Interventional Study 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

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 competed 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'.

Interventional Study Participant Information Statement and Consent Form

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

Principal Investigator: *Insert the academic title, first name and surname, include position of the principal researcher (for example anaesthetist/ emergency department consultant etc.)*

Student researcher: *Only If appropriate to include, delete if not applicable*

Please take the time to read the following information carefully and discuss it with your family, friends and family doctor if you would like to. This information will explain to you what the study is about, what participation for your child involves and any risks or benefits of participation. It will also explain any alternatives to participation and your rights and responsibilities. Once you have read and understood the information, take time to decide what you would like to do.

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.)
- Include the current registration status of each drug/device to be used in the research making the distinction between registration in Australia and overseas and if it is approved in this indication or another. Include whether or not the drug/device is approved for use in children

{Name of drug/device} is not approved for use in Australia by the Therapeutic Goods Administration (TGA) to treat {condition}, or by other regulatory authorities around the world. The use of {name of drug/device} is an experimental treatment. This means that it must be tested to see if it is an effective treatment for {condition}.

OR

{Name of drug/device} is approved in Australia to treat {other condition}. However it is not approved to treat {condition}. This means that {name of drug/device} is an experimental treatment and needs to be tested to treat {condition}.

- Why is this research 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 includes genetic research a description of what genes are and what the research is looking at must be included:

Our bodies are made up of different types of cells. Inside these cells you find genes. Genes are passed down in families from parents to children: you get half your genes from your mother and half

from your father. Our genes contain all the information that makes us what we are, including our eye colour, blood type, and height and whether we are born as a boy or a girl.
There are about 23,000 genes that make up a human being and genes are arranged along a chemical substance called DNA. Sometimes a gene contains a 'spelling mistake' (also called a variation) that upsets the gene's coded message. This makes the gene not work properly and is known as a mutation or change.
Many health conditions or diseases are caused by a change in one or more genes. These conditions may be present at birth or may appear later in life.
Genetic research involves testing and studying genetic material, usually DNA. Genetic research is done for many reasons including finding out why some diseases run in families and how it is passed on from one generation to the next, working out the chance of a future baby having a genetic condition, and discovering more accurate ways of predicting disease in a group of people or where there is a strong family history of a disease.
In this research, we will be doing genetic research to look at {insert information}

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 sponsor name}. {Insert sponsor name} is a company that make medicines/devices. {Insert sponsor name} pays the Child and Adolescent Health Service to run this study. All money paid goes to the hospital to cover the costs of equipment, tests and staff to run this study.

OR:

This study has been started by the investigator.

OR

The Investigator together with colleagues from {insert} has started this study.

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 name} University and is funded by the University.

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

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

We are looking for healthy volunteers OR your child has been asked to take part because they have {insert 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}.
At these visits your child will have {insert type of tests/procedures}. Each visit will take approximately {insert time frame}
OR
Your child will have {insert number} study visits over a period of {insert timeframe}.What will happen at each visit and how long that will take is as follows:

1. *At the first visit {explain what will happen and how long it will take for each visit in a series}*

- Explain what their participation will involve include
  - any screening for eligibility,
  - medication wash out periods
  - all study procedures including a description of any tests or scans and blood or tissue samples that will be collected, include the number of times each procedure will be repeated and the amount (or volume) of samples collected
  - method of medication administration or device monitoring
- Any pregnancy testing if required

If your child is a girl who has reached puberty and is able to have children, she will have a {blood/urine} pregnancy test. Girls must have a negative pregnancy test to be able to take part in this project.

- 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.
OR
All study visits will take place at {insert department} at {insert 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?
- Is it completed at home or in the clinic?
- How do they return a completed questionnaire? Is it electronic, posted in, or collected by hand
- If participants are randomised to groups, explain how this will be done and what the differences are between groups .For example:

We will put your child in to one of 2 groups. Group 1 will (describe what will be given) and Group 2 will (describe what will be given including no treatment/standard treatment or placebo).A placebo is a medication with no active ingredients. It looks like the real thing but it is not.

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 the parent nor the researcher will know what group the child is in)

- If a participant needs to keep a diary or fill in a chart, explain this.
- If you are accessing medical records

In this project we will collect and use health information that is in your child's medical records at (state location) for research purposes. The information we collect includes: (list information and include scans/images/results).

- Clarify what is required regarding other treatments or medications

It is important to tell us about any treatments or medicines your child may be taking. This includes prescription and over the counter medicines or any herbs or vitamins or other treatments. You also need to tell us if these change while your child is taking part in the study.

If Applicable:

Your child may not be able to take some of their usual treatments or medicines while they are on the study. The study doctor will explain all this to you and make sure you understand what medicines need to be stopped.

- Informing the Child's GP:

We will tell your child's GP that your child is taking part in this study because (state why it is important to inform the child's GP i.e. he /she will need to know the medication your child is taking on this study).

- After the study ends: explain if the drug/device will be available after the end of the study:

After the study has ended:

  - *the drug will not be available until it is registered in Australia*

OR

  - *your child may be able to take part in an extension study to continue taking the study drug*

- If you are looking at data linkage/future research this will need to be explained and optional consent requested
  - Optional Consent Data linkage: *We would like your permission to let us link to other databases or organisations (identify the relevant database 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)

    OR *We would like you to consider letting us store any leftover blood samples collected as part of this study for us in future research related to {condition}. The ethics committee*

will have approved any research. If you give your permission we will store your child's blood sample at {institution} for an indefinite period of time. The sample will be stored using an ID number and your child's name will not be on the sample. We do not plan to contact you or your child if the sample is used in future research. Please indicate in the appropriate area on the consent form if you agree to this or not.

- **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.
OR
We will give you up to {insert amount} to cover travel expenses such as car parking while you attend study appointments

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 doing 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 CAHS in any way.
If you chose to withdraw your child from the study we will continue to 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 this must be explained, consider the following:

Your child's alternatives to taking part in this study are:

- *Standard treatment*
- *Taking part in another study (if applicable)*
- *No treatment and comfort care only*

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

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

There will be no direct benefit to your child from participating in this research.

- If your project gives people/children 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 e.g.

We hope the results of this research will help us to:

- *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.
- *Medical treatments often have side effects. Your child may have none, some or all of the side effects listed below. They may be mild moderate or severe. If your child has any of these side effects or you are worried about them, talk with the study doctor. We will also be looking out for side effects.*
- *It is possible that your child may develop a side effect that the researchers do not expect or do not know about yet and that side effect might be serious. Tell the study doctor immediately about any new or unusual symptoms that your child has.*
- *Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, we may need to stop your child's treatment. We will talk to you and your child about the best way of managing any side effects.*
- *Please call us straight away if your child feels unwell in any way or has any of the symptoms listed below. You should also call us if you notice something that worries you about your child.*

Very common	Common	Uncommon	Rare	Very rare
affects more than 1 in 10 patients	affects between 1 and 10 in every 100 patients	affects between 1 and 10 in every 1,000 patients	Affects between 1 and 10 in every 10,000 patients	Affects between 1 and 10 in every 100,000
•	•	•	•	•

- 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 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.

- 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 you or your child feels anxious about any of the questions they do not need to answer them. You can tell us at any time to stop the questionnaire or, if you are completing the questionnaire at home, you can contact us. 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 for your child. It may be that this new information means that your child 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.

- Reproductive Risks; The following wording should be included as appropriate to your study:
  - *If your child is of childbearing age, it is important to be aware that the drug treatment in this project can affect an unborn baby.*
  - *Your child should not become pregnant or father a baby while in this project. We can advise on appropriate contraceptive methods, if you or your child wishes.*
  - *Your child should not breastfeed a baby while in this project.*
  - *Your child must agree not to take contraceptive pills because of possible effects of the drug treatment. Your child must use some other form of contraception instead.*
  - *We can give your child more information about preventing pregnancy.*
  - *If your child becomes pregnant during the project, we need to be told immediately.*
- Any risks from interventional treatment related to potential future fertility should also be listed if not included in previous table

Genetic test Risks:

If your research includes genetic testing please review the possible information sheet content below and select the relevant statements most appropriate to your research. It is important to consider if results from the research, including incidental findings, will be made available to the participant and their family. The information provided under genetic testing risks should also be carefully considered. To be able to consent to genetic testing all the implications of the testing must be clear to the participant and/or the parent.

Genetic tests

We will look at your child's genes for features relevant to the research project, and not for any other purpose.

Genetic test results – no results being given

We will not give you or your child the results of any genetic tests because it is not known how reliable the results are.

Genetic test results – results will be given

The genetic tests results will be available if you would like to know them. It is your choice to be informed of the results. It is important that you read the information about genetic test risks carefully so you can make an informed decision. If you decide to get your child's test results, genetic counsellors are available to help you through the process, at no cost to you.

(Please ensure your protocol has details of genetic counselling management related to research related results, incidental findings and confirmation of results before inclusion of this statement in the information sheet. Please also ensure there is an optional consent check box to indicate if the participant does/does not wish to receive the results.)

Genetic testing risks

Genetic testing can raise important issues. Although we do not expect many issues to arise, you should be aware of this and think carefully before agreeing to let your child participate.

- *It is important to understand that the results from genetic research may not show that a person has a particular condition or whether they will develop it. Research may only show that a person has an increased risk of developing a condition. Even then, there is no guarantee that a person will develop the condition, or show when they may get the condition or how serious it may be.*
- *We are only searching for genes that are related to [condition], but it is possible that we may find genes responsible for other genetic conditions that you do not know about. Any research results that could be of significance to your child or your family will need to have the tests repeated and the results verified. This will involve having a blood sample taken and having it retested in an accredited testing laboratory. This is standard practice for all patients receiving the results of genetic testing and would be provided free of charge.*
- *On rare occasions, we may find a genetic change unrelated to the research that could have implications for your child's health. Any research results that could be of significance to your child or your family will need to have the tests repeated and the results verified. This will involve having a blood sample taken and having it retested in an accredited testing laboratory. This is standard practice for all patients receiving the results of genetic testing and would be provided free of charge.*

- *It is possible that we will find a change in your child's genes but not know for certain if it is important or how it relates to [condition/disease]. If we find a change in their genes that we are certain about, your doctor will contact you to talk about it.*
- *If something is found in the genetic testing, you may need to tell your child about this sometime in the future. You will be able to talk to your child's doctor about these issues.*
- *The genetic tests we do may tell us something about you or your wider family. Learning about the results from genetic research may affect you and your family emotionally and could interfere with family relationships. You may need to decide about telling your family about the genetic results. Family members may or may not wish to know this information.*
- *Some people in your family might want to know about your child's results and whether the result has implications for them. Results will only be provided with your permission.*
- *Your child may need to tell insurance companies or employers in the future of any genetic information that they learn about themselves through this project.*
- *By chance, we may discover that parents and children or siblings may not be biologically related. Information regarding paternity or maternity will not be available through this project.*
- *Some people find it stressful to get information about their child's genetic make-up and future health. There is also the possibility that genetic information may be important in understanding the risks of having a child with [condition] in the future.*
- *If you want to talk about any personal issues or need supportive counselling as a result of your child's participation in this study, we can refer you to an independent genetic counsellor who is available to you free of charge. We are also available to discuss any concerns you may have.*
- *While all attempts will be made by the investigator to contact study participants, their parents or their GP if important medical findings are identified from contributed samples, there may be occasions when this is not possible.*
- *We will keep test results private but we cannot guarantee complete confidentiality. Because some genetic conditions are very rare it may be possible to identify test results to the person who gave the sample.*
- Risks associated with scans/tests as part of research include the discovery of unexpected findings

The scans we are taking are for research purposes. They are not meant to be used to help diagnose, treat or manage a particular medical condition. After the scan a radiologist will look at your child's scans for unusual features or unexpected findings. If the radiologist finds something that needs further examination, a referral to an appropriate medical doctor will be organised. The discovery of an unusual feature could have consequences for your child and may affect their ability to work in certain professions or get life insurance cover. However, the discovery of an unusual feature may also help your child get treatment that may be of benefit.
If anything unexpected is found on your child's MRI scan, we will contact you to talk about it.

Please take time to consider the advantages and disadvantages of discovery of a health risk before deciding to let your child take part in this research project.

- Risks associated with Anaesthesia

Anaesthesia is generally very safe but there are some risks associated with it.
The most common problems of anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Some children may have a fear of and become upset by the procedure. Most patients do not have these problems. If these problems do happen, they usually get better very quickly.
Anaesthesia can cause problems that are more serious where damage may be permanent, but this is rare. Damage to the teeth is less common in children than in adults. The risk of brain damage or death due to anaesthesia is very rare.
The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss this with the anaesthetist looking after your child.

- Radiation Risks

  If radiation procedures fall outside of standard clinical care, they need separate review by the Radiation Safety Officer at RPH. If required it will be forwarded to the Radiological Council for review. After review a statement regarding risk will be provided and relevant information should be included in the information sheet.

Who will have access to my child's 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 research will be identifiable, this means that any information we collect that can identify your child will stay on the information we collect. We will treat it as confidential and only use it in this 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, for example Respiratory Department at CAHS).
    The following people will have access to the information we collect in this research: the research team and a representative of the CAHS Ethics Office.
  - *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. No personal information about your child will leave the hospital. Any information we collect we will treat as confidential and only use*

in this 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.
The following people will have access to the information we collect in this research: the research team and a representative of the CAHS Ethics Office.

- *The information collected in this research will be non-identifiable (anonymous). This means that we do not need to collect individual names or the 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 child's 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 a representative of the CAHS Ethics Office.*

- If a sponsored study:

Occasionally, at any time during or after the study, your child's health records and any information collected during the study may be inspected by representatives of the sponsor company and health authorities(such as the Therapeutic Goods Administration). These representatives will be granted direct access to your child's medical records so that they can confirm that the information collected during the study is accurate. By signing the consent form you authorise access to this confidential information to the relevant study personnel and regulatory authorities.

- 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 CAHS 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 CAHS/Department of Health (Detail can be found in the 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 Record keeping Plan. The number of years that patient information is retained depends upon various factors including the age of the study participant and the type of research being conducted.

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.

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 participants/families 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).

If a clinical trial, include the web address where the study is registered.

Can the research be stopped unexpectedly?

- State any Stopping rules you are aware of, consider the following.

The research may be stopped for a variety of reasons. This may include the following:

- *If your child has side effects from the treatment that are too severe*
- *If your child becomes pregnant*
- *If the study treatment is shown not to be effective*
- *If the study treatment is found to be effective and the testing can stop*
- *If your child does not come to the study visits and follow the study instructions*
- *If the sponsor stops the study unexpectedly. (You must clearly state any sponsor stopping rules per protocol)*

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

- State process for emergency care during study participation

If your child suffers an accident or illness while at the hospital and requires emergency medical care, your child will be offered all full and necessary treatment from the hospital. If the medical emergency occurs during your child's participation in the study, the research team will ensure that the necessary medical care is given.

Compensation

Wording for commercially sponsored trials regarding compensation for injury will be provided by the study sponsor for inclusion in the information sheet. Please ensure it is included under a separate heading or sub heading to distinguish it from emergency medical treatment.

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 for your child 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. You will be given a copy of this information sheet and the consent form to keep.

- Provide a title, first name and surname for the most appropriate researcher or contact person to obtain further information or answer questions.

Dr/Prof/Mr/Mrs/Ms {insert name} can be contacted on {insert phone number} to answer any questions you have about your child's participation in this research.

- Give the most direct telephone number (avoid using the hospital switchboard if possible).
- If you are using a participant information card explain that contact details will also be available on the card
- If a 24 hour contact number is required please test the process for 24hr contact and make sure it works

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 Child and Adolescent Health Service 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 child's rights as a research participant, and would like to speak to someone independent of the project, please contact:

The Director of Clinical Services at CAHS via the switchboard on 6456 2222

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

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. The discussion has included my child to the level of their understanding.
- I believe I understand the purpose, extent and possible risks of my/my child's involvement in this project.
- I voluntarily consent to taking part/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 the Child and Adolescent Health Service Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) –inclusive of any updates...
- I understand I will receive a copy of this Information Statement and Consent Form.

Child's Name (If deemed to be a mature minor) | Child's signature | Date

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Parent's Name | Parent's Signature | Date

Declaration by researcher: I have supplied an Information Sheet, version listed as above, and Consent Form to the participant/parent who has signed above, and believe that they understand the purpose, extent and possible risks of their/their child's involvement in this project. Where the participant is a child, not assessed as a mature minor, I have explained their participation at an age appropriate level which may have included the use of a simplified information sheet to guide discussion with the child.

Research Team Member Name | Research Team Member Signature | Date

Note: All parties signing the Consent Form must date their own signature.

Examples of optional consent boxes

If you are offering consent choices, information about each option MUST be described in Section "**Why is my child invited to take part and what will they have 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.

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