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| **Instructions for creating a Participant Information Sheet and Consent Form (PICF)**   * **This template is a guide only for low-risk projects that are to be conducted in NNSW LHD, and are reviewed through a** [**non-Human Research Ethics Committee (HREC) pathway (i.e. Quality Activity projects)**](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance)**. Please tailor the PICF to the sites where the project will be conducted.** * The 14 headings included in this template ensure all the [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) elements are addressed. * Delete any headings and sections including the consent and withdrawal forms 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 orange) and instructions regarding the format of your document (in *blue italics*). * Plain language (between Grade 6 and 8 grade reading level) and Australian spelling of words should be used. You can reduce the complexity of your information by using shorter sentences and paragraphs, and separating large lists into dot points, for further details see [Health Literacy Northern NSW Checklist for designing consumer-friendly health information](https://healthliteracy.nnswlhd.health.nsw.gov.au/wp-content/uploads/2018/07/NNSW-Patient-Information-Checklist-2018.pdf). Microsoft Word can calculate the reading level, but for those wanting a visual of how complex their writing is use this [online editor](https://sydneyhealthliteracylab.org.au/health-literacy-editor/). * Text should be at least font size 11 in an easily readable font style ([NSW branding guidelines require public sans font to be used](https://digitalnsw.github.io/public-sans/download/) alternatively Arial font can be used). * Include the version number and date of the document in the footer of each page. * Ensure that all font styles and sizes, and bolding are intended and that any variations are consistent throughout the document. Bold should be used to highlight important parts of the text.   **Delete this information page, all prompts (orange) and instructions (*blue italics*) from the final document.**  **Resources:**  For more information on Participant information Sheets and Consent Forms including order of questions and suggested text:   * [**National Health and Medical Research Council Standardised participant information and consent forms**](https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources) for interventional (clinical trial), non-interventional, and genetic studies, and health research depending on the person who is providing the consent (Self, or a Person Responsible e.g. Parent and Guardian). * [**National Statement on Ethical Conduct in Human Research (2007) – Updated 2018**](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) * Health Literacy Northern NSW. [Checklist for designing consumer-friendly health information](https://healthliteracy.nnswlhd.health.nsw.gov.au/wp-content/uploads/2018/07/NNSW-Patient-Information-Checklist-2018.pdf) |

**PARTICIPANT INFORMATION SHEET**

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| **Project title:** | [Add the title of your project] |
| **Project lead:** | [Add the name of the Project] |
| **Project team:** | [Add the name(s) of the Associate Investigators] |
| **Site(s):** | [Add the name(s) of the site(s) where the project will be conducted] |

**Introduction**

*The purpose of this section is to state the reason the participant is being invited to take part in the project and to explain the purpose of the form and the nature of informed consent. For example;*

You are invited to take part in this project because you have [name of condition or reason the individual is being invited]. Before you decide if you wish to take part in this project, it is important you understand why the project is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **What is purpose of this project?**

*Provide some background to the project, including aims and objectives, how your project intends to fill any gap in knowledge.*

The purpose of this project is to [lay description of the project].

1. **What does this project involve?**

*Provide clear and concise information on what the project involves and the time commitment required from the participant’s perspective. This may include information about:*

* *Any screening procedures that will be used to determine their eligibility to participate.*
* *The nature, location, and timing of their involvement in project activities (e.g. questionnaires, surveys, focus groups, interviews, observation, assessments, medical and other procedures).*
* *A detailed description of what project activities will involve for the participant (e.g. the types of questions asked in interviews, focus groups or questionnaires).*
* *Describe or include information about how the project will be conducted, i.e. Face to face or online etc.*
* *If interviews, focus groups or questionnaires will be undertaken online, include information about what platform will be used and where the information will be stored, i.e. Within Australia or overseas*
* *Whether there will be any audio/video/other recording of information involved.*
* *Any access to participants’ personal information or records, including specific details of any health information being requested, how this information will be accessed e.g. database/records, and for what purpose they will be used. This could include medical records, academic records, personal letters and journals, photographs etc.*
* *Whether an interpreter will be provided*
* *A description of any opportunity for participants to review information generated about them prior to publication.*

If you take part in this project, you will be asked to [lay description of what participation in the project will involve and overall time commitment required – this can be in point form].

1. **What if I don’t want to take part in the project?**

Participation in the project is voluntary. If you do not want to take part, you do not have to. If you choose not to take part in the project you will continue to receive [standard care from your doctor/treating medical team which may include (briefly describe standard care as specific and simply as possible)]. Your decision to participate or not participate will not affect your relationship with [mention specific part of the health service].

1. **Are there any risks to me in taking part in this project?**

*Please provide information on the possible risks associated with taking part in the project, it is recommended that you consistently use one format for risk i.e. don’t switch from rates to percentages as it is too hard to compare. Include the likelihood if available e.g. 1 in 1000. Use lay language to describe the nature, likelihood and severity of any risks to participants, as well as any measures that will be taken to manage these risks.*

*Possible risks may include, but are not limited to:*

* *Physical harms e.g. injury, illness, pain.*
* *Psychological harms e.g. feelings of distress or anger, learning about the possibility of developing a genetic disease, diagnosis of previously unknown medical conditions.*
* *Devaluation of personal worth e.g. being humiliated or manipulated.*
* *Social harms e.g. damage to social networks or relationships, discrimination in access to benefits, services, employment or insurance.*
* *Economic harms e.g. direct or indirect costs.*
* *Legal harms e.g. discovery and prosecution of criminal conduct if the project team is obliged to disclose information relating to criminal activity by participants.*
* *Discomfort e.g. minor physical side-effects or negative feelings.*
* *Inconvenience e.g. giving up time to participate in the project.*
* *Breach of confidentiality e.g. inadequate storage, transfer, sharing of confidential information.*

*Please also use this section to provide information on how identified risks will be managed i.e. provide participants with the information and/or contact details of where they can obtain help or support if required e.g. include contact details of counselling services or referral to specific sources of information or services e.g. General Practitioner, Emergency Department).*

1. **What will happen to information about me?**

*Information should be provided regarding the following:*

* *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*
* *Whether the participant is being asked to provide consent for the use of their data for this project only, or for extended (related activities) or unspecified (any future) activities*

By signing the consent form, you consent to the project team collecting and using information about you for the project. Your information for this project will be stored for a minimum of [Delete the options that do not apply to your project: 5 years after the publication of results; 7 years after the completion of the project; 15 years after the publication of results; Other [insert the retention period]]. The information about you will be stored in [Delete the options that do not apply to your project: an/a Identifiable format, where your identity will be known; Re-identifiable format where any information such as your name, address, date of birth will be replaced with a unique code; Non-identifiable format where your identify will be unknown].

[Storage of information, please remove the options that do not apply to your project: Information collected from you in an electronic format is stored on a NNSW LHD password protected computer. It is only accessible to the approved project team; Information collected from you using paper-based measures will be stored in the following [insert the health service facility] and only the approved project team will have access to this information; Audio or video recordings will be stored on a NNSW LHD password protected server only accessible to the approved project team [if applicable, will be made available to a professional transcription service. Recordings will only be made available after a confidentiality agreement has been signed].

1. **What if I want to withdraw from the project?**

If you do consent to take part in the project, you may withdraw at any time. You can withdraw by [Please specify the process a participant must undertake to withdraw their consent e.g. completing the ‘Withdrawal of Consent Form’ which is provided at the end of this document or you can ring the project team and tell them you no longer want to participate]. Withdrawing from the project will not affect your relationship with [mention specific part of the health service]. If you decide to leave the project, the project team will not collect any more information from you. You can ask that any identifiable information about you be taken out of the project. [If applicable, include a point in time where the data may not be able to be removed from analysis.]

1. ***OPTIONAL PARAGRAPH HEADINGS*** *include these in your participant information sheet as is appropriate to your project, otherwise* ***delete*** *this paragraph and all the points listed below. You can move and renumber the paragraph headings as required.*

* **Why have I been invited to participate in this project?**
* **Will I benefit from this project?**
* **Will taking part in this project cost me anything, and will I be paid?**
* **How will my confidentiality be protected?**
* **What will happen with the results?**
* **What happens to my treatment when the project is finished?**
* **How is this project being paid for**?
* **Are there any conflicts of interest that I should be aware of**?

1. **Where can I get more information about the project?**

If you would like to know more about the project, or if you have any concerns which may be related to your involvement in the project, you can contact the following member of the project team:

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| **Name:** | [INSERT full name] |
| **Position:** | [INSERT position title] |
| **Telephone:** | [INSERT work telephone number. Please do not use personal mobile numbers] |
| **Email:** | [INSERT work email address.] |

**Ethics approval**

This project has been reviewed and approved by the North Coast NSW Human Research Ethics Committee (HREC) as meeting the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*. The ethics approval number is QA [insert QA approval number here].

If you are concerned about the way this project is being conducted or you wish to make a complaint to someone independent from the project, please contact the Research Ethics and Governance Officer:

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| Rebecca Lavery | Research Ethics and Governance Officer |Northern NSW Local Health District |
| Email: | [NNSWLHD-Ethics@health.nsw.gov.au](mailto:NNSWLHD-Ethics@health.nsw.gov.au) |
| Telephone: | (02) 6672 0269 |

**Thank you for considering taking part in this project.**

**This information sheet is for you to keep.**

**PARTICIPANT CONSENT FORM**

*Consent to participate in the project must be voluntary and based on sufficient information and adequate understanding of both the proposed project and the implications of participating in it. Depending on the nature, complexity and level of risk of the project, explicit written consent may not always be required, and it may be justifiable to obtain verbal consent, implied consent or employ an opt out approach or a waiver of consent. Please refer to the* [*National Statement Chapter 2.2 “General requirements for consent”*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__235) *and* [*Chapter 2.3 “Qualifying or waiving conditions for consent”*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__296) *for details. If a consent form is not required, please delete this page***.**

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| **Project title:** | [Add the title of your project] |
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| **Project team:** | [Add the name(s) of the Associate Investigators] |
| **Site(s):** | [Add the name(s) of the site(s) where the project will be conducted] |

**Declaration by Participant**

I, ................................................................................... [PRINT NAME], agree to take part in this project. In giving my consent, I state that:

* I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
* I understand the purpose, procedures and risks 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 care.
* I understand that I will be given a signed copy of this document to keep.
* I understand that the interview/focus group will be recorded [delete if not applicable]

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| Name of Participant (please print) | |  | | |  |
|  | | | | | |
| Signature |  | | Date |  |  |
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| Name of Project team member (please print) | |  | | |  |
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| Signature |  | | Date |  |  |
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**WITHDRAWAL FORM**

*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 for later use, if necessary. Explicit written withdrawal may not always be required, and participants can provide notification of withdrawal via other methods e.g. verbal, email or text message. It is more important that notification of withdrawal is clearly documented and stored securely. If a withdrawal form is required please save and submit the withdrawal form for review as its own document. If a withdrawal form is not required please delete this page.*

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| **Site(s):** | [Add the name(s) of the site(s) where the project will be conducted] |

**Declaration by Participant**

I wish to withdraw my participation in the above project and understand that such withdrawal will not affect my routine care, or my relationship with the project team or *[Institution/site/service]*.

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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 [please specify by name/role i.e. Project lead/named team member] must provide a description of the circumstances below. Participants may withdraw their consent at any time without giving a reason.

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**Declaration by Project team member†**

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

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| Name of Project team member (please print) | |  | | |  |
|  | | | | |  |
| Signature |  | | Date |  |  |
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† An appropriately qualified member of the project team must provide information concerning withdrawal from the project.

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