

CHAPTER 2

ORGANISATIONAL OVERSIGHT OF HUMAN RESEARCH IN DEFENCE**Introduction**

2.1 DI (G) Admin 24-3 requires that human research proposals are 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 carried out using sound scientific methodology.

2.2 As well as the requirement to optimise resource use, there is an ethical dimension to organisational oversight of human research in Defence. The use of human volunteers in the conduct of research will always involve some element of risk or inconvenience to those volunteers, regardless of risk minimisation efforts. When considering the ethics implications of human research, that risk or inconvenience must be balanced against the value of the potential research outcomes, particularly to the Australian Defence Organisation. The value of the potential research outcomes will also be influenced by the strength of the scientific methodology.

Defence research priorities and plans

2.3 Most human research undertaken by Defence organisations should be in response to established research requirements and organisational plans¹, because this is the most effective way to establish research priorities. Research undertaken for Defence as part of a Defence project should be in accordance with the project management requirements. This may include the establishment of a Scientific Advisory Committee (SAC).

2.4 Human research proposals which are not specifically in response to the established or documented Defence requirements or plans are to be assessed by the appropriate Defence strategic area responsible for the subject matter of the proposed research. This is to ensure that Defence research priorities are met and Defence resources are properly applied.

Methodology

2.5 Human research protocols must use sound scientific methodology. The application of unsound, inadequate or inappropriate science will not answer research questions and Defence resources will not be appropriately utilised. The use of human volunteers to undertake methodologically unsound research is unethical and Defence organisations responsible for organisational oversight of human research must ensure that protocols employ sound methodology. If necessary, subject matter experts (SME) are to be engaged to assist in the assessment of protocols.

Organisational responsibility for research

2.6 Human research protocol applications are to be submitted first to the responsible strategic level Defence organisation for organisational clearance and confirmation of scientific merit. Only after these requirements have been met will the protocol be submitted to ADHREC for human research ethics clearance (if such ethics clearance is required).

2.7 Organisations which routinely undertake research in Defence (such as DSTO) must have established mechanisms to ensure the organisational and scientific merit of proposed research. Provided those mechanisms are demonstrably robust, further organisational assessment of human research protocol applications may not be required before submission to ADHREC for human research ethics clearance.

¹ Examples of requirement documents include the Science and Technology plans of DSTO-Client committees. Examples of organisational plans include the task plans of DSTO and the business plans of Defence health research organisations.

2.8 Submission procedures. The detailed requirements for the submission and assessment of human research protocols for both organisational and human research ethics approval are contained in Chapter 4—‘Protocol Submissions’.

2.9 Overall responsibility. Defence Health Services Division² (DHSD) provides the secretariat and support services for ADHREC. DHSD will direct human research protocol applications to the area of Defence with appropriate strategic responsibility for the research before submission to ADHREC, if such assessment has not already occurred. Where protocol applications have already been assessed to ensure that the requirements for organisational and scientific merit have been met, DHSD is to ensure the procedures are demonstrably robust. Protocols which have not received adequate organisational oversight will not be accepted by the ADHREC secretariat for ethics consideration.

Specific areas of responsibility

2.10 Health research. DHSD is responsible for strategic oversight of health, including health research. This oversight will normally be the responsibility of a committee established for that purpose. DHSD also provides the secretariat and support services for ADHREC. ADHREC is chaired by the Surgeon General Australian Defence Force (SGADF).

2.11 Human performance research. Because human performance research may involve research up to the limits of physiological and/or psychological integrity of humans, strategic oversight of such research normally rests with DHSD. ADHREC approval will normally be required for human performance research projects.

2.12 Psychology research. The Defence Force Psychology Organisation (DFPO) is responsible for strategic oversight of psychology in Defence, including psychology research. Some psychology research, for example some mental health research, is also health research and the Directorate of Mental Health (DMH) is to be consulted for such research. DFPO Psychology Research and Technology Group (PRTG) promulgates procedures for organisational oversight of psychology research and must be consulted prior to undertaking psychology research.

2.13 Personnel research. Most personnel and organisational research is not human research within the scope of this publication and does not require ethics approval. However, some personnel and organisational research will require ethics approval – for example where it involves the collection of sensitive information with possible implications for the mental or physical health of the respondent or their cultural sensitivities. The strategic responsibility for personnel and organisational research rests with the Directorate of Strategic Personnel Planning and Research (DSPPR) within the Defence Personnel Executive. DSPPR promulgates procedures for organisational oversight of personnel research including surveys.

2.14 Equipment trials and human factors research. Equipment trials may involve some human factors research and sponsoring authorities are to carefully assess whether human research ethics review may be required. Any trial that may lead to the exposure of personnel to a situation that approaches the limits of physiological or psychological integrity, or have the potential to induce significant discomfort, should be submitted to ADHREC for final review and approval.

2.15 Other research. DHSD retains overall responsibility for ensuring that organisational oversight of human research is undertaken. DHSD is to ensure that any human research protocol applications which do not fall into the preceding categories are directed to an appropriate area of Defence for organisational review².

2.16 Some research requiring human ethics consideration is not human research (as defined) because humans are not the research subject. Involvement of humans may occur secondarily (e.g. some weapons systems trials). Where human participation in the proposed research has a potential for adverse physical or psychological effects, it must receive ethics approval from ADHREC. DHSD is to ensure appropriate organisational review of such research has been undertaken before submission to ADHREC².

² This DHSD function is only to provide secretariat and administrative support.

Human research in DSTO

2.17 DSTO maintains established procedures to ensure the quality and relevance of research involving human participants. The majority of these studies conform to the definition of Human Factors Research (Chapter 1 paragraph 1.7) or Personnel Research (Chapter 1 paragraph 1.9) and, having been reviewed and approved internally, do not require review and approval by ADHREC. In cases where a DSTO research protocol includes activities that may lead to the exposure of subjects to a situation that approaches the limits of physiological or psychological integrity or have the potential to induce significant discomfort, the protocol is reviewed internally and submitted to ADHREC for final review and approval.

External Organisations

2.18 Defence personnel are sometimes involved in human research which does not fall into any of the above categories. For example, external organisations may conduct research involving Defence or ex-Defence personnel (such as some DVA sponsored research). Where there is no Defence involvement Defence oversight cannot be required. However, if there is any Defence involvement (for example if Defence resources are used to identify or target potential participants) Defence organisational and ethics approval requirements must be met. DHSD is to ensure protocols are directed to the appropriate area of strategic responsibility before submission to ADHREC².