**Participant Information Sheet/Consent Form**

**Genetic Study** -*Adult providing own consent*

Use this PICF for genetic research that is non-interventional OR genetic research that has an interventional component that does not involve research on a drug or device.

Refer to *The National Statement on Ethical Conduct in Human Research* (Chapter 3.3) for information on genetic research.

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

⮞ **This template is a guide only.**

⮞ 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 23 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 are (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/Consent Form 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 23 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 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.**

**Version Control of a PICF for Multi-Site Research**

There may be more than one Master Participant Information Sheet/Consent Form if special consent requirements apply (e.g. consent forms for parents/guardians of children, persons responsible, participant continuation).

⮞ **Master Participant Information Sheet/Consent Form**

The Master Participant Information Sheet/Consent Form is for the Coordinating Principal Investigator (CPI) to submit where the Participant Information Sheet/Consent Form is identical for each site in a multi-centre study. The CPI or their delegate must submit a Master Participant Information Sheet/Consent Form to the reviewing HREC. A Master Participant Information Sheet/Consent Form contains the required wording applicable to all study sites, and includes the name and contact details of the reviewing HREC. It should be a generic form for multi-centre research (i.e. no site letterhead).

⮞ **Use of Master Participant Information Sheet/Consent Form at sites**

Following HREC approval, the Master Participant Information Sheet/Consent Form must be used at all sites the HREC has approved. The approved document may only be modified to reflect individual sites’ details. Permissible changes are:

• Letterhead of the site

• Name of the site where recruitment is to occur

• Name and contact details of the site PI

• Name and contact details of the person dealing with complaints at the PI’s organisation

• Local governance changes to the page footer (see instructions below)

⮞ **Site Master Participant Information Sheet/Consent Form**

Where there is a specific site policy and standard wording is required by an organisation (e.g. for religious reasons or site policy), the CPI/delegate may also submit a Site Master Participant Information Sheet/Consent Form for review by the HREC.

The Site Master Participant Information Sheet/Consent Form with the special site-specific wording must include the:

• Letterhead of the site that has the special policy requirements

• Name of the site where recruitment is to occur

• Name and contact details of the site PI

• Name and contact details of the person dealing with complaints at that site

• Name and contact details of the reviewing HREC

• Master Participant Information Sheet/Consent Form version date (on which the Site Master Participant Information Sheet/Consent Form is based) and the Site Master Participant Information Sheet/Consent Form version date in the footer of each page

• Front page explanatory statement, e.g. “Based on the *[project title] [HREC Reference Number]* Master Participant Information Sheet/Consent Form *[Version date]*

⮞ **Both the Master and the Site Master Participant Information Sheet/Consent Form must be approved by the reviewing HREC. The version date must be the same as that which received HREC approval.**

⮞ **Use of footer for version control**

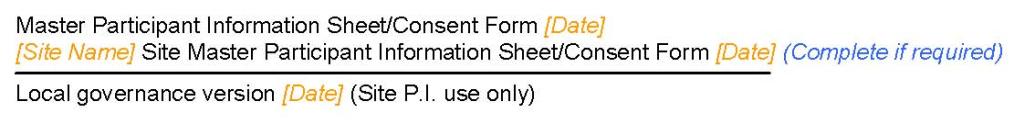
For example:

A Master Participant Information Sheet/Consent Form was approved by a HREC on 17 August 2011 and there is no requirement for a Site Master. The local governance Participant Information Sheet was adapted at a site on 14 September 2011.

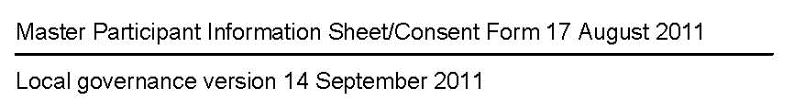
Text above the line relates to Master (and Site Master if required) version tracking of **HREC approved versions**.

Text below the line is for tracking of local governance versions that have had details changed for a particular site and do not require HREC approval (i.e. contact details).

Template



Complete



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

**Participant Information Sheet/Consent Form**

**Genetic Study** -*Adult providing own consent*

*[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 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]*. You will be asked to donate a sample of *[Specify biospecimen]* which will be used for genetic research.

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 genetic research?**

Genes are made of DNA – the chemical structure carrying your genetic information that determines many human characteristics such as the colour of your eyes or hair.

Researchers study genes in order to understand why some people have a certain condition such as *[Name condition]* and why some people do not. Understanding a person’s genes also may be able to explain why some people respond to a treatment, while others do not, or why some people experience a side effect and others do not.

**3 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 purpose of the research project is to *[Provide details]*

*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 international pharmaceutical company]* and sponsored in Australia by *[name of local sponsor]*.

**4 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*

*⮞ Procedures*

*• All procedures*

*• Nature, number, timing and time commitment of tests, procedures, visits and questionnaires*

*• Nature, number and other details of any tissue samples to be collected (include scientific and lay terms for the sample sizes to be taken)*

*• Nature of follow-up*

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

*• Duration of the research project (if this is different from the participant’s involvement)*

*⮞ Reimbursement and costs (if applicable)*

*⮞ How the research will be monitored*

*⮞ The commitment required by the participant*

*Provide a description of the sample collection procedure as well as details of the number and timing of visits.*

If you agree to take part in this research project, a *[Describe type of sample collection and amount]* will be taken.

*Provide an explanation of the research project’s design with regard to minimising bias*

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.

*Provide an explanation regarding additional costs to the participant*

There are no additional costs associated with participating in this research project, nor will you be paid. Any 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]*.

*If the participant will be reimbursed for any costs, include details of the applicable items. If there is a maximum amount for this reimbursement then this should be stated.*

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

*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 the 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.

**5 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 research project*

**6 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*

**7 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]*.

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

*If the data will be in a non-identifiable form, include an explanation*

The results of this research project will not provide you with any direct benefit because the link between you and your *[Specify biospecimen]* will be removed before your *[Specify biospecimen]* is analysed. However, it may provide valuable information to improve the diagnosis, treatment or care of people with *[Provide details]* in the future.

*If the data will be in an identifiable form, include*

You will be contacted if the testing shows important information about you, and you will be asked if you wish to know the results. The results may be important to you as they may provide:

*•* Information about risk of an inherited condition

*•* Information that might influence a decision to have children

*•* Information that might affect your ability to obtain insurance or employment.

*Include all that are relevant*

*If the testing yields important information about the participant’s relatives, the researcher must prepare an ethically defensible plan to disclose or withhold that information.* [NS 3.3.36 – 3.3.37]

In addition, if the testing shows important information about your relativescontact with your relatives about the testing is encouraged. You may wish to do this yourself or ask the researchers to contact them on your behalf.

Should you inform your relatives and they wish to know your results, expert counselling will be provided by *[Provide details]* to explain what the results mean for you and to support you as necessary.

It will be necessary to refer you for re-testing by genetic services outside this research project.

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

*Describe foreseeable risks, side effects, discomforts and inconveniences of the sample collection process, and also the implications of receiving the test results.*

*Specifically consider and address the risk of breach of confidentiality or psychological trauma.*

*• Breach of confidentiality could impact insurability, employability, family plans and family relationships.*

*• Psychological risks include the impact of learning results if no effective therapy for the disorder exists, and the risk of stigmatization.*

*Participants should be informed of the potential risks that may result from receiving genetic test results. This paragraph should be omitted if the test results will not be available to participants.*

Genetic testing involves the study of genetic material (typically DNA) that is shared with your blood relatives. Genetic research is undertaken for many reasons, including discovering more accurate ways of predicting disease within a group of people, or in people where there is strong family history or predisposition of disease.

Genetic testing may raise important issues. Although few may be expected to arise, your awareness of this is important for you to think about and carefully consider before agreeing to participate.

Learning about the results from genetic research might affect you and your family emotionally. In some cases, the result may give certainty that you do not have a disease but could also create uncertainty or be upsetting; if for instance, the test indicates an increased risk of developing a disease which has no known prevention, treatment or cure.

It is important to understand that results from genetic research will usually not indicate that you have a disease or disorder, or whether you will develop it. Research may only show that you have an increased **risk** of developing a disease or disorder. Even then, there is no guarantee that you will develop the condition or any indication of the likely age you might get the disease or how serious the disease might be.

You may learn information from your test result about inherited diseases or disorders that may affect others, such as your brothers or sisters. This could interfere with family relationships. You may be faced with the decision to make the family aware of the existence of genetic information. Family members may or may not wish to know this information.

Any research results that could be of significance to you or your family will need to have the tests repeated and the results verified. This will involve having a blood sample taken and having it retested in an accredited testing laboratory. This is standard practice for all patients receiving the results of genetic testing and would be provided free of charge to you. Counselling may also be provided free of charge if it is appropriate. Before a test is repeated to verify a research finding, you will be informed about the possible risks involved for you. This is especially important for individuals who are found to have a genetic mutation that is associated with an increased risk of developing a disease such as cancer or heart disease.

*Receiving genetic analysis may have implications for the participant with regard to insurance in the future, although participants do not have to disclose a genetic test result if they do not receive the result. The Genetic tests and applying for life insurance Key Facts from the Financial Services Council provides further information -* [*https://www.fsc.org.au/resources-category/publication/1785-moratorium-key-facts/file*](https://www.fsc.org.au/resources-category/publication/1785-moratorium-key-facts/file)

*This paragraph should be omitted if the test results will not be available to participants.*

Statutory or contractual duties may require you to disclose results of genetic tests or analysis to third parties (for example, insurance companies, employers, financial and educational institutions), particularly where results provide information about health prospects. If the results of your genetic tests are not available to you or you choose not to have the results given to you, then your future requests for insurance will not be affected by participating in this research.

If you do obtain the results of your genetic tests, you may then be obliged to disclose this on any future application for insurance or employment should it be requested.

**10 What will happen to my test samples?**

*As 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 related to this, including that outlined below, should be included in this Participant Information Sheet.*

*• 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 it will be stored, and how it will be destroyed, if applicable*

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

*If consent for tissue use is ‘specific’*

Your *[Specify biospecimen]* will only be used for the purpose of this research project. The *[Specify biospecimen]* that you provide during the research project will be destroyed at the completion of this research project, although some samples may be kept if required by the laboratory.

*If consent for tissue use is ‘extended’*

We would like to store your *[Specify biospecimen]* for future use in research projects that are an extension of this research project. Alternatively we may use your sample for future research that is closely related to the original research project or as a control tissue sample. Further information can be found in this document’s section on banking.

*If consent for tissue use is ‘unspecified’*

We would like to store your *[Specify biospecimen]* for use in any future research studies that may or may not be related to the original research project. Further information can be found in this document’s section on banking.

*Where unspecified consent is being sought with respect to the use of samples for future research, its terms and wide-ranging implications should be clearly explained to potential participants.*

**11 What is the potential impact on my family if I take part?**

*If there is any intent to gather information about the participant’s relatives, the participant must be informed of this intent and the type of information to be gathered should be described. Explain what measures will be taken to protect the privacy of the participant’s relatives. Participants may not be asked to release their relatives’ contact information without obtaining the relatives’ permission. Researchers may not contact the relatives without both the participant’s and the relative’s permission.*

*The National Statement 3.3.32 – 3.3.33 provides guidelines for the families of those participating in genetic research. If the research requires that other family members of the participant are recruited, then the participant, or someone else they choose, should be given the opportunity to make initial contact. Note: under the National Statement 3.3, if the research discloses that a participant’s family member may be at risk of a life-threatening or serious illness for which treatment is available or pending, the reviewing HREC may authorise disclosure of this information without the participant giving their consent.*

You may be asked to give us health information about your relatives. Any information you give us will be kept confidential. We will not contact your relatives without your permission. We may discuss with you the possibility of including your relatives in the research project in the future. If the research discloses that one of your family members may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, with the prior approval of a Human Research Ethics Committee, be offered by the study doctor to the family member, even if you as the participant do not consent to this.

**12 Will I be given the results of the research project?**

*If the participant will NOT be given the results:*

You will not be given your genetic test results because the research is still in an early phase and the reliability of the results is unknown.

*If the participant WILL be given the results:*

Your genetic test results will be available to you should you wish. It is your decision whether you wish to be informed of your results. Before you decide if you wish to have your genetic test results, it is important that you read the information above regarding risks carefully so that you can make an informed decision.

If you decide to see your genetic test results, specialist clinical geneticists and genetic counsellors will speak with you and assist you through the process. This will be at no cost to you.

Genetic information is complex and can be influenced by other factors including environment and lifestyle. Because genetic information is complex and sensitive, the results should be discussed with a clinical geneticist and genetic counsellor who can give you details that are relevant to you, answer your questions and discuss your concerns.

In the future, if during the course of this research project we discover new information that is important for your health care, you will be asked whether you wish to receive the results (this may require you to have the test repeated in a clinical laboratory). If you agree, we may contact you if such a situation arises.

**13 Will drug or biotechnology companies be able to use my sample for profit in the future?**

There is the possibility that this research may result in commercially viable technology or treatments. However, you will not be able to claim financial benefit from any discoveries arising from the use of your *[Specify biospecimen]*.

**14 Banking (Long term storage of samples)**

*Provide an explanation regarding banking and a definition of a bank. Explain whether the blood/tissue will be collected, stored or disclosed as individually identifiable, re-identifiable (coded) or non-identifiable.*

“Banking” is storing health information and/or blood or tissue for future research studies. A “bank” is the place where the health information and/or blood or tissue is stored.

Your *[Specify biospecimen]* will be stored as *individually identifiable/re-identifiable/non-identifiable* specimen(s).

*Provide an explanation of why storage of biospecimens is desirable for the researcher*

The study doctor seeks your permission to store your *[Specify biospecimen]* for future research. The study doctor would like you to consider taking part in this bank because you have *[Specify condition]*. In the future, other doctors and scientists at this and other medical and research centres may use your *[Specify biospecimen]* to learn about many different diseases and conditions. Their goal is to improve health outcomes and develop new treatments.

*Obtainment of the specimen to be banked*

The study doctor will store your *[Specify biospecimen]* from *[Specify procedure]*.

*Leftover specimen*

The study doctor will store your leftover *[Specify biospecimen]* from *[Specify procedure]* in a bank. This procedure was recommended by your doctor as part of your routine care for your condition and is not part of the research.

*Additional sample(s) which are part of routine procedure*

The study doctor will take *[Number of samples]* additional samplesduring *[Specify procedure]* from the main research project and store *them/it*. This procedure is part of your routine care and is not part of the research.

*Location of biospecimen storage*

The study doctor will store your *[Specify biospecimen]* at *[Provide details]* along with samples of many other people.

*Duration of biospecimen storage – for limited time*

Your *[Specify biospecimen]* will be stored for *[Number of years]* after the research project is over, which we expect will be *[Indicate year]*.

*Duration of biospecimen storage – for future research*

The purpose of storing your *[Specify biospecimen]* in a bank is to answer questions in the future, so we expect to keep your *[Specify biospecimen]* for a long time.

*Removal/destruction of stored biospecimen – identifiable*

Your *[Specify biospecimen]* will be stored at *[Name of bank]*. It will be identified as yours. You can have it removed or destroyed by contacting the study doctor, *[Name of Principal Investigator]*, in writing at *[Address]*.

*Removal/destruction of stored biospecimen – re-identifiable*

Your *[Specify biospecimen]* will be stored at *[Name of bank]*. It will be stored as a re-identifiable sample. This means that your sample will be identifiable by a code; it can be identified as yours even though the bank does not know your identity. You can have it removed, destroyed or returned to you by contacting the study doctor, *[Name of Principal Investigator]*, in writing at *[Address]*.

*Removal/destruction of stored biospecimen – non-identifiable*

Your *[Specify biospecimen]* has been stored in a bank as non-identifiable. This means that all identifying codes were removed from the specimen. We are unable to identify which *[Specify biospecimen]* is yours, and so you will not be able to have the specimen removed or destroyed.

**15 What are the possible benefits of banking my *[Specify biospecimen]*?**

There is no direct benefit to you. Other people might benefit if researchers learn more by using your banked *[Specify biospecimen]*.

**16 What are the possible risks and disadvantages of banking?**

*Researchers should read the National Statement Chapter 3.1 on databanks (including databases) when providing information to participants on the risks of banking data or biospecimens.*

*If the biospecimen to be collected for the bank would otherwise be discarded from a clinically indicated procedure or obtained from a procedure in the main research project, then no physical risks are part of the research itself.*

*If more biospecimen will be collected for the bank than is required for clinical research purposes, describe the amount, procedures and physical risks in obtaining the biospecimen.*

*If the biospecimen will be collected only for banking, describe the amount, procedures, and physical risks in obtaining the biospecimen:*

*If future research identifies a genetic marker for disease and the participant will be informed, what are the implications to the participant?*

*Provide information relating to how the participant’s confidentiality will be maintained and associated risks. Include:*

*• Where the biospecimen will be banked*

*• Information on potential insurance implications*

*• What happens if a genetic trait is found*

*Part of main research project*

This procedure forms part of the main research project. There is no extra physical risk to you as part of the research.

*Explain the risks associated with the type of storage (individually identifiable, re-identifiable or non-identifiable)*

Your *[Specify biospecimen]* will be stored in a(n) *identifiable/non-identifiable* form in the bank. The risk of identifying you *[Explain how it will be confidential and, if it is identifiable, where it will be kept and who will have access to it]*.

*Part of routine care*

This procedure was recommended by your doctor as part of your routine care for your condition and is not part of the research. There is no extra physical risk to you as part of the research.

**17 Will I be informed of results of future research using my biospecimen?**

*Provide information on whether the participant will be informed of future results. In particular, if future research uncovers a genetic trait will the participant be informed? What are the risks associated with this?*

**18 Banking of Health Information**

*Specify what health information will be stored (if any). List the types of information to be collected or used for the research project including the time period from which they are collected.*

The health information we will collect and store in a bank for this research project is: *[Provide details]*

*Provide information relating to who may see the participant’s health information.*

We will not use your personal health information for a different research project without the permission of a Human Research Ethics Committee. Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the research project may be presented in public talks or written articles but information will not be presented that identifies the participant.

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

**19 What will happen to information about me?**

***Victorian law***

*Your collection, use and disclosure of a person’s health information is governed by the Health Records Act 2001 (Vic) (HR Act).* ***Health information*** *is defined in the HR Act and includes (amongst other things) information or an opinion, whether true or not, about the physical, mental or psychological health (at any time) of an individual about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.*

*There are eleven Health Privacy Principles (HPPs). HPP 1 and 2 govern the collection, use and disclosure of health information, including for the purposes of research. The HR Act is administered by the Victorian Health Services Commissioner, who may issue or approve Guidelines in relation to the HPPs. The Guidelines in relation to research can be obtained from the Health Services Commissioner’s website:* [www.health.vic.gov.au/hsc](http://www.health.vic.gov.au/hsc)*.*

*Any researcher who considers that the HPPs might apply to their research should read these guidelines. It is important to note that this Victorian Act applies generally to private sector organisations when they handle health information in Victoria.*

*Your collection, use and disclosure of a person’s personal information is governed by the Privacy and Data Protection Act 2014 (Vic) (PDP Act).* ***Personal information*** *means information or an opinion (including information or an opinion forming part of a database), that is recorded in any form and whether true or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion, but does not include health information.*

*The PDP Act sets out ten Information Privacy Principles (IPPs) that regulate the responsible collection and handling of personal information by organisations in the Victorian public sector, including universities set up by state legislation. IPPs 1, 2 and 10 deal with the collection, use and disclosure of this information for the purposes of research.* The *PDP Act is administered by the Victorian Privacy Commissioner:* [www.privacy.vic.gov.au](http://www.privacy.vic.gov.au)*.*

***Commonwealth law and trans-border data flow***

*The Privacy Act 1988 (Cth) (Privacy Act) applies to Commonwealth and ACT government agencies, and to certain private sector organisations. It applies to private sector health service providers, and to private and ACT universities. It does not apply to State or Northern Territory government agencies, including state and territory public hospitals and health care facilities except in relation to certain records in certain circumstances. It does not cover universities (other than private and ACT universities).*

*The Privacy Act outlines thirteen Australian Privacy Principles (APPs), which establish requirements for the collection, storage, use and disclosure of* ***personal information*** *and* ***health information****. Sections 16A and 16B of the Privacy Act set out certain circumstances in which it is permissible to collect, use and disclose personal information and health information for the purposes of research.*

*APP 8.1 requires an organisation, before it discloses personal information to an overseas recipient, to take reasonable steps to ensure that the overseas recipient does not breach the APPs in relation to the information. APP 8.1 applies to the disclosure (APP 8.1 applies to all cross-border disclosures of personal information, unless an exception in APP 8.2 applies), and the overseas recipient is not subject to the APPs, but the act or practice would be a breach of the APPs if they were.*

*APP 8.2 lists a number of exceptions to APP 8.1, including where:*

*• the organisation reasonably believes that the recipient is subject to a law or binding scheme that has the effect of protecting the information in a way that is, overall, substantially similar to the APPs; and there are mechanisms available to the individual to enforce that protection or scheme (APP 8.2(a)). The requirement for an overseas jurisdiction to have accessible enforcement mechanisms introduces a higher threshold than the equivalent NPP 9 exception; or where*

*• an individual consents to the cross-border disclosure, after the organisation informs them that APP 8.1 will no longer apply if they give their consent (APP 8.2(b)).*

*There are other exceptions to the application of APP8.1 set out in APP 8.2.*

*Any researcher wishing to obtain information from a Commonwealth agency, and any researcher who considers that the APPs might apply to their research, should read the Guidelines under Section 95, 95A and 95AA of the Privacy Act 1988, issued by the NHMRC (see* [www.nhmrc.gov.au/publications/synopses/e26syn.htm](http://www.nhmrc.gov.au/publications/synopses/e26syn.htm)*).*

*The health information and personal information that you collect about an individual for the purposes of your study MUST be dealt with on a strictly confidential basis and in accordance with the HPPs, IPPs and APPs as applicable.*

*The participant should be advised of a data management plan that addresses the uses which will be made or may be made of their health and/or personal information (National Statement Chapter 3). You should make this clear to the participant in your text below. This includes:*

*• 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*

*• Whether the research project involves the possibility of trans-border transfer of the individual’s health information or health information]*

* *A data management plan should include the researcher’s intention related to generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information, the risks associated with these activities and any strategies for minimising those risks.*

*Information about the participant*

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 the data management plan and information 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.

*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.

*If there is any possibility that other investigators will be given access to samples or genetic information for research in the future, the participants must be informed of, and specifically consent to, this possibility.*

In the future, *[Provide details]* may be given to researchers as part of the search for a genetic cause of *[Name of disease]* or other research purposes. The samples will be labelled as described in Part 1 of this document.

*If data will be individually identifiable*

Your sample will be stored in such a way that your identity could reasonably be ascertained. Only those persons authorised will have access to the information. Your samples and data will not be released for any use without your prior consent, unless required by law.

*If data will be re-identifiable*

Your sample will have all identifiers (e.g. name and personal details) removed and replaced with a code. It will be possible to re-identify the sample as yours using the code. *[Provide details regarding who will have the information]*. Your samples and data will not be released for any use without your prior consent, unless required by law.

*If data will be non-identifiable*

It is anticipated that your sample will not be identified with any individual identifiers (e.g. name, date of birth) or, if it is, all identifiers will be permanently removed prior to storage.

*Review of health records*

Your health records and any information collected and stored by the study doctor during the research project may be reviewed for the purpose of verifying the procedures and the data. This review may be done by the ethics committee which approved this research project, regulatory authorities and authorised representatives of the Sponsor, *[Sponsor’s name (include international AND Australian sponsor, if applicable)]*, this organisation *[Organisation's name]*, or as required by law. In these circumstances, the Sponsor will not collect (i.e. record) your personal information. By signing the consent form, you authorise release of, or access to, this confidential information as noted above.

*Participant accessing their own information*

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 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 your information.

*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 express permission.

**20 Complaints and compensation**

***Complaints***

*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.*

*As a default, any participant with a complaint about a clinical trial should be directed to the Office of the Australian Information Commissioner. Please note, however, that this may change: The Privacy Act would continue to be administered by the Privacy Commissioner and supporting staff from an office based in Sydney. The FOI Act would be administered jointly: by the Attorney General’s Department (advice, guidelines, annual reporting), the Administrative Appeals Tribunal (merits review) and the Commonwealth Ombudsman (complaints).*

***Treatment available***

*For ALL clinical trials (commercially sponsored, collaborative group and investigator driven)*

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.

***Compensation***

*For all commercially sponsored Phase I and II clinical trials*

*ALL participants in Phase I and II clinical trials MUST be given a copy of the Medicines Australia (MA) compensation guidelines.*

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 of this research project, *[Full name of Australian corporate sponsor]* 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 Guidelines can be accessed from the Medicines Australia website at: <https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2020/11/Clnical-Trials-Compensation-Guidelines-1.pdf>. A copy of Guidelines must be made available to you by the research staff on request.

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

*For all other commercially sponsored clinical trials*

*A copy of the MA compensation guidelines should be made available on request.*

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 of this research project, *[Full name of Australian corporate sponsor]* 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 Guidelines can be accessed from the Medicines Australia website at: <https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2020/11/Clnical-Trials-Compensation-Guidelines-1.pdf>. A copy of the Guidelines must be made available to you by the research staff on request.

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

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

You do not give up any legal rights to compensation by participating in this research project. In the event of loss or injury, the parties involved in this research project have agreed to *[Description of compensation agreements]*.

**21 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)]

**22 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.

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

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 | *[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 research project). Contact your local HREC administrator (single site research project) 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**

|  |  |
| --- | --- |
| **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]* |

**Consent Agreement**

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 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 project without affecting my future health care.

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

*Optional paragraph:*

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

In respect to receiving information in relation to my genetic materials:

If research with my DNA and/or tissue reveals some other medical condition relating to me or my family for which treatment is available or pending:

|  |  |
| --- | --- |
| a. I wish to be informed | Yes  No |
| b. I wish for affected family members to be informed and I give my consent for the researcher to approach my relatives on my behalf | Yes  No |

In respect to the storage and use of my genetic samples, I give permission for the use of my DNA and/or tissue for the purpose of:

|  |  |
| --- | --- |
| 1. this research project only | Yes  No |
| 2. this research project and any closely related future research projects | Yes  No |
| 3. future research projects that may or may not be related to this research project | Yes  No |

*Additional consent for banking (if appropriate):*

I understand that I can withdraw my consent to participate in this research project by completing a “Withdrawal of Consent” form. I can also specify whether I wish to have my *[Specify biospecimen]*, which has already collected and stored, deleted, destroyed or returned to me if it is still identifiable as mine.

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.

**Declaration by Participant – for participants who have read the information**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | |
|  | Name of Participant (please print) | |  | |  |  |  |
|  | | | | | | | |
|  | Signature |  | | Date | |  |  |
|  | | | | | | | |

|  |
| --- |
| Declaration - for participants unable to read the information and consent form  See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness\*.  Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*Witness is not to be the Investigator, a member of the study team or their delegate. 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.

**Form for Withdrawal of Participation**

*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)**  *(if required by institution)* | *[Associate Investigator(s)]* |
| **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]*

*Optional paragraph:*

I request that all my *[Specify biospecimen]* collected and banked be deleted, destroyed or returned to me if it is still identifiable.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | |
|  | 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.*

|  |
| --- |
|  |

**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.