

## CHAPTER 1

**HUMAN RESEARCH ENVIRONMENT****Introduction**

**1.1** Human research conducted in Defence is intended to support and enhance Defence capability. Defence has a broad range of research interests and resources which it will attempt to advance in a variety of ways - through Defence Scientific and Technology assets, military research organisations, project-engaged organisations, the work of individual or group researchers, and collaborations with allied nations, other Government departments, academic institutions and commercial organisations.

**Scope**

**1.2** This publication addresses the management of human research where the research is supported in some way by Defence and applies where that research requires ethical and organisational clearance before it is conducted. The Australian Defence Human Research Ethics Committee (ADHREC, Chapter 3—'Human Research Ethics') provides ethical oversight and monitoring of human research, as required under the *National Health and Medical Research Council Act 1992* (NHMRC Act). Defence Instruction (General) Admin 24-3, *The Conduct of Human Research in Defence*, provides authority to ADHREC and establishes the requirement to obtain organisational approval. This publication provides detailed guidance on how that authority is administered and how organisational approval is obtained. However, it should be noted that not all research activities which might involve humans are necessarily *human research* which requires ethics clearance.

**Definitions**

**1.3 Research.** The National Health and Medical Research Council (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.

**1.4 Human research.** Human research includes investigations involving the study of human subjects. In the context of this manual, it refers to research which is conducted using human volunteers or which accesses data collected from human volunteers. Chapter 3, 'Human Research Ethics', provides guidance on when ethics clearance is required for research involving humans. Further guidance on human ethics consideration may be sought from NHMRC publications, including, but not limited to, the *National Statement on Ethical Conduct in Human Research* (NHMRC 2007).

**1.5 Health research.** Health research is defined as that body of investigation aimed at increasing 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.

**1.6 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. It is further concerned with that aspect of human-systems integration that focuses on minimising negative effects of systems and equipment on human performance.

**1.7 Human factors research.** Human Factors Research is defined as the assessment of a system's performance with a focus on the degree to which the design of its equipment, processes and/or training meet the needs of its user population, account for their limitations and utilise their strengths to maximise the performance of the total system and the wellbeing of its users, and others, in its intended operational context. This category of research excludes studies that explore the limits of physiological or psychological integrity of the individual or have the potential to induce significant discomfort.

**1.8 Psychology research.** Psychology research can be defined as the application of scientific methods developed within the discipline of the study of human behaviour. Within Defence it overlaps with, but extends beyond health related research and human performance related research.

**1.9 Personnel research.** Personnel and organisational research which fall within the *human research* domain will be investigations aimed at increased understanding, maintenance or improvement of the functioning of humans and social systems that constitute organisations. Personnel and organisational research employs applied quantitative and qualitative research methods such as the utilisation of surveys, interviews, focus groups, and observational techniques to elicit attitudes, beliefs, behaviours, experiences or opinions of persons.

**1.10 Survey Research.** Survey research is defined as any research that involve the use of survey instruments to collect data from participants. Such instruments can be paper, telephone or computer-based.

**1.11 Other research.** Other research, including systems trials, may have a dimension which requires human research ethics clearance even though the primary subject of the research is not the human.

### **Coordination and approval of research activities**

**1.12** ADHREC provides ethical approval, oversight and monitoring of human research in Defence. Additionally, when ethics clearance is required, DI (G) Admin 24-3 also requires human research proposals 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 will be carried out using sound scientific methodology. **When human research requires ADHREC clearance, organisational review and endorsement of protocols is to be obtained prior to that consideration by ADHREC.**

**1.13** Organisational review and, where appropriate, endorsement of the broad range of human research proposals, which can include epidemiological studies, psychological research, personnel surveys, entomological studies, equipment trials, clinical audits or operational research, rests with the relevant responsible area of Defence. In addition, those research proposals that require ethical approval must be approved by ADHREC. The detailed procedures for obtaining review, endorsement and ethical clearance are contained in Chapter 4—'Protocol submissions'.

**1.14** ADHREC reviews the ethics of, and when appropriate, approves proposals for human research to be conducted by, or on, Defence personnel. This research may utilise Defence resources. ADHREC also monitors the progress of the protocols it has approved to ensure compliance with the conditions of that approval.

**1.15** No element of Defence is to perform or sponsor human research, as defined by this publication, on human volunteers without ethics approval from ADHREC. Ethical approval through ADHREC might not be required in some circumstances—for example, human factors research. Chapter 3—'Human Research Ethics' provides guidance on when ethics approval is required for research involving humans. If there is any uncertainty as to whether or not a proposal requires review by ADHREC, the protocol should be forwarded to the ADHREC secretariat for consideration and guidance.