



Australian Government
Department of Defence

DEFENCE INSTRUCTIONS (GENERAL)

Amendment

ADMIN 24-3 *Conduct of human research in Defence*
AMDT NO 1
Complete Revision

Department of Defence
CANBERRA ACT 2600

4 April 2005

Issued with the authority of the Chief of the Defence Force and the Secretary of the Department of Defence pursuant to section 9A of the *Defence Act 1903* for members of the Australian Defence Force.

Issued with the authority of the Secretary pursuant to section 20 of the *Public Service Act 1999* for Department of Defence Australian Public Service employees.

R.C. SMITH, AO, PSM
Secretary

P.J. COSGROVE, AC, MC
General
Chief of the Defence Force

LIST B—ISSUE NO ADMIN B/3/2005

Single Service filing instructions

This instruction should be filed as:

1. NAVY ADMIN 40-3
2. ARMY ADMIN 60-1
3. AIR FORCE PERS 51-13

Sponsor:

Vice Chief of the Defence Force

Sponsor contact:

Director Health Capability Development

Review Date: 4 April 2008

Cancellation

DI(G) ADMIN 24-3 ISSUE NO ADMIN B/4/89 of 1 AUG 89 is cancelled.

Note

This amendment incorporates a title change.

This Instruction supersedes Health Policy Directive 205—*Australian Defence Medical Ethics Committee* of 15 July 1994.

CONDUCT OF HUMAN RESEARCH IN DEFENCE

References:

- A. Australian Defence Force Publication (ADFP) 1.2.5.3—*Health and Human Performance Research in Defence—Manual for Researchers* (see http://intranet.defence.gov.au/home/documents/adfdocs/ADFP/adfp1_2_5_3.htm)
- B. *Privacy Act 1988* (see http://www.austlii.edu.au/au/legis/cth/consol_act/pa1988108/)
- C. National Health and Medical Research Council (NHMRC) 1999—*National Statement on Ethical Conduct in Research Involving Humans* (see <http://www.health.gov.au/nhmrc/publications/pdf/e35.pdf>)
- D. NHMRC 2000—*Guidelines under section 95 of the Privacy Act 1988* (see <http://www.health.gov.au/nhmrc/publications/pdf/e26.pdf>)
- E. NHMRC 2001—*Guidelines approved under section 95A of the Privacy Act 1988* (see <http://www.health.gov.au/nhmrc/publications/pdf/e43.pdf>)
- F. NHMRC 2001—*Human Research Ethics Handbook* (see <http://www.health.gov.au/nhmrc/hrecbook/misc/contents.htm>)
- G. NHMRC 2003—*When does quality assurance in health care require independent ethical review?* (see <http://www.health.gov.au/nhmrc/publications/pdf/e46.pdf>)
- H. Defence Force Psychology Organisation (DFPO)—*Defence Psychology Research Policy* (see <http://intranet.defence.gov.au/prtg/>)

INTRODUCTION

1. This instruction addresses the requirements for obtaining clearance for conducting human research in Defence. It pertains to research conducted on humans where this research is supported in some way by Defence. It covers both authorisation to undertake the research and its ethical clearance. Human research in this context could include health, human performance, psychology, personnel and equipment trials research.
2. This instruction is to be read in conjunction with references A to H.

AIM

3. The aim of this instruction is to provide policy on the conduct of human research, as defined, in Defence.

DEFINITIONS

4. **Research.** The NHMRC defines research as a systematic investigation to establish facts, principles or knowledge or a study of matter with the objective of obtaining or confirming knowledge.
5. **Human research.** In the context of human ethics, human research is that which is conducted using human volunteers or which accesses data collected from human volunteers. Reference C provides guidance on what constitutes human research in the ethical context. That document should be consulted particularly in cases of doubt as to the requirement for ethical review. In the context of human ethics, the document provides guidelines on what is human involvement and where there is the potential for the infringement of ethical principles. The body charged with the ethical review of human research in Defence is the Australian Defence Human Research Ethics Committee (ADHREC).
6. **Health research.** Health research is defined as that body of investigation aimed at increased understanding, maintenance or improvement of the physical and/or mental health of personnel. Further, it includes the examination of processes or other events that may directly or indirectly impact on the physical and/or mental health of personnel. References C to F provide further guidance.

7. **Human performance research.** Human performance research is defined as the group of investigations where the aim is to improve the normal performance, output and capability of humans to complete tasks and maintain or improve performance levels. This research has a focus on the development of human capacity and sustainability with respect to both physical and cognitive performance. Human performance research is further concerned with those aspects of human-systems integration that focus on the minimisation of the detrimental effects of systems and equipment on humans.

8. **Psychology research.** Psychology research covers the broad domain of the discipline of Psychology. In this context, it can be defined as the application of scientific methods developed within the discipline to the study of human behaviour. Within Defence it overlaps with, but extends beyond, health and human performance related research.

9. **Personnel research.** That personnel research which is within the *human research* context can be defined broadly as the utilisation of survey or focus group techniques to sample attitudes, beliefs or opinions of Defence members or their families. It represents a subset of Organisational Psychology and Human Resource research paradigms.

10. **Equipment trials.** Defence personnel are periodically required to participate in trials of new Defence equipment. In some circumstances the conduct of these trials may also cause them to fall within the *human research* framework.

AUTHORISATION

11. Before *human research* is conducted in Defence, it is to be assessed by a properly constituted responsible Defence organisation to ensure that Defence research priorities are met, Defence resources are properly applied and the research is to be carried out using sound scientific methodology.

Health and human performance research

12. Oversight of health research and human performance research is provided by the Defence Health and Human Performance Research Committee (DHHPRC). The DHHPRC seeks to define the research and development priorities and resource processes to ensure that health research and human performance research are given appropriate support to meet Australian Defence Force needs. The DHHPRC will review, and endorse where appropriate, research proposals covering a broad range of health and human performance, including epidemiological studies, psychological research, entomological studies, equipment trials, clinical audits, clinical trials, operational research and animal research. The functions and structure of DHHPRC are detailed in reference A.

13. **Research prioritisation.** The DHHPRC identifies and prioritises health and human performance research in Defence through the development and publication of the annual Health and Human Performance Research Master Plan. Before a health or human performance research project is forwarded to ADHREC it will be assessed by DHHPRC for its ability to address endorsed priorities and the appropriateness of the allocation of Defence resources required. This assessment will be consistent with, and not supplant, the research programs and priorities determined within Defence research organisations in accordance with the priorities of higher Defence capability and research requirements committees.

14. **Scientific methodology.** DHHPRC should ensure the presence of sound scientific methodology in proposed health or human performance research protocols. Before a health or human performance research project is forwarded to ADHREC, it will be assessed by appropriate technical experts, unless the DHHPRC is satisfied the protocol has undergone properly constituted internal scientific review within a Defence research organisation.

Psychology research

15. Within Defence, responsibility for the development and application of Defence psychology research policy rests with the Psychology Research and Technology Group (PRTG) of the DFPO. Defence psychology research policy is freely available from PRTG and can be obtained through the PRTG web site (see <http://intranet.defence.gov.au/prtg/>). The policy contains procedures for obtaining authorisation and conducting psychology research. All psychology research requires approval in accordance with these procedures. Health and human performance related psychology research requires this approval prior to being submitted to DHHPRC for final endorsement.

Personnel research

16. The organisation primarily responsible for the conduct and coordination of personnel research within Defence is the Directorate of Strategic Personnel Planning and Research (DSPPR) within the Defence Personnel Executive. Personnel research surveys are to be registered on the DSPPR database (see <http://aurora/DSPPR/default.shtml>).

Equipment trials

17. A number of Defence organisations conduct equipment trials. Organisations which conduct trials which might involve humans include, but are not limited to, the Directorate of Trials within the Defence Science and Technology Organisation and the Aircraft Research and Development Unit. The internal procedures of those organisations provide the mechanism for authorisation of such research.

ETHICAL CLEARANCE

18. While not always the case, research involving humans in any of these areas may have the potential to infringe human ethics principles including privacy or safety issues. Where there is potential to infringe human ethics principles a protocol submission is to be made to ADHREC.

19. Consequent upon the Declaration of Helsinki and the World Health Organisation Proposed Guidelines for Biomedical Research Involving Human Subjects, NHMRC has recommended that:

'In every institution in which human research is undertaken there must be a properly constituted institutional ethics committee.'

20. On the advice of the Surgeon General Australian Defence Force, the Chief of the Defence Force (CDF) and the Secretary of Defence formed ADHREC (formerly the Australian Defence Medical Ethics Committee), a properly constituted human research ethics committee as laid down in reference C. ADHREC reports to CDF and the Secretary annually on research during the previous year involving humans. The functions and structure of ADHREC are detailed in reference A.

Australian Defence Human Research Ethics Committee clearance

21. ADHREC reviews the ethics of, and where appropriate, approves proposals for human research to be conducted by, or on, Defence personnel and/or utilising Defence resources. ADHREC also monitors the progress of research protocols it has approved to ensure compliance with the conditions of that approval. No element of Defence is to perform or sponsor a human research project involving human volunteers, which requires human ethics consideration, without the clearance of ADHREC.

22. Detail of when to seek ADHREC approval can be found in reference A. Further guidance is contained in references B to G. Key ethical principles to be applied are *autonomy, beneficence, non-malevolence, and justice*. Key tests are the potential for doing harm to individuals, infringement of their privacy, the burden placed on them and their ability and freedom to give informed consent. Defence organisations are encouraged to develop criteria, as per the references, against which to assess research protocols in order to determine the requirement for human ethics clearance. If there is any uncertainty as to whether or not a proposal requires review by ADHREC, the research protocol is to be forwarded to ADHREC for consideration.¹

¹ It is not possible to define all of the circumstances when human ethics review is required. The references indicated must be consulted; however the following guidance is provided without seeking to limit those circumstances. As examples, ethical clearance is required when:

- a) a research protocol involves invasive procedures;
- b) investigation explores the limits of the physiological or psychological integrity of humans;
- c) individual personal health information, including that obtained for other purposes, is to be used for human research. The use of de-identified information, as defined in reference A, allows some health surveillance to be carried out without ethical clearance; and
- d) there is an identified potential risk to the physical health or psychological wellbeing of humans participating in research protocols, including investigations and trials of man/machine systems, particularly where the protocol electively exposes individuals to this risk. Where other means could be used which would obviate the need for placing humans at risk, these should be used.

PROTOCOL SUBMISSIONS

23. The detailed procedures for formats, administrative requirements and methods of Health and Human Performance research protocol submissions are contained in reference A. The contact details for the secretariats of ADHREC and DHHPRC are also contained in reference A. For health and human performance research applications a single submission procedure addressing all the required aspects as per reference A is used. All health and human performance research protocols are to be submitted to DHHPRC for endorsement. They will then be forwarded for consideration by ADHREC when human research ethics clearance is required. Protocols which do not involve health or human performance research, but which do require human research ethics consideration, may be submitted directly to ADHREC provided they have been assessed by the relevant responsible Defence organisation.

24. Psychology, Personnel and Equipment trials research protocols are to be assessed in accordance with the requirements of the relevant authorities outlined in [paragraphs 16. to 18.](#) above before any submission to ADHREC or any submission to DHHPRC and ADHREC.

25. Details of when submissions to ADHREC can be made are promulgated by the ADHREC secretariat. Strict time frames must be met and approvals obtained for submissions to be reviewed by ADHREC. Potential researchers must be cognisant of the requirements for prior assessment of submissions by bodies such as DHHPRC and PRTG when timing submissions. Relevant web sites are:

- a. For ADHREC and DHHPRC (see <http://defweb2.cbr.defence.gov.au/dpedhs/>) and follow the links to *research* from the *info centre*.
- b. For PRTG (see <http://intranet.defence.gov.au/prtg/>).
- c. For DSPPR (see <http://aurora/DSPPR/default.shtml>).

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