

Template for Survey/Questionnaire Participant Information Statement and Consent Form

Instructions for Creating a Participant Information Sheet and Consent Form

All research participation requires informed consent. 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’.”

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, we have provided **in bold** and set out 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. The template looks long but there is likely to be information that is not relevant to your study that can be deleted.

The red italics are details you must enter relevant to your project. Delete the red italics and save as black text prior to submission for review.

Additionally please:

- Ensure you use plain, non-technical 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.

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



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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.

These instruction pages do not form part of your completed Information sheet /consent form. Please delete the instruction pages prior to submission for HREC review and ensure the page numbering of your submitted document begins at '1'.

SAMPLE



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Project Title: *This must be in plain English and match the consent form title*

Principal Investigator: *Insert the academic title, first name and surname, position of the principal researcher*

Student researcher: *Only If appropriate to include*

What is the Research About?

Briefly describe, in simple terms:

- The background to the research project (what you already know).
- Why you are doing it? (What earlier projects haven'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.
- If your study involves blood testing for genetic studies please refer to standard wording available on the interventional study template

Who is doing the Research?

- *{Insert name to align with PI stated on the first page} is conducting this research.*
- 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 {insert company name}

OR

This study has been started by the investigator

OR

This study has been started by the investigator together with colleagues from {insert}.

OR

Funding for this study has been provided by {insert grant details or supporting institution details}.

OR

The results of this research project will be used by {insert name} to obtain a Doctor of Philosophy at {insert}University and is funded by the University.

Why is my child being asked to take part and what will they have to do?

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



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We are looking for healthy volunteers OR Your child is being asked to take part because they have {insert the name of the condition being researched}.

- Include duration of study participation and how much time is required for each aspect associated with the project

Your child will have {insert number} study visits over a period of {insert timeframe}.

- 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 your child has had it and what makes it feel worse or feel better.

- How often does the questionnaire need to be completed?
- Is it completed at home or in the clinic?
- 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 we will not pay you for taking part.

We will give you up to {insert amount eg\$25} to cover your car parking while your child attends appointments.

- If participants will be randomised standard wording is available on the interventional study template
- 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*



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this area. Explain how the information will be shared (identified, re-identifiable or non-identifiable)

Does my child have to take part in the research project?

- Must state the following:

Taking part in a research project is voluntary. It is your choice for your child to take part or not. You do not have to agree if you do not want to. If you decide to let your child take part and then change your mind, that is okay, you can withdraw them from the project. You do not have to give us a reason; just tell us that you want your child 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 your child can withdraw safely. If you chose not to let your child take part or start and then stop the study, it will not affect your child's access to treatment or your relationship with the doctors and staff at PMH.

If you chose for your child to leave the study

- *we will use any information collected up until your child leaves the study. This is to ensure that the results of the research can be measured properly and comply with the law.*

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)

Are there any benefits to my child from being in the research project?

- State if your project provides any benefits to the child.
- If there are no direct benefits, this must be made clear to the parent. It is acceptable to state: *There will be no direct benefit to you/your child 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, children appreciate the opportunity to discuss their opinions/ feelings/condition* (delete as applicable to your study).
- Explain how your project may benefit other children in the future eg *We hope the results of this research will allow us to:*



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- *develop education programs about {identify the purpose of the education program}*
- *prevent /find a better way to treat {the condition being researched}*
- *promote health*
- *Add to the knowledge we have about {the condition being researched}*

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 state that there are “no risks”. You can state:

There are no foreseeable risks from this research project.

Or

There are no risks of physical injury associated with your child's participation in the study.

- 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.

- Explain how you will manage any risks or side-effects eg :

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 your child will be able to sit/lie down during the procedure. We can use a cream to numb the skin to decrease the discomfort. There will only be a maximum of 2 attempts to get the blood sample, at each visit.

OR

We can arrange the study visits to be out of school hours to minimise any inconvenience to you and your child.

- If the risk is psychological/emotional then state :

We have been careful to make sure that the questions in the survey will not cause you or your child any distress. But, if they 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 your child 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
- 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 let your child be in this research but feel distressed from considering it, then please contact {insert Samaritans or Lifeline contact number}

Who will have access to my child's information?

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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 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 you have agreed to another use. We can let others know this information only if you say so or if the law says we must.*
All information will be stored securely (state where) at (PMH or other institution)
The following people will have access to the information we collect in this research: the research team and the PMH Ethics office representative.
 - *The information collected in this research will be re-identifiable (coded). This means that we will remove identifying information on any data or sample and replace it with a code. Only the research team have access to the code to match the data or sample to your child's name, if it is necessary to do so. Any information we collect we will treat as confidential and only use it in this project unless you have agreed to another use. The following people will have access to the information we collect in this research: the research team and the PMH Ethics Office representative.*
 - *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. Any information we collect and use during this research will be treated as confidential. The following people will have access to the information we collect in this research: the research team and the PMH Ethics office representative.*
- If Biological samples collected, you must distinguish between routine care samples and research samples.
Your child's samples may be/will be sent to another laboratory for testing {insert name of Lab if it is known}. Any samples sent from PMH are labelled with your child's code number only {if applicable}. It will not be possible for the testing laboratory to identify your child's sample.
Australian laws and regulations do not protect any samples sent overseas.
- 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 PMH/ Department of Health (Patient Information Retention and Disposal Schedule Version 4, 2014) and any collaborating institutions.
Research information that identifies study participants and patients will be stored, managed and disposed of in accordance with the relevant Departmental Recordkeeping Plan. The number of years

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that patient information is retained depends upon various factors including the age of the study participant and the type of research being conducted.

OR

Research information that is non-identifiable (anonymous) will be stored, managed and disposed of in accordance with the relevant Departmental Recordkeeping Plan.

- Explain participant's right to access information:

You have the right to access, and request correction of, your child's information in accordance with relevant privacy laws.

- 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. Your child 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 your child may feel embarrassed or upset if one of the group members repeats things said in a confidential group meeting.

Will you tell us the results of the research?

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

We are not able to send you any results from this research, as we do not collect any personal information to be able to contact you.

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)

What happens if my child needs emergency medical treatment while enrolled in this study?

- State process for emergency care during study participation

As discussed, the study is non-interventional and therefore poses no risk/minimal risk (select as appropriate) to your child. Nonetheless, if your child suffers an accident or illness while at the



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hospital and requires emergency medical care, your child will be offered all full and necessary treatment from the hospital.

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

- Describe how you will obtain their consent:

If you decide to let your child take part in this research, we will ask you to sign the consent form. By signing you are 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 their health information used as described. Please take your time and ask any questions you have before you decide what to do. We will give you a copy of this information sheet 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.

- 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 (avoid using the hospital switchboard if possible).

The following statement must be included in every information sheet:

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the PMH HREC. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). If you have any concerns and/or complaints about the project, the way it is being conducted or your rights or child's rights as a research participant, and would like to speak to someone independent of the project, please contact:

The Executive Director of Medical Services at PMH on 09340 8222.

Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

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CONSENT FORM

Project Title: *This must be in plain English*

Principal Investigator: *Insert the academic title, first name and surname, position of the principal researcher*

Student researcher: *Only if appropriate to include*

- I have read, or had read to me the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of {*my child's/Our - as appropriate if there is child/parent participation*} involvement in this project.
- I voluntarily consent to my child taking part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by PMH Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – updated March 2014.
- I understand I will receive a copy of this Information Statement and Consent Form.

Child's Name (if appropriate, delete if using separate assent form)	Child's signature	Date
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Parent's Name	Parent's Signature	Date
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Declaration by researcher: I have supplied an Information Sheet and Consent Form to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name	Research Team Member Signature	Date
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Note: All parties signing the Consent Form must date their own signature.

The following are examples of additional consent statements. If they are applicable to your study, they should be included on the consent form prior to the signature panel.



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Examples of optional consent tick boxes

If you are offering consent choices, information about each option **MUST** be described in Section “What am I being asked to do?” of the Information Statement under a heading titled OPTIONAL CONSENT

Please cut and paste the relevant statement to the consent page to precede the signature panel; ensure all relevant check boxes are completed and initialled.

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to being video-recorded
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to being audio-recorded
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to being photographed
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent for the researchers to contact my GP/family doctor
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to the researchers accessing my medical record
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent for the researchers to contact my child’s school teacher
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to data linkage
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to be contacted about future research projects that are related to this project
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to the storage and use of my information in future ethically-approved research projects related to this (project/disease)

FOR USE IN PROJECTS WITH IMPLIED CONSENT

Please insert the following tick box at the top of your questionnaire.

I have received information regarding this research and had an opportunity to ask questions. I believe I understand the purpose, extent and possible risks of my involvement in this project and I voluntarily consent to take part.