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Participant Information Sheet and Consent Form – Participant

Guidance and Template

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| --- |
| **Instructions for producing a Participant Information Sheet and Consent Form** |
| * In this template, there are prompts (in purple italics) and instructions (blue italics). Please ensure you that you delete all prompts and instructions from the final document. * Suggested text for usage is provided under each section. * Text size should be between 12 to 16. * The entire document should be reviewed for health literacy. You should aim for a Grade 8 Readability. The following tools will assist you <https://www.webfx.com/tools/read-able/>or <http://www.readabilityformulas.com/free-readability-formula-tests.php> * Unfamiliar concepts, for example, ‘Consumer Directed Care’, should have a short explanation. * Unfamiliar medical and clinical jargon should be avoided. If you must use jargon, provide a short explanation. * Whenever possible, acronyms are not used. If they must be used, they have been spelt out in full with a short explanation. * The active rather than the passive voice is used, for example, ‘Our nurse will change the catheter’ is better than ‘The catheter will be changed by our nurse’. * The sections in the template are not exhaustive, and other information may need be included in the informed consent form if the investigator, the funder, and/or the   HREC believes that the information is needed to better inform the participant and assist the decision-making process.   * You may also wish to draw on the [NHMRC PICF templates](https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources) to complement this guidance. |

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Your logo

**Consent Form: *[Participant Group]***

|  |  |
| --- | --- |
| **Study date period:** | *[Dates of Study]* |
| **Full study title:** | *[Study Title]* |
| **Short study title:** | *[Short Study Title]* |
| **Researchers:** | *[Research Team Members and Organisations]* |

# Introduction

*This section tells the participant why they are being invited to take part in the project, what the purpose of this sheet/form is and what constitutes informed consent*

You are invited to take part in this research study. This is because *[Explain reason for invitation]*

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. The research team are here to help you do this. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

* Understand what you have read,
* Consent to take part in the research project,
* Consent to be involved in the research described, and
* 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.

# What is the purpose of the study?

* + *The aim of the study and why it is significant*
  + *How it will fill a knowledge gap or improve care or future research*
  + *Any relevant background information*
  + *Whether the study builds on previous research conducted at Bolton Clarke*
  + *Include a statement that confirms the study has the support of the Bolton Clarke Business Stream Leader (if the project involves Bolton Clarke Staff)*
  + *Include a statement of who is funding and conducting the research*

# Who can take part in this study?

* + *Outline eligibility criteria for the study*
  + *You may also include how many people/sites will be taking part in the project, and whether any other groups are involved*

You can take part in this study if *[insert criteria for eligibility]*

# What does taking part in this study involve?

* + *Explain any screening procedures*
  + *Explain research procedures or activities, including the nature, number and time commitment*
  + *Any follow up activities*
  + *Where any research activities will be conducted*
  + *Any reimbursements of costs*
  + *Whether any research activities will be recorded (audio/video)*

If you want to participate in the study, we will ask you to:

# Do I have to be a part of this study?

* + *Explain that taking part in the study is entirely voluntary.*
  + *Clearly articulate that choosing not to participate will not impact on any care or relationship with any of the study institutions.*
  + *A statement should be included that if the participant agrees to take part in the study, they should sign the consent form (if written consent given) and retain information sheet.*
  + *Include who will collect the consent form, and that a copy can be left with the participant*
  + *Include a statement of who to contact should the participant decide to withdraw, and the process for withdrawal*
  + *See example of text below that you can use*

No, you do not have to take part in this study. It is completely up to you. Most importantly, whether you choose to be a part of the study or not, your *[care or relationship with provider/institution]* will not be affected. If you agree to be a part of the study and then change your mind, you will still get the same *[care from*

*provider/institution]* but any information already collected about you will still be used in our reports, presentations and articles*,* unless you request otherwise.

If you want to be a part of the study please sign the attached Consent Form.

You can keep the pages with information about the study but the signed consent form will be given to the researcher. If you want, you can keep a copy of the signed consent form as well.

You can change your mind whenever you want to. If you don’t want to be part of the study and then change your mind and want to be part of it again you can. If you wish to change your mind about taking part at any time - just contact the research team.

# What happens with the information collected?

* + *Provide a description of the level of confidentiality that will be applied to the participant’s private health information and who may have access to the participant’s records, where they are stored and how and when they will be disposed of;*
  + *Include a statement that data collected may be used to inform publications, reports and conference presentations.*
  + *See example of text below that you can use*

Any information that we collect from you will be confidential. If you choose to be a part of the study, the information will be changed so that no-one can identify you. All of your information will be stored securely at *[Location].* Only the researchers involved in the study will have access to your information.

We will publish and present the information we collect at conferences and in reports or articles. We will combine your information with other people who also participated in the study. However, your name will never be used, and no one will be able to tell that you were part of this study.

In keeping with the Australian guidelines for health related research, we will securely store your information for *[Length of time dependent on research type and/or organisational requirements]* and then it will be destroyed in a secure way.

# What are the possible benefits of taking part?

* + *Provide a description of possible benefits to the participant or the broader community, if any, that are reasonably expected. Take care not to raise expectations of participant benefits.*

By taking part in this study, we cannot guarantee or promise that you will receive any benefits from this research. *[Outline potential benefits]*.

# What are the possible risks and disadvantages of taking part?

* + *Provide a description of possible risks or disadvantages that may be associated with participation in the study, and how participants will be supported. If there are limited risks or disadvantages to participants, but psychological discomfort may be possible, the following wording may be useful.*

We do not expect that there are any risks or disadvantages related to you participating in this project. However, there is a chance that you may feel worried/some discomfort *[Provide reason/situation why they may feel worried/where they may experience discomfort e.g. discussing your circumstances, talking with someone new over the phone/concerned about their health information being collected]*. If you do become worried or uncomfortable, you can talk to a member of the research team *[Or appropriate individuals depending on project e.g. Bolton Clarke nurse/care staff member*] at any time. Depending on how you are feeling, we can refer you to free support services such as Lifeline (13 11 14) or BeyondBlue (1300 224 636; [beyondblue.org.au](https://www.beyondblue.org.au/)). *[You may wish to provide a second free service specific to the cohort e.g. if the project is about carers include a carer- specific service, or for staff, include reference to access to the Bolton Clarke Employee Assistance Program].* We can also help by advising you of the process to access psychology or counselling support in your local area, through your General Practitioner who can help set this up.

# How do I hear about the study results?

* + *Provide information about how the participant will find out about the project results. State how, and approximately when, participants will be provided with a summary of the results e.g., when the research project is completed.*
  + *All consent forms should provide the option to receive a summary of the results, and request address details of where to send the report (e.g. via email or postal mail)*

At the end of the study you will be provided with a one page summary of what the study has found, if you wish. You can indicate this on the consent form.

# If you have any questions about this study please contact:

**Research Team Member**

*[Name]*

*[Role] [Address] [Phone] [Email]*

# If you have any concerns or complaints about the conduct of this study please contact:

The Secretary

Bolton Clarke Human Research Ethics Committee Level 1, 347 Burwood Highway, Forest Hill, 3131

Phone: 9814 2736

Email: [ethics@boltonclarke.com.au](mailto:ethics@boltonclarke.com.au)

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Your logo

|  |  |
| --- | --- |
| **Full study title:** | *[Study Title]* |

# Participant details:

Name:...........................................................................................................

(in block letters)

I hereby agree to take part in the above study.

* The details of the study have been explained to me.
* I have a copy of the study Information Sheet.
* I understand that my information collected by the study team will be used as part of this study.
* Any questions I have asked regarding this study have been answered.
* I know that I can stop being a part of the study whenever I want.
* I understand co-design sessions, interviews or focus groups will be audio recorded.
* I agree that my data may be used as a case study or report or presented at conferences or published on the condition that my name or any other identifying information is not used.
* I understand that any information I provide will be treated as strictly confidential

I wish to receive a one-page summary of the study findings: Yes No

Email /postal address …………………………………………………………………………………………….

**Signature of participant:**……………………………………………………(Date)…………………………….

# Researcher’s declaration:

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

…………………………………………………………………………………………………………………………………. (Print name) (Signature) (Job Title) (Date)