**Participant Information Sheet/Consent Form**

**Genetic Study** -*Person responsible consenting on behalf of participant*

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 3.5) for information on genetic research.

A Participant Information sheet should be aimed at persons responsible when the potential participant is unable or not competent to provide consent for themselves. Refer to *The National Statement on Ethical Conduct in Human Research* (Chapters 4.4 & 4.5) for more information. This Participant Information Sheet/Consent Form should not be used for parents/guardians of minors; an alternative template is available for parents/guardians.

**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/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 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 person responsible (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 – Person Responsible**

**Genetic Study** -*Person responsible consenting on behalf of participant*

*[Insert site name]*

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

**Part 1 What does 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.*

The participant is invited to take part in this research project because they have *[Name of condition]*. They 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 the participant to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not the participant can 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 do not wish for the participant to take part, they do not have to. They will receive the best possible care whether or not they take part.

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

• Understand what you have read

• Consent to the participant taking part in the research project

• Consent to the participant having the tests and treatments that are described

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

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

**2 What is genetic research?**

Genes are what make up 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 and the person responsible*

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

If you agree to the participant taking 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 person responsible*

There are no additional costs associated with participating in this research project, nor will you or the participant be paid. Any medication, tests and medical care required as part of the research project will be provided 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 person responsible 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 the decision to participate in a research project, the following additional sentence should be included*

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

**5 What does the participant have to do?**

*The purpose of this section is to provide the person responsible with information they need for the participant 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 Does the participant have to take part in this research project?**

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

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

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

Your decision whether the participant can or cannot take part, or can take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them or 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 the participant with any direct benefit because the link between them and their *[Specify biospecimen]* will be removed before their *[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 the participant, and you will be asked if you/they wish to know the results. The results may be important as they may provide:

• Information about risk of an inherited condition

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

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

*Include all that are relevant*

*Consideration should be given to the situation where the person responsible is a member of the participant’s family. Information obtained from the participant’s test could disclose important information regarding the person responsible themself, or other members of their family.*

Genetic testing involves the study of genetic material (typically DNA) that is shared with blood relatives. Therefore, if you are a relative of the participant, finding out the results of the participant’s genetic tests may reveal information that is important for your own, or other family members’ health. Expert counselling will be provided by *[Provide details]* to explain what the results mean for the participant as well as you and other family members.

*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 3.5.1 – 3.5.3]

In addition, if the testing shows important information about the participant’s relatives,contact with the relatives about the testing is encouraged. You may wish to do this yourself or ask the researchers to contact them on your behalf *[provide advice to the participant and justify the decision]*.

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

It will be necessary to refer the participant 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 for both the participant and their person responsible.*

*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.*

*Persons responsible/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 persons responsible/participants.*

Genetic testing involves the study of genetic material (typically DNA) that is shared with 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 provide consent for the participant.

Learning about the results from genetic research might affect you and/or the family emotionally. In some cases, the result may give certainty that the participant does 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 the participant has a disease or disorder, or whether they will develop it. Research may only show that the participant has an increased **risk** of developing a disease or disorder. Even then, there is no guarantee that the participant will develop the condition or any indication of the likely age they might get the disease or how serious the disease might be.

You and the particpant may learn information from their test result about inherited diseases or disorders that may affect others, such as their 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 the participant or their 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. Counselling may also be provided free of charge if it is appropriate. Before a test is repeated to verify a research finding, you/the participant will be informed about the possible risks involved. 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. This paragraph should be omitted if the test results will not be available to persons responsible/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 the participant’s genetic tests are not available to you or you choose not to receive the results, any future requests for insurance will not be affected by participating in this research.

If you/the participant do obtain the results of the participant’s 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 the participant’s 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 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.*

*• 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’*

The participant’s *[Specify biospecimen]* will only be used for the purpose of this research project. The *[Specify biospecimen]* provided 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 the participant’s *[Specify biospecimen]* for future use in research projects that are an extension of this research project. Alternatively we may use the 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 the participant’s *[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’ persons responsible.*

**11 What is the potential impact on the participant’s family if the participant takes part?**

*If there is any intent to gather information about the participant’s relatives, the person responsible/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. The person responsible may not be asked to release the participant’s relatives’ contact information without obtaining the relatives’ permission. Researchers may not contact the relatives without both the person responsible/participant’s permission and the relative’s permission.*

*The National Statement 3.5.8(a-h) 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 person responsible/participant, or someone else they choose, should be given the opportunity to make initial contact. Note: under the National Statement 3.5.8(g), 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 person responsible/participant giving their consent.*

You may be asked to give us health information about the participant’s relatives. Any information you give us will be kept confidential. We will not contact the participant’s relatives without your permission. We may discuss with you the possibility of including the relatives in the research project in the future. If the research discloses that one of the participant’s 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 person responsible for the participant do not consent to this.

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

*If the person responsible/participant will NOT be given the results:*

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

*If the person responsible/participant WILL be given the results:*

The participant’s genetic test results will be available to you should you wish. It is your/the participant’s decision whether you wish to be informed of the results. Before you decide if you wish to have the 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 the genetic test results, specialist clinical geneticists and genetic counsellors will speak with you and the participant, 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 and the participant, 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 the participant’s health care, you will be asked whether you and the participant wish to receive the results (this may require them to have the test repeated in a clinical laboratory). We may contact you if such a situation arises.

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

There is the possibility that this research may result in commercially viable technology or treatments. However, neither you nor the participant will be able to claim financial benefit from any discoveries arising from the use of the participant’s *[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.

The participant’s *[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 the participant’s *[Specify biospecimen]* for future research. The study doctor would like the participant to consider taking part in this bank because they have *[Specify condition]*. In the future, other doctors and scientists at this and other medical and research centres may use the participant’s *[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 the participant’s *[Specify biospecimen]* from *[Specify procedure]*.

*Leftover specimen*

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

*Location of biospecimen storage*

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

*Duration of biospecimen storage – for limited time*

The participant’s *[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 the participant’s *[Specify biospecimen]* in a bank is to answer questions in the future, so we expect to keep the *[Specify biospecimen]* for a long time.

*Removal/destruction of stored biospecimen – identifiable*

The participant’s *[Specify biospecimen]* will be stored at *[Name of bank]*. It will be identified as theirs. You/the participant 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*

The participant’s *[Specify biospecimen]* will be stored at *[Name of bank]*. It will be stored as a re-identifiable sample. This means that the sample will be identifiable by a code; it can be identified as the participant’s even though the bank does not know their identity. You/the participant 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*

The participant’s *[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 the participant’s, and so you/the participant will not be able to have the specimen removed or destroyed.

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

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

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

*⮞ 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 more future research identifies a genetic marker for disease and the person responsible/participant will be informed, what are the implications to the person responsible/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)*

The participant’s *[Specify biospecimen]* will be stored in a(n) *identifiable/non-identifiable* form in the bank. The risk of identifying the participant *[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 the participant’s doctor as part of the routine care for their condition and is not part of the research. There is no extra physical risk as part of the research.

**17 Will the participant and I be informed of results of future research using the participant’s biospecimen?**

*Provide information on whether the person responsible/participant will be informed of future results. In particular, if future research uncovers a genetic trait, will the person responsible/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 the participant’s 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 or the participant. 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 the participant?**

*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 the participant for the research project. Any information obtained in connection with this research project that can identify them will remain confidential. *[Explain how it will be confidential and, if it is identifiable, where it will be kept and who will have access to it].* The participant’s information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

*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 participation in this research project may be recorded in the participant’s 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 person responsible 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*

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

*If data will be re-identifiable*

The participant’s 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 theirs using the code. *[Provide details regarding who will have the information]*. The participant’s 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 the participant’s 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*

The participant’s 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) any 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/the participant have the right to request access to the participant’s information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access the participant’s information.

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

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your express permission.

**20 Complaints and compensation**

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

If the participant suffers any distress or psychological injury as a result of this research project, you should contact the study team as soon as possible. They will assist you in arranging appropriate treatment and support.

*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 for seeking compensation if the participant suffers an injury as a result of 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 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, as follows: Phase One First-in-human trials – a “nominated person” in the department capable of explaining them; Other Phase One and Phase Two trials – Ethics Office contact or the ‘complaints contact’].*

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

*For all other commercially sponsored clinical trials*

There are two avenues that may be available to you for seeking compensation if the participant suffers an injury as a result of 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 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 Ethics Office contact or the ‘complaints contact’]*.

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

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

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

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

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

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

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

No member of the research team will receive a personal financial benefit from 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 the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor on *[phone number]* or any of the following people:

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

 **Clinical contact person**

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

For matters relating to research at the site at which 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 – Person Responsible**

|  |  |
| --- | --- |
| **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 Person Responsible**

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 the participant taking part in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

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

*Optional paragraph:*

I give permission for the participant’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning their 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 the participant’s genetic materials:

If research with the participant’s DNA and/or tissue reveals some other medical condition relating to them or their family for which treatment is available or pending:

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

In respect to the storage and use of the participant’s genetic samples, I give permission for the use of the participant’s 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 the participant’s participation in this research project by completing a “Withdrawal of Consent” form. I can also specify whether I wish to have the participant’s *[Specify biospecimen]*, which has already collected and stored, deleted, destroyed or returned to me if it is still identifiable as theirs.

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

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Participant (please print) |  |  |
|  |  |  |  |
|  | Signature of Participant*(Optional: remove if not required)* |  | Date |  |  |
|  |  |  |  |  |  |
|  | Name of Person Responsible (please print) |  |  |
|  |  |  |  |
|  | Signature of Person Responsible |  | 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\* toPerson Responsible’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 person responsible for 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 – Person Responsible**

*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 Person Responsible**

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

*Optional paragraph:*

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

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Participant (please print) |  |  |
|  |  |  |  |
|  | Signature of Participant*(Optional: remove if not required)* |  | Date |  |  |
|  |  |  |  |  |  |
|  | Name of Person Responsible (please print) |  |  |
|  |  |  |  |
|  | Signature of Person Responsible |  | Date |  |  |
|  |

*In the event that the 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 person responsible for 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.