**Participant Information Sheet/Consent Form**

**Interventional Study** -*Parent/Guardian consenting on behalf of participant*

An **Interventional Study** is defined as administration of a drug, device or procedure that is not part of routine care, including all phases of a clinical trial.

A Participant Information sheet should be aimed at parents/guardians when the potential participant is a child. Refer to *The National Statement on Ethical Conduct in Human Research* (Chapter 4.2) for more information. Consideration should also be given to explaining the procedure to the child themselves in a manner appropriate to their maturity level.

**Instructions for Creating a** **Participant Information Sheet/Consent Form**

⮞ **This template is a guide only.**

⮞ For projects that do not involve trialling a clinical drug, procedure or device, one of the other participant information and consent form templates should be used.

⮞ If more than one Participant Information Sheet/Consent Form is required for your research project, please label the different forms clearly for the different participant groups. Please note that if there is a sub-study, a separate form is required.

⮞ There are 20 numbered sections in this template. Please ensure that all relevant sections are included and numbered appropriately in your final document. These headings are included to ensure that all the National Statement and ICH/GCP elements are addressed.

⮞ You should delete any headings and sections that are not relevant to your study and/or modify paragraphs so that they are relevant to your study.

⮞ In this template, there are prompts for the content of your Participant Information Sheet/Consent Form (in *orange italics*) and instructions regarding the format of your document (in *blue italics*). Please ensure that you delete all prompts (*orange italics*) and instructions (*blue italics*) from the final document.

⮞ **Preferred language** recommendations for use in your Participant Information Sheet are in black text with a border around paragraphs. Ensure that the border is removed from the ‘Preferred language’ sections in the final document. Note that this formatting does not apply to section 20 or to the Consent Form.

⮞ If institutional letterhead/logo is to be used, leave space for the letterhead/logo in accordance with the institution’s requirements.

⮞ Include the version date of the document in the footer of each page. Do not use the ‘automatic’ date insertion function (see over).

⮞ Use the ‘1 of X’ pagination option. Ensure that all references to version date or pagination in the text are correct and consistent with the information in the footer (see over).

⮞ Do not include a place for initialling the document on each page.

⮞ Study participants should be referred to as ‘participants’ and not ‘subjects’ or ‘patients’.

⮞ References to the National Statement (NS) and ICH/GCP Guidelines are noted in relevant sections as footnotes for your information only and do not need to be included in the final document.

⮞ This guide proposes preferred language for some sections of the Participant Information Sheet/Consent Form. This preferred language may be the totality of what is required for the section or it may be a series of suggested phrases to be used along with other information in the section, as indicated by the guidelines pertaining to the section.

⮞ The reviewing institution may have additional preferred language or standard clauses that you are required to include. Please check with the relevant HREC administration to determine whether additional requirements apply.

⮞ Language used should be readily understandable by the parent/guardian (Grade 8 reading level or below) and include Australian spelling of words.

⮞ If translated Participant Information Sheet/Consent Forms are to be used, please check with the relevant HREC administration in case additional requirements apply.

⮞ You should state whether an interpreter will be used in the consent process and/or during the collection of data.

⮞ Text should be at least font size 11 in an easily readable font style.

⮞ Ensure that all font styles and sizes, bolding, italicisation and underlining are intended and that any variations are consistent throughout the document.

⮞ **Please ensure that your final document is proofread.**

 This space is reserved for use by jurisdictions or institutions for instructions regarding version control of Participant Information and Consent Forms or other matters specific to jurisdictions or institutions.

*Insert Header with institution’s name or institution’s letterhead*

**Participant Information Sheet/Consent Form – Parent/Guardian**

**Interventional Study** -*Parent/Guardian consenting on behalf of participant*

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/ Principal Investigator** | *[Coordinating Principal Investigator/**Principal Investigator]* |
| **Associate Investigator(s)***(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location]* |

**Part 1 What does the child’s participation involve?**

*The purpose of Part 1 is to state the reason the participant is being invited to take part in the research project and to explain the purpose of the study and what it will involve.*

**1 Introduction**

*The purpose of this section is to state the reason the participant is being invited to take part in the research project and to explain the purpose of the form and the nature of informed consent.*

This is an invitation for the child in your care to take part in this research project because they have *[Name of condition]*. The research project is testing a new treatment for *[Name of condition]*. The new treatment is called *[name of treatment]*.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want the child to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not the child can take part, you might want to talk about it with a relative, friend or the child’s local doctor.

Participation in this research is voluntary. If you do not wish the child to take part, they do not have to. The child will receive the best possible care whether or not they take part.

If you decide you want the child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to the child taking part in the research project

• Consent for the child to have the tests and treatments that are described

• Consent to the use of the child’s personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

*Briefly describe the following aspects of your project in simple terms and in only a couple of sentences for each point:*

*• Aim of the study and its significance.*

*• How your project intends to fill any gap in knowledge.*

*• How it may contribute to care or education or research in the future.*

*• Any relevant background including what is already known.*

*• The current registration status of each drug/device to be used in the research. Indicate whether the drug/device is approved for this indication or another. Also, distinguish between registration in Australia and overseas.*

Medications, drugs and devices have to be approved for use by the Australian Federal Government. *[Name of investigational product]* is approved in Australia to treat *[Name of condition]*.

OR

*[Name of investigational product]* is an experimental treatment. This means that it is not an approved treatment for *[Name of condition]* in Australia.

OR

*[Name of investigational product]* is approved in Australia to treat *[Name of OTHER condition]*. However it is not approved to treat *[Name of condition]*. Therefore, it is an experimental treatment for *[Name of condition]*. This means that it must be tested to see if it is an effective treatment for *[Name of condition]*.

*Where the research is for the purpose of obtaining a degree or other educational qualification:*

The results of this research will be used by the study doctor *[name of researcher]* to obtain a *[full name of degree]* degree.

*Where the research project is investigator-initiated:*

This research has been initiated by the study doctor, Dr/Professor *[name]*.

*Where the research project is funded by a grant:*

This research has been funded by *[name of granting body]*.

*Where the research is being coordinated outside the institution:*

This research is being conducted by *[name of collaborative research group or other]*.

*Where commercial sponsorship is available:*

This research is being conducted by *[name of company]* and sponsored in Australia by *[name of local sponsor]*.

**3 What does participation in this research involve?**

*Tables and diagrams may only be used if they enhance the comprehensibility of this section. Tables and diagrams should not be a substitute for written explanation.*

*Include information and clear explanation of the following:*

*⮞ Consent form will be signed prior to any study assessments being performed*

*⮞ Initial steps*

*• Screening for eligibility*

*• Randomisation and blinding, use of a control group (including use of placebo)*

*⮞ Procedures*

*• All procedures*

*• Nature, number, timing and time commitment of tests, procedures, visits and questionnaires (include scientific and lay measurements of samples to be taken)*

*• Nature, number and other details of any optional tissue samples to be collected (see further instructions in Section 10)*

*• Nature of follow-up*

*• Duration of participant’s involvement (including follow-up)*

*• Duration of the research project (if this is different from their involvement)*

*• Device monitoring (if applicable). In the case of medical device trials, information should be provided about the mechanisms in place to track participants for the lifetime of the device, to detect any relevant adverse events and to enable remedial action if a significant defect is detected.*

*⮞ Reimbursement and costs (if applicable)* [NS 2.2.6(j), 2.2.10]

*⮞ How the research will be monitored* [NS 2.2.6(b)]

*⮞ The commitment required of the participant and the parent/guardian*

*⮞ If a drug: the dosage of the drug and method of administration*

*Insert the relevant paragraph(s) from Options 1 – 4 below, ensuring that all information is relevant to the design of the research project.*

*Option 1 – randomised controlled study*

The child will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

*You should tell the parent/guardian what chance their child has of receiving the investigational product e.g. a one in four chance.*

*Option 2 – blind study*

The child will be participating in a blind study. In a blind study it will not be known which of the treatments the child is receiving. The study doctor will know which treatment the child is receiving.

*Option 3 – double blind study*

The child will be participating in a double-blind study. This means that it will not be known which or the treatments the child is receiving; the study doctor will also not know. However, in certain circumstances the study doctor can find out which treatment the participant is receiving.

*Option 4 – cross-over study*

The child will be participating in a cross-over study. In a cross-over study the groups each have the different treatments in turn.

*If the research is a drug trial then the following should also be stated.*

There may be a break between treatments so that the first drugs are cleared from the child’s body before they start the new treatment.

*If the research uses a placebo, then this should be stated. The following explanation should be used.*

A placebo is a medication with no active ingredients or a procedure without any medical benefit. It looks like the real thing but is not.

*Bias (to be used in all research projects)*

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

*Additional costs*

There are no additional costs associated with participation in this research project, nor will you or the participant be paid. All medication, tests and medical care required as part of the research project will be provided to the child free of charge.

*[If applicable, also add]* You will have to pay for some medicines according to hospital policy. For example, *[give an example e.g. dispensing fees for PBS-listed drugs]*.

*Reimbursement*

You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

*If there is a maximum amount for this reimbursement then this should be stated.*

*Where considered* ***desirable*** *that a child’s local doctor be informed of the decision for the child to participate in a research project, the following additional sentence should be included*

It is desirable that the child’s local doctor be advised of your decision for the child to participate in this research project. If the child has a local doctor, we strongly recommend that you inform them of the child’s participation in this research project.

*Where considered that a child’s local doctor MUST be informed of the decision for the child to participate in a research project, the following additional sentence should be included*

If you decide that the child can participate in this research project, the study doctor will inform the child’s local doctor.

**4 What does the child have to do?**

*The purpose of this section is to provide the parent/guardian with information they need for the child to fully participate in the study. You should explain:*

*• Lifestyle restrictions e.g. physical restrictions, participation in sport*

*• Dietary restrictions*

*• Whether the child can take their regular medication*

*• What medication they should not take*

*• Whether the child can still donate blood*

*• What would restrict the child from taking part in this research project*

*• The responsibility and commitment of the parent/guardian/participant to ensure the investigational product is taken regularly and in accordance with the instructions provided.*

**5 Other relevant information about the research project**

*You should explain any other relevant information including:*

*• How many people will be taking part in the project overall and at this site*

*• Whether there are different arms to the project or case/control groups*

*• The size or scope of the project e.g. number of hospitals or countries involved*

*• Whether this is a follow-on study/sub-study/extension study. If so, state the relationship to the previous research*

*• Whether the project involves researchers from a number of organisations working in collaboration*

**6 Does the child have to take part in this research project?**

*Explain that taking part in the research is entirely voluntary.*

Participation in any research project is voluntary. If you do not wish for the child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw the child from the project at any stage.

If you do decide that the child can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision that the child can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them, or their relationship with *[Institution]*.

**7 What are the alternatives to participation?**

*For therapeutic research the parent/guardian should be told what other treatments are available and how the research differs from standard treatment. The important potential benefits and risks should be stated (this is an ICH GCP requirement).*

The child does not have to take part in this research project to receive treatment at this hospital. Other options are available; these include *[give examples of standard treatment]*. The study doctor will discuss these options with you before you decide whether or not the child can take part in this research project. You can also discuss the options with the child’s local doctor.

**8 What are the possible benefits of taking part?**

*Do not attempt to build up parent/guardian/participant hope in this section. Reference to the potential benefit to future patients may be appropriate, but should not be exaggerated.*

We cannot guarantee or promise that the child will receive any benefits from this research; however, possible benefits may include *[describe any likely benefits to participants or other people in the future]*.

*If the significant benefits from the research project are to accrue to members of society in the future and NOT to the individuals taking part in the trial, this should be made clear.*

There will be no clear benefit to the child from their participation in this research.

**9 What are the possible risks and disadvantages of taking part?**

*The layout of this section will depend on the nature of the research and the number, severity and significance of the risks.*

*For readability:*

*• Use headings (e.g. a heading for each investigational product or procedure)*

*• Use short and well spaced paragraphs*

*• Use short uncomplicated sentences*

*• Use a table or bullet points where possible*

*• Avoid or minimise repetition (e.g. if multiple drugs have the same side effects, group them together)*

*• Use proportions for more severe risks (e.g. 1 in 100). If using % follow with a qualifier e.g. “1% or 1 in 100”. Do not use < or > symbols.*

*An introductory paragraph is recommended as follows:*

Medical treatments often cause side effects. The participant may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If the participant has any of these side effects, or you are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms that the participant gets.

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, the study doctor may need to stop the child’s treatment. The child’s study doctor will discuss the best way of managing any side effects with you.

*Clearly list, for each medication/device, the possible side effects including the type of symptoms, how often, how severe they might be and how long they may last. This should be done in language the parent/guardian can clearly understand, e.g. ‘damage to the heart’ rather than ‘cardio-toxicity’ or ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’. For any relatively new medication/device it should be explained that there may be unknown side effects and that these could be serious.*

*Risks may be grouped according to frequency, severity, duration and/or significance (i.e. what implications the risks may have for participants).*

*It is suggested that this information is provided in either table form (see the headings displayed below), or in bullet points.*

*Suggested table for side effects; this table is a* ***guide only****.*

|  |  |  |  |
| --- | --- | --- | --- |
| Side Effect | How often is it likely to occur? | How severe might it be? | How long might it last? |
| *List possible side effects* |  |  |  |
|  |  |  |  |

*You should state what will happen should the child’s participation in this research uncover a medical condition of which the parent/guardian was unaware. State what support services would be in place and how this may affect their participation in the research project.*

*If participation in the research project might diagnose previously unknown conditions that may affect insurance in the future, this should be stated.*

*Provide information regarding who will pay for and/or treat the participant for side effects.*

*If relevant, a section regarding risks related to conception, pregnancy and breast-feeding is required. If sterility is a possible risk of participation in the research project, then this should be stated in a separate paragraph in this section. This section should not be entitled ‘Risks Related to Pregnancy,’ as there are other risks being described.*

*Please remember to adapt this clause if the project is specifically for female or male participants only and check for any site-specific requirements in relation to this statement.*

The effects of *[Name of investigational product]* on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. Females must not participate in the research if they are pregnant or trying to become pregnant, or breast-feeding. If child-bearing is a possibility, the female participant will be required to undergo a pregnancy test prior to commencing the research project. If the participant is male, he should not father a child for at least *[number]* months after the last dose of study medication.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of *[number]* months after completion of the research project. You and/or the participant should discuss methods of effective contraception with the study doctor.

*[For parent/guardian of female participants]* If the participant does become pregnant during the research project, you should advise her study doctor immediately. The study doctor will withdraw her from the research project and advise on further medical attention should this be necessary. The participant must not continue in the research if she becomes pregnant.

*[For parents/guardian of male participants]* You should advise the study doctor if the participant fathers a child during the research project. The study doctor will advise on medical attention for the participant’s partner should this be necessary.

*If relevant a paragraph regarding risks associated with psychological distress must be included.*

If you or the child become upset or distressed as a result of participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

*If relevant a paragraph regarding risks associated with chemotherapy.*

Chemotherapy may cause temporary or permanent sterility. Please discuss this with the child’s study doctor if you have any concerns about future fertility.

*If relevant a paragraph regarding risks associated with the collection of data regarding use of illegal substances is required.*

This research project involves the collection of information about the participant’s use of drugs. Participation in the research project includes blood *and/or* urine analysis to determine the presence of *[Name of substances]*. The test may reveal that the participant has previously used illegal drugs. That information will be stored in a re-identifiable (or coded) format. In the event that *[Name of institution]* is required to disclose that information, it may be used in legal proceedings or otherwise.

*If relevant a paragraph regarding risks associated with injections is required.*

Having a drug injected or blood (or tissue sample) taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

*If relevant insert a paragraph regarding risks associated with studies involving anaesthesia*

These days, whilst anaesthesia is generally very safe there are some risks associated with anaesthesia. The most common problems associated with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. 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 them with the study team.

*If relevant insert a paragraph regarding risks associated with studies involving MRI scans*

MRI stands for magnetic resonance imaging. A MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans.

We will ask the participant to lie on a table inside the MRI scanner. The scanner will record information about their *[Body part]*. It is very important that the participant keeps very still during the scanning. When the participant lies on the table, we will make sure they are in a comfortable position so that they can keep still. The scanner is very noisy and we can give the participant some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If the participant does experience discomfort at any time during the scan, they will be able to alert staff by pressing on a call button provided to them.

There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

We will thoroughly examine the participant to make sure there is no reason for them not to have the scan. You must tell us if the participant has metal implanted in their body, such as a pacemaker or metal pins.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at the child’s MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to the child’s health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features.

*If relevant, a paragraph regarding risks associated with exposure to ionising radiation is required.*

*Parents/guardians/participants must be clearly informed whether participation in the research project involves exposure to radiation.*

*For research projects involving ionising radiation, insert the relevant paragraph from Options 1 – 4 below*

*Option 1 - Effective dose less than 2 mSv*

This research project involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this research project is about *[Enter mSV]* mSv. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. This risk is believed to be minimal (if dose less than 0.2mSv) or very low (if dose 0.2mSv or less than 2mSv).

*Option 2 - Effective dose in range 2 mSv to 20 mSv*

This research project involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this research project is about *[Enter mSV]* mSv. The dose from this research project is comparable to that received from many diagnostic medical x-ray and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. This risk is believed to be low and, theoretically, is approximately equivalent to *[risk comparator]*.

*Option 3 - Effective dose greater than 20 mSv, up to 50 mSv or greater than 50 mSv*

This research project involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this research project is about *[Enter mSV]* mSv. The dose from this research project is comparable to that received from several computed tomography x-ray (CT) and nuclear medicine procedures. The benefits from the research project should be weighed against the possible detrimental effects of radiation, including an increased risk of fatal cancer. In this particular research project, the risk is moderate and the estimated risk of such harm is about 1 in *[relevant figure]*. For comparison, this risk is about *[relevant figure]*  times lower than the cancer mortality rate in the general population of about one case in every four people and, theoretically, is approximately equivalent to *[risk comparator]*.

**10 What will happen to the child’s test samples?**

*If the research project involves the collection of tissue (including blood or urine), even if the samples are collected as part of routine care, specific consent is required from parent/guardian for taking, storage, testing and analysis of these samples for research purposes. Therefore, any information outlined in the following list that applies to this project should be provided either in this Participant Information Sheet/Consent Form or in a separate Participant Information Sheet/Consent Form (e.g. for optional sub-studies). If multiple samples are being collected for different purposes, provide details for each sample type.*

*• Whether the collection of tissue, as described, is an optional or mandatory component of the research*

*• The specific purpose for which tissue is to be taken, stored and used (clearly differentiate between the use of samples taken for routine care, and those taken for research purposes, especially with respect to any proposed storage and destruction of samples)*

*• Whether tissue samples will be individually identifiable, re-identifiable (coded) or non-identifiable and, if individually identifiable or re-identifiable, how privacy/confidentiality of stored tissue samples will be maintained*

*• Where tissue will be stored, the length of time for which tissue will be stored, and how it will be destroyed, if applicable*

*• Whether the research project involves the storage of tissue for future research*

*• Whether consent for the use of tissue is specific (for this research only), extended (for related research) or unspecified (for any future research)*

*• Whether the research project involves the establishment of a tissue bank*

*• The purpose of any contemplated future use of the samples, including any commercial uses*

*• With respect to the use of tissue for future research, establishment of a tissue bank, or any contemplated commercial uses - that these matters will be overseen by an appropriately constituted HREC*

*In addition, parents/guardians of potential participants should be informed that specific consent for the collection of blood and tissue may be sought. If it is to be sought, include the following*

You will be asked to provide additional consent for the collection of the child’s blood *and/or* tissue during the research project.

*Additional information to be included in the case of genetic analysis or tests:*

*⮞ It is not necessary to include a section on genetic testing if the project does not involve genetic testing that would result in information about an identifiable participant’s future health risk or having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the project. However, you should advise parents/guardians of participants that this is the case.*

 *If the project is intended to produce or could yield such information, then this should be stated and information should be provided regarding the following:*

*• The nature of the testing*

*• The parent’s/guardian’s/participant’s rights*

*• The risks related to application for future insurance/employment*

*• The potential for the research to detect/generate information of social significance e.g. non-paternity or non-maternity*

*• The availability of counselling regarding the possible consequences of consenting to this use of genetic material.*

*⮞ If relatives are also to be approached, the study doctor will need the consent of the parent/guardian to do this and should provide information concerning the method of approach to relatives in this Participant Information Sheet/Consent Form*

*⮞ Whether parent/guardian will be advised of project results and, if so, whether this will be grouped data or relate to individual participants*

*⮞ If no information concerning genetic disease predisposition is to be made available to research participants, this should be clearly stated, noting all the implications*

*⮞ Whether feedback of information of potential significance to their relatives’ future health will be discussed with parent/guardian of participants*

*⮞ Assurance that the participant’s genetic material and information, where identified or potentially identifiable, will not be released for other uses without the parent/guardian’s prior consent, unless required by law. Information should also be provided about the procedures to be followed in response to a request for access (e.g. requests by a donor, relative, other researchers, insurer or employer) to stored genetic material, or related information generated by the research*

*⮞ State that, if consent for future research use is declined, the genetic material and information (unless de-identified) should be disposed of after a specified period following completion of the research*

*⮞ If a genetic register is proposed, state that genetic registers will be established and conducted in accordance with the* Guidelines for Genetic Registers and Associated Genetic Material *(NHMRC, 1999).*

Samples of the child’s blood *and/or* tissue obtained for the purpose of this research project *may/will* be transferred to *[Name of organisation/company]*. The child’s tissue will not be sold by *[Name of institution]*, however *[Name of institution]* may charge study doctors a fee to recover some of the costs of storing and administering the tissue samples.

Once the child’s blood *and/or* tissue samples are transferred to *[Name of organisation/company]*, *[Name of institution]* will not be able to control whether the *[Name of organisation/company]* transfers or sells the samples at some future date, however *[Name of institution]* will not knowingly transfer the child’s samples to anyone who has expressed intent to sell the samples.

*Additional requirements regarding HIV and hepatitis testing:*

*Under State/Territory law, a medical practitioner is required to provide information about the legal, medical and social consequences of being tested for HIV and hepatitis (A-E) and possible results of such a test both before and after the conduct of such a test. Clearly state that information and counselling will be provided in accordance with State/Territory Law.*

The proposed blood tests include a screening test for HIV (also called the ‘AIDS’ virus) and Hepatitis. This is because the study doctors need to know *[state reason]*. You and the participant will receive information and counselling before the test. If a test shows that the participant has HIV or Hepatitis, follow-up counselling and medical advice will be provided. If the test results are positive, the study doctors are required by law to notify government health authorities. Signing the consent form means that you agree to the participant having this testing; it will not be done without your consent.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want the participant to continue in the research project. If you decide to withdraw the participant, their study doctor will make arrangements for their regular health care to continue. If you decide that the participant can continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, the study doctor might consider it to be in the participant’s best interests to withdraw them from the research project. If this happens, the doctor will explain the reasons and arrange for the participant’s regular health care to continue.

**12 Can the child have other treatments during this research project?**

Whilst the child is participating in this research project, they may not be able to take some or all of the medications or treatments they have been taking for their condition or for other reasons. It is important to tell the study doctor and the study staff about any treatments or medications the participant may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these during the child’s participation in the research project. The study doctor should also explain to you which treatments or medications need to be stopped for the time the child is involved in the research project.

*If applicable (you may wish to consult your institution regarding the suitability of the statement below)*

It may also be necessary for the participant to take medication during or after the research project to address side effects or symptoms that they may have. You may need to pay for these medications and so it is important that you ask the study doctor about this possibility.

**13 What if I withdraw the child from this research project?**

*Provide information on how participants can be withdrawn and implications (e.g. medical health risks) for them if this happens.*

If you decide to withdraw the participant from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to further discuss any health risks or special requirements linked to withdrawing.

*Where appropriate, explain that if a participant is withdrawn part-way through a research project that data collected to that point will be kept and will not be able to be deleted.*

If you do withdraw the participant during the research project, the study doctor and relevant study staff will not collect additional personal information, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time of withdrawal will form part of the research project results. If you do not want them to do this, you must tell them before the participant joins the research project.

**14 Could this research project be stopped unexpectedly?**

*The parent/guardian should be advised of the potential for the project to be terminated before completion and the reasons that might make termination necessary.*

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• Unacceptable side effects

• The drug/treatment/device being shown not to be effective

• The drug/treatment/device being shown to work and not need further testing

• Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities. *Reference to a sponsor's interests should be omitted where a trial is initiated by an investigator or a collaborative group.*

**15 What happens when the research project ends?**

*Provide details regarding follow-up arrangements.*

*If the treatment will not be available after the research finishes this should be explained to the parent/guardian. You should also explain to them what treatment will be available instead. If the investigational product/treatment is to be made available, specify any requirements or limitations, including cost to the participant.*

*Provide information on how the parent/guardian will find out about the success of the project. State how, and approximately when, parents/guardians/participants will be provided with a summary of the results when the research project is completed.*

**Part 2 How is the research project being conducted?**

**16 What will happen to information about the child?**

*Information should be provided regarding the following:*

*• Whether the data collected or used is individually identifiable, re-identifiable (coded) or non-identifiable*

*• Where the data will be kept and who will have access to it*

*• How long it will be stored and what will happen to the data at the end of the storage period (Refer to your institution’s policy on retention of study data for research involving children)*

*• Whether the parent/guardian is being asked to provide consent to the use of the child’s data for this project only or for extended (related research) or unspecified (any future research) use*

*• Whether the research project involves the establishment of a databank*

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about the child for the research project. Any information obtained in connection with this research project that can identify the child will remain confidential. *[Explain how it will be confidential and, if it is identifiable, where it will be kept and who will have access to it].* The child’s information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

*If it is likely that additional health information relating to participants will be sought from their health records, the following should be included:*

Information about the child may be obtained from their health records held at this and other health services, for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to the child’s participation in this research project.

*If relevant, provide information regarding the review of health records by researchers and by representatives of regulatory authorities and the sponsor for the purpose of verifying the procedures and the data.*

The child’s health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, *[Name of International and Australian sponsor]*, the institution relevant to this Participant Information Sheet, *[Name of institution]*, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

*If it is anticipated that the results will be published include the following paragraph:*

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the child cannot be identified, except with your permission. *[Describe how confidentiality will be maintained.]*

*Where it is likely that the child’s participation in the research will be noted in their health record, the following should be included:*

Information about the child’s participation in this research project may be recorded in their health records.

*Can the parent/guardian access the child’s information/data?*

In accordance with relevant Australian *and/or* *[Name of state/territory]* privacy and other relevant laws, you have the right to request access to the participant’s information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access the participant’s information.

Any information obtained for the purpose of this research project *and for the future research described in Section [Section #]* that can identify the particpant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

*If additional use of the information is contemplated, this should be explained and specific consent should be sought from the parent/guardian for that additional use.*

**17 Complaints and Compensation**

*You should inform the parent/guardian how complaints will be handled and what redress may be available. Clarify whether there is a procedure in place for this and, if so, what the procedure is. You will need to distinguish between complaints from parent/guardian/participant regarding their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial, e.g. a serious adverse event.*

If the participant suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment for the participant. If the participant is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

*ALL participants in Phase 1 & 2 studies (or their parent/guardian if applicable) MUST be given a copy of the Medicines Australia (MA) compensation guidelines. For all other clinical trials, the MA compensation guidelines should be made available on request.*

*For Phase 1 & 2 Commercially Sponsored Clinical Trials*

There are two avenues that may be available to you for seeking compensation if the child suffers an injury as a result of their participation in this research project:

• The pharmaceutical industry has set up a compensation process, with which the Sponsor *[Full name of Australian corporate sponsor]* of this research project has agreed to comply. Details of the process and conditions are set out in the *Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial*. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. The research staff will give you a copy of the Guidelines together with this Participant Information and Consent Form. If you have any questions about the Guidelines, please ask to speak to *[Name of designated person, associated with the research trial or in the organisation, capable of explaining the Guidelines].*

• You may be able to seek compensation through the courts.

*For all other commercially sponsored clinical trials*

There are two avenues that may be available to you for seeking compensation if the child suffers an injury as a result of their participation in this research project:

• The pharmaceutical industry has set up a compensation process, with which the Sponsor *[Full name of Australian corporate sponsor]* of this research project has agreed to comply. Details of the process and conditions are set out in the *Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial*. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request. If you have any questions about the Guidelines, please contact *[Name of designated person, associated with the research trial or in the organisation, capable of explaining the Guidelines]*.

• You may be able to seek compensation through the courts.

*For non-commercially sponsored clinical trials insert the following information about compensation:*

In the event of loss or injury, the parties involved in this research project have agreed to *[Description of compensation agreements]*.

**18 Who is organising and funding the research?**

*Organising and funding research*

This research project is being conducted by *[Name of person]*.

*Where commercial sponsorship is available*

This research project is being conducted by *[Name of international company]* and sponsored in Australia by *[Name of local sponsor]* and is being funded by *[Name of funding organisation]*.

*Provide a description of the financial benefits that might arise from the conduct of the research*

*[Company/University]* may benefit financially from this research project if, for example, the project assists *[Company/University]* to obtain approval for a new drug/device.

By consenting to the child taking part in this research project you agree that samples of the child’s blood or tissue (or data generated from analysis of these materials) may be provided to *[Company/University]*.

*[Company/University]* may directly or indirectly benefit financially from the child’s samples or from knowledge acquired through analysis of the child’s samples.

You will not benefit financially from the child’s involvement in this research project even if, for example, the child’s samples (or knowledge acquired from analysis of the samples) prove to be of commercial value to *[Company/University]*.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to *[Company/University]*, the study doctors or their institutions, there will be no financial benefit to you, the child, or family from these discoveries.

*[Name of institution]* will receive a payment from *[Name of funding organisation]* for undertaking this research project.

No member of the research team will receive a personal financial benefit from the child’s involvement in this research project (other than their ordinary wages).

*Add any declarations of interest of study doctors, sponsors and institutions* [NS 2.2.6 (i)]

**19 Who has reviewed the research project?**

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 HREC of *[Name of institution]*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

*Where relevant, state that approval has been given by the institution where research will be carried out or by the institution responsible for supervising the standard of care where the research will be carried out.*

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor on *[phone number]* or any of the following people:

*List the names and contact phone numbers of other appropriate persons involved in the project including research nurses and study coordinators. The name and contact phone number of a person who can act as a 24-hour medical contact* ***must*** *be provided and clearly denoted*.

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

For matters relating to research at the site at which the child is participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

*This person should be someone independent of the research, such as the Executive Officer of the reviewing HREC that approved the project (if a multi-centre clinical trial). Contact your local HREC administrator (single site trial) for the requirements at your institution.*

|  |  |
| --- | --- |
| Reviewing HREC name | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form – Parent/Guardian**

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/****Principal Investigator** | *[Coordinating Principal Investigator/**Principal Investigator]* |
| **Associate Investigator(s)***(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**Declaration by Parent/Guardian**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for the child’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning the child’s disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to the child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Child (please print) |  |  |
|  |  |  |  |
|  | Signature of Child*(Optional: remove if not required)* |  | Date |  |  |
|  |  |  |  |  |  |
|  | Name of Parent/Guardian (please print) |  |  |
|  |  |  |  |
|  | Signature of Parent/Guardian |  | Date |  |  |
|  |

*Under certain circumstances (see* Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness\* to informed consent is required*

|  |
| --- |
|  |
|  | Name of Witness\* to Parent/Guardian’s Signature (please print) |  |  |
|  |  |  |  |  |
|  | Signature |  |  Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

*Optional paragraph:*

I understand that, if I decide to discontinue the child’s study treatment, a request may be made for them to attend follow-up visits to allow collection of information regarding their health status. Alternatively, a member of the research team may request my permission to obtain access to the child’s medical records for collection of follow-up information for the purposes of research and analysis.

*Additional component to be added to the consent section when the research project involves the collection, storage, testing and analysis of blood or tissue.*

*If there is an option for blood or tissue samples to be taken and stored for this or further research, it is suggested that consent to the use and storage of tissue be separate from the general consent to participate in the study. This is because it is often the case that participation in the testing and further storage of tissue is contemplated as a separate option for the participant. By utilising an additional consent component (either integrated into the main project Consent Form or through use of a separate additional Consent Form) for this aspect of the research, parents/guardians can, in some cases, still consent to the main study but not the additional use of tissue/genetic testing component.*

*If you choose to integrate this component into this Consent Form, the following phrase should be inserted:*

I consent to the storage and use of blood and tissue samples taken from the child for use, as described in the relevant section of the Participant Information Sheet, for:

• This specific research project

• Other research that is closely related to this research project

• Any future research

*If appropriate, include the following statement:*

By signing this consent section, I agree to the use of the child’s tissue samples for genetic testing, as outlined in the relevant section of the Participant Information Sheet. *If genetic testing is optional, make this clear.*

*If the study contemplates the use of tissue samples obtained from previous surgery/procedures, a separate specific consent should be obtained for this additional use of tissues previously taken and stored. In this situation, include the following statement:*

By signing this consent section, I agree to the use of tissue samples obtained previously from the child’s *routine biopsy or surgery* for the purposes of additional testing for *[Test to be performed on tissue(s)]*.

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| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Child (please print) |  |  |
|  |  |  |  |
|  | Signature of Child*(Optional: remove if not required)* |  | Date |  |  |
|  |  |  |  |  |  |
|  | Name of Parent/Guardian (please print) |  |  |
|  |  |  |  |
|  | Signature of Parent/Guardian |  | Date |  |  |
|  |

*Under certain circumstances (see* Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness\* to informed consent is required*

|  |
| --- |
|  |
|  | Name of Witness\* to Parent/Guardian’s Signature (please print) |  |  |
|  |  |  |  |  |
|  | Signature |  |  Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

|  |
| --- |
|  |
|  | Name of Study Doctor/Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation – Parent/Guardian**

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a parent/guardian’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/****Principal Investigator** | *[Coordinating Principal Investigator/**Principal Investigator]* |
| **Associate Investigator(s)***(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**Declaration by Parent/Guardian**

I wish to withdraw the child from participation in the above research project and understand that such withdrawal will not affect their routine treatment, relationships with those treating them or the relationship with *[Institution]*.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Child (please print) |  |  |
|  |  |  |  |
|  | Signature of Child*(Optional: remove if not required)* |  | Date |  |  |
|  |  |  |  |  |  |
|  | Name of Parent/Guardian (please print) |  |  |
|  |  |  |  |
|  | Signature of Parent/Guardian |  | Date |  |  |
|  |

*In the event that the parent/guardian’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the parent/guardian has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.