

INFORMATION SHEET AND CONSENT FORM

NAME OF STUDY

Brief description of the study. Cover 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 a lay person can understand. If the research is being undertaken as part of a requirement to obtain qualifications this must be indicated.

Your part in the study. This section should include the following points:

- participation in the study is entirely voluntary; there is no obligation to take part in the study, and if the person chooses not to participate there will be no detriment to their career or future health care;
- you may withdraw at any time with no detriment to your career or to your future health care; and
- the procedures to be followed and what is expected of the subject, including how much time will be required.

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

On duty, where appropriate, include a statement that Australian Defence Force members will be considered 'on duty' during participation.

Statement of Privacy. Discuss how personal or attributed data is to be stored and handled; eg stored under lock and key, investigators only have access, treated confidentially, anonymity preserved in reports or published articles. There is also to be a written assurance that any personal data collected will be used for the purpose of this study and no other, without the express permission of the subject.

Participant records. Where the study is a clinical trial, as per the National Health and Medical Research Council definition, a nominal roll of study participants will be provided to the Australian Defence Human Research Ethics Committee (ADHREC) 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 protocol file, will only be accessible to the ADHREC Executive Secretary and may assist the future health care of individual study participants.

ADHREC's Guidelines for Volunteers.

(<http://www.defence.gov.au/health/research/adhrec/docs/Guidelines.pdf>) A copy of ADHREC's Guidelines for Volunteers is to be given to every participant.

Other relevant human research ethics considerations. Section 14 of the protocol application form lists various potential human research ethics considerations. Where appropriate a statement addressing any relevant elements of those considerations should form part of the informed consent process.

Name the investigators. Provide details on how to contact the investigators if necessary, including telephone numbers where appropriate. 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 in person, or you may prefer to contact the Australian Defence Human Research Ethics Committee at the following address:

Executive Secretary
Australian Defence Human Research Ethics Committee
Department of Defence
CP2-7-101
PO Box 7911
CANBERRA BC ACT 2610
AUSTRALIA

Telephone: (02) 6266 3837
Facsimile: (02) 6266 3072
Email: ADHREC@defence.gov.au

ADHREC Protocol number:
Information/Consent form version number,
Dated:

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CONSENT ^{4.1}

Name of Study

I, give my consent to participate in the project mentioned 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 above.

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, and
- 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 ADHREC's *Guidelines for Volunteers*. (<http://www.defence.gov.au/health/research/adhrec/docs/Guidelines.pdf>)

I understand that:

- there is no obligation to take part in this study,
- if I choose not to participate there will be no detriment to my career or future health care, and
- I am free to withdraw at any time with no detriment to my career or future health care.

I have been given a copy of the information/consent sheet, signed by me and by the principal researcher (name) to keep.

Video/still images

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

'Video clips and still shots may be used for reports and presentations, therefore if these images are used you may be identifiable. Please sign and date one of the following options.

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

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

I DO NOT GIVE permission for the researcher to use video clips or still shots that may identify me whether de-pixelated or not.

(For clinical trials only) I understand that, as I am participating in a clinical trial, my name and regimental details (where applicable) will be provided to the Australian Defence Human Research Ethics Committee (ADHREC) in case I need to be traced at some time in the future. This information will be kept secure and will only be accessible to ADHREC for this purpose and none other.

_____ Signature of volunteer

_____ Name in full

_____ Date

_____ Signature of Researcher

_____ Name in full

_____ Date

ADHREC Protocol number:

Information/Consent form version number,

Dated:

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