

## CHAPTER 3

# HUMAN RESEARCH ETHICS

## BACKGROUND

### Introduction

**3.1** Human Research Ethics Committees (HRECs) are an essential component of all research involving humans in Australia. Currently, more than 180 different HRECs monitor the safety and dignity of those individuals who volunteer to participate in human research.

**3.2** As the HREC for Defence, ADHREC takes its place in this national perspective of human research, and in several areas has been a national leader in the discipline of health ethics. For example, ADHREC insists on declared intent to publish research, wide dissemination of research outcomes, biannual monitoring of the progress of approved protocols, and provides advice to Australian Defence Force (ADF) commanders at all levels on broader issues of health ethics. Since its establishment in 1988, ADHREC has been a vital supervisory body approving and monitoring research involving ADF personnel.

**3.3** Human research ethics ensures that the themes of autonomy, beneficence, non-malevolence and justice provide a basis for all aspects of human research. Human research involving ADF personnel has additional ethical themes. Special safeguards are needed to ensure that volunteers for research are completely independent and informed in their choice to participate in research, or to decline such involvement. All men and women who serve in the ADF are subject to the constraints and restrictions that military service implies, but in the area of extra voluntary participation, it is one of ADHREC's terms of reference to ensure that individuals remain empowered with respect to their potential or continuing involvement in discretionary research. **The principles of freely given informed consent from all participants in Defence human research is of paramount importance.**

**3.4** The ADF acknowledges the desirability of its members to be able to volunteer, altruistically, to advance knowledge by participation in research. Within the constraints of training and operational requirements, ADHREC does not seek to limit opportunities for altruistic volunteering. In the military domain, special issues of confidentiality and privacy are nevertheless important. Risks, particularly those involving the human-machine and human-environment interfaces, need to be known in proposed research. Risks must be minimised and be understood by potential participants prior to volunteering. There is a duty for ADHREC to act as a watchdog, on behalf of Service personnel, to ensure that best-practice ethics are an integral part of any Defence-based research.

### History of the Australian Defence Human Research Ethics Committee

**3.5** After World War II there was growing concern worldwide regarding the ethical conduct of human experimentation. This led to the Declaration of Helsinki in 1964, which defined the basic principles to be followed whenever human subjects are used in research. In 1982 NHMRC published a statement on human experimentation. The Australian Defence Medical Ethics Committee (ADMEC) was subsequently formed to ensure that the ADF, and the Department of Defence as a whole, complied with these guidelines.

**3.6** The Chief of the Defence Force (CDF) and the Secretary of Defence formed ADMEC as a non-statutory body in 1988. The policy documents covering ADMEC and its functions were:

- a. Defence Instruction (General) (DI(G)) ADMIN 24-3—Function, Structure and Procedures for Obtaining Clearance for Research from the Australian Defence Medical Ethics Committee; and
- b. Health Policy Directive 205—Australian Defence Medical Ethics Committee.

**3.7** DI(G) ADMIN 24-3 was published in 1989, and was followed by the Health Policy Directive 205 in 1994. The first meeting of ADMEC was held in November 1989. Meetings were originally held biannually or as needed, but because the volume of human research conducted in Defence has grown

over the years the Committee now meets five to seven times a year - with some out of session determinations being made as required.

**3.8** In an attempt to reflect more accurately the scope of its charter, the Committee's name was altered to the Australian Defence Human Research Ethics Committee (ADHREC) in 2001. DI(G) ADMIN 24-3 was subject to a complete revision in 2005. This manual was originally published in 2003 as ADFP 1.2.5.3 *Health and Human Performance Research in Defence – Manual for Researchers*, and as a consequence Health Policy Directive 205 has been cancelled.

### **Mission**

**3.9** ADHREC's mission is to promote and encourage ethical human research in the military context. Such research needs to be of the highest ethical standard since the best research has as its essential ingredient best ethical practice.

### **Functions of the Australian Defence Human Research Ethics Committee**

**3.10** The functions of ADHREC are to:

- a. consider the ethical implications of all proposed human research projects on human volunteers, and any other human research subject to paragraphs 3.14 to 3.16, and to advise research sponsors of ethical acceptability;
- b. monitor experiments involving human research on volunteers to completion to ensure compliance with approved ethical standards;
- c. maintain a register of experiments in sufficient detail to provide for adequate monitoring; and
- d. establish and maintain communication with the Australian Health Ethics Committee (AHEC) of NHMRC.

**3.11** In carrying out its functions the committee is to:

- a. conform with the NHMRC *National Statement on Ethical Conduct in Human Research* (NHMRC 2007) and other relevant NHMRC policies;
- b. take account of local cultural and social attitudes in making decisions;
- c. ensure that procedures for obtaining free and informed consent are observed;
- d. ensure that no members of the committee adjudicate on proposals in which they may be personally involved; and
- e. ensure that, while accepting that researchers have a duty to advance knowledge by human research, the rights of the individual volunteers, or participants in research, take precedence over the expected benefits to human knowledge or to Defence.

### **Structure of the Australian Defence Human Research Ethics Committee**

**3.12** ADHREC is structured in accordance with NHMRC Guidelines, as detailed in the *National Statement on Ethical Conduct in Human Research* (NHMRC 2007). It comprises, as a minimum, the following persons:

- a. Chair (Surgeon General Australian Defence Force);
- b. laywoman not associated with the ADF, and not currently involved in medical, scientific, or legal work;
- c. layman not associated with the ADF, and not currently involved in medical, scientific, or legal work;

- d. member with knowledge and current experience in the areas of research most regularly considered by the Committee;
- e. member with knowledge and current experience in the professional care, counselling or treatment of people;
- f. minister of religion;
- g. lawyer; and
- h. two health graduates from Defence (at least one being a medical graduate).

**3.13** The Secretariat (Executive Secretary, Minute Secretary and administrative support) is provided by the Defence Health Services Division (DHSD). Committee members are appointed by CDF for five-year terms. All members of the Committee, and the Executive and Minute Secretaries, hold a minimum security clearance of SECRET. All members are strictly bound by privacy and confidentiality laws and regulations.

#### **When to seek ADHREC approval**

**3.14** Since its inception ADHREC's role and scope of responsibilities have changed. The social and political climates have also changed in that time. ADHREC's primary role is to ensure that human research carried out in Defence is ethical and lawful. ADHREC approval must therefore be sought when human research, as defined in Chapter 1—'Human Research Environment', is conducted:

- a. on ADF or other Defence personnel<sup>1</sup>, and/or
- b. by Defence personnel, and/or
- c. on/in a Defence establishment.

**3.15** This applies if the research involves direct human participation, as in the invasive testing of new therapies, or testing responses to conditions devised by researchers. It also applies to cases of indirect participation, including the use and collection of data from health or other records, research based on observations of individual or communal activities, and the administration of surveys.

**3.16** The *National Statement on Ethical Conduct in Human Research* (NHMRC 2007) provides further clarification. In cases of doubt as to the requirement for ethical review this document should be consulted along with a number of other relevant and useful publications which are available on the NHMRC web site <<http://www.nhmrc.gov.au>>.

**3.17** In summary, the following questions need to be addressed:

- a. **Is there human involvement?** In accordance with the National Statement if the research:

*...involves humans or definable human involvement and has a purpose of establishing facts, principles or knowledge or of obtaining or confirming knowledge, the features of human involvement will be the focus of deciding whether it is research and so subject to review by an HREC.*

- b. **Is there potential for infringement of basic ethical principles?** If the human involvement has the potential for infringing any of the basic ethical principles, review by an ethics review body is required. The basic ethical principles are:

- (1) beneficence;

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<sup>1</sup> Defence personnel includes all personnel employed or engaged within Defence organisations. It includes ADF Members, APS Members and Contractors providing services within Defence organisations (such as Contract Health Practitioners).

- (2) non-malevolence;
- (3) autonomy; and
- (4) justice.

**3.18** The potential to infringe the above basic ethical principles with regard to a volunteer exists when, but is not limited to:

- a. with respect to their person—physical, psychological, spiritual or emotional harm may be inflicted;
- b. with respect to information about themselves—infringement of their privacy or confidentiality may occur; and
- c. with respect to their involvement—the research imposes burdens without concomitant benefit.

## **BOUNDARY BETWEEN RESEARCH AND PRACTICE**

### **Epidemiological research**

**3.19** Epidemiological research related to human research includes study of the factors that determine a change in the rates of occurrence of disease in a population. It is concerned with the description of health and welfare in populations through the collection of data related to health and the frequency, distribution and determinants of disease in populations with the goal of improving health. In epidemiological research, medically relevant information about individuals and groups is accumulated so those features may be investigated, whether the information was or was not originally obtained for research purposes.

**3.20** All human epidemiological research (such as disease prevalence or treatment utilisation studies) must be approved by ADHREC.

### **Public health surveillance**

**3.21** Public health surveillance should be distinguished from epidemiological research. It is defined as the ongoing systematic collection, collation, analysis and interpretation of data and the dissemination of information to those who require such information in order to allow appropriate action to be taken. Public health surveillance in the ADF is conducted in order to monitor the health status of the ADF and also to monitor risk factors and emerging threats to the health of ADF personnel. Its purpose is to facilitate prompt, effective and corrective responses. It may be carried out for reasons of disease surveillance, provision of information to the Defence Health Services (DHS) or the wider ADF, or to provide information for the development of health policy.

**3.22** Public health surveillance does not normally require the approval of ADHREC.

### **Quality Assurance**

**3.23** The systematic collection, collation, analysis, interpretation and dissemination of data to ensure improvement and maintenance of service delivery standards will not normally constitute human research. The privacy of personal information must be respected, but quality assurance activities will not normally require the approval of ADHREC. *National Statement on Ethical Conduct in Human Research* (NHMRC 2007) provides guidance on quality assurance activities.

### **Clinical audits**

**3.24** Where the review of an individual's health records or other personal information is required to assess levels of deployability, operational capability and the like, as required by the ADF, ADHREC approval is not required.

## Operational and safety imperatives

**3.25** Where research activities are required to meet operational imperatives or to address safety imperatives, human research ethics approval may not be required if it is impractical to obtain such approval.

## ADDITIONAL CONSIDERATIONS

### Multi-centre research

**3.26** ADHREC recognises that researchers will often need to approach other HREC's for approval of their protocols, for example, when conducting research through a civilian university or hospital. In these cases, ADHREC will take the other HREC's deliberations into account when considering the protocol. Where other HREC's are involved, the protocol submission to ADHREC should clearly state that the protocol has been, or will be, considered by another HREC and, if available, the outcome of such consideration should be provided.

### ADHREC's philosophy

**3.27** Essentially, ADHREC assesses each submitted research protocol to determine whether or not the proposed research is ethical. ADHREC applies the Privacy Principles established in the *Privacy Act 1988* and other relevant legislation to each protocol. The Committee pays particular attention to the issues of informed consent, quantification of risk, confidentiality, voluntary participation and that there be no detriment to the careers or health care of volunteers if they choose to withdraw from the project.

**3.28** There are several reasons why ADHREC may not approve a research protocol. ADHREC does not generally give retrospective approval, that is, approval for research that has already been conducted. The Committee will not approve protocols that are likely to have adverse outcomes to the volunteers or their military careers. Where a researcher requests access to health records maintained by the ADF (eg medical documents), ADHREC pays particular attention to the guidelines under section 95 of the *Privacy Act 1988* and other relevant legislation. If ADHREC determines that the benefit of the research does not outweigh relevant privacy considerations, the protocol will not be approved.

### Military command approval

**3.29** It is the researcher's responsibility to seek command approval for access to military personnel. Prospective researchers should note that ADHREC views and approves research submissions from an ethical aspect. **Organisational endorsement and ADHREC approval does not provide access to Defence personnel for the study.** Although ADHREC may assist by placing the researcher in contact with the appropriate military commanders, ethical approval in no way implies command approval for access to military personnel. Importantly, it is ultimately the individual's decision whether or not to participate in the research.

**3.30** In the case of health-related research, the Senior Medical Officer, or Senior Psychologist where appropriate, of the supporting health facility is to be notified by the Principal Researcher of the intent to conduct research on personnel under their care.

**3.31** ADHREC will not assist with the organisation or conduct of a project.

### Security and confidentiality

**3.32** All ADHREC protocol files are held securely in a locked filing cabinet, separate from any other documents or files held by DHSD. This cabinet is accessible only to the ADHREC Secretariat. Researcher details are not provided to third parties. Whenever a third party requests details of a particular type of protocol or details of who conducted particular protocols, the Secretariat will contact the researcher and provide details of the third party. The researcher can then, if agreeable, contact the third party directly. Research protocols may be discussed with other directorates within the DHSD if there is an operational need.

**Payments to investigators, departments, institutions or participants by commercial interests**

**3.33** An investigator should not derive direct personal or financial benefit from the conduct of a commercially sponsored protocol. However, adequate compensation can be provided for personal expenses arising from the protocol.

**3.34** All remuneration should be paid into a fund used to finance the execution of the study, and should be administered under a formal contractual arrangement that is open to scrutiny. Other uses of the money must adhere to Defence guidelines.

**3.35** Payments on a per capita basis pose an additional problem because they raise the possibility of a conflict between the clinical responsibilities of a researcher and their financial gain. Here it is especially important that the arrangements are specifically approved by ADHREC. If such payments are approved, care should be taken that participants are included in the study only according to the approved protocol and inclusion is not influenced by the payment system.

**3.36** In the case of research conducted by civilian personnel where monetary compensation is paid to the researcher by a commercial interest, adequate compensation for personal expenses arising from the study should be provided. The nature of the compensation to be paid to the investigators should be declared in the information sheet given to potential volunteers.

**3.37** A grant of money or equipment by a commercial interest to an institution or health centre is generally acceptable but should always be made to the institution and not to individuals, and should be appropriately acknowledged in research and other publications. If the donation is linked to a specific protocol, a formal contractual arrangement that is open to scrutiny should be in place.

**3.38** Any payments made to volunteer study participants should be for 'out-of-pocket' expenses only, and follow NHMRC guidelines. ADF members and Defence employees should be considered 'on duty' when participating as study volunteers.

**REPORTING REQUIREMENTS****Annual report**

**3.39** As a non-statutory body within Defence, ADHREC is obliged to provide an annual report to CDF and the Secretary of Defence. The report is also circulated to researchers who have a protocol that has ADHREC approval, to both health and non-health units within Defence and to some external agencies, such as NHMRC and AHEC. The annual report covers the previous calendar year.

**Compliance report to Australian Health Ethics Committee**

**3.40** As an HREC, ADHREC is required to complete a compliance report to AHEC each financial year. These reports cover aspects of ADHREC's compliance with the NHMRC National Statement, including:

- a. membership and membership changes;
- b. number of meetings;
- c. confirmation of participation by required categories of members;
- d. the number of protocols presented, the number approved, and the number rejected;
- e. monitoring procedures in place and any problems encountered; and
- f. complaint procedures and number of complaints handled.

**Compliance report to ADHREC**

**3.41** At each meeting, a report is presented to the Committee detailing researchers' compliance with reporting procedures.

## COMPLAINTS

**3.42** The Executive Secretary of ADHREC is the initial point of contact for all complaints from research participants regarding the conduct of that research. The Executive Secretary will endeavour to resolve the complaint in the first instance. If this is not possible, the complaint may be put to the Chair or the Committee for consideration and resolution.

**3.43** Where a complaint is made against a researcher or the conduct of a study, it may be necessary to suspend the research pending resolution of the complaint. Depending on the nature of the complaint, it may also be necessary to withdraw ethical clearance from the project temporarily until the matter is resolved, or permanently if significant problems are identified.

**3.44** Where a complaint arises from a researcher regarding the consideration of their research protocol by ADHREC, they should contact the Executive Secretary in writing with details of the complaint. The Executive Secretary will endeavour to resolve any issues raised. ADHREC will make a decision based on all evidence received, including any response submitted by the researcher.

**3.45** Where a complaint arises regarding the conduct of ADHREC, the Executive Secretary should be the initial point of contact. Where appropriate the complaint will be directed to the office of CDF.

**3.46** ADHREC is required to keep a complaints register for audit purposes.

### HOW TO CONTACT THE AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE

**3.47** The primary point of contact for ADHREC is the Executive Secretary. Contact details are as follows:

Executive Secretary  
Australian Defence Human Research Ethics Committee  
CP2-7-130  
Department of Defence  
CANBERRA ACT 2600

Telephone: (02) 62663837  
Facsimile: (02) 62663933  
Email: [ADHREC@defence.gov.au](mailto:ADHREC@defence.gov.au)