**Instructions for creating a Participant Information Sheet and Consent Form (PICF)**

- **This template is a guide only for studies to be conducted in NNSW and/or MNC LHD. Please tailor the PICF to the LHD where the study will be conducted.**
- The 14 headings included in this template ensure all the National Statement elements are addressed.
- Delete any headings and sections including the consent and withdrawal forms that are not relevant to your study and/or modify paragraphs so that they are relevant to your research study.
- 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. Microsoft Word can calculate the reading level, but for those wanting a visual of how complex their writing is use this online 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 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** 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**
- Health Literacy Northern NSW. Checklist for designing consumer-friendly health information

**Study title (in plain language – it may be different to your official title)**

**PARTICIPANT INFORMATION SHEET**

**Introduction**

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

You are invited to take part in this research study because you have [name of condition or reason the individual is being invited]. Before you decide if you wish to take part in this study, it is important you understand the study and what it will involve. Please read the following information carefully and discuss it with others if you wish. For more information about this study please contact the [Coordinating Principal Investigator/Principal Investigator or other named investigator] (contact details listed below).

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

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

The purpose of this study is to [lay description of study].

**2. What is involved in this study?**

*Provide clear and concise information on what the study 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 study activities (e.g. questionnaires, surveys, focus groups, interviews, observation, assessments, medical and other procedures).*
- *A detailed description of what study 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 study 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 study, you will be asked to [lay description of what participation in the study will involve and overall time commitment required – this can be in point form].

**3. What if I don't want to take part in the study?**

Participation in the study is voluntary. If you do not want to take part, you do not have to. If you choose not to take part in the study 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].

**4. Are there any risks to me in taking part in this study?**

*Please provide information on the possible risks associated with taking part in the study, 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 researcher 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 study.*
- *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).*

**5. 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 study only, or for extended (related activities) or unspecified (any future) activities*

By signing the consent form, you consent to the research team collecting and using information about you for the research study. Any information collected that can identify you will remain confidential. [Explain how it will be confidential and, if it is identifiable, where it will be kept and who will have access to it]. The information you provide for this research project will be stored for a minimum of [Delete the options that do not apply to your research: 5 years after the publication of the research results; 7 years after the completion of the research; 15 years after the publication of research results; Other [insert the retention period]]. The information about you will be stored in [Delete the options that do not apply to your research: 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]. Your information will only be used for the purpose of this research study and it will only be disclosed with your permission, except as required by law. [Remove the last sentence if the data will be shared.]

[Remove the following information if the data will not be shared: You consent for the research team to share or use your information in future research that [Delete the options that do not apply to your research: will be specific to the aims of this research; will be an extension of, or closely related to, the original project; or is in the same general area of research; will be used in any future research. Your information will only be shared in a format that will not identify you].

[Storage of information, please remove the options that do not apply to your research: Information collected from you in an electronic format is stored on a [NNSW LHD/ MNC LHD] password protected computer. It is only accessible

to the approved research team; Information collected from you using paper-based measures will be stored in the following [insert the health service facility] and only the approved research team will have access to this information; Audio or video recordings will be stored on a NNSW LHD / MNC LHD password protected server only accessible to the approved research 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].

**6. What if I want to withdraw from the research study?**

If you do consent to take part in the study, 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 research team and tell them you no longer want to participate]. Withdrawing from the study will not affect your relationship with [mention specific part of the health service]. If you decide to leave the research study, the researchers will not collect any more information from you. You can ask that any identifiable information about you be taken out of the research project. [If applicable, include a point in time where the data may not be able to be removed from analysis.]

7. ***OPTIONAL PARAGRAPH HEADINGS*** *include these in your participant information sheet as is appropriate to your study, 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 study?**
   - **Will I benefit from this study?**
   - **Will taking part in this study 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 study is finished?**
   - **How is this study being paid for**?
   - **Are there any conflicts of interest that I should be aware of**?

**8. Where can I get more information about the study?**

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

| | |
|---|---|
| **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 research 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 HREC reference number is [insert REGIS reference number here e.g. ETH_2021/ETH000000].

If you are concerned about how this study is being run or you wish to make a complaint to someone independent from the study, please contact:

| | |
|---|---|
| **Contact:** | The Executive Officer, North Coast NSW Human Research Ethics Committee |
| **Email:** | NNSWLHD-Ethics@health.nsw.gov.au |
| **Telephone:** | (02) 6672 0269 |

**Details of the study and the research team:**

| | |
|---|---|
| **Study title:** | [Add the title of your research study] |
| **Human Research Ethics Committee Reference number:** | [Add REGIS reference number e.g. ETH_2021/ETH000000] |
| **Study Sponsor:** | [Add Sponsor in Australia. For most health services research this will be the organisation that employs the Coordinating Principal Investigator (CPI) or the Principal Investigator (PI)] |
| **Coordinating Principal Investigator / Principal Investigator:** *select the title that best describes their role and delete the alternative* | [Add the name of the Coordinating Principal Investigator or the Principal Investigator] |
| **Associate Investigators** | [Add the name(s) of the Associate Investigators] |
| **Site(s):** | [Add the name(s) of the study site(s) where the CPI/PI will recruit] |

**Thank you for considering taking part in this study.**
**This information sheet is for you to keep.**

## PARTICIPANT CONSENT FORM

*Consent to participate in research must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participating in it. Depending on the nature, complexity and level of risk of the research study, 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" and Chapter 2.3 "Qualifying or waiving conditions for consent" for details. If a consent form is not required, please delete this page.*

| | |
|---|---|
| **Study title:** | [Add the title of your research study] |
| **HREC ref:** | [Add REGIS reference number e.g. ETH_2021/ETH000000] |
| **Study Sponsor** | [Add Sponsor in Australia. For most health services research this will be the organisation that employs the Coordinating Principal Investigator or the Principal Investigator] |
| **Coordinating Principal Investigator / Principal Investigator:** *select the title that best describes their role and delete the alternative* | [Add the name of the Coordinating Principal Investigator or the Principal Investigator] |
| **Associate Investigators** | [Add the name(s) of the Associate Investigators] |
| **Site(s)** | [Add the name(s) of the study site(s) where the CPI/PI will recruit] |

**Declaration by Participant (or Person Responsible)** [delete if not applicable]

I, ..... [PRINT NAME], agree to take part in this study. 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 study.
- 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 study as described and understand that I am free to withdraw at any time during the study 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]

Name of Participant (please print) _____

Signature _____ Date _____

Name of Person Responsible (please print) [delete this section if not applicable]

Relation to the person being consented: [delete this section if not applicable] _____

Signature _____ Date _____

Name of Researcher (please print) _____

Signature _____ Date _____

**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 to researchers 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 HREC review as its own document. If a withdrawal form is not required please delete this page.*

| | |
|---|---|
| **Study title:** | [Add the title of your research study] |
| **HREC ref :** | [Add REGIS reference number e.g. ETH_2021/ETH000000] |
| **Study Sponsor** | [Add Sponsor in Australia. For most health services research this will be the organization that employs the Coordinating Principal Investigator or the Principal Investigator] |
| **Coordinating Principal Investigator / Principal Investigator:** *select the title that best describes their role and delete the alternative* | [Add the name of the Coordinating Principal Investigator or the Principal Investigator] |
| **Associate Investigators** | [Add the name(s) of the Associate Investigators] |
| **Site(s)** | [Add the name(s) of the study site(s) where the CPI/PI will recruit] |

**Declaration by Participant (or substitute authority)** [delete if not applicable]

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

Name of Participant (please print) _____

Signature _____ Date _____

Name of Substitute authority (please print) [delete this section if not applicable]

Relation to the person being consented: [delete this section if not applicable] _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the [please specify by name/role i.e. CPI/PI/named team member] must provide a description of the circumstances below. Participants may withdraw their consent at any time without giving a reason.

**Declaration by Researcher**[†]

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

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research study.

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