

Participant Information Sheet/Consent Form

Interventional Study - Adult providing own consent

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.

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
- ▶ 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.
- ▶ 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 participant (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

Interventional Study - Adult providing own consent

[Insert site name]

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

Part 1 What does my 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.

You are invited to take part in this research project. This is because you 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 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 to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want 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 take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your 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 by the participant
 - 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

You 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 participant what chance they have of receiving the investigational product e.g. a one in four chance.

Option 2 – blind study

You will be participating in a blind study. In a blind study you do not know which of the treatments you are receiving. Your study doctor will know which treatment you are receiving.

Option 3 – double blind study

You will be participating in a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving.

Option 4 – cross-over study

You 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 your body before you 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 participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you 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 participant's local doctor be informed of their decision to participate in a research project, the following additional sentence should be included

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

Where considered that a participant's local doctor MUST be informed of their decision to participate in a research project, the following additional sentence should be included

If you decide to participate in this research project, the study doctor will inform your local doctor.

4 What do I have to do?

The purpose of this section is to provide the participant with information they need to fully participate in the study. You should explain:

- *Lifestyle restrictions e.g. physical restrictions, participation in sport*
- *Dietary restrictions*
- *Whether the participant can take their regular medication*
- *What medication they should not take*
- *Whether the participant can still donate blood*
- *What would restrict them from taking part in this study*
- *The responsibility and commitment of the participant taking/using the investigational product 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 Do I 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 to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to 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 whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

7 What are the alternatives to participation?

For therapeutic research the participant 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).

You do 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]*. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

Do not attempt to build up 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 you 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 you from your 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. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your 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 your study doctor immediately about any new or unusual symptoms that you get.

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, your study doctor may need to stop your treatment. Your 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, frequency, severity and duration. This should be done in language the participant 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 (e.g.. 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?
<i>List possible side effects</i>			

You should state what will happen should their participation in this research uncover a medical condition of which they were 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. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm 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 should discuss methods of effective contraception with your study doctor.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the

research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

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

If you become upset or distressed as a result of your 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 your 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 your 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 you have 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 against you 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 you to lie on a table inside the MRI scanner. The scanner will record information about your *[Body part]*. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so that you can keep still. The scanner is very noisy and we can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

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 you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your 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 your 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 your 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.

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 my 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 participants 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, 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 your 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 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 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 research participant to do this and should provide information concerning the method of approach to relatives in this Participant Information Sheet/Consent Form*
- *Whether participants 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 participants*

- ▶ Assurance that the participant's genetic material and information, where identified or potentially identifiable, will not be released for other uses without the participant'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 your blood *and/or* tissue obtained for the purpose of this research project *may/will* be transferred to *[Name of organisation/company]*. Your 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 your 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 your samples at some future date, however *[Name of institution]* will not knowingly transfer your 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 will receive information and counselling before the test. If a test shows you have HIV or Hepatitis, you will have follow-up counselling and medical advice. If your 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 have 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, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies,

acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are 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 you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

13 What if I withdraw from this research project?

Provide information on how participants withdraw and implications (e.g. medical health risks) for them if they do so.

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

Where appropriate, explain that if a participant withdraws 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 your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, 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 you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

The participant 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 participant. 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 participant will find out about the success of the project. State how, and approximately when, 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 me?

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)*
- *Whether the participant is being asked to provide consent to the use of their data for this project only or for extended (related research) or unspecified (any future research) use of their data*
- *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 you for the research project. Any information obtained in connection with this research project that can identify you 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].* Your 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 you may be obtained from your 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 your 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.

Your 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 you cannot be identified, except with your permission. *[Describe how confidentiality will be maintained.]*

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

Information about your participation in this research project may be recorded in your health records.

Indicate whether the participant can access their own 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 your information collected and stored by the research 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 your information.

Any information obtained for the purpose of this research project *and for the future research described in Section 16* that can identify you 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 participants for that additional use.

17 Complaints and compensation

You should inform participants 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 participants 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 you suffer 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. If you are eligible for Medicare, you 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 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 you suffer an injury as a result of your 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 you suffer an injury as a result of your 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 taking part in this research project you agree that samples of your 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 your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your 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 or your 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 your 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 you have any medical problems which may be related to your 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	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

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

Complaints contact person

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

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 approving this research and HREC Executive Officer details

Reviewing HREC name	<i>[Name of HREC]</i>
HREC Executive Officer	<i>[Name]</i>
Telephone	<i>[HREC Executive Officer Phone number]</i>
Email	<i>[HREC Executive Officer Email address]</i>

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

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

Consent Form - Adult providing own consent

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) *[Associate Investigator(s)]*
(if required by institution)
Location *(where CPI/PI will recruit)* *[Location where the research will be conducted]*

Declaration by Participant

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 my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning my 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 participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

Name of Participant (please print) _____
Signature _____ 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 Participant'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 participant 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.

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

Optional paragraph:

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my 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, participants 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 me 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 my 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 my *routine biopsy or surgery* for the purposes of additional testing for *[Test to be performed on tissue(s)]*.

Name of Participant (please print) _____
Signature _____ Date _____

Name of Witness* to Participant'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/ Senior 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 - *Adult providing own consent*

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 participant'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) *[Associate Investigator(s)]*
(if required by institution)
Location *(where CPI/PI will recruit)* *[Location where the research will be conducted]*

Declaration by Participant

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

Name of Participant (please print) _____
Signature _____ Date _____

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

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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 participant 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.