**Participant Information Sheet/Consent Form**

**Health/Social Science Research** -*Person responsible consenting on behalf of participant*

**Health/Social Science Research** involves quantitative and/or qualitative research of issues in health and society.

A Participant Information sheet should be aimed at persons responsible when the potential participant is unable or not competent to provide consent for themselves. Refer to *The National Statement on Ethical Conduct in Human Research* (Chapters 4.4 & 4.5) for more information. This Participant Information Sheet/Consent Form should not be used for parents/guardians of minors; an alternative template is available for parents/guardians.

**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 project, please label the different forms clearly for the different participant groups. Please note that if there is a sub-study, a separate form is required.

⮞ There are 15 numbered sections in this template. Please ensure that all relevant sections are included and numbered appropriately in your final document. These headings are included to ensure that all the National Statement elements are addressed.

⮞ You should delete any headings and sections that are not relevant to your research project and/or modify paragraphs so that they are relevant to your research project.

⮞ In this template, there are prompts for the content of your Participant Information Sheet/Consent Form (in *orange italics*) and instructions regarding the format of your document (in *blue italics*). Please ensure that you delete all prompts (*orange italics*) and instructions (*blue italics*) from the final document.

⮞ **Preferred language** recommendations for use in your Participant Information Sheet are in black text with a border around paragraphs. Ensure that the border is removed from the ‘Preferred language’ sections in the final document. Note that this formatting does not apply to section 15 or to the Consent Form or Withdrawal Form.

⮞ If institutional letterhead/logo is to be used, leave space for the letterhead/logo in accordance with the institution’s requirements.

⮞ Include the version date of the document in the footer of each page. Do not use the ‘automatic’ date insertion function.

⮞ Use the ‘1 of X’ pagination option. Ensure that all references to version date or pagination in the text are correct and consistent with the information in the footer.

⮞ Do not include a place for initialling the document on each page.

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

⮞ References to the National Statement (NS) are noted in relevant sections as footnotes for your information only and do not need to be included in the final document.

⮞ This guide proposes preferred language for some sections of the Participant Information Sheet/Consent Form. This preferred language may be the totality of what is required for the section or it may be a series of suggested phrases to be used along with other information in the section, as indicated by the guidelines pertaining to the section.

⮞ The reviewing institution may have additional preferred language or standard clauses that you are required to include. Please check with the relevant HREC administration to determine whether additional requirements apply.

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

⮞ If translated Participant Information Sheet/Consent Forms are to be used, please check with the relevant HREC administration in case additional requirements apply.

⮞ You should state whether an interpreter will be used in the consent process and/or during the collection of data.

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

⮞ Ensure that all font styles and sizes, bolding, italicisation and underlining are intended and that any variations are consistent throughout the document.

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

This space is reserved for use by jurisdictions or institutions for instructions regarding version control of Participant Information and Consent Forms or other matters specific to jurisdictions or institutions.

*Insert Header with institution’s name or institution’s letterhead*

**Participant Information Sheet/Consent Form – Person Responsible**

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/ Principal Investigator** | *[Coordinating Principal Investigator/*  *Principal Investigator]* |
| **Associate Investigator(s)**  *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location]* |

**Part 1 What does participation involve?**

*The purpose of Part 1 is to state the reason the participant is being invited to take part in the research project and to explain the purpose of the research project and what it will involve.*

**1 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.*

The participant is invited to take part in this research project, which is called *[Name of research project]*. They have been invited because *[Explain reason for invitation]*. Their contact details were obtained *by/from [provide details]*.

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 the participant to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not the participant can take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you do not wish the participant to take part, they do not have to.

If you decide you want the participant 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 the participant taking part in the research project

• Consent to the participant being involved in the research described

• Consent to the use of the participant’s personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

*Briefly describe the following aspects of your project in simple terms and in only a couple of sentences for each point:*

*• Aim of the project and its significance*

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

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

*• Any relevant background including what is already known*

*• Whether the research is for the purpose of obtaining a degree or other educational*

*qualification, is funded by a grant, or has sponsorship of some other sort.*

*Where the research is for the purpose of obtaining a degree or other educational qualification:*

The results of this research will be used by the researcher *[name of researcher]* to obtain a *[full name of degree]* degree.

*Where the research project is investigator-initiated:*

This research has been initiated by the researcher, *[Title &* *name]*.

*Where the research project is funded by a grant:*

This research has been funded by *[name of granting body]*.

*Where the research is being coordinated outside the institution:*

This research is being conducted by *[name of collaborative research group or other]*.

*Where commercial sponsorship is available, provide the international sponsor (if applicable) AND the Australian sponsor:*

This research is being conducted by *[name of international sponsor]*.

This research is sponsored in Australia by *[name of local sponsor]*.

**3 What does participation in this research involve?**

*Tables and diagrams may only be used if they enhance the comprehensibility of this section. Tables and diagrams should not be a substitute for written explanation.*

*Include information and clear explanation of the following:*

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

*⮞ Initial steps:*

*• Screening for eligibility*

*• Randomisation and/or the use of a control group*

*⮞ 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 project (if this is different from their involvement)*

*⮞ Reimbursement and costs (if applicable)* [NS 2.2.6(j), 2.2.10]

*⮞ How the research will be monitored* [NS 2.2.6(b)]

*⮞ The commitment required by the participant and the person responsible*

*⮞ Access to personal records that may be required*

*⮞ Whether any part of the research project 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/persons responsible may choose the venue*

*Screening procedures (questionnaire)*

If you decide that the participant may take part in the research project, they will first be given a questionnaire asking about *[provide details]*; this will determine if they are eligible to take part. Completing the questionnaire will take approximately *[specify expected time]*.

If the screening questionnaire shows that the participant meets the requirements, then they will be able to start the research project. If the screening questionnaire shows that the participant cannot be in the research project, the study coordinator will discuss other options with you.

*Bias (to be used in all research projects)*

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or persons responsible/participants jumping to conclusions.

*Additional costs and reimbursement*

There are no costs associated with participating in this research project, nor will you or the participant be paid. However, you may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

*If there is a maximum amount for this reimbursement then this should be stated.*

**4 Other relevant information about the research project**

*Explain any other relevant information including:*

*• How many people will be taking part in the project overall and at this site*

*• Whether there are different groups e.g. case/control groups, different types of focus groups*

*• The size or scope of a project e.g. number of schools or hospitals or countries involved*

*• Whether the project involves researchers from a number of organisations working in*

*collaboration*

*• Whether this is a follow-on study/sub-study/extension study. If so, state the relationship to the previous research*

**5 Does the participant have to take part in this research project?**

*Explain that taking part in the research is entirely voluntary.*

Participation in any research project is voluntary. If you do not wish for the participant to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw the participant from the project at any stage.

If you do decide that the participant can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether the participant can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine care, relationship with professional staff or relationship with *[Institution]*.

**6 What are the possible benefits of taking part?**

*Do not attempt to build up person responsible/participant hope in this section. Reference to the potential benefit to others in the future may be appropriate, but should not be exaggerated.*

We cannot guarantee or promise that the participant will receive any benefits from this research; however, possible benefits may include *[describe any likely benefits to participants or other people in the future]*.

*If the significant benefits from the research project are to accrue to members of society in the future and NOT to the individuals taking part in the research, this should be made clear.*

There will be no clear benefit to the participant from their participation in this research.

**7 What are the possible risks and disadvantages of taking part?**

*Provide information on the possible risks with taking part in this research project.*

*The layout of this section will depend on the nature of the research. For readability:*

*• Use headings*

*• Use short and well spaced paragraphs*

*• Use short uncomplicated sentences*

*• Use a table or bullet points where possible*

*• Avoid or minimise repetition*

*Psychological distress*

The particpant may feel that some of the questions we ask are stressful or upsetting. If they do not wish to answer a question, they may skip it and go to the next question, or they may stop immediately. If the participant becomes upset or distressed as a result of their participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

*Group discussions*

Whilst all care will be taken to maintain privacy and confidentiality, the participant may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

**8 What if I withdraw the participant from this research project?**

*Provide information regarding how participants can be withdrawn and implication for them if this happens. Include information on the use and submission of the withdrawal of consent form.*

If you do consent to the participant taking part, you may withdraw them at any time. If you decide to withdraw the participant from the project, please notify a member of the research team before withdrawal. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw them, you will be asked to complete and sign a ‘Withdrawal of Consent’ form; this will be provided to you by the research team.

*Where appropriate, explain that if a participant is withdrawn part-way through a research project that data collected to that point may not be able to be deleted.*

If you decide that the participant is to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time of withdrawal will form part of the research project results. If you do not want the participant’s data to be included, you must tell the researchers when withdrawing from the research project.

**9 Could this research project be stopped unexpectedly?**

*The person responsible/participant should be advised of the potential for the project to be terminated before completion and the reasons that might make termination necessary.*

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as *[provide details].*

**10 What happens when the research project ends?**

*Provide details regarding follow-up arrangements.*

*Provide information on how the person responsible/participant will find out about the success of the project. State how, and approximately when, persons responsible/participants will be provided with a summary of the results when the research project is completed.*

**Part 2 How is the research project being conducted?**

**11 What will happen to information about the participant?**

*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 (Refer to your institution’s policy on retention of study data)*

*• Whether the person responsible is being asked to provide consent for the use of the participant’s data for this project only, or for extended (related research) or unspecified (any future research) use of their data*

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

By signing the consent form you consent to the research team collecting and using personal information about the participant for the research project. Any information obtained in connection with this research project that can identify them 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 participant’s information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information that the research team collect and use is *[types of information, e.g. information from questionnaires]*.

*If it is likely that additional health information relating to participants will be sought from their health records, the following should be included:*

Information about the participant may be obtained from their health records held at this and other health organisations, for the purpose of this research. By signing the consent form you agree to the research team accessing the participant’s health records if they are relevant to participation in this research project.

*If relevant, provide information regarding the review of health records by researchers and by representatives of regulatory authorities and the sponsor for the purpose of verifying the procedures and the data.*

The participant’s health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives, *[Name of Australian representative]*, the institution relevant to this Participant Information Sheet, *[Name of institution]*, 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.

*If it is anticipated that the results will be published include the following paragraph:*

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your express permission. *[Describe how confidentiality will be maintained.]*

*Indicate whether the person responsible/participant can access the participant’s information/data.*

In accordance with relevant Australian and/or *[name of state/territory]* privacy and other relevant laws, you have the right to request access to the information about the participant that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access the participant’s information.

Any information obtained for the purpose of this research project *and for the future research described* that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

*If additional use of the information is contemplated, this should be explained and specific consent should be sought from the person responsible for that additional use.*

**12 Complaints and compensation**

*You should inform persons responsible how complaints will be handled and what redress may be available. Clarify whether there is a procedure in place for this and, if so, what the procedure is. You will need to distinguish between complaints from persons responsible/participants regarding their treatment by members of staff/the research team and something serious happening during or following their participation in the research project.*

If the particpant suffers any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

In the event of loss or injury, the parties involved in this research project have agreed to *[description of compensation agreements]*.

**13 Who is organising and funding the research?**

*Organising and funding research*

This research project is being conducted by *[Name of person]*.

*Where commercial sponsorship is available, provide the international sponsor (if applicable) AND the Australian sponsor:*

This research is being conducted by *[name of international sponsor]*.

This research is sponsored in Australia by *[name of local sponsor]*.

It is being funded by *[Name of funding organisation]*.

*Provide a description of the financial benefits that might arise from the conduct of the research*

*[Company/University]* may benefit financially from this research project if, for example, the project assists *[Company/University]* in any commercial enterprise.

The participant will not benefit financially from their involvement in this research project even if, for example, knowledge acquired from their information proves to be of commercial value to *[Company/University]*.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to *[Company/University]*, the researchers or their institutions, there will be no financial benefit to you, the participant, or family from these discoveries.

*[Name of institution]* will receive a payment from *[Name of funding organisation]* for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

*Add any declarations of interest of researchers, sponsors and institutions* [NS 2.2.6 (i)]

**14 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of *[institution]*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**15 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if the participant has any problems which may be related to involvement in the project, you can contact the researcher on *[Phone number]* or any of the following people:

*List the names and contact phone numbers of other appropriate persons involved in the project including researchers and study coordinators.*

**Research contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

*This person should be someone independent of the research, such as the Executive Officer of the reviewing HREC that approved the project. Contact your local HREC administrator for the requirements at your institution.*

|  |  |
| --- | --- |
| Reviewing HREC name | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form – Person Responsible**

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/**  **Principal Investigator** | *[Coordinating Principal Investigator/*  *Principal Investigator]* |
| **Associate Investigator(s)**  *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**Declaration by Person Responsible**

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 the participant taking part in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future care.

I understand that I will be given a signed copy of this document to keep.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | | | | | | |  |
|  | Name of Participant (please print) |  | | | | | | |  |
|  |  |  | | | | | | |  |
|  | Name of Person Responsible (please print) | | |  | | | | |  |
|  |  | | |  | | | | |  |
|  | Relationship of Person Responsible to Participant | | | | |  | | |  |
|  |  | | | |  | | | |  |
|  | Signature of Person Responsible | |  | | | | Date |  |  |
|  | | | | | | | | | |

**Declaration by Researcher†**

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† An appropriately qualified 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.

**Form for Withdrawal of Participation – Person Responsible**

*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.*

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/**  **Principal Investigator** | *[Coordinating Principal Investigator/*  *Principal Investigator]* |
| **Associate Investigator(s)**  *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**Declaration by Person Responsible**

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect their routine care, or relationships with the researchers or *[Institution]*.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | | | | | | |  |
|  | Name of Participant (please print) |  | | | | | | |  |
|  |  |  | | | | | | |  |
|  | Name of Person Responsible (please print) | | |  | | | | |  |
|  |  | | |  | | | | |  |
|  | Relationship of Person Responsible to Participant | | | | |  | | |  |
|  |  | | | |  | | | |  |
|  | Signature of Person Responsible | |  | | | | Date |  |  |
|  | | | | | | | | | |

In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

|  |
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|  |

**Declaration by Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the person responsible for 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 project.

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