**Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Person responsible/Medical treatment decision maker consenting on behalf of participant*

A **Non-Interventional** research project involves clinical research where no interventional treatment is given to participants other than their routine care. It does not involve the administration of an investigational product, treatment or procedure. Examples include observational research and monitoring of participants.

A Participant Information sheet should be aimed at persons responsible/medical treatment decision makers when the potential participant does not have decision making capacity 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.** Non-Interventional research is a very broad area; the template should be adapted to suit the particular research project.

⮞ For projects that involve trialling a clinical drug, procedure or device, one of the other participant information and consent form templates should be used.

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

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

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

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

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

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

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

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

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

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

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

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

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

⮞ Language used should be readily understandable by the person responsible/medical treatment decision maker (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**

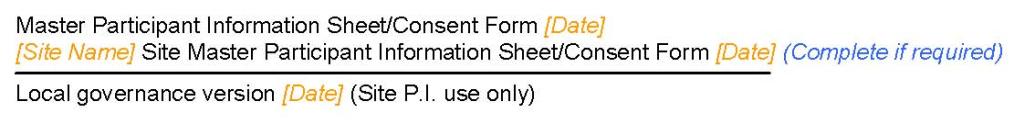
For example:

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.

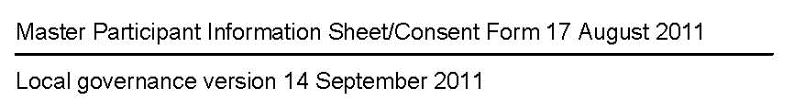
Text above the line relates to Master (and Site Master if required) version tracking of **HREC approved versions**.

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 - Person Responsible/Medical treatment decision maker**

**Non-Interventional Study** -*Person responsible/Medical treatment decision maker 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, *[Name of research project]* because *[explain reason for invitation]*. The research project is aiming to *[briefly outline the purpose/aim of the research project]*.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research 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 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 research 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 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*

*• Whether the research is for the purpose of obtaining a degree or other educational qualification, is funded by a grant, or has sponsorship of some other sort.*

*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 study doctor]* 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]*.

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

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

*Include information and clear explanation of the following:*

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

*⮞ Initial steps*

*• Screening for eligibility*

*• Randomisation and blinding, use of a control group (if applicable)*

*⮞ Procedures*

*• All procedures*

*• Nature, number, timing and time commitment of tests, procedures, visits and questionnaires (include scientific and lay measurements where relevant)*

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

*• Nature of follow-up*

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

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

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

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

*⮞ The commitment required by the participant*

*⮞ Access to personal records that may be required*

*⮞ Whether any part of the project will be recorded (video/audio)*

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

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

*Additional costs & reimbursement*

There are no costs associated with participating in this research project, nor will you or the participant be paid. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

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

*Where considered* ***desirable*** *that a participant’s local doctor be informed of participation 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 participation in a research project, the following additional sentence should be included*

If you decide that the participant can take part in this research project, the study doctor will inform the participant’s local doctor.

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

*The purpose of this section is to provide the person responsible/medical treatment decision maker 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 study*

*• The responsibility and commitment required of the person responsible/medical treatment decision maker/participant*

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

*You should explain any other relevant information including:*

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

*• Whether there are different groups e.g. case/control groups*

*• The size or scope of a project e.g. number of sites or countries involved*

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

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

*collaboration*

**6 Does the 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 take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them or relationship with *[Institution]*.

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

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

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

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

*Do not attempt to build up person responsible/medical treatment decision maker/participant hope in this section. Reference to the potential benefit to others in the future may be appropriate, but should not be exaggerated.*

We cannot guarantee or promise that the participant will receive any benefits from this research, however possible benefits may include *[describe any likely benefits to participants, others or the community]*.

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

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

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

*The layout of this section will depend on the nature of the research.*

*For readability:*

*• Use headings*

*• Use short and well-spaced paragraphs*

*• Use short uncomplicated sentences*

*• Use a table or bullet points where possible*

*• Avoid or minimise repetition*

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

*An introductory paragraph is recommended as follows:*

While this research does not involve any interventional treatment, the participant may be receiving medical treatments that cause side effects. The participant may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If they have any of these side effects, or are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

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

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the doctor may need to stop the treatment. The doctor should discuss the best way of managing any side effects with you.

*Clearly list the possible side effects including the type of symptoms, frequency, severity and duration. This should be done in language the participant can clearly understand, e.g. ‘damage to the heart’ rather than ‘cardio-toxicity’ or ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’.*

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

*It is suggested that this information is provided in either table form (see the headings displayed below), or in bullet points. Suggested table for side effects; this table is a* ***guide only****.*

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

*You should state what will happen should participation in this research uncover a medical condition of which they were unaware. State what support services would be in place and how this may affect their participation in the research project.*

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

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

*If relevant, a section regarding risks related to conception, pregnancy and breast-feeding is required. If sterility is a possible risk of participation in the research project, then this should be stated in a separate paragraph in this section. This section should not be entitled ‘Risks Related to Pregnancy,’ as there are other risks being described. The text should be adapted in to take account of the nature of the research project. It should also be altered if the project is specifically for female or male participants only. Check for any site-specific requirements in relation to this statement.*

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

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

*[For* *person responsible/medical treatment decision maker for female participants]* If the participant becomes pregnant during the research project, you should advise her study doctor immediately. The study doctor *will/may* withdraw her from the research project and advise on further medical attention should this be necessary. The participant must not continue in the research if she becomes pregnant.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Participants must be clearly informed whether participation in the research project involves exposure to radiation.*

***For Victoria only:*** *Researchers must submit a radiation safety risk assessment (Medical Physics Risk assessment form) for each site in Victoria and must consult with the Radiation Safety Officer (RSO) at the institution where the ionising radiation procedure will occur. The risk statement used must be approved by the institution’s RSO.*

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

*Option 1 - Effective dose less than 2 mSv*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*• The nature of the testing*

*• The person responsible’s/medical treatment decision maker’s/participant’s rights*

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

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

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

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

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

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

*⮞ Whether feedback of information of potential significance to the participants’ relatives’ future health will be discussed with persons responsible/participants*

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

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

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

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

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

*Additional requirements regarding HIV, hepatitis and any other reportable diseases testing:*

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

The proposed blood tests include a screening test for HIV (also called the ‘AIDS’ virus) and Hepatitis. The swab taken of the back of the participant’s throat and nasal passage will be tested for Covid-19 *[(also referred to as ‘Coronavirus’) to be deleted if it is a Covid-19 study and already explained].* This is because the study doctors need to know *[state reason]*. You and the participant will receive information and counselling before the test. If a test shows the participant has HIV or Hepatitis or Covid-19 or any other reportable diseases, you will both have follow-up counselling and medical advice. If the participant’s test results are positive, the study doctors are required by law to notify government health authorities. Signing the consent form means that you agree for the participant to have this testing; it will not be done without your consent.

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

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

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

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

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

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

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

**13 What if the participant is withdrawn from this research project?**

*Provide information regarding how participants can be withdrawn and implications for them if they do so. Include information on the use and submission of the withdrawal of consent form.*

If you decide to withdraw the participant from this research project, please notify a member of the research team before withdrawal. A member of the research team will inform you if there are any special requirements linked to withdrawing.

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

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

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

*The person responsible/medical treatment decision maker/participant should be advised of the potential for the project to be terminated before completion and the reasons that might make termination necessary.*

This research project may be stopped unexpectedly for a variety of reasons. These may include *[provide possible reasons]*.

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

*Provide details regarding follow-up arrangements*

*If the treatment will not be available after the research finishes this should be explained to the person responsible/medical treatment decision maker. You should also explain to them what treatment will be available instead. If the treatment is to be made available, specify any requirements or limitations, including cost to the person responsible/medical treatment decision maker/participant.*

*Provide information on how the person responsible/medical treatment decision maker/participant will find out about the success of the project. State how, and approximately when, they will be provided with a summary of the results when the research project is completed.*

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

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

***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.*

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 the participant 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].* 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.

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

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

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

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

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

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

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

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

*Indicate whether the participant can access their own information/data.*

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

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

*If additional use of the information is contemplated, this should be explained and specific consent should be sought from the person responsible/medical treatment decision maker for that additional use.*

**17 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.*

*As a default, any participant with a complaint about a study 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).*

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 the participant is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

*Compensation*

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

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

*Organising and funding research*

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

*Where commercial sponsorship is available*

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

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

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

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

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

Neither you nor the participant will benefit financially from involvement in this research project even if, for example, the participant’s samples (or knowledge acquired from analysis of the samples) prove to be of commercial value to *[Company/University]*.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to *[Company/University]*, the study doctors or their institutions, there will be no financial benefit to you, the 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 the participant’s involvement in this research project (other than their ordinary wages).

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

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

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *[Name of institution]*.

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

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

**20 Further information and who to contact**

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

If you want any further information concerning this project or if the participant has any medical problems which may be related to 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 clinical contact* ***must*** *be provided and clearly denoted*.

**Clinical contact person**

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

For matters relating to research at the site at which the participant is taking part, 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. Contact your local HREC administrator 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/Medical treatment decision maker**

|  |  |
| --- | --- |
| **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 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 the participant’s condition and treatment for the purposes of this project. I understand that such information will remain confidential.

*Optional paragraph:*

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

**Declaration by Person Responsible/Medical treatment decision maker – for Person Responsible/Medical treatment decision maker who has read the information**

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Person providing consent (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Relationship of Person providing consent to Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Person providing consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Declaration - for Person Responsible/Medical treatment decision maker 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 person responsible/medical treatment decision maker 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/Medical treatment decision maker**

*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.*

|  |  |
| --- | --- |
| **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/Medical treatment decision maker**

I wish to withdraw the participant from taking part 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]*.

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Person providing consent (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Relationship of Person providing consent to Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Person providing consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 person responsible/medical treatment decision maker 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.