telephone number.
- Describe how you will obtain their consent: *If you decide to take part in this project 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 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.*
- 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.*