

SAMPLE RESEARCHER'S AGREEMENT

**PROTOCOL NUMBER:
TITLE**

The Australian Defence Human Research Ethics Committee (ADHREC) requires your agreement to the following conditions in order to secure its endorsement of your project:

**Please
initial**

- 1 You must quote your ADHREC number and title of your protocol in all correspondence.**

PROTOCOL NUMBER: TITLE

- 2** If you do not commence data collection within twelve months of this approval, the protocol will need to be resubmitted.
- 3** The approval of your protocol is for a period of three years. If your research is to continue beyond the three-year approval time, an extension is to be sought in writing.
- 4** You are required to submit six-monthly progress reports, the first of which is due **DATE**.
- 5** The Committee requires confirmation that your project has begun, or notification that it has been delayed or abandoned.
- 6** The Committee requires that a copy of the ADHREC *Guidelines for Volunteers* be given to every participant when they are recruited for the protocol.
- 7** Committee approval **must** be sought before any modifications to the protocol are instituted.
- 8** The Committee **must** be informed of any deviations from the approved protocol and immediately informed of any protocol deviations with real or potential ethical implications.
- 9** The Committee **must** be informed immediately of unforeseen event that might affect the continued ethical acceptability of this project.
- 10** The Committee **must** be informed immediately of any untoward effects with respect to the medical, personal or administrative management of participants, or which may have ethical and/or publicity implications.
- 11** The Committee **must** be informed of any 'adverse events', and **must immediately** be informed of any 'serious adverse events' (SAE) which are considered by the Principal Investigator (PI) to be possibly drug related **within 72 hours of their occurrence**. 'Adverse events' should be reported in the course of routine (progress or final) report submissions.
- 12** ADHREC gives its ethical approval subject to your explicit agreement to an *intention to publish*. Publication should be in a refereed journal or other source open to public audit. It would be appropriate to include in your submission for publication the phrase 'Ethical clearance for this project was provided by the Australian Defence Human Research Ethics Committee'. Should a security classification make publish in an open source inappropriate, ADHREC is to be notified in writing.
- 13** Subsequent to the conduct of the research, you must submit for clearance any manuscripts which are prepared for publication (including abstracts of verbal presentations) to the relevant Defence authority. The relevant Defence authority is _____. Health Manual—*Human Research in Defence—Instructions for Researchers*, volume 23, chapter 6—'Manuscript review' refers. This requirement does not apply to Defence Science Technology Organisation Technical Reports. You agree not to seek publication of any manuscripts until that clearance is obtained.
- 14** ADHREC requires a comprehensive Final Report which details the conduct of the project and its findings. This report is to be submitted as soon as possible after the project has finished.

- 15 The ADHREC Secretariat requires that you provide notification of any change in your contact details. Point of contact is the Executive Secretary at ADHREC@defence.gov.au.

For Clinical Trials Only

- 16 ADHREC requires that the nominal roll of participants, for the purpose of future tracing, is to be sent to the ADHREC Executive at the conclusion of the trial. This is to enable ADHREC to be able to access this roll should the need arise. For large trials conducted by Defence organisations ADHREC may require that organisation to continue to retain that roll on ADHREC's behalf.
- 17 You **must** retain records of your volunteers' details, any who withdraw, the reasons for that withdrawal (if known) and provide such on request.

I agree to abide by the conditions above:

Signature:

Surname:

First Name:

Position/Rank:

Contact number work: **Work Mobile:**

Email:

Date:

Executive Secretary
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