**PARTICIPANT DOCUMENT GUIDELINES**

*For research to be ethical the right of people to make their own decisions, including deciding to participate in research, must be respected.*

*To enable an informed decision about whether to participate in research, an individual must be provided with sufficient information regarding the nature of the proposed research and the implications of participating in it.*

*This information must be comprehensible to a person with average literacy levels. It has been demonstrated that 59% of Australian adults have a health literacy level below the minimum required to meet the complex demands of everyday life (ABS 2009). The NHMRC recommends a reading level of Grade 8 or below and complex medical terms and abbreviations must be explained.*

*This summary sheet is based on guidelines issued by the NHMRC and should be suitable to adapt for the majority of research projects typically reviewed by the Ramsay Health Care Human Research Ethics Committee. For more complicated projects, further advice can be obtained from Ethics staff or from the NHMRC Ethics Portal (*[*https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/standardised-participant-information-and*](https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/standardised-participant-information-and)*)*

Please remember to keep to a reading level of Grade 8 or below and explain complex terms and abbreviations). Ensuring that your document has a logical and readable flow is more important than addressing each dot-point in turn.

**TITLE OF PROJECT:**

**HREC Approval Number:**

**INTRODUCTION/ WHAT IS THIS PROJECT ABOUT?**

* Explain (briefly) the purpose and significance of the study.
* Why have I been approached to take part in this study? (*Optional -* Approximately how many participants will be recruited?)
* What does this Participant Information document tell me and how can I get more information if I need it?
* General statement about who (researcher/discipline/institution) is primarily responsible for conducting this research. A complete list of researchers/disciplines/institutions/contact details will be included at the end of the document and does not need to be specified at this point.
* Is this project being undertaken for the purpose of obtaining an educational qualification?

**WHAT WILL I BE EXPECTED TO DO?**

* Only describe what a Participant is being asked to do for the research project.
* Please list all research activities/procedures, including duration, nature and number. Include lay measurements where possible (e.g. 20ml of blood = 1 tablespoon, 2mm biopsy = matchstick head). Clearly identify any procedures which are experimental.
* What is the overall duration of participation?
* Please describe any follow-up or monitoring.
* Are there any restrictions while in the study e.g. dietary/medication restrictions?
* Will there be any costs or will the participant be reimbursed/receive payment?
* Will researchers need to access participant medical records or any other source of data? Describe briefly what information is being sought (e.g. demographics, medical history, prescribed drugs etc.)
* Please ensure that the additional/altered activity for research purposes is clearly defined and differentiated from that performed as part of routine care.

**DO I HAVE TO TAKE PART IN THIS RESEARCH PROJECT?**

* Explain that participation in any research project is voluntary and participants can change their mind at any time. Explain that the participant’s relationship with the Hospital and/or the researchers will not be affected by either declining to participate or later withdrawing from the study.
* Outline the process for withdrawing from the study and whether and when it will be possible to withdraw samples/data.
* (*If relevant*) Alternatives to participation: Are there other treatments available and how does the research differ from standard care?

**WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART? (This and the following paragraph may be combined.)**

* Please explain potential benefits to the participant. (There may not be any.)
* Please explain potential benefits to the wider community.

**WHAT ARE THE POSSIBLE RISKS OR DISADVANTAGES OF TAKING PART?**

* Include physical, psychological, privacy or other risks.
* (*If relevant*) Outline any services which will be provided to participants who are adversely affected by the research. If the project is of a clinical nature, ensure that there is a clear process for participants to follow in the case of medical problems.

**HOW WILL PRIVACY BE PROTECTED/HOW WILL CONFIDENTIALITY BE ASSURED?**

* What measures are in place to ensure security of samples/data?
* Where will samples/data be stored? How long will they be stored?
* Who will have access to samples/data?
* How will they be identified (e.g. will codes be used)? Will they be de-identified before storage?

**WHO WILL SEE THE RESULTS OF THE RESEARCH?**

* Will the results of this study will be published in medical journals, circulated internally to staff and/or sent to participants?
* State that in any dissemination of the results, identifying details about individuals will not be included unless specific consent is given.

**FINANCIAL DISCLOSURE/CONFLICT OF INTEREST**

* Is this project funded by a grant or any other source?
* Do the researchers have a financial or other interest in this project? Will the researcher receive payment for this research?

**CONSENT PROCESS**

* Explain whether a signature will be taken (and what signing the consent form means), whether consent will be implied (i.e. through the submission of an anonymous survey) or whether an opt-out approach will be used (refer below for more information.)
* State that the participant will be given a copy of the participant information sheet and their signed consent form to keep.

**WHERE CAN I GET MORE INFORMATION ABOUT THE PROJECT?**

* Ensure the following paragraph has been included:

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:

|  |  |
| --- | --- |
| **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 Ramsay Health Care Human Research Ethics Committee A or WA|SA HREC (HREC) as meeting the requirements of the *National Statement on Ethical Conduct in Human Research,* 2023*.* The ethics approval number is [insert HREC application 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 HREC Executive Officer:

|  |  |
| --- | --- |
|  |  |
| Email: | HREC.RHC@ramsayhealth.com.au or RamsayHREC.WA-SA@ramsayhealth.com.au (select which is appropriate) |
| Telephone: | (02) 9433 3854  |

Text should be at least a font size 12 and in an easily readable font style. Include the version number and date in the footer.

**PLEASE ENSURE THAT YOUR FINAL DOCUMENT IS PROOFREAD.** We recommend you have a layperson review your document and have them explain it back to you.

**The Consent Form**

A number of considerations apply to the consent form:

* The primary source of information about the project and what participation involves is the PI document; there should be no new material presented in the consent form.
* A consent form is not necessarily required for every instance in which participant information (PI) is supplied.
* When participation involves the completion/submission of anonymous surveys/questionnaires, for example, consent is implied when these documents are returned to the researchers: the PI should include the stipulation that return of documents is taken as consent.
* Some information-gathering projects make provision for an opt-out approach, in which case the participant is given an opportunity to refuse the use of their data by returning the signed opt-out document to the investigator.
* The consent form serves as a summary of the agreement between the researcher and the participant; it can be as brief or detailed as reasonable in the circumstances. Specific details about elements which appear in the PIL do not need to be repeated/included in the consent document (for example, how a participant may withdraw from a study or the details of information to be accessed from patient records).

**CONSENT FORM**

**Study Title:**

**Coordinating Principal Investigator:**

**HREC Approval Number:**

**Declaration by Participant**

* 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 health care.
* I understand that this project has been approved by the Ramsay Health Care XXXXX Human Research Ethics Committee. I understand that the project is required to be carried out in line with the *National Statement on Ethical Conduct in Human Research*, 2023 (and updated from time-to-time)
* I understand that I will be given a signed copy of this document to keep.
* I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the researchersconcerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential *(optional delete if not required)*.
* I consent for my de-identified data (including scans, tissue samples) to be stored and used for future ethically approved research projects related to <specify condition or area of research> (optional delete of not required).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name of Participant (please print) |  |  |  |  |
|  | Signature |  |  Date |  |  |
|  |

*OPTIONAL - Under certain circumstances (see* Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness\* to informed consent is required*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  | Signature |  |  Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

***OPTIONAL -* Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation. I have answered all of the participant’s questions.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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