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| **Instructions for creating a Participant Information Sheet/Consent Form****Quality Assurance PICF Template version dated July 2024.*** \*Minimal Risk Research has now replaced the previous terminology “Negligible Risk Research” in the NHMRC National Statement on Ethical Conduct of Human Research 2023 and updates.
* This template is a guide only. Quality Assurance and Minimal Risk Research is a very broad area; the template should be adapted to suit the methodology of the 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 12 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 (2023 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 e.g., if the participant is a staff member, then the text referring to medical treatment or relationships with your doctor or suggesting you consult your doctor may not be relevant.
* 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 only relevant text remains in the final document. This formatting does not apply to the Consent form section.
* Include the Document name, QA reference number and the version and 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 just in case additional requirements apply. E.g., A certification of translation.
* You should state whether an interpreter will be used in the consent process and/or during the collection of data. If yes, the interpreter will need to complete an interpreter declaration in the PICF.
* Researchers are to be aware of and check that the Australian Charter of HealthCare Rights is displayed and/or is available for patients to read in any location where recruitment may occur. E.g., consulting rooms, Outpatients etc. as this is a requirement of the Australian Commission on Safety and Quality in Health Care and relates to the NSQHS Standards.
* Please consider obtaining consumer engagement at the PICF development stage of your project. For more information or to connect with a consumer email: consumers@wh.org.au
* Text should be at least font size 11 in an easily readable font style. Arial is the preferred WH font.
* 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 Quality Assurance/Minimal Risk Research/Evaluation project, (Select the type of project and delete non applicable text) *[Name of project]*. This is because *[Explain reason for invitation]*. The project is aiming to *[briefly outline the purpose/aim of the project]*.

This Participant Information Sheet/Consent Form tells you about the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) and what it involves involved. Knowing what is involved will help you decide if you want to take part in the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text).

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether to or not to take part, you might want to talk about it with a relative, friend or local doctor. *[if the participant is a staff member it may be relevant to delete local doctor and insert colleague]*

Participation in this Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) 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 Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text), you will be asked to sign the consent section by signing it you are telling us that you: *[if consent is implied revise this statement to reflect actual method of consent.] e.g. If you decide you want to take part in the project by completing the survey questions you will have implied your consent and you will be telling us that you:*

* Understand what you have read.
* Consent to take part in the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text)
* Consent to the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) requirements 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. [or if applicable you can add] *[ It will be an attachment in the email invitation or it can be downloaded from the link in the invitation or at the beginning of the survey.]*

1. **What is the purpose of this Quality Assurance/Minimal Risk Research/Evaluation project** (select the type of project and delete non applicable text)**?**

*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/number of records being collected.*
* *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 project is for the purpose of obtaining a degree or other educational qualification, is funded by a grant, or has sponsorship of some other sort.*

*If applicable include details for the following:*

* *Details regarding who if anyone will benefit from the project. It is for the purposes of attaining an educational qualification, an investigator-initiated project, funded, collaborative group, or externally initiated.*

*Where the project is for the purpose of obtaining a degree or other educational qualification:*

The results of this Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) will be used by the Investigator *[name of Investigator]* to obtain a *[full name of degree]* degree.

*Where the project is investigator-initiated:*

This Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) has been initiated by the Investigator, *[name]*.

*Where the project is funded by a grant:*

This Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) has been funded by *[name of granting body]*.

*If the project involves a collaboration with external institution:*

This Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) is being conducted in collaboration with *[name of collaborative research group or other]*.

1. **What does participation in this Quality Assurance/Minimal Risk Research/Evaluation project**, (select the type of project and delete non applicable text) **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 activity being performed or if applicable consent will be implied by completion of the survey or questionnaire etc.*
* *Inclusion Criteria*
* *Procedures*
	+ *All procedures*
	+ *Nature, number, timing and time commitment of visits, interviews, focus groups and questionnaires (include scientific and lay measurements where relevant).*
	+ *Nature of follow-up.*
	+ *Duration of participant’s involvement (including follow-up).*
	+ *Duration of the project (if this is different from their involvement).*
* *Reimbursement and costs (if applicable).*
* *How the project 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 projects)*

This Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) has been designed to make sure the Investigators interpret the results in a fair and appropriate way and avoids Investigators or participants jumping to conclusions.

*Additional 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 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 Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) *[list relevant costs that will be reimbursed]*. You may be reimbursed for any reasonable travel, parking, meals, and other expenses associated with the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) visit.

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

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

Participation in any Quality Assurance/Minimal Risk Research/Evaluation 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 the participation involves an online anonymous survey or any anonymous survey or data collection, then the participant must be advised that they may withdraw up until their survey responses are submitted or the data collection is completed. If they withdraw after the data is submitted there will be no way to identify their data so it cannot be excluded from the study]*

If you do decide to take part, you will be given this Participant Information and Consent Form to sign *[leave to sign if applicable, otherwise ‘to sign’ can be deleted if implied consen*t] 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. *This sentence will need to be revised if the participant is staff. A suggested replacement is [Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your employment status or employment prospects or your relationship with Western Health]*

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 Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text), however possible benefits may include *[describe any likely benefits to participants, others, or the community]*.

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

There will be no direct benefit to you from your participation in this Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text).

1. **What are the possible risks and disadvantages of taking part?** *(If applicable)*

*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.*

*If relevant a paragraph regarding risks associated with psychological upset and or uncomfortable feelings must be included.*

If you become upset or uncomfortable as a result of your participation in the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text), the Investigator 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 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 they are feeling upset or uncomfortable.*

*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 project uncovers 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 project.*

1. **What if I withdrew from this Quality Assurance/Minimal Risk Research/Evaluation project** (select the type of project and delete non applicable text)**?**

*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 or verbal withdrawal.*

If you decide to withdraw from this Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text), please notify a member of the project team before you withdraw. A member of the project team will inform you if there are any special requirements linked to withdrawing. You may be asked why you are withdrawing from this project and you do not have to give a reason and it is entirely up to you.

*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 Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) , the Investigators and relevant project staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) can be measured properly and to comply with law. You should be aware that data collected by the Investigators up to the time you withdraw will form part of the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) results. *If applicable- for anonymous data collection the participant will need to know their data will not be able to be removed if they withdraw after the data collection is completed. E.g., online survey, anonymous once submitted there is no way to retrieve an individual's data as there are no identifiers* If you do not want them to do this, you must tell them before you join the project.

1. **What happens when the Quality Assurance/Minimal Risk Research/Evaluation project** (select the type of project and delete non applicable text) **ends?**

*Provide details regarding follow-up arrangements, if applicable.*

*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 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 Investigator 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 Legislation Amendment Act 2006 (Cth) made changes to the Privacy Act 1988(Cth) (the Privacy Act) to allow health practitioners to disclose patient’s genetic information, whether or not they give consent, in circumstances where there is reasonable belief that doing so is necessary to lessen or prevent a serious threat to the life, health or safety of their genetics relative(s). The amendments do not oblige disclosure of information but provide the framework for this to occur under the appropriate circumstances.*

*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 several 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 like 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 Investigator wishing to obtain information from a Commonwealth agency, and any Investigator 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*  [Guidelines approved under Section 95A of the Privacy Act 1988 | NHMRC)](https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988)*).*

*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 Investigator’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 or if applicable. After reading this consent form and completing the survey/questionnaire and submitting it you will have implied your consent] to the Principal Investigator and authorised project staff collecting and using personal information about you for the research project. Any information obtained in connection with this project that can identify you will remain confidential. Or in the case of non-identifiable data use. There is no identifying information obtained. *[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 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 project. By signing the consent form, you agree to the project team accessing health records if they are relevant to your participation in this project.

*Provide information regarding the review of health records by Investigators 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 project is 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 project 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 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 project will be noted in their health record, the following should be included:*

Information about your participation in this 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 project team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the project 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 project *and for the future research described in Section 9* 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?**

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

*Organising and funding this project*

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

*Where commercial sponsorship is available*

This 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]*.In addition, if knowledge acquired through this project leads to discoveries that are of commercial value to *[Company/University]*, the Investigators 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 Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) project.

No member of the project team will receive a personal financial benefit from your involvement in this Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) project (other than their ordinary wages).

*Add any declarations of interest of Investigators, sponsors, and institutions.*

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

The ethical aspects of this Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) have been reviewed and approved by the Office for Research of Western Health.

This project is consistent with Ethical Considerations in Quality Assurance and Evaluation Activities (NHMRC, 2014) and it will be carried out according to the National Statement on Ethical Conduct in Human Research (2023 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 the project will be carried out or by the institution responsible for supervising the standard of care where the project 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 (If staff involved then deletion of the word medical may be appropriate- also side effects) problems which may be related to your involvement in the project (for example, any side effects), you can contact the following people: (copy and paste table if more than one contact)

**Project contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Institutional email address, do not use Gmail, Hotmail etc.]* |

**Other resources available to participants**

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| Wilim Berrbang (Aboriginal Health Unit): Telephone: (03) 8345 0952 or email: wilim.berrbang@wh.org.au |
| Diversity, Equity, and Inclusion: Telephone: 0466 651 146 or email: wh-dei@wh.org.au |
| Disability Liaison: Telephone:0481 396 300 or email: Disabilityliaison@wh.org.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a participant in general, then you may contact the local site complaints person at Western Health:

**Complaint contacts person**

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

You will need to tell the Research Program Directorthe name of the project contact person(s) provided in the section above.

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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 project/activities/ requirements 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 project as described and understand that I am free to withdraw at any time during the project without affecting my future health care. *(If staff is participant replace future health care with future employment/relationship with Western Health)*
* 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 the Interpreter (if applicable)**

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| Name of Interpreter\* (please print) |   |  |
|   |
| Signature |   |  Date |   |
|  |

\*Required when this document is read to the participant in a language other than English.

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

I have given a verbal explanation of the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) project; its procedures and risks and I believe that the participant has understood that explanation.

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

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

*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 Investigators 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 Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Western Health. *(If staff participant - replace routine treatment with ‘employment’ and delete my relationship with those me)*

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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 Investigator will need to provide a description of the circumstances below.*

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**Declaration by the Interpreter (if applicable)**

|  |  |  |
| --- | --- | --- |
| Name of Interpreter\* (please print) |   |  |
| Signature |   |  Date |   |

\*Required when this document is read to the participant in a language other than English.

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

I have given a verbal explanation of the implications of withdrawal from the Quality Assurance/Minimal Risk Research/Evaluation project, (select the type of project and delete non applicable text) project, and I believe that the participant has understood that explanation.

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

† A senior member of the project team must provide the explanation of and information concerning withdrawal from the project.

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