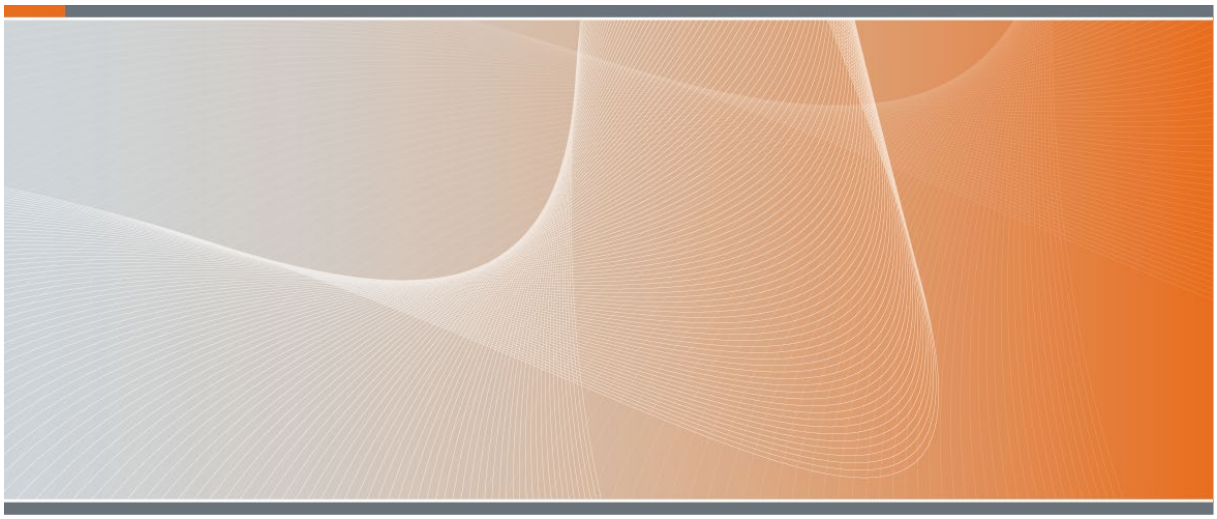
Australian Government
Department of Defence

INTERIM HUMAN AND ANIMAL RESEARCH MANUAL



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INTERIM HUMAN AND ANIMAL RESEARCH MANUAL

Issued by:	This interim manual has been revised and issued by Deputy Secretary Defence People. It will be replaced by the Human and Animal Research Policy in the second half of 2021.
Purpose:	The Human and Animal Research Manual (the Manual) provides an interim policy and guidance for researchers, delegates and ethical review bodies involved in the development, review, authorisation and implementation of human and/or animal research that is 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 interim manual is an administrative policy framework document. It applies to all Defence personnel. The terms of a relevant contract may extend the application of this policy to a person/s engaged under a contract. Defence Instruction – Administrative policy should be read in conjunction with this policy. In accordance with Defence Instruction – Administrative Policy, the Secretary and the CDF expect Defence personnel to comply with this interim manual. Defence personnel who award or manage contracts should consider whether there is a specific and documented reason to include the requirement to comply. If so, include such terms in the contract.
Management:	This interim manual will be reviewed and replaced by a policy in the second half of 2021.
Availability:	This interim manual is available at http://intranet.defence.gov.au/home/documents/departme.htm. Its currency cannot be guaranteed if sourced from other locations. It is available for public release.
Policy domain:	People
Accountable officer:	Deputy Secretary Defence People
Policy owner:	Head People Capability
Policy contact:	Director People Intelligence and Research
Cancellation:	This interim manual replaces the *Human and Animal Research Manual 2017*.
Definitions:	Definitions that apply to this interim manual are at Annex 1A.

CONTENTS

CHAPTER 1

DEFENCE RESEARCH

INTRODUCTION

1.1 The Department of Defence (Defence) is committed to high quality research that benefits Defence capability and/or contributes to institutional knowledge, including program and policy development implementation and evaluation. To ensure research, quality assurance and evaluation activities associated with Defence are conducted to the highest standards of research ethics and research integrity, 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 all research, quality assurance and evaluation activities associated with Defence, inside and outside Australia.

AIM

1.2 The aim of the Human and Animal Research Manual is to provide a policy framework for participants in research, quality assurance and evaluation activities, researchers, delegates and ethics review bodies involved in the development, review, authorisation, implementation and ongoing monitoring of human and/or animal research that is associated with Defence.

APPLICATION

1.3 Personnel and organisations planning to conduct human research, quality assurance or evaluation activities involving Defence personnel or animals require organisational approval (via sponsorship and ethical approval) prior to proceeding. Researchers are required to seek ethical review and approval of their activity through the appropriate ethical review body prior to commencing the activity. This ensures that Defence maintains the highest ethical standard and that Defence maintains its duty of care to its personnel and animals involved in research, quality assurance and evaluations.

1.4 All Defence personnel, researchers, internal Groups and Services and external institutions who wish to undertake human and/or animal research, quality assurance or evaluation activities must comply with this 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

d. is supported in any way by Defence (including financially).

1.5 Defence personnel who award or manage contracts are to include a contract requirement that contractors, sub-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 and through it the National Statement on Ethical Conduct in Human Research and/or Australian Code for the Care and Use of Animals for Scientific Purposes.

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 Australian institutions and researchers for the conduct of research, quality assurance and evaluation activities. Defence follows these principles for all research, quality assurance or evaluation activities.

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

2.3 This chapter establishes and outlines the responsibilities of all Defence researchers involved in the conduct of research, quality assurance or evaluation associated with Defence.

POLICY STATEMENT

2.4 Personnel and organisations planning to conduct human and/or animal research, quality assurance or evaluation activities which involve Defence personnel, funding or resources will require sponsorship and ethical approval prior to commencing the activity.

INSTITUTIONAL RESPONSIBILITIES

2.5 The Code sets out the responsibilities for research institutions. As a research institution, Defence assumes responsibility for:

a. Establishing and maintaining good governance and management practices for responsible research conduct.

b. Identifying and complying with relevant laws, regulations, guidelines and policies related to the conduct of research.

c. Developing and maintaining the currency and ready availability of a suite of policies and procedures which ensure that institutional practices are consistent with the principles and responsibilities of the Code.

d. Providing ongoing training and education that promotes and supports responsible research conduct for all researchers and those in other relevant roles.

e. Ensuring research supervisors of research trainees have the appropriate skills, qualifications and resources.

f. Identifying and training Research Integrity Advisors who assist with the promotion and fostering of responsible research conduct and provide advice to those with concerns about potential breaches of the Code.

g. Supporting the responsible dissemination of research findings. Where necessary, taking action to correct the record in a timely manner.

h. Providing access to facilities for the safe and secure storage and management of research data, records and primary materials and, where possible and appropriate, allow access and reference.

i. Facilitating the prevention and detection of potential breaches of the Code.

j. Providing mechanisms to receive concerns or complaints about potential breaches of the Code.

k. Investigating and resolving potential breaches of the Code.

l. Ensuring that the process for managing and investigating concerns or complaints about potential breaches of the Code is timely, effective and in accord with procedural fairness.

m. Supporting the welfare of all parties involved in an investigation of a potential breach of the Code. Basing findings of investigations on the balance of probabilities and ensure any actions are commensurate with the seriousness of the breach.

2.6 The Defence Human Research Governance Board (DHRGB) is the governance mechanism for overseeing prioritisation and collaboration of Defence human and animal research. The DHRGB is responsible for overseeing human research ethics and research integrity practice in Defence, including the investigation of potential breaches and research misconduct under the Code, and any other complaint of research misconduct, and ensuring Defence meets its obligations under Section 5 of the National Statement and Section 2 of the Animal Code. Additionally, the DHRGB facilitates information sharing with regard to Defence-wide research priorities and collates and distributes the research priorities for the Services and Groups within Defence.

2.7 Defence will collaborate with other institutions for the purpose of conducting / sponsoring human and/or animal research, quality assurance and evaluation. Defence Sponsors (defined in Annex 1A), researchers and ethical review boards are responsible for ensuring appropriate arrangements are agreed to and implemented prior to the commencement of an activity. 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.

2.8 Where the research, quality assurance or evaluation activity 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.

2.9 Defence has an obligation to ensure employees invited by Defence or other institutions to participate in medical and health research of greater than low risk or a clinical trial are afforded a 48 hour cooling off period prior to giving their consent. Participants are also afforded the opportunity to seek advice and guidance from an Independent Participant Advocate prior to consenting to participate in research. Examples of such an advocate is the participant's doctor, trusted friend or family member and their role would be to assist the participant in deciding whether or not to proceed in participating in the research.

2.10 Defence has an obligation to consider the cumulative effect of the burden associated with the volume of human research, quality assurance or evaluation activities conducted with Defence personnel. A Defence Sponsor or ethical review body may withhold approval from an otherwise approvable activity on the grounds that conducting the activity creates an unacceptable burden on the Defence workforce. A Defence Sponsor or ethical review body can request researchers justify an activity relative to burden. If an activity involves contacting more than 25% of the total Defence workforce, researchers must justify the activity relative to burden.

POTENTIAL AND ACTUAL BREACHES OF THE AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH (THE CODE)

2.11 Receipt of a complaint by a Research Integrity Advisor and/or an ethical review body or other relevant Departmental process that appears to be related to a potential breach of the Code, triggers a process consistent with the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (hereafter, 'the Investigation Guide').

2.12 Following the Investigation Guide, a breach is defined as a failure to meet the principles and responsibilities of the Code, and may refer to a single breach or multiple breaches. The Investigation Guide provides the following as non-limiting examples of breaches of the Code:

a. Not meeting required research standards:

(1) Conducting research without ethics approval as required by the National Statement and the Animal Code.

(2) Failing to conduct research as approved by an appropriate ethics review body.

(3) Conducting research without the requisite approvals, permits or licenses.

(4) Misuse of research funds.

(5) Concealment or facilitation of breaches (or potential breaches) of the Code by others.

b. Fabrication, falsification, misrepresentation:

(1) Fabrication of research data or source material.

(2) Falsification of research data or source material.

(3) Misrepresentation of research data or source material.

(4) Falsification and/or misrepresentation to obtain funding.

c. Plagiarism:

(1) Plagiarism of someone else's work, including theories, concepts, research data and source material without acknowledgment of the source.

(2) Duplicate publication (also known as redundant or multiple publication, or self-plagiarism).

d. Research Data Management:

(1) Failure to appropriately maintain research records.

(2) Inappropriate destruction of research records, research data and/or source material.

(3) Inappropriate disclosure of, or access to, research records, research data and/or source material.

e. Supervision - Failure by appointed manager/supervisor to provide adequate guidance or mentorship on responsible research conduct to researchers or research trainees under their supervision.

f. Authorship:

(1) Failure to acknowledge the contributions of others fairly.

(2) Misleading ascription of authorship including failing to offer authorship to those who qualify or awarding authorship to those who do not meet the requirements.

Defence recommends referring to the Vancouver Convention for guidance on questions of authorship.

g. Conflicts of interest – failure to disclose and manage conflicts of interest.

For guidance please refer to Disclosure of interests and management of conflicts of interest: A guide supporting the Australian Code for Responsible Conduct of Research.

h. Peer review – failure to conduct peer review responsibly.

For guidance please refer to Peer Review: A guide supporting the Australian Code for the Responsible Conduct of Research.

2.13 In addition to the example breaches identified in the Investigation Guide, the following represent non-limiting examples of breaches of the Code from the Defence context:

a. Directly or indirectly coercing people to participate in a research, quality assurance or evaluation activity.

b. Preventing or interfering with access to an Independent Participant Advocate.

c. Failure by Defence Sponsors, supervisors or research supervisors to ensure researchers undertaking directed research, quality assurance or evaluation activities have the appropriate skills, qualifications and/or experience to conduct such an activity.

d. Failure to protect data with security implications in accordance with the Defence Security Principles Framework.

2.14 Breaches occur on a spectrum of severity. Where a breach occurs on a spectrum is a matter of judgement, taking account of a range of factors, which may include:

a. The extent of the departure from accepted practice.

b. The extent to which participants, animals, Defence or the wider community are, or may have been, affected by the breach.

c. The extent to which it affects the trustworthiness of Defence research specifically, and research more broadly.

d. The level of experience of the researcher.

e. Whether there are repeated breaches by the researcher.

f. Whether institutional failures (such as unqualified or inexperienced researchers being directed to conduct an activity) have contributed to the breach.

g. Other mitigating or aggravating circumstances.

2.15 Breaches fall into three major categories:

a. Minor (less serious) breaches.

b. Major (more serious) breaches or repeated minor (less serious) breaches (three or more breaches by a researcher).

c. Research Misconduct, which is a major (more serious) breach of the Code which is intentional or negligent.

2.16 In responding to potential breaches of the Code, the institutional roles are assigned as:

a. The Deputy Secretary – Defence People is the Responsible Executive Officer.

b. Head People Capability is the Designated Officer.

2.17 The Assessment Officer is appointed by the Designated Officer based on the following criteria:

a. A senior member of Defence of rank/classification no lower than 06/Executive Level 2.

b. A member who has no conflict of interest with the project.

c. A member who is able to make an assessment based on the nature of the potential breach.

2.18 Any person appointed by the Designated Officer as a Review Officer should be appropriately qualified and experienced in the responsible conduct of research.

2.19 People wishing to make a complaint relating to a potential breach of the Code may do so in-person, by telephone or in writing to any Defence ethical review body. People wishing to make a complaint may do so anonymously. The person making a complaint is referred to as the ‘complainant’. The person or activity (represented by the accountable person) that is the subject of the complaint is referred to as the ‘respondent’.

2.20 Upon receipt of a complaint, the Defence ethical review body (DDVA HREC, DAEC, DPR-LREP or DSTG-LREP) makes an initial assessment whether the potential breach can be considered an administrative error, such as a missed e-mail or failure to submit a report due to administrative delays (e.g. clearance processes). Administrative errors can be resolved at the level of the ethical review body. For all potential breaches, the ethical review body passes the complaint to the Designated Officer with due regard for preserving confidentiality.

2.21 The welfare of complainants and respondents is a central concern for Defence.

2.22 Where the Designated Officer identifies the welfare of the complainant and/or respondent is at risk, the Designated Officer may delegate management of the complainant and/or respondent’s welfare to appropriate support mechanisms.

2.23 Upon receipt of a complaint, the Designated Officer is responsible for ensuring consequent action follows the principles of procedural fairness identified in the Investigation Guide; the investigation must be proportional, fair, impartial, timely, transparent and confidential. Based on the information provided in the complaint, the Designated Officer determines whether the complaint relates to a potential breach of the Code and, if it does, proceeds to the next step. If the Designated Officer determines the complaint does not represent a potential breach of the Code, then it may be dismissed or referred to other institutional processes. The Designated Officer then sends a summary of their determination to the complainant and the respondent.

2.24 If the Designated Officer determines the complaint is a potential breach of the Code, the Designated Officer advises the respondent. The Designated Officer then appoints an Assessment Officer to conduct a Fact Finding to gather and evaluate facts and information, and assess whether the complaint, if proven, would constitute a breach of the Code, supported by the Research Integrity Office as appropriate (e.g. no conflict of interest). Where a complaint is received in relation to a respondent from a non-Defence institution, the Designated Officer may choose to refer the complaint to a non-Defence Research Integrity Office; for example, the Designated Officer may refer the complaint to the university supervising a higher degree by research for that institution to undertake the equivalent of a Defence Fact Finding. Such referral makes the Designated Officer obliged to interpret the outcome of the non-Defence review for the Defence context to determine whether a potential breach has occurred.

2.25 If, as a consequence of the Fact Finding, there is no apparent breach of the Code, the Designated Officer may refer the complaint to other Defence processes to determine whether other action should be taken in response to the complaint.

2.26 If there is evidence of a breach following the Fact Finding, the Designated Officer determines whether the breach may be considered minor (less serious), major (more serious) or research misconduct. Following the Investigation Guide, the Designated Officer may, in accordance with Defence policies, seek to resolve the complaint locally, refer the complaint for investigation, refer the complaint to be resolved using other Defence processes, or dismiss the complaint. In the case of a minor (less serious) breach, the complaint should be resolved at the lowest possible level taking due regard for the response, evidence and complexity of the breach. Allegations categorised as major (more serious) breaches, repeated minor (less serious) breaches or research misconduct by the Designated Officer must be investigated by a Defence-appointed Panel constituted as specified at 2.28c.

2.27 The complainant (if identified) and respondent are to be advised of the outcome of the Fact Finding in writing.

2.28 Where the Designated Officer determines an investigation is justified, the Designated Officer:

a. Prepares a clear statement of allegations.

b. Develops the terms of reference for the investigation.

c. Nominates the investigation Panel and Chair where the Panel is comprised of more than one appropriately qualified and experienced person (with due regard for the Investigation Stage outlined in the Investigation Guide).

d. Seeks legal advice from Defence Legal on matters of process where appropriate.

2.29 The Panel report against the terms of reference is used by the Designated Officer to determine whether a breach occurred, and the seriousness if a breach is found to have occurred. If there is no evidence of a breach, the Designated Officer may dismiss the allegation or refer the allegation to other Defence processes. Where a breach has occurred, the Designated Officer sets out required corrective actions to comply with Defence research integrity in writing to the researcher and any other

relevant parties, and refers the respondent for action to other Defence processes when appropriate.

2.30 Where the Designated Officer determines a Defence researcher has breached the Code, the researcher has 10 business days to lodge a request for review of the investigation on the grounds of procedural fairness. This may be to the Designated Officer or to the Australian Research Integrity Committee. As a consequence of the request for review, corrective and/or disciplinary action is suspended until the outcome of the review is known. When a request for review has been lodged with the Designated Officer, the Designated Officer appoints a Review Officer who reports back to the Designated Officer. Where a review has been conducted by the Australian Research Integrity Committee, the Designated Officer is obliged to interpret the outcome of the review for the Defence context. The outcome of the review should be made known to the researcher and other relevant parties in writing, and the Designated Officer proceed with corrective and/or disciplinary action as required.

2.31 Where a Defence researcher has been found in breach of the Code by the Australian Research Integrity Committee, the Designated Officer determines whether the corrective and/or disciplinary actions recommended by the non-Defence institution are sufficient, or whether additional action is needed to protect the integrity of Defence research, quality assurance or evaluation activity.

2.32 If the complainant has chosen to identify themselves, they are advised that the Designated Officer has come to a determination and, upon request, may be sent a written summary of the determination (written with due regard for the complainant's and the respondent's welfare).

2.33 Breaches are recorded on a Register of Research Misconduct held by the Designated Officer. The Register is made available only to the Chairs of the Defence ethics review body and senior ethics administrative officers as nominated by the Chair. The Register records the name of the person found to have committed the breach, the date, a summary of the circumstances and any corrective and/or disciplinary action taken.

2.34 Non-Defence ethical review bodies may make written requests to determine whether an applicant appears on the Register of Research Misconduct to the Designated Officer. The Designated Officer or their delegate determines whether to identify Defence members who appear on the Register with due regard for relevant Commonwealth, State and Territory legislation, guidelines, codes of practice and Defence interests. The level of detail provided is at the discretion of the Designated Officer, their delegate or as a required under legislation.

2.35 Defence ethical review bodies may use information from the Register of Research Misconduct to guide additional conditions on ethical approvals, including but not limited to:

a. additional reporting requirements

b. additional supervision requirements

c. safeguards against coercion (where coercion may involve ordering Defence members to participate in a research, quality assurance and/or evaluation activity).

2.36 The Designated Officer or delegate will provide de-identified information to the secretariat of the DDVA HREC to ensure Defences HREC obligations of reporting breaches, complaints and approval statistics are able to be met.

INTELLECTUAL PROPERTY

2.37 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 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

2.38 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.

RESEARCH AUTHORISATION

2.39 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).

2.40 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.

2.41 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

2.42 All human and 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)f/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.

2.43 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. 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.

c. The study adheres to relevant research guidelines and standards.

2.44 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.

2.45 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.

2.46 Defence personnel 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

2.47 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.

2.48 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.

2.49 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.

2.50 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.

2.51 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.

2.52 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.

2.53 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

2.54 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. Researchers must offer authorship to all people, including research trainees, who meet the criteria for authorship as outlined in the Australian Code. Authorship should not be offered to those who do not meet the requirements outlined in paragraph 2.49. Researchers are to ensure that all those who have contributed to the research facilities or materials are properly acknowledged.

2.55 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.

2.56 A person who qualified as an author according to the Australian Code must not be included or excluded from authorship without their written agreement and a record of this agreement must be kept by the corresponding author. The record of authorship must include the description of the contribution of each author. Where

individuals are to be acknowledged for their contribution, written consent must also be obtained.

COMPLAINTS AND CONCERNS

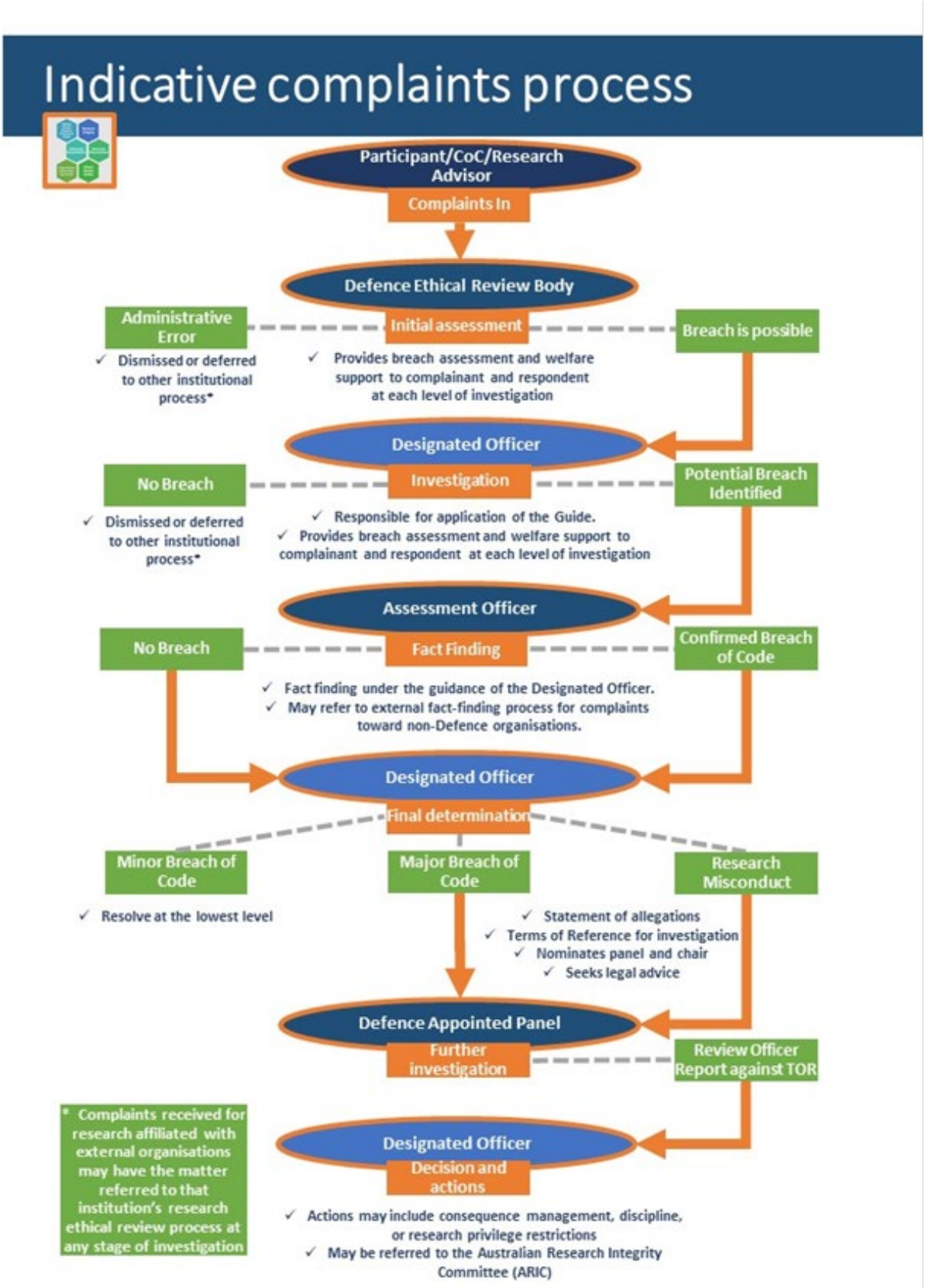
2.57 Researchers are to establish and inform research participants of a complaints process. Research participants are to be provided with points of contact in case they wish to express concerns or submit a complaint about the research project. The Principal Investigator is to inform the approving ethical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

RESEARCH DATA

RETENTION OF MATERIALS AND RESEARCH DATA

2.58 Research documents created by Defence research institutions and researchers are Commonwealth records and must to 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.

2.59 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.


Indicative complaints process
Participant/CoC/Research Advisor
Complaints In
Defence Ethical Review Body
Administrative Error
Initial assessment
Breach is possible
✓ Dismissed or deferred to other institutional process*
✓ Provides breach assessment and welfare support to complainant and respondent at each level of investigation
Designated Officer
No Breach
Investigation
Potential Breach Identified
✓ Dismissed or deferred to other institutional process*
✓ Responsible for application of the Guide.
✓ Provides breach assessment and welfare support to complainant and respondent at each level of investigation
Assessment Officer
No Breach
Fact Finding
Confirmed Breach of Code
✓ Fact finding under the guidance of the Designated Officer.
✓ May refer to external fact-finding process for complaints toward non-Defence organisations.
Designated Officer
Final determination
Minor Breach of Code
Major Breach of Code
Research Misconduct
✓ Resolve at the lowest level
✓ Statement of allegations
✓ Terms of Reference for investigation
✓ Nominates panel and chair
✓ Seeks legal advice
Defence Appointed Panel
Further investigation
Review Officer Report against TOR
* Complaints received for research affiliated with external organisations may have the matter referred to that institution's research ethical review process at any stage of investigation
Designated Officer
Decision and actions
✓ Actions may include consequence management, discipline, or research privilege restrictions
✓ May be referred to the Australian Research Integrity Committee (ARIC)

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 (hereafter, DDVA HREC). The DDVA HREC is the final authority for ethical review in Defence and reports to the DHRGB on matters of compliance with the National Statement.

3.5 The scope, responsibilities and functions of the DDVA HREC 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 ddva.hrec@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. 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.

b. Defence People Research Low Risk Ethics Panel for people research. The Panel can be contacted at peopleresearch.ethics@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 DDVA HREC.

3.8 All research deemed a Clinical Trial or 'greater than low risk' must be reviewed by the DDVA HREC. All Clinical Trials will automatically require a mandatory cooling off period. If research is 'greater than low risk' but not a Clinical Trial, the DDVA HREC will determine if the mandatory cooling off period is required.

3.9 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

3.10 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.

3.11 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.

3.12 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.

3.13 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.

3.14 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 Principles and guidelines for the care and use of non-human primates for scientific purposes (2016).

3.15 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.

3.16 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.

3.17 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.

3.18 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.

3.19 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

3.20 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.

3.21 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 quality assurance and evaluation activities must adhere to the relevant State, Territory and Commonwealth legislation and relevant ethical principles.

3.22 Personnel who are planning on conducting quality assurance or 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.

3.23 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

(4) information may include bio-specimens or additional investigations

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

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

(7) the activity design involves the use of control groups or placebos

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

ANNEX 3A

DEFINITIONS

The following list of terms are defined in Defence Instruction – Administrative policy. The definitions are intended to apply to their use in administrative policy framework documents:

Accountable officer
Administrative policy
Australian Public Service employee
Commander
A person/s engaged under a contract
Defence
Defence civilian
Defence locally engaged employee
Defence member
Defence personnel
Defence-wide administrative policy framework document
Framework documents
Manager
Period of effect
Policy domain
Policy owner
Supervisor

For the purpose of the policies described in this document, the following definitions apply:

Adverse event is an expected or unexpected event that has a negative impact on participants or researchers in a study.

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

Approval occurs in stages across the ethical review process. Written approval is needed from commanders/managers and ethics review bodies prior to commencing an activity (e.g. participant recruitment).

Assessment Officer is a person or persons appointed by an institution to conduct a preliminary assessment of a complaint about research.

Breach refers to a violation of the principles outlined in the Australian Code for Responsible Conduct of Research (2018).

Burden is created when the volume of research, quality assurance and evaluation activity has, or is likely to have, a negative impact on participation and/or data. For example, receiving 100 invitations to participate in Defence surveys in 10 days creates ‘survey fatigue’, and undermines the capacity to collect useful data.

Coercion or undue influence occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.

Clinical Trial is an empirical study that prospectively assigns human participants to one or more intervention conditions to evaluate the effects of that intervention on health outcomes. Interventions can be either diagnostic or treatment-focused and may include (but are not limited to) surgical, therapeutic, educational or preventative procedures and devices, drugs or other bio-chemical agents and diagnostic procedures or devices.

Command Approval is when approval has been provided by commanders/managers no lower than a Brigadier (E)/Senior Executive Service Band 1 level for the research to occur. This takes place prior to application for review by an ethical body. Both Command Approval and ethical review are required for research to occur.

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

Cooling off Period is the requirement that 48 hours needs to elapse prior to any agreement by participants to take part in research deemed to be 'Clinical Trials' or research deemed 'greater than low risk'.

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

Defence Sponsor is a commander or manager who takes responsibility for initiation, authorisation, management and/or financing of research, quality assurance or evaluation activities. The Defence Sponsor must be a senior commander or manager of no lower rank/Australian Public Service classification than Brigadier (E)/Senior Executive Service Band 1.

Designated Officer is a senior Defence person appointed to receive complaints about the conduct of research or potential breaches of the Code and to oversee their management and investigation where required. For this policy, Head People Capability, Defence People Group is the Designated Officer.

Ethical review is the review of research or by an ethical review body complaint with the National Statement or Animal Code.

Ethical Review Body refers both to Human Research Ethics Committees (HRECs) and to non-HREC review bodies.

Ethics is the concept of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

Evaluation is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goals or objectives.

Executive Member is a member of ethical review body who is also an office bearer, including the Chair, Deputy Chair or any member specifically identified as an Executive Member. It excludes personnel providing administrative support to an ethical review body, such as an Executive Officer.

External refers to agencies, organisations or individuals outside Defence.

Greater than low risk is 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 participants 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.

Independent Participant Advocate is a person chosen by a participant to advocate for them prior to consenting to participate in research and assist them in deciding whether or not to proceed in participating in the research. Examples of such an advocate is the participant's doctor, trusted friend or family member.

Informed Consent is a person's or group's voluntary agreement to participate in specific research, quality assurance and evaluation activities, based on informed knowledge and an adequate understanding of relevant material (research and the implications of participating in it).

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

Internal means inside the Department of Defence.

Invitee is a person who has been sent an invitation to participate in a research, quality assurance or evaluation activity.

Low risk research is research in which the only foreseeable risk is one of discomfort to participants. The National Statement (s2.1) states that discomfort "can involve body and/or mind…and can include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview." Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

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 requires the subsequent 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.

Participant refers to a person or animal from whom data has been collected that is being used as part of a research, quality assurance or evaluation activity.

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

Privacy is designed to inform individuals about the way Defence collects, stores, uses and discloses personal information. The Defence Privacy Policy 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 or 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.

Quality Assurance is an activity whose primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.

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 of confirming knowledge.

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

b. Defence personnel are involved as participants

c. Defence personnel are involved in conducting the activity

d. the activity is conducted in/on a Defence establishment

e. the activity is supported in any way by Defence.

Research Ethics is the body of work that strives to ensure that research, quality assurance and evaluation activity is conducted in a way that protects the interests of participants (whether human or animal). Research ethics is different to professional ethics, clinical ethics and military ethics, such that what may be ethical in terms of military practice may be unethical in terms of research practice.

Research Governance is the administrative framework that supports research ethics and research integrity.

Research Integrity is the consequence of research, quality assurance and evaluation activities being conducted with a search for knowledge or understanding, following principles of research conduct, conducting activities honestly, and reporting the outcomes of activities in ways that are open to scrutiny.

Research Integrity Advisor is a person or persons with knowledge of the Code and institutional processes nominated by an institution to promote the responsible conduct of research and provide advice to those with concerns or complaints about potential breaches of the Code.

Research Supervisor is a person who has the appropriate qualifications and experience to guide a research, quality assurance or evaluation activity.

Researcher is any person conducting a research, quality assurance or evaluation activity.

Responsible Executive Officer is a senior officer in an institution who has final responsibility for receiving reports of the outcomes of processes of assessment or investigation of potential or found breaches of the Code and deciding on the course of action to be taken.

Review Officer is a senior officer of the institution not fulfilling any of the roles Designated Officer, Responsible Executive Officer or Assessment Officer, who has responsibility for receiving requests for a procedural review of an investigation of a breach of the Code.

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

Serious adverse event is any event that has a significant impact on the welfare of a researcher or participant in a research, quality assurance or evaluation activity. In health research, this may include 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. In animal research, this may include greater pain or distress than expected. In human research, quality assurance or evaluation activities, this may include responses being used for unapproved purposes or trauma as a result of participation.

Social Research includes studies of knowledge, skills, aptitudes, attitudes, personalities, behaviours and other psychological, sociological or economic phenomena. Social research is epistemologically diverse across positivist (including post-positivist) and non-positivist traditions (including pragmatism, constructivism, interpretivism, phenomenology, semiotics and hermeneutics). Social research may involve combinations of quantitative and qualitative methods to observe and study the human condition.

Unexpected adverse effect is any event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity. This may include greater pain or distress than expected. In human research, quality assurance or evaluation activities, this may include responses being used for unapproved purposes or trauma as a result of participation.

Voluntary Participation is participation that is free from coercion and any other pressure.

ANNEX 3B

RELATED DOCUMENTS

RELATED LEGISLATION

The following legislation is referenced in this Manual:

a. *Defence Force Discipline Act 1982*

b. *Public Service Act 1999*

c. *Privacy Act 1988*

d. *Therapeutic Goods Act 1989*

e. *Defence IP Policy 2014*

RELATED PUBLICATIONS

The following publications are referenced in this Manual:

a. Australian Code for the Responsible Conduct of Research, (2018)

b. National Statement on Ethical Conduct in Human Research, (2007, updated 2018)

c. Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, (2003)

d. Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)

e. Ethical Considerations in Quality Assurance and Evaluation Activities,

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

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

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

i. Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals. (2018)

j. Principles and guidelines for the care and use of non-human primates for scientific purposes (2016)

k. ICH Guideline for Good Clinical Practice (2016)

l. Code of Practice for Exposing of Humans to Ionising Radiation for Research Purposes (2005)

m. Defence Security Principles Framework (2018)

n. Records Management Policy Manual (2014)