HUMAN AND ANIMAL RESEARCH MANUAL

Roxanne Kelley
Deputy Secretary Defence People

Department of Defence
CANBERRA ACT 2600

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HUMAN AND ANIMAL RESEARCH MANUAL

Date Issued: This manual has been issued by Deputy Secretary People on 08 September 2017.

Purpose: The Human and Animal Research Manual (the Manual) provides a policy for researchers, delegates and ethical review bodies involved in the development, review, authorisation and implementation of human and/or animal research associated with Defence. The Manual facilitates compliance with the National Statement on Ethical Conduct in Human Research, the Australian Code for the Responsible Conduct of Research, the Australian code for the care and use of animals for scientific purposes and other relevant guidelines and legislation.

Scope and applicability: This manual is an administrative policy framework document (framework document) and applies to all Defence personnel.

The terms of a relevant contract may extend the application of this manual to a contractor, consultant or outsourced service provider.

The Secretary and the Chief of the Defence Force require Defence personnel to comply with provisions in manuals unless the particular circumstances warrant departure from the provisions.

Some provisions in policies and manuals support Defence personnel to comply with obligations that exist in:

a. applicable laws

b. the Defence Enterprise Agreement

c. directives and determinations issued under the Public Service Act 1999 or the Defence Act 1903 or the Defence Enterprise Agreement

or

d. Defence Instructions.

Defence personnel must not depart from manual or policy provisions in a way that would result in any breach of those obligations.
When considering a possible departure from a manual the Secretary and the Chief of Defence Force require Defence personnel to:

a. consider whether the proposed departure would be inconsistent with:

   (i) applicable laws

   (ii) the *Defence Enterprise Agreement*

   (iii) directives and determinations issued under the *Public Service Act 1999* or the *Defence Act 1903* or the *Defence Enterprise Agreement*

   or

   (iv) Defence Instructions.

If yes, the departure is not permitted;

b. consider whether a proposed departure is reasonable and justified in the circumstances and will produce a better outcome for Defence

c. consult their supervisor, wherever practicable, about a proposed departure – a properly informed decision also involves consulting the policy owner

d. be responsible and accountable for the consequences of departing from, or not adhering to, the content of a manual including where such departure or non-adherence results in a breach of applicable laws or leads to adverse outcomes for Defence.

Defence personnel may be subject to performance management, administrative action or, in some circumstances, disciplinary action where their decision to depart from manual provisions involves serious errors of judgement.

Failure to adhere to administrative policy may result in a breach of legislation or other legal requirement and sanctions under that legislation may apply.

Defence personnel who are authorised by the Secretary to execute contracts on behalf of the Commonwealth should consider whether there is a specific and documented reason to include in the terms of a contract the requirement for contractors, consultants and outsourced service providers to comply with the provisions of this manual and, if so, include such terms.
Structure: Chapter 1 – Defence Research

Chapter 2 – Responsible Conduct of Defence Research

Chapter 3 – Defence Research Ethical Review

Management: This manual will be reviewed annually from its date of issue or sooner if necessitated by business requirements to ensure it continues to meet the intent of Defence’s policy on this subject. Minor amendments may be made at quarterly intervals commencing three months after the date of issue.

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Policy owner: Head People Capability

Policy contact: Deputy Director People Intelligence and Research

DPI.Research@defence.gov.au

Cancellation: Defence Health Manual Volume 1 Part 18 Chapter 1 Conduct of human research in Defence

Definitions: Definitions that apply to this manual are at annex 1A.

Related Documents: A list of documents relating to this manual is at Chapter 1.
## CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PURPOSE</td>
<td>i</td>
</tr>
<tr>
<td>CHAPTER 1</td>
<td></td>
</tr>
<tr>
<td>DEFENCE RESEARCH</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td>1-1</td>
</tr>
<tr>
<td>Aim</td>
<td>1-1</td>
</tr>
<tr>
<td>Contract Requirements</td>
<td>1-2</td>
</tr>
<tr>
<td>Related Legislation</td>
<td>1-3</td>
</tr>
<tr>
<td>Related Publications</td>
<td>1-3</td>
</tr>
<tr>
<td>Annex 1A - Definitions</td>
<td></td>
</tr>
<tr>
<td>CHAPTER 2</td>
<td></td>
</tr>
<tr>
<td>RESPONSIBLE CONDUCT OF DEFENCE RESEARCH</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td>2-1</td>
</tr>
<tr>
<td>Institutional Responsibilities</td>
<td>2-1</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>2-2</td>
</tr>
<tr>
<td>Conflicts of Interest</td>
<td>2-2</td>
</tr>
<tr>
<td>Sponsor and Approver Responsibilities</td>
<td>2-2</td>
</tr>
<tr>
<td>Research Authorisation</td>
<td>2-2</td>
</tr>
<tr>
<td>Organisational Support and Command Approval</td>
<td>2-3</td>
</tr>
<tr>
<td>Researcher Responsibilities</td>
<td>2-4</td>
</tr>
<tr>
<td>Authorship</td>
<td>2-4</td>
</tr>
<tr>
<td>Complaints and Concerns</td>
<td>2-5</td>
</tr>
<tr>
<td>Research Data</td>
<td>2-5</td>
</tr>
<tr>
<td>Retention of Materials and Research Data</td>
<td>2-5</td>
</tr>
<tr>
<td>CHAPTER 3</td>
<td></td>
</tr>
<tr>
<td>DEFENCE RESEARCH ETHICAL REVIEW</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td>3-1</td>
</tr>
<tr>
<td>Ethical Review Requirements in Defence</td>
<td>3-1</td>
</tr>
<tr>
<td>Human Research</td>
<td>3-2</td>
</tr>
<tr>
<td>Federal Wide Assurance</td>
<td>3-2</td>
</tr>
<tr>
<td>Animal Research</td>
<td>3-2</td>
</tr>
<tr>
<td>Quality Assurance and Evaluation Activities</td>
<td>3-3</td>
</tr>
</tbody>
</table>
CHAPTER 1
DEFENCE RESEARCH

INTRODUCTION

1.1 The Department of Defence (Defence) is committed to high quality research that benefits Defence capability or contributes to institutional knowledge, including program and policy development implementation and evaluation. To ensure research and quality assurance/evaluation activities associated with Defence are conducted to the highest ethical standards, Defence adheres to relevant Commonwealth, State and Territory legislation, guidelines and codes of practice governing the responsible conduct of Human and Animal research in Australia. These standards are to be applied to research activities involving Defence personnel working in side and outside of Australia.

AIM

1.2 The aim of the Human and Animal Research Manual is to provide a policy framework for researchers, research sponsors and ethical review bodies involved in the development, review, authorisation, implementation and ongoing monitoring of human and/or animal research associated with Defence.

POLICY STATEMENT

1.3 Personnel and organisations planning to conduct human research involving Defence personnel or animals require sponsorship and ethical approval prior to proceeding. Researchers are required to seek ethical review and approval of their research project through the appropriate ethical review body prior to approaching Defence personnel. This will ensure that Defence maintains the highest ethical standards and that Defence maintains its duty of care to its personnel.

1.4 All Defence personnel, academic researchers, internal Groups and Services and external institutions who wish to undertake human and/or animal research must comply with the manual and related publications where one or more of the following apply:

a. involves Defence personnel as participants, either directly or indirectly;
b. is conducted by Defence personnel;
c. is conducted on/in a Defence establishment; and/or
d. is supported in any way by Defence (including financially).
**Contract Requirements.**

1.5 Defence personnel who award or manage contracts are to include a contract requirement that contractors, consultants and outsourced service providers must comply with relevant Defence research policies and practices when conducting research, evaluation or quality assurance activities associated with Defence. This in turn ensures compliance with the Australian Code for the Responsible Conduct of Research, (from here on referred to as the ‘the Code’).
1.6 The following legislation is referenced in this Manual:

a. *Defence Force Discipline Act 1982*

b. *Public Service Act 1999*

c. *Privacy Act 1988*

d. *Archives Act 1983*

e. *Therapeutic Goods Act 1989*

f. *Defence IP Policy 2014*

1.7 The following publications are referenced in this Manual:

a. *Australian Code for the Responsible Conduct of Research*

b. *National Statement on Ethical Conduct in Human Research*

c. *Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*

d. *Ethical Considerations in Quality Assurance and Evaluation Activities*

e. *Guidelines approved under section 95A of the Privacy Act 1988*

f. *Guidelines approved under section 95AA of the Privacy Act 1988*

g. *Australian code for the care and use of animals for scientific purposes 8th edition (2013)*

h. Section 9B of the Privacy Act 1988 – an external service provider (or any of it’s subcontractors) must not breach the provisions of the *Privacy Act 1988*

i. National Health and Medical Research Council *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008)*


k. *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95-Annnotated with TGA comments)*

l. *Australian Radiation Protection and Nuclear Safety Agency – Code on Exposure of Human and Ionizing Radiation for Research 2005*
m. Defence Security Manual
o. Defence Health Manual, Volume 3, Part 18, Chapter 1, ―‘Health and Medical Research’

1.8 A list of definitions that apply to this Manual is found in annex 1A.
DEFINITIONS

**Adverse event** is an untoward occurrence that has resulted in one or more of the following; participant distress, requirement for medical treatment or a breach of privacy or confidentiality.

**Animal research** is research which is conducted utilising animals or their tissue in pursuit of constructive knowledge.

**Australian Public Service employee** is a person employed under the *Public Service Act 1999* in the Department of Defence.

**Commander** is an Australian Defence Force officer, who by virtue of a delegation or instrument of appointment exercises authority and holds responsibility for assigned Defence personnel and includes an Administrative Commanding Officer.

**Conflict of Interest** is where a person’s individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research, or an institution’s interests or responsibilities have the potential to influence the carrying out of its research obligations.

**Consent** is a person’s or group’s agreement to participate in research based on informed knowledge and understanding of relevant material.

**Consultant** is a person or organisation engaged by Defence under contract to undertake a consultancy that meets the following Department of Finance criteria for reporting on AusTender:

a. the services to be provided involve the development of an intellectual and scientific output that assists with Defence decision-making;

b. the output will reflect the independent views of the consultant; and

c. the output is the sole or majority element of the contract, in terms of relative value and importance.

**Contractor** is a person engaged by Defence under a contract that represents a business resource and is subject to direct management by Defence. Contractors would normally undertake Defence roles and are engaged as an alternative to normal Australian Public Service employee resources. This would also apply in circumstances where the engagement of a firm is for labour hire involving specific personnel remunerated at hourly or daily rates. Defence members and Australian Public Service employees are not included in this definition.

**Data** is the recorded factual material or information commonly accepted in the scientific community as necessary to validate research findings.

**Defence** is the Department of Defence and the Australian Defence Force (ADF).
Defence civilian, as defined in section 3 of the Defence Force Discipline Act 1982 is a person (other than an Australian Defence Force member) who:

a. with the authority of an authorised officer as defined in the Defence Force Discipline Act, accompanies a part of the Australian Defence Force that is outside Australia, or on operations against the enemy; and

b. has consented, in writing, to subject themselves to Australian Defence Force discipline while so accompanying that part of the Australian Defence Force.

Defence locally engaged employee is any person engaged overseas by contract or under section 74 of the Public Service Act 1999.

Defence member. As defined in the Defence Force Discipline Act 1982 is a person who is:

a. a member of the Permanent Navy, the Regular Army or the Permanent Air Force; or

b. a member of the Reserves who:

   (i) is rendering continuous full-time service; or

   (ii) is on duty or in uniform.

Ethical review is the review of research by a Human Research Ethics Committee or other body.

Ethics is the concept of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply. It also includes the consideration of what is good (values) and right (principles) in relation to a core purpose.

Evaluation (also known as quality assurance) is an activity where the primary purpose is to monitor, evaluate or improve the quality of a specified activity.

External refers to agencies, organisations or individuals outside Defence.

Greater than low risk where the risk, even if unlikely, is more serious than discomfort. The greater the risk to participants, the more certain it must be both that the risks will be managed, and participant's have a clear understanding of the risks they are accepting.

Health research is research aimed at understanding or treating a human disease or health condition. This includes research tools that involve the examination of processes or other events that impact on the physical and/or mental health of personnel.

Human systems performance research applies scientific methods to guide the design and integration of technologies and processes that aid the effective completion of role specific tasks. It investigates opportunities to enhance physical
and mental performance and to mitigate risks, such as fatigue and injury. The research ranges from the selection and nutritional sustainment of personnel to their physiological, biomechanical and ergonomic interaction with their environment and equipment through to the cognitive and behavioural implications of alternative system designs for the performance of a team or organisation.

**Human research** is research which is conducted with or about people, their data or tissue.

**Internal** means inside the Department of Defence.

**Institution** includes other government entities, universities, academic organisations and other non-government entities.

**Low risk research** is research in which the only foreseeable risk is one of discomfort to participants.

**Manager** includes Defence personnel or contractors, who direct a range of human and physical resources and their associated financial responsibilities to achieve corporate objectives. A manager may be a first-level supervisor or performs the role of a first-level supervisor where they have immediate subordinates, as well as the role of a second-level supervisor where they have Defence personnel supervised by those subordinates.

**Monitoring** is the process of verifying that the conduct of the research conforms to the approved proposal.

**Negligible risk research** is research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is of inconvenience only.

**New application** is where a research proposal has not been considered by the committee previously or where significant time has elapsed since the research proposal was first considered and it requires the submission to be treated as a new application.

**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 humans, their data or tissue.

**Outsourced service provider** is a person or organisation engaged by Defence under a service contract to deliver a specified service or supply, usually against agreed milestones and deliverable requirements.

**Peer review** is a process by which proposed research or publications is evaluated by a group of experts in the appropriate field.

**People research** includes studies of knowledge, skills, aptitudes, attitudes, personalities, behaviours and other psychological or sociological phenomena. People research may involve quantitative studies of human phenomena and their relationships. It may also involve qualitative research, which entails the examination,
Human and Animal Research Manual

1A-4

analysis and interpretation of observations for the purpose of discovering underlying meanings and patterns of relationships.

Privacy is designed to inform individuals about the way Defence collects, stores, uses and discloses personal information. The Defence Privacy Knowledge Site provides guidance about how personal information can be accessed, corrected and stored.

Publication is any book, journal, periodical, thesis or such publication, including any abstract or poster created for a conference, or any part thereof, which contains materials, articles or text written by members of educational or research bodies on areas of educational or scholastic learning, research or debate. It does not include any publication that is brought into existence for the dominant purpose of seeking financial gain or commercial benefit.

Research includes investigation undertaken to gain knowledge and understanding or to train researchers. It involves a systematic process for establishing facts, principles or knowledge, or a study of matter with the objective of obtaining or confirming knowledge. It includes investigation undertaken to gain knowledge and understanding or to train researchers.

Research associated with Defence is research that is characterised by one or more of the following:

a. Defence personnel are involved as participants;
b. Defence personnel are involved in conducting the activity;
c. the activity is conducted in/on a Defence establishment; and/or
d. the activity is supported in any way by Defence.

Research governance are those matters concerning the authorisation, monitoring, quality, safety, privacy, risk management, legislative and regulatory guidance, financial management and ethical acceptability of research.

Risk is the probability of damage, injury, negative occurrence or adverse events.

Research participant is anyone who is the subject of research in any of the ways set out in the purpose and scope of the National Statement on Ethical Conduct in Human Research.

Serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires in-patient hospitalisation or extension of existing hospitalisation, results in persistent or significant disability/incapacity or a congenital anomaly/birth defect, or is a medically important event or reaction.

Sponsor is a senior commander or manager of no lower rank/Australian Public Service classification than Brigadier (E)/Senior Executive Service Band 1 who takes responsibility for initiation, authorisation, management and/or financing of research.
Supervisor means Defence personnel or contractors who have direct or line supervisory responsibilities for Defence personnel.
CHAPTER 2
RESPONSIBLE CONDUCT OF DEFENCE RESEARCH

INTRODUCTION

2.1 The Australian Code for the Responsible Conduct of Research (the Code), the National Statement on Ethical Conduct in Human Research (the National Statement) and the Australian Code for the care and use of animals for scientific purposes (the Animal Code) outline the responsibilities of all Australian institutions and researchers for the conduct of research.

2.2 Defence human research is conducted in a broad number of research domains including but not limited to health and medical research, people research, human systems performance and animal research.

2.3 This chapter establishes and outlines the responsibilities of the sponsors and researchers involved in the conduct of research associated with Defence.

POLICY STATEMENT

2.4 Personnel and organisations planning to conduct people research require sponsorship and ethical approval prior to proceeding. Researchers are required to seek ethical review and approval of their research project through the appropriate ethical review body prior to approaching Defence research participants.

INSTITUTIONAL RESPONSIBILITIES

2.5 The Defence Human Research Governance Board is the governance mechanism for overseeing the prioritisation and collaboration of Defence human and animal research. Additionally, the Defence Human Research Governance Board provides strategic advice, facilitates information sharing regarding Defence-wide research priorities and collates and distributes the research priorities for the Services and Groups within Defence.

2.6 The Department of Defence will collaborate with other institutions for the purpose of conducting / sponsoring people research. Research sponsors, researchers and ethical review bodies are responsible for ensuring appropriate arrangements are agreed to and implemented prior to the commencement of a research project. Collaborative arrangements may include, but are not limited to financial management, intellectual property, data capture, authorship, publication, ethics approval and ownership of equipment, data and research methodology.

2.7 Where research involves collaboration with international stakeholders and/or recruitment or use of data of individuals from other countries, compliance with their relevant legislations, regulations and guidelines is also required.
Intellectual Property

2.8 The Defence sponsor is to ensure that written agreements are in place which outline the ownership of intellectual property related to human research conducted by researchers from institutions external to the Department of Defence. This should include, but is not limited to, ownership of foreground and background intellectual property. These agreements on intellectual property ownership must be established prior to approval for research to be undertaken. Defence sponsors are encouraged to seek advice from Defence Legal to ensure agreements for ownership of human research intellectual property are established prior to research commencing.

Conflicts of Interest

2.9 Institutions and researchers are responsible for disclosing actual or perceived conflicts of interest to the appropriate ethical review body for the research being conducted. Conflicts of interest may relate to financial interests, affiliations and private, professional or institutional benefits that depend significantly on the research outcomes, or influence research outcomes. Where the potential for a conflict of interest is identified, ethical review bodies are responsible for ensuring that appropriate measures are implemented to report and manage conflicts of interests.

SPONSOR AND APPROVER RESPONSIBILITIES

Research Authorisation

2.10 Research governance is the responsibility of the research sponsor/s, in collaboration with the Defence Human Research Governance Board, to ensure compliance with the relevant national guidelines and legislation. This includes management of contracts (where appropriate), ensuring ethical approval is obtained from the appropriate committee or panel within Defence prior to the commencement of research, oversight of changes to approved research protocols are endorsed and provision of periodic reports (at least annually).

2.11 Prior to submission of an ethics application to a Defence ethical review body, Defence sponsorship and where appropriate, command approval are to be obtained by researchers.

2.12 Subject matter expert review, either via formalised peer review or by a scientific committee, may be required to inform the relevant decision maker (Defence sponsor) regarding specific considerations including but not limited to legal, financial, technical or scientific expertise, intellectual property rights or other institutional knowledge or information including duplication of research, strategic direction, relevance and fit to systems methodology.

Organisational Support and Command Approval

2.13 All human/or animal research associated with Defence must be sponsored by a senior representative from within the applicable Service or Group in which the research is to be conducted. The sponsor must be a senior commander or manager
of a rank/APS classification no lower than a Brigadier (E)/Senior Executive Service Band 1. In principle approval to conduct the research must be sought and obtained by the research team prior to submitting an ethics application. Final authorisation to undertake research can only be granted once ethical approval has been obtained from a Defence ethical review body and any other relevant institutional body.

2.14 Senior commanders or managers who are requested to sponsor a research activity, should only support activities that are either aligned with their respective areas of responsibility and in accordance with the Defence research priorities, or have been assessed by senior leadership as providing considerable benefit to the Department of Defence.

2.15 Sponsors must ensure that human or animal research or quality assurance/evaluation activities comply with all relevant legislation, national guidelines and Defence policy. In particular, the sponsor should ensure that the following issues are or have been addressed:

a. there is documented evidence of ethical approval from the relevant Defence ethical review body or an appropriately constituted and registered animal ethics committee prior to providing final approval of the project;

b. that any conflicts of interest have been declared and managed; and

c. that the study adheres to relevant research guidelines and standards.

2.16 In addition to the requirement for sponsorship approval to undertake research, approval is also required from the local commander/manager of the intended research participants. Researchers who are seeking access to Defence personnel as research participants must obtain in-principle approval from the relevant Unit/Area Commander, Branch Head or Director prior to submission of their ethics application to the relevant ethical review body.

2.17 Final command approval may be granted once ethical approval has been obtained from the appropriate ethical review body within Defence and any other relevant institutions.

2.18 Defence employees are deemed to be on duty whilst participating in research activities and therefore, any payments made to participants are to be for out-of-pocket expenses only.
RESEARCHER RESPONSIBILITIES

2.19 Researchers are required to seek Defence sponsorship and ethical review of their research activity through the appropriate ethical review body prior to approaching Defence personnel to participate in a research activity. Further details for this requirement are outlined in Chapter 3.

2.20 Researchers are responsible for ensuring compliance with this manual and the relevant ethical review bodies' research guidelines and conditions of ethical approval, national guidelines and legislative requirements.

2.21 Researchers are required to obtain approval from a sponsor prior to submitting an ethics application. This sponsor must be a senior commander of a rank/APS classification no lower than Brigadier (E)/ SES Band 1.

2.22 Researchers are responsible for disclosing actual or perceived conflicts of interest for the research being conducted to the sponsors and ethical review bodies. Conflicts of interest may relate to financial interests, affiliations and/or private, professional or institutional benefits that depend significantly on the research outcomes, or can influence research outcomes.

2.23 Researchers are to notify the ethics review body of any event that requires a modification to the research protocols or other project documents and submit any required amendments in accordance with the instructions provided by the body.

2.24 Researchers are to provide immediate notification of adverse and serious adverse events to the Defence sponsor, research participant’s chain of command / Australian Public Service manager and the approving ethical review body as soon as possible.

2.25 Researchers are to provide regular updates on the progress of their research activity to both the Defence sponsor and the approving ethical review body. The frequency of updates should be negotiated with the Defence sponsor and ethical review body, but must be at least annually. Additionally, Researchers are to ensure that all research outcomes/outputs obtain clearance from the Defence sponsor prior to presentation or publication.

Authorship

2.26 Attribution of authorship depends to some extent on the discipline, but in all cases, authorship must be based on substantial contribution in a combination of conception and design of the project; analysis and interpretation of the research data; drafting significant parts of the work or critically revising it so as to contribute to the interpretation.

2.27 Researchers must offer authorship to all people, including research trainees, who meet the criteria for authorship as outlined in the Code. Authorship should not be offered to those who do not meet the requirements outlined in paragraph 2.25. Researchers are to ensure that all those who have contributed to the research facilities or materials are properly acknowledged.
2.28 Collaborating researchers should agree on the authorship at an early stage in the research project and review their decisions periodically. Where there are several authors, an executive author should be appointed to record authorship and manage communications about the work with publishers.

2.29 A person who qualified as an author must not be included or excluded without their written agreement and a record of this agreement must be kept by the executive author. The record of authorship must include the description of the contribution of each author. Where individuals are to be acknowledged for their contribution, as outlined in paragraph 2.25, written consent must also be obtained.

Complaints and Concerns

2.30 Researchers are to establish and inform research participants of a complaints process. Research participants are to be provided with points of contact in case they wish to express concerns or submit a complaint about the research project. The Principal Investigator is to inform the approving ethical review body and Defence sponsor as soon as possible of any complaints being made.

RESEARCH DATA

Retention of materials and research data

2.31 Research documents created by Defence research institutions and researchers are Commonwealth records and must be managed in accordance with the Archives Act 1983 (the Archives Act) and the Records Management Policy Manual (RECMAN). For research that is conducted by agencies external to Defence and DVA, the records are to be stored in accordance with the Privacy Act 1988 (the Privacy Act), the Archives Act and other appropriate legislation.

2.32 Research data and materials are to be retained by the Principal Investigator for not less than five years from the date of publication, or 15 years for clinical trials. If the research results are challenged, research data and materials are to be retained until the matter is resolved. Where records may be relevant to allegations of research misconduct, research data and materials must not be destroyed (noting also the provisions of the Archives Act 1983 and the Privacy Act 1988). Additionally, if the research has community or heritage value, the data should be retained permanently as determined by the Defence sponsor and approved by the relevant ethical review body.

2.33 Researchers must ensure data is collected, stored, accessed, amended, used and, where necessary, disclosed or destroyed in accordance with the approved research protocol, in addition to statutory and policy requirements. Research data must not be removed from the approved storage location and must not be copied, emailed or downloaded to laptops or other electronic mobile devices, unless otherwise approved.

2.34 Unauthorised access and/or use of data for a purpose other than that indicated in the approved protocol and permitted under the Privacy Act are strictly prohibited.
2.35 Researchers are to provide a research report to their Defence sponsor at the completion of their research activity. The report is to include, but is not limited to, an overview of the research conducted, research methodologies used and outcomes or conclusions of their analysis. Additionally, the report is to be distributed to the appropriate ethical review body prior to public release or publication. Ethical review bodies are to ensure research reports from their approved research projects are made available to the wider Defence community.

2.36 At the completion of the approved research, data must be either returned, stored or destroyed in accordance with approved protocols, the Archives Act, any other relevant legislation and any contractual requirements.
CHAPTER 3

DEFENCE RESEARCH ETHICAL REVIEW

INTRODUCTION

3.1 Defence recognises the need to conduct research ethically, including the protection of Defence personnel participating in research by minimising risks to research participants and the humane treatment of animals used in research. This chapter establishes the standards and pathways for the ethical review of human and animal research within Defence.

POLICY STATEMENT

3.2 Human and animal research proposals will be reviewed and assessed in order to determine the level of risk inherent to the proposed research, and to ensure the adequacy of any protective measures proposed by the research team.

ETHICAL REVIEW REQUIREMENTS IN DEFENCE

Human Research

3.3 Defence has established an ethical review process for the conduct of human research to ensure that potential risks to research participants are identified and managed in accordance with the ‘National Statement on the Ethical Conduct in Human Research (the National Statement). Human research can be deemed to be either negligible risk, low risk or greater than low risk.

3.4 Defence has established a Human Research Ethics Committee to conduct ethical review of research applications that require full ethical review in accordance with the National Statement. This committee is referred to as the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee.

3.5 The scope, responsibilities and functions of the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee are outlined in their Terms of Reference. Guidance on the process to seek ethical approval to conduct research that is higher than low risk can be sent to ddvahrec@defence.gov.au. Applications assessed as low risk will be distributed to Low Risk Ethical Research bodies for assessment as appropriate.

3.6 Defence has established non-High Risk Ethics Committee review level pathway for the review of low and negligible risk research in accordance with the National Statement. They include the following:

a. Joint Health Command Low-Risk Ethics Panel for health and medical research in accordance with the Defence Health Manual, Volume 3, Part 18, Chapter 1. The Directorate of Health Research can be contacted at health.research@defence.gov.au.
b. Defence Science and Technology Group (DSTG) Low Risk Ethics Panel for human systems performance research where a DSTG researcher is a member of the research team. The Panel can be contacted at HumanSciencesEthics@dsto.defence.gov.au.

c. Defence People Research Low Risk Ethics Panel for people research. The Panel can be contacted at peopleresearch.ethics@defence.gov.au.

d. Defence Animal Research Low Risk Ethics Panel for animal research. The Panel can be contacted at heath.research@defence.gov.au.

3.7 Low and negligible risk research that does not fall into the remit of the panels listed at paragraph 3.6 will be referred to the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee.

3.8 No element of Defence should conduct or sponsor a human or animal research project without ethical approval being granted by the relevant ethical review body. Potential researchers must be cognisant of both the requirements for prior ethical approval and the timing of submissions to relevant ethical review bodies.

**Animal research**

3.9 Defence has established the Defence Animal Ethics Committee which is registered as an Animal Ethics Committee with the Department of Agriculture and Fisheries. The scope, responsibilities and functions of the Defence Animal Ethics Committee are outlined in their Terms of Reference.

3.10 The *Australian code for the care and use of animals for scientific purposes 8th edition (2013)* (Animal Code) outlines the ethical framework, governing principles and responsibilities in using animals for scientific purposes.

3.11 The Animal Code provides guidance regarding ethical, humane and responsible conduct in animal use and is based upon the principles of reduction, replacement and refinement. The guiding principles for the ethical use of animals in research and are:

a. **Reduction.** Use of methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals

b. **Refinement.** Use of methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used

c. **Replacement.** Preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aims.

3.12 The above principles have a broader scope than simply encouraging alternatives to animal research. They aim to improve animal welfare and the quality of scientific research when the use of animals is justified.
3.13 In addition, the National Health and Medical Research Council have issued a number of other national guidelines to assist in the ethical review of animal research that must be considered during ethical deliberations. These include but are not limited to:

a. National Health and Medical Research Council *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals* (2008)

b. National Health and Medical Research Council *Principles and guidelines for the care and use of non-human primates for scientific purposes* (2016).

3.14 There must be scientific or educational justification for using animals in research or teaching within Defence. The use of animals in Defence research should also aim to benefit Defence capability, people, animals, or the environment and the research must be conducted with integrity.

3.15 Subject to the nature and scope of the research or teaching, the number of animals involved should be minimal. The wellbeing of the animals must be supported and harm, including pain and distress, to those animals must be avoided or minimised.

3.16 Defence research involving the use of animals must comply with all applicable State, Territory and Commonwealth legislation and be approved by an Animal Ethics Committee which is constituted in accordance with the Animal Code.

3.17 Although Defence has established the Defence Animal Ethics Committee, Defence should also consider the ethical review deliberations by other Animal Ethics Committees which are established under the Animal Code.

3.18 Researchers should ensure that the Defence sponsor, who must be a senior commander of a rank/APS classification no lower than Brigadier (E)/Senior Executive Service Band 1, is in receipt of the relevant Animal Ethics Committee approved research protocols prior to commencing the research.

**QUALITY ASSURANCE AND EVALUATION ACTIVITIES**

3.19 The ‘Ethical Considerations in Quality Assurance and Evaluation Activities’ has been issued by the National Health and Medical Research Council to provide guidance for determining whether a project meets the parameters of quality assurance quality assurance and evaluation activities.

3.20 Personnel conducting these activities are required to ensure that participants are afforded appropriate protections and respect. The activity undertaken is to generate outcomes that are used to assess and/or improve the provision of service. Personnel undertaking QA/evaluation activities must adhere to the relevant State, Territory and Commonwealth legislation and relevant ethical principles.
3.21 Personnel who are planning on conducting quality assurance/evaluation activities are to substantiate that their activity does not constitute human research, and whether they consider their activity to be a quality assurance or evaluation activity.

3.22 For an activity to be defined as a quality assurance/evaluation, it must meet all of the following criteria:

a. the data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols

b. the data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained

c. the data being collected and analysed is not linked to individuals

d. none of the following sub-paragraphs which require consideration of ethical review are present:

(1) the activity potentially infringes the privacy, confidentiality or professional reputation of participants, providers or organisations;

(2) there is the potential for the data to be used for other, unrelated purposes;

(3) information collected about the participant is beyond that which is collected routinely. Information may include bio-specimens or additional investigations;

(4) non-standard (innovative) protocols or equipment are tested on people or animals;

(5) data from cohorts of the same people or animals is captured over time;

(6) the activity design involves the use of control groups or placebos; and/or

(7) data is captured on vulnerable groups (as defined in the National Statement) with that data analysed separately as part of the activity.