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| **Instructions for creating a participant Information Sheet/Consent Form****LREP Low & Negligible Risk PICF Template version dated August 2019*** This template is a guide only. Research is a very broad area; the template should be adapted to suit the particular research project
* If more than one type of Participant Information Sheet/Consent Form (PICF) is required for your project, please label the different forms clearly for the different participant groups.
* There are 13 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 NHMRC National Statement (2007 and updates) and ICH-GCP elements are addressed.
* You should delete any headings and sections that are not relevant to your project and/or modify paragraphs so that they are relevant to your project
* In this template, there are prompts for the content of your PICF in ***blue italics***and instructions regarding the format of your document in ***purple italics***. Please ensure you delete all prompts (***blue italics***) and instructions (***purple italics***) from the final document.
* Preferred language recommendations for use in your Participant Information Sheet are in **black text**. Ensure that relevant texts are removed in the final document. This formatting does not apply to the Consent form section.
* For interventional projects where participant clinical care may be impacted, please ensure that the electronic scanning booklet barcode, patient label and page numbers remain on the first page to be scanned into the patient’s digital medical records
	+ For non-interventional, observational or audit projects that do not impact the participants clinical care – booklet barcode and patient label can be removed from the header of the first page.
	+ For projects obtaining consent from staff only – booklet barcode and patient label can be removed from the header of the first page.
* Include the version date of the document in the footer of each page
* 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.
* Study participants should be referred to as ‘participants’ and not ‘subjects’ or ‘patients’
* 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.
* Language used should be readily understandable by the participant (Grade 8 reading level or below) and include Australian spelling of words.
* If translated Participant Information Sheet/Consent Forms are to be used, please check with the Office for Research 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
* **Please delete this instructional box before submitting**
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| --- | --- |
| **Title** | *[Project Title]* |
| **Sponsor** | *[Sponsor name, generally the institution that funds/owns/initiated the project]* |
| **Principal Investigator (PI)** | *[Title, First Name, Surname of PI]* |
| **Associate Investigator/s (AI)** | *[Title, First Name, Surname of AI/s]* |
| **Location** | *[Location e.g. Sunshine Hospital, Footscray Hospital etc.]* |

1. **Introduction**

You are invited to take part in this research project, *[Name of research project]*. This is 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 to take part in the research.

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

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

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

* Understand what you have read
* Consent to take part in the research project
* Consent to the tests and research that are described
* Consent to the use of your personal and health information as described.

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

1. **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*
* *Number of people who will participate in this project*
* *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 researcher *[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 researcher, *[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]*.

1. **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 (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 of follow-up*
	+ *Duration of participant’s involvement (including follow-up)*
	+ *Duration of the research project (if this is different from their involvement)*
* *How the research will be monitored*
* *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 researchers or participants jumping to conclusions.

*Costs & reimbursement*

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

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

You will be reimbursed for any of the following costs that you incur as a result of participating in this research project *[list relevant costs that will be reimbursed]*. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

*Where considered DESIRABLE and relevant that a participant’s local doctor is informed of their decision to participate in a research project, the following additional sentence should be included*

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

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

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

1. **Do I have to take part in this research project?**

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

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

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

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Western Health.

*Alternatives to participation, if there are other treatments that 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).*

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

1. **What are the possible benefits of taking part?**

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

We cannot guarantee or promise that you will receive any benefits from this research, however possible benefits may include *[describe any likely benefits to participants, 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 direct benefit to you from your participation in this research.

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

*For readability:*

* *Use headings*
* *Use short and well-spaced paragraphs*
* *Use short uncomplicated sentences in a language the participant can clearly understand*
* *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*

Possible risks, side effects and discomforts include *[list and quantify all risks, for example, one in fifty]*

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

If you become upset or distressed as a result of your participation in the research, the researcher 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.

*Include a general statement advising that participants can suspend or even end their participation in the project if distress occurs.*

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

*It may be advisable to include a statement such as:*

There may be additional unforeseen or unknown risks.

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

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

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

1. **What if new information arises during this research project?**

Sometimes during the course of a research project, new information about the risks and benefits of the project may become known to the researchers. If this happens, the researchers will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the researchers will make arrangements for your regular health care to continue if applicable. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the researchers or your doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue. In all cases, you will be offered all available care to suit your needs and medical condition.

1. **What if I withdrew from this research project?**

*Provide information regarding how participants withdraw 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 from this research project, please notify a member of the research team before you withdraw. 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 withdraws part-way through a research project that data collected to that point will be kept and will not be able to be deleted.*

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

1. **What happens when the research project ends?**

*Provide details regarding follow-up arrangements*

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

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

1. **What happens to the information about me?**

*Victorian law*

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

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

*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.*

*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).*

*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 Principal Investigator and authorised research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. *[Explain how the data management plan and information will be confidential and, if it is identifiable, where it will be kept and who will have access to it].* Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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

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

*Provide information regarding the review of health records by researchers and by representatives of regulatory authorities, WH Office for Research and the sponsor (if applicable) for the purpose of verifying the procedures and the data.*

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. 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, Western Health, 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 you cannot be identified, except with your permission. *[Describe how confidentiality will be maintained.]*

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

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

*The participant can access their own information/data according to relevant National and/or state laws.*

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. 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 your information.

Any information obtained for the purpose of this research project *and for the future research described in Section 10* that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

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

1. **Who is organising and funding the project?**

*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.

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

*[Western Health/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 researchers, sponsors and institutions*

1. **Who has reviewed the research project?**

The ethical aspects of this research project have been approved by the Low Risk Ethics Panel of Western Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007 and updates). 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.*

1. **Further information and who to contact**

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

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the Principal Investigator, *[Name]* 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*.

**Research contact person**

|  |  |
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| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Institutional email address, do not use gmail, hotmail etc.]* |

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 the local site complaints person at Western Health:

**Complaint contact person**

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| Position | Research Program Director/Director of Research, Western Health Office for Research |
| Telephone | (03) 8395 8073 |
| Email | ethics@wh.org.au |

You will need to tell the Research Program Director/Director of Researchthe name ofone of the researchers given in section above.

**Consent Form**

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| **Title** | *[Project Title]* |
| **Sponsor** | *[Sponsor name, generally the institution that funds/owns/initiated the project]* |
| **Principal Investigator (PI)** | *[Title, First Name, Surname of PI]* |
| **Associate Investigator/s (AI)** | *[Title, First Name, Surname of AI/s]* |
| **Location** | *[Location e.g. Sunshine Hospital, Footscray Hospital etc.]* |

**Consent Agreement**

* I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
* I understand the purposes, procedures and risks of the research described in the project.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received.
* I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
* I understand that I will be given a signed copy of this document to keep.

*Optional paragraph:*

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

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

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration - for participants unable to read the information and consent form**

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| See ICH Guideline for Good Clinical Practice (Nov 2016) Section 4.8.9. The subject’s legally acceptable representative may be a witness\*.Witness to the informed consent processName (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\*Witness must be 18 years or older. |

**Declaration by Principal Investigator/Senior Researcher†**

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

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|  | Name of Principal Investigator/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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

**Form for Withdrawal of Participation**

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary.*

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| --- | --- |
| **Title** | *[Project Title]* |
| **Sponsor** | *[Sponsor name, generally the institution that funds/owns/initiated the project]* |
| **Principal Investigator (PI)** | *[Title, First Name, Surname of PI]* |
| **Associate Investigator/s (AI)** | *[Title, First Name, Surname of AI/s]* |
| **Location** | *[Location e.g. Sunshine Hospital, Footscray Hospital etc.]* |

**Declaration by Participant**

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

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Principal Investigator/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Principal Investigator/Senior Researcher†**

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

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|  |
|  | Name of Principal Investigator/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† 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.