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**Participant Information Statement**

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| ***Study Title*** |  |
| ***Coordinating Principal Investigator/Principal Investigator*** |  |
| ***Associate Investigator(s)*** |  |
| ***Site(s)*** |  |

**Introduction**

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

**What is this research?**

*Provide some background to the study, including aims and objectives, in layman terms*

**What does this research involve?**

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

* *Any screening procedures that will be used to determine their eligibility for the study.*
* *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).*
* *Whether there will be any audio/video/other recording of information involved.*
* *Any access to participants’ personal information or records, including health, that is being requested, including specific details of which records/information will be accessed, how, 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 involved.*
* *A description of any opportunity for participants to review information generated about them prior to publication.*

**What are the risks associated with this research?**

*Please provide information on the possible risks associated with taking part in the research project. 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 research project.*

*Please also use this section to provide any information on how identified risks will be managed (e.g. provision of information on counselling services or referral to specific sources of information or services).*

**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 research) or unspecified (any future) research*
* *Whether the research project involves the establishment of a databank*

**What if I would like further information about the study?**

If you would like to know more about the study, and your potential involvement, please contact *[INSERT name of appropriate study investigator(s)]* who will be able to answer any questions you may have.

**Ethics approval**

This research has been reviewed and approved by the North Coast NSW (NCNSW) Human Research Ethics Committee (HREC). The approval number is *xxxxx*.

**Complaints or concerns about the study**

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the NCNSW HREC Executive Officer on:

Executive Officer|NCNSW HREC(NNSW and MNC LHDs)Email: NNSWLHD-Ethics@health.nsw.gov.au

Telephone: 02 6672 0269

All information is confidential and will be handled as soon as possible.

**Thank you for taking the time to consider this study.**

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

**Participant Consent Form**

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| ***Study Title*** |  |
| ***Coordinating Principal Investigator/Principal Investigator*** |  |
| ***Associate Investigator(s)*** |  |
| ***Site(s)*** |  |

**Declaration by Participant**

I, ................................................................................... [PRINT NAME], agree to take part in this research 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 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 care.
* I understand that I will be given a signed copy of this document to keep.

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|  | Name of Participant  |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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