**INSTRUCTIONS FOR CREATING A PARTICIPANT INFORMATION SHEET/CONSENT FORM**

* **This template is a guide only.**
* The *National Statement on Ethical Conduct in Human Research* is referred to as NS in the guidance text provided in this template.
* The use of the term ‘informed consent’ should be avoided. Informed consent is an action which requires ongoing communication between the researcher and the participant through a variety of mediums (as appropriate).
* 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.
* You should delete any headings and sections that are not relevant to your study and/or modify paragraphs so that they are relevant to your study.
* In this template, there are prompts for the content of your Participant Information Sheet/Consent Form (in *orange italics*) and guidance regarding the content 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.
* If institutional letterhead/logo is to be used, please include this on the forms.
* Include the version number and date of the document in the footer of each page. Do not use the ‘automatic’ date insertion function.
* Do not include a place for initialling the document on each page.
* Study participants should be referred to as ‘participants’ and not ‘subjects’ or ‘patients’.
* References to the National Statement (NS) and ICH/GCP Guidelines 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(s) may have additional preferred language or standard clauses that you are required to include. Please check with the relevant HREC administrator(s) to determine whether additional requirements apply.
* Language used should be readily understandable by the participant and include Australian spelling of words.
* 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.**

*Insert relevant letter head. Where multiple organisations/institutions are involved, all relevant letter heads should be used.*

**PARTICIPANT INFORMATION SHEET**

|  |  |  |
| --- | --- | --- |
| **Title** | *[Project Title]* | |
| **Short title** | *[Short Project Title]* | |
| **Project number** | *To be provided by the Secretariat* | |
| **Project Sponsor** | *[Project Sponsor – those who have funded the study]* | |
| **Principal Investigator(s)** | *[name]* | *[Contact details (NS 2.2.6(e))]* |
|  | *[name]* | *[Contact details]* |
|  | *[name]* | *[Contact details]* |
|  | *[name]* | *[Contact details]* |
| **Student researcher** | *[name]* | *[Contact details]* |
|  |  |  |

Delete the brackets from around the ‘s’ if there are multiple Principal Investigators. If there is only one Principal Investigator, remove the bracket and the ‘s’.

***Note:*** *For clinical research you will also need to ensure the specific considerations under the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)are addressed.*

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. Ask questions about anything that you don’t understand or want to know more about. We encourage you to discuss your participation with a member of your support network, such as a spouse, sibling, parent, friend etc, if you feel this would be beneficial. (NS paragraph 4.3.2)

Participation in this research is entirely voluntary; there is no obligation to take part in the study. If you choose not to participate there will be no detriment to your career *(for Defence personnel)* or future health care (for Defence members). *Where the study involves third parties as a research cohort (e.g. family, friend, treating clinicians) this paragraph should be adapted to state that participation will not impact on the related persons career or future health care. Further guidance is available from the Secretariat.*

**Your answers will be completely confidential and any personal details, which may identify you in any way, will not be passed to the Department of Veterans’ Affairs. Your answers will not in any way affect any pension, benefits or health services which you are entitled to from DVA or to which to may become entitled in the future.** *This clause is relevant to studies involving veterans and/or ex-serving Defence member. Further guidance is available in the DDVA HREC Standard Operating Procedures paragraphs 159 to 160.*

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

*or*

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

If you decide you want to take part in the research project, you will be asked to sign the consent section.

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

**Brief description of the study**

*Describe what is being done and why it is being done. It may be appropriate to paraphrase the ‘aims’ of the study. Do not use jargon, and explain in a manner that the ethics review body can understand (NS paragraph 5.3.5).*

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

*Include information and clear explanation of the following:*

* *Initial steps*

*• Screening for eligibility*

*• Randomisation and blinding, use of a control group and the probabibility of assigment to each treatment(if applicable)*

* *Procedures*

*• All procedures*

*• Nature, number, timing and time commitment of tests, procedures, visits and questionnaires (include scientific and lay measurements where relevant)*

*• Nature, number and other details of any optional tissue samples to be collected (where appropriate))*

*• 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 *paragraphs* 2.2.6(j), 2.2.10]
* *How the research will be monitored* [NS *paragraph* 2.2.6(b)]
* *The time commitment required by the participant*
* *Access to personal records that may be required*
* *Whether any part of the project will be recorded (video/audio)*

*This section should also include the following point for studies involving Defence personnel:*

Defence members *(uniformed members)* /Defence personnel *(includes uniformed members, Australian Public Servants and contractors)* are deemed to be ‘on duty’ whilst participating in research. *Where appropriate include this statement and delete the terms that are not relevant to your project. Refer to the definitions in the DDVA HREC Researcher and Administrative Guidelines for further guidance.*

**Alternatives to participation** (if applicable - NS *paragraph* 2.2.6(a))

*For therapeutic research the participant should be told what other treatments are available and how the research differs from standard treatment. Their important potential benefits and risks should be stated (this is an ICH GCP requirement).*

**Benefits**

*Do not attempt to build up 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 you will receive any benefits from this research, however possible benefits may include [describe any likely benefits to participants, others or the community].

*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 trial, this should be made clear.*

Any payments to participants [NS *paragraph* 2.2.6(j)]

There will be no direct benefit to you from your participation in this research.

*If there are expected benefits to the wider community (NS paragraph 2.2.3(l)) this should be indicated.*

**Risks of participating**

*Each of these must be laid out separately, described in full and quantified, no matter how trivial or remote they may seem, for example the risks of blood collection. Risks are to be sufficiently emphasised and quantified, and the expression of the quantification should be positive not negative. You must include provision of services, as part of your risk mitigation strategy, to those that are adversely affected by the research (NS paragraph 2.2.6(c)). Some of the standard referral services can be found on the Defence Health Portal* [*http://www.defence.gov.au/health/healthportal/*](http://www.defence.gov.au/health/healthportal/)*. This list is meant as a guide and should be tailored to the individual project.*

**Withdrawal from the research** (NS *paragraphs* 2.2.6 (g) and NS 3.1.31)

*Provide information regarding how participants withdraw and implications for them if they do so.*

You may withdraw [specify when they can withdraw their data up until and how] with no detriment to your career or future health care. *The wording of this clause is specific to Defence personnel and should be reviewed dependent on the research cohort.*

**Privacy and confidentiality** (NS *paragraph* 2.2.6(f))

*Information should be provided regarding the following:*

* *Whether the data collected or used is individually identifiable, re-identifiable (coded) or non-identifiable*
* *Whether the participant is being asked to provide consent to the use of their data for this project only or for extended (related research) or unspecified (any future research) use of their data (see NS paragraph 2.2.14 for further guidance)*
* *Whether the research project involves the establishment of a databank*
* *Where the data will be kept and who will have access to it eg stored under lock and key, investigators will only have access*
* *How long it will be stored and what will happen to the data at the end of the storage period*
* *Intellectual property and copyright arrangements [include NS paragraph 3.1.30].*

*Where it is likely that the participant’s participation in the research will be noted in their health record, the following should be included:*

Information about your participation in this research project may be recorded in your health records.

**Participant records**

*For clinical trials - Where the study is a clinical trial, as per the National Health and Medical Research Council definition the following statement is to be included:*

A nominal roll of study participants will be retained for all clinical trials and may be provided to the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee (DDVA HREC) for the sole purpose of facilitating the tracing of participants should anything untoward develop in the future that may be related to this study. This information will be stored in the project file, will only be accessible to the DDVA HREC Secretariat and may assist the future health care of individual study participants.

**Other relevant human research ethics considerations** (NS *paragraph* 2.2.6 (m))

*If there is any other relevant information that should be provided to participants it should be listed here to ensure that their decision to participate is based on sufficient information (NS 2.2.2) as part of the informed consent process. This should include information required under specific chapters of the National Statement.*

The ethical aspects of this research project have been approved by the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee *[where approporiate include name/s of other relevant HREC(s) or non-HREC level review pathways]*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**Dissemination of research findings** (NS *paragraph* 2.2.6 (k))

It is anticipated that the results of this research project will *[describe how the results will be used eg. thesis, reports, journal articles, publications, presentation etc ]*. In any publication and/or presentation, information will be provided in such a way that you cannot be identified (amend this as neccesary). *[Describe how confidentiality will be maintained.]*

*A statement regarding access to research findings should also be included here (NS 1.5) eg. You will be provided a copy of the research findings by the Principal Investigator upon your request.*

**Concerns or complaints** (NS *paragraph* 2.2.6 (d))

*The following statement should always be included here.*

Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers *[provide details on how to contact the researchers, including telephone numbers where appropriate]*, or you may prefer to contact the DDVA HREC on Telephone: (02) 6192 7821 or via [ddva.hrec@defence.gov.au](mailto:ddva.hrec@defence.gov.au)

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

This research has been funded by *[name of funding organisation]* [NS *paragraph* 2.2.6(h)]

This research is being conducted by *[name of international pharmaceutical company]* and sponsored by *[name of local sponsor]*.

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

*[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 study doctors, sponsors and institutions* [NS *paragraph* 2.2.6 (i)]

*Insert relevant letter head. Where multiple organisations/institutions are involved, all relevant letter heads should be used.*

**CONSENT FORM**

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short title** | *[Short Project Title]* |
| **Protocol number** |  |

I, ................................................................………………... give my consent to participate in the project named above on the following basis:

I have had explained to me the aims of this research project, how it will be conducted and my role in it.

I understand:

* the risks involved as described in the Participant Information Sheet
* there is no obligation to take part in this study
* if I choose not to participate there will be no detriment to my career (for Defence personnel only) or future health care (for Defence members only)
* I am free to withdraw [specify when they can withdraw their data up until] with no detriment to my career (for Defence personnel only) or future health care (for Defence members only)
* I am deemed to be on duty whilst participating in this research (for Defence personnel only).

I am cooperating in this project on condition that:

* the information I provide will be kept confidential
* the information will be used only for this project *If it is intended that the results of this research will be used for future studies, this statement will need to be amended to reflect this. See NS paragraph 2.2.14 for further guidance.*
* the research results will be made available to me at my request and any published reports of this study will preserve my anonymity

I have been given a copy of the participant information sheet and consent form, signed by myself and by the principal investigator *[name]* to keep.

**Video/still images** *[delete if not applicable].*

*The following wording should be included here if video or other images are to be used:*

‘Video clips and/or still shots may be used for reports and presentations, therefore if these images are used you may be identifiable. Please indicate yes or no on the following options.

I GIVE permission for the researchers to use video clips or still shots which may identify me.

Yes  No

I GIVE permission for the researchers to use video clips, or still shots only where my face is pixelated (thus de-identifying me).

Yes  No

**Audio recordings** *[delete if not applicable].*

*The following wording should be included here if an audio recording is to be used:*

An audio recording of the interview/focus group will be made for the purposes of transcription. Please indicate yes or no.

I GIVE permission for the researchers to record the interview/focus group via an audio device for the purposes of transcription.

Yes  No

**For clinical trials only** *[delete if not applicable].*

I understand that, as I am participating in a clinical trial, my name and Service details (where applicable) will be retained for this study and may be provided to the DDVA HREC in case I need to be traced at some time in the future. These records will not be used to consider you medical employment standard or for compensation purposes. This information will be kept secure and your contact information will not be passed onto a third party without your permission.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name in full

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Principal Investigator [witnessing of the signature is not always necessary and this should be adapted based on the method for collecting consent. Researchers should ensure that this requirement remains for clinical trials and studies that may disclose illegal activities]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name in full

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers in person, or you may prefer to contact the DDVA HREC on (02) 6192 7821 or via [ddva.hrec@defence.gov.au](mailto:ddva.hrec@defence.gov.au)