**NSW Population & Health Services Research Ethics Committee**

**TEMPLATE**

**Participant Information Sheet & Consent Form**

**Instructions for Creating a Participant Information Sheet/Consent Form**

⮞ **This template is a guide only.**

⮞ If more than one Participant Information Sheet/Consent Form is required for your research study, please label the different forms clearly for the different participant groups.

⮞ You should delete any headings and sections that are not relevant to your research 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 Participant Information Sheet/Consent Form in *orange italics*.

⮞ Include the version # and date of the document in the footer of each page.

⮞ Use the ‘1 of X’ pagination option.

⮞Research study participants should be referred to as ‘participants’ and not ‘subjects’ or ‘patients’.

⮞ Language used should be readily understandable by the participant (Grade 8 reading level or below) and include Australian spelling of words.

⮞ Text should be at least font size 11 in an easily readable font style.

⮞ **Please ensure that your final document is proofread.**

*Insert Header with institution’s name or institution’s letterhead, if required*

**Title of study:** *Insert name of study*

**Participant Information Sheet/Consent Form**

**Introduction**

We are inviting you to consider taking part in a research study into *[Insert].*

The following researchers are conducting the study: *[List investigators and affiliations]*.

Before you decide whether you wish to participate in this study, it is important for you to understand why the research is occurring and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

**What is the purpose of this study?**

*Briefly describe the following aspects of the study in one or two sentences:*

 *• Aim of the study and its significance*

*• How the study is intended to fill any gap in knowledge*

*• How it may contribute to care, education, or research in the future*

*• Any relevant background including what is already known*

*• Whether the research is for obtaining a degree or other educational qualification, is funded by a grant, or has sponsorship of some other sort.*

**Why are you inviting me to participate in this study?**

We are inviting you to participate in this study because *[Explain reason for invitation].*Your contact details were obtained by/from *[provide details]*

**What if I don’t want to take part in this study?**

Participation in this study is voluntary. It is completely up to you whether you decide to take part. If you decide not to participate, it will not affect the treatment or care that you receive *[if appropriate]*, or your relationship with the researchers, your doctor or the staff caring for you *[if appropriate]*.

**What do I need to do?**

To take part all you need to do is *[provide details]*

*Include information and clear explanation of the following, as applicable:*

*⮞ Consent form will need to be signed prior to any study assessments being performed*

*⮞ Initial steps:*

*• Screening for eligibility*

*• Randomisation and/or the use of a control group (if applicable)*

*⮞ Procedures:*

*• All procedures*

*• Nature, number, timing and time commitment of procedures, visits and questionnaires*

*• Nature of follow-up*

*• Duration of participant’s involvement (including follow-up)*

*• Duration of the research study (if this is different from their involvement)*

*⮞ Whether any part of the research study will be recorded (video/audio)*

*⮞ Details on the use of interpreters in the consent and/or data collection process*

*⮞ Venue details and a statement whether participants may choose the venue*

**What information will you collect about me?**

*Include:*

 *⮞ Details of information that will be collected from the participant (eg demographics such as age, date of birth, sex, postcode of residence, Indigenous status)*

 *⮞ Details of access to personal records that may be required (including medical records; hospital charts; information held in State and Commonwealth registries or administrative databases)*

*⮞ Details of any planned data linkage*

**Linking your personal and health information**

**What does it mean to provide consent to using my health information?**

The NSW Ministry of Health and Cancer Institute NSW use personal and health information extracted from health records to run the health system. The health information exists in a number of NSW and Commonwealth administrative datasets and are de-identified to ensure your personal privacy is protected.

By supporting this research study, you are agreeing to the use of **your health information** as held in the administrative databases that have come from **your health records**. On behalf of the research team, the [specify the data linkage unit or units] will **link your health information** from the following sources:

* Public and private hospital admissions, emergency departments, ambulance services, outpatient records, and birth, marriage or death registry records held by the NSW Ministry of Health. (delete the datasets that do not apply to your research study)
* Cancer registries (NSW only)
* Medicare Benefits Scheme (MBS) records (i.e., your visits to health professionals); (delete if MBS does not apply to your research study)
* Pharmaceutical Benefits Scheme (PBS) records (i.e., your use of prescription medicines) (delete if PBS does not apply to your research study)

The linked health information provided to the research team will be in a form that will not identify you. Any health information used from these data sources are managed completely confidentially and are used only for the purpose of the research as described for this study. With your agreement, **your health information** (as drawn from your health records into the administrative datasets listed above) will be included in the linked health information.

**To participate in the study, do I have to consent to linking my health information?**

No. If you want **to opt-out** of the linking of your health information, there is an option to indicate this choice on the consent form by ticking the box for opt-out.

**Will my participation involve any risk or discomfort for me? How do I know my health information is kept confidential?**

For the linking of your health information there is a small risk to your privacy because personal information is used in the record linkage process. This risk is minimised by separating the processes of record linkage and data analysis. The record linkage only uses personal information such as name, date of birth, and home address. At the time of linkage a unique personal identification number will replace your personal information.

The linked health information provided to the researchers contains personal identification numbers and health information but no names, dates of birth or home addresses. All privacy measures have been put in place to ensure that the confidentiality of your personal and health information are maintained, including removal of identifying information, the use of unique study numbers and adherence to strict guidelines regarding data transfer, storage and access.

**How will information from the study be used to help others and me?**

In order for the wider community to benefit from the study, we plan to produce reports and/or articles that are publicly available. We will ensure that in any publication or presentation of these reports, information are presented in a non-identified and summary form, so that you or anyone else cannot be identified. Your privacy will be protected at all times.

**How will my personal and health information be managed?**

The linked health information as provided by the NSW Ministry of Health [and/or Cancer Institute NSW] will not be shared beyond the research team.

The linked health information does not include any identifying information and therefore cannot be connected back with other records for you or any other participant.

The linked health information will be retained for [xx years – minimum 5 years] and will be destroyed at the completion of this data retention period after the end of the study.

**What if I want to withdraw from the study?**

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason, by contacting *[provide researchers’ details]*. Please be assured that if you withdraw, it will not affect the treatment or care that you receive *[if appropriate]*, or your relationship with the researchers for this study *[if appropriate]*.

If you withdraw from the study, *[Provide advice on what will happen eg your samples will be destroyed; your study records will be erased; the transcripts will be destroyed]*

*[If appropriate]* However, it may not be possible to withdraw your health information from the study results if these have already had your personal identifying details removed.

If you decide to leave the study, we will not collect additional personal or health information from you, although health information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law. You should be aware that data collected, including any linked health information, up to the time you withdraw will form part of the study results.

**Confidentiality**

*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 research) or unspecified (any future research) use of their data*

*• Whether the research study involves the establishment of a databank*

By signing the consent form you consent to the research team collecting and using personal and health information about you for the research study. All this information will be treated confidentially. *[Explain how it 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 study and *[if appropriate]* it will only be disclosed with your permission, except as required by law.

*[If relevant, provide information regarding the review of health records by researchers and by representatives of regulatory authorities and the sponsor for verifying the procedures and the data].* Your health records and any information obtained during the research study may be subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the sponsor, 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.

Results of this research study will be published or presented in such a way that you cannot be identified. *[If applicable]* We will provide you with a summary of the study results if you indicate that you wish to receive them.

***For direct participant involvement***

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

*Provide information on the possible risks of taking part, including the possibility for psychological distress. Describe how risks or side effects will be managed.*

**What happens if I suffer injury or complications because of the study?**

If you suffer any distress or psychological injury because of this research study, you should contact the research team as soon as possible. We will assist you by arranging appropriate treatment and support.

*[If appropriate]*In the event of loss or injury, the parties involved in this research study have agreed to *[describe any compensation agreements]*.

**Will I benefit from the study?’**

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 or other people in the future]*.

OR

There will be no clear benefit to you from your participation in this research, but we hope that it may improve *[eg the treatment of a condition]* in the future.

**Will it cost me anything to take part in this study, and will I be paid?**

Participation in this study will not cost you anything and you will not receive any payment for your involvement in the research. *[If appropriate]* However, you may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research study visit.

**Who should I contact for further information?**

If you would like any further information concerning this study or if you have any problems that may be related to your involvement in the study, you can contact the researcher on *[Phone number]* or any of the following people:

*[Insert names and contact details]*

**What if I have a complaint?**

If you have concerns or complaints about the study or the use of your personal and health information, you should contact the Executive Officer from the Human Research Ethics Committee that has approved this study and quote [*HREC reference number*].

[Insert name of Lead HREC and contact telephone number and email address]

This study has been approved by the NSW Population & Health Services Research Ethics Committee. Any person with concerns or complaints about the conduct of the study should contact the Research Ethics Manager who is the person nominated to receive complaints from research participants. You should contact them on 02 8374 5662, or email ethics@cancerinstitute.org.au and quote [*HREC reference number*].

You may also wish to contact the Research Governance Officer or other officer for the sites involved in this study.

[Insert name of Research Governance and contact telephone number and email address]

Any issues you raise will be treated in confidence and investigated fully and you will be informed of the outcome.

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

**Participant Consent Form**

Title: *[Study Title]*

**Declaration by Participant** (Select the statements below that are appropriate for the study)

* 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 study. I am aware of any known or expected inconvenience, risk or discomfort.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received.
* I understand that my participation in this study will allow the researchers to collect and process information about my health, including health information for future medical research.
* I understand that my private personal information and medical records may be inspected by the organisations coordinating or sponsoring the study, health government authorities and ethics committees, for the purposes of audits and verification.
* I freely choose to participate in this study and I understand that I am free to withdraw at any time. If I do leave the study, it will not affect my future care.
* If I decide to leave the study, I agree that the information collected about me up to the point when I withdraw, may continue to be used by the researchers.
* I understand that the research study is strictly confidential.
* I agree to participate in this research study. By signing my name below, I am agreeing that a copy of this document was given to me.
* I agree to the researchers notifying my local doctor of my participation in the research study.

**Consent to linking health information**

**I consent to:**

* The linking of my personal and health information with the NSW Ministry of Health records for hospital and emergency departments, ambulance service, births, marriage or death registries [and cancer registries]. (delete the datasets that do not apply to your research study)
* The researchers affiliated with the study using my linked health information for the purposes of the study in a manner that does not disclose my identity.

**OR** I choose to **opt out** of the linking of my personal and health information as described in the information sheet. I understand this opt out does not impact on my participation in the other parts of the study.

|  |
| --- |
| Participant Name |
| Participant AddressStreet address, Suburb, State, Postcode |
| Participant Signature | Date dd/mm/yyyy |
| Investigator Signature(or authorised delegate) | Date dd/mm/yyyy |

**[OPTIONAL Declaration – if relevant to your study protocol]**

**Declaration by Person performing the informed consent discussion**

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

|  |
| --- |
| Name |
| Signature | Date dd/mm/yyyy |

**Revocation of Consent**

Title: *[Study Title]*

To: *[insert PI name]*

* I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** affect my rights as a patient, including health care I may need when I am no longer in the study.
* I understand that the researchers may continue to use and disclose health information about me that have already been collected if such continued use is necessary to protect the integrity of this research study. However, they will use and disclose health information only for the reasons discussed in the Participant Consent Form I signed when I joined the study.
* I agree to the researchers continuing to collect information about my health status up to [xx years] after I entered the study. **Yes / No (please circle)**

|  |
| --- |
| Participant Name |
| Participant Signature | Date dd/mm/yyyy |

The section for Revocation of Consent should be forwarded to:

(INSERT name and address of Principal Investigator)

**Participant Consent Form for MBS/PBS**

**Note to Researchers**

**Department of Human Services: MBS and PBS**

**Please note:** Consent for MBS and PBS data requires a specific and separate consent form. Please refer to the Department of Human Services for further guidance.

<https://www.humanservices.gov.au/customer/dhs/medicare>

**To obtain the current version of the MBS/PBS consent form, please email:**

statistics@humanservices.gov.au

**Insert the current version of the MBS/PBS consent form as provided by the Department of Health Services**