CHAPTER 1

HEALTH AND MEDICAL RESEARCH

INTRODUCTION

1.1 Human research that is conducted in Defence is to be reviewed and assessed by the appropriate ethical review body within Defence. Joint Health Command (JHC) established the JHC Low–Risk Ethics Panel (LREP) in 2014 to review low and negligible risk health and medical research in accordance with the National Statement on Ethical Conduct in Human Research'[1] (the National Statement) sections 5.1.18 – 5.1.21.

AIM

1.2 The aim of this policy is to provide guidance to internal and external stakeholders on the processes for seeking ethical approval and oversight of low and negligible risk health and medical research and, where appropriate approval of quality assurance/evaluation activities (specifically relating to the fields of health and medicine) in Defence. Guidance on the requirements for health and medical research that is deemed to be greater than low risk, or exempt from non-human research ethics committee level review as outlined in the National Statement, is provided in the Departments of Defence and Veterans' Affairs Researcher and Administrative Guidelines (pending).

1.3 This guidance should be read in conjunction with the Defence Human and Animal Research Manual (pending).

JOINT HEALTH COMMAND LOW-RISK ETHICS PANEL

Terms of Reference

1.4 The JHC-LREP Terms of Reference are available on the Directorate Health Research Coordination (DHRC) website[2].

Fees for ethical review

1.5 The JHC-LREP does not charge a fee for ethical review.

Appointment and termination of members

1.6 The Director General Strategic Health Coordination (DGSHC) will issue a Minute, as required, advising of all appointments to the panel. Individuals who are appointed to the panel are to be familiar with the National Statement and have an understanding of the ethical issues that can arise in the research that is under review.

1.7 As Defence employees or members of the Australian Defence Force, members are provided indemnity in respect of liabilities that may arise in the course of bona fide conduct of their duties as a JHC-LREP member.

---

[1] National Statement on Ethical Conduct in Human Research

https://www.nhmrc.gov.au/guidelines-publications/e72

[2] Directorate Health Research Coordination website

http://www.defence.gov.au/health/shc/ddhrc/research/healthresearch.asp#LowRisk

1.8 DGSHC may terminate the appointment of any member of the panel if they are of the opinion that:

a. it is not necessary for the proper and effective functioning of the panel

b. the person is not a fit and proper person to serve on the panel

c. the person has failed to carry out their duties as a panel member.

MEMBER RESPONSIBILITIES

Confidentiality

1.9 Members are to sign a statement of undertaking to acknowledge that all matters they become aware of during their work as a panel member will be kept confidential.

Training

1.10 Members are required to attend continuing education or training programs in research ethics at least every three years. Advice of training attendance is to be provided to the Secretariat for inclusion on the Member Training Register. Failure to attend ongoing training may result in termination of appointment.

Conflicts of interest

1.11 Members are required to notify the Secretariat of any conflicts of interest, pecuniary or otherwise, including potential or perceived conflicts of interest, which may arise during their tenure on the panel. Declarations should fully disclose the circumstances giving rise to the conflict of interest.

1.12 Where a conflict of interest pertains directly to an application that the member has been asked to consider, the member is to declare their conflict and the Chair will make a determination if the individual should remove themself from the review process.

Consideration of research applications

1.13 Members are responsible for deciding whether in their judgement a proposal submitted to the panel meets the requirements of relevant national and international research guidelines, legislative instruments and the specific institutional requirements outlined in the DHM Volume 1 Part 18 Chapter 1 'Conduct of Human Research in Defence'[3], this policy, and other relevant policy/guidelines. In order to do this, members are to make themselves familiar with the relevant guidelines, policy and legislative instruments where appropriate.

RESEARCH GOVERNANCE

1.14 For research conducted by or involving Defence personnel (or their data), evidence of organisational support and command approval must be obtained prior to submission to the JHC-LREP. Approval should be obtained from a commander or manager of a rank/Australian Public Service (APS) classification no lower than a one Star/Senior Executive Service (SES) Band 1. In-principle approval must be sought

[3] Defence Health Manual Volume 1 Part 18 Chapter 1 Conduct of Human Research in Defence http://intranet.defence.gov.au/home/documents/data/ADFPUBS/DHM/volume1/part18/01.pdf

and achieved prior to submitting an ethics application. Final organisational authorisation is to be sought once ethical approval has been obtained from JHC-LREP and other relevant institutions.

1.15 Organisational endorsement of research does not imply access to Defence personnel for studies. Researchers who are seeking access to Defence personnel as research participants must obtain in-principle approval from the relevant unit/areas commander/manager prior to submission of their ethics application to JHC-LREP. Final command approval is to be sought once ethical approval has been obtained from JHC-LREP and any other relevant institutions.

CONSIDERATION AND REVIEW OF APPLICATIONS

When should I seek approval from the Joint Health Command Low-Risk Ethics Panel?

1.16 Ethical approval should be sought from the JHC-LREP for low or negligible risk health and medical research, where one or more of the following apply:

a. research is conducted on Defence personnel, their information or tissue

b. research is conducted by Defence personnel

c. participants are to be recruited, either directly or indirectly, through a service provided by Defence

d. research is conducted on/in a Defence establishment, or is sponsored, endorsed or funded in all or in part by Defence.

Quality Assurance/Evaluation Activities

1.17 The term quality assurance is often used interchangeably with ‘peer review’, ‘quality improvement’, ‘quality activities’, ‘quality studies’ and ‘audit’. Personnel who are unsure as to whether their activity is a quality assurance activity or research should familiarise themselves with the National Health and Medical Research Councils ‘Ethical Considerations in Quality Assurance and Evaluation Activities’[4] .

1.18 Prior to commencement of a quality assurance/evaluation activity, personnel should submit the Quality Assurance and Evaluation Checklist, along with all relevant supporting documentation, to the Directorate Health Research Coordination at health.research@defence.gov.au.

Frequency of meetings and presentation of research protocols

1.19 The panel does not have a formal meeting schedule therefore all applications submitted to the JHC-LREP will be considered out of session. Where necessary, a teleconference or face-to-face meeting may be scheduled between the Chair and appropriate panel members and where appropriate, the Principal Investigator and other relevant research personnel, to discuss any matters of concern raised during the consideration of an individual application.

[4] Ethical Considerations in Quality Assurance and Evaluation Activities

https://www.nhmrc.gov.au/guidelines-publications/e111

Minimising duplication of ethical review

1.20 The JHC-LREP will take into consideration the deliberations of other ethical review bodies when considering research proposals where the research involves a civilian cohort. The research proposal should clearly state that the protocol has been, or will be, considered by another ethical review body and, if available, the outcome of such consideration should be provided. If it is not available upon submission the JHC-LREP should be advised on the outcome of the review once it is available.

1.21 Where research proposals overlap research fields, the JHC-LREP will liaise with either the Defence People Research Low-Risk Ethics Panel or the Defence Science and Technology Low-Risk Ethics Panel to obtain subject matter expert review of an individual protocol.

1.22 Researchers whose projects fall under the auspices of multiple institutions should engage with the administrators of the relevant ethical review bodies to ascertain if ethical approval is required for research that has been granted ethical approval by the JHC-LREP.

New applications

1.23 Applications are considered to be ‘new’ when:

a. the research proposal has not previously been considered by the JHC-LREP or

b. the original research proposal submission was not approved by the JHC-LREP and resubmission has been delayed by three months or more.

1.24 The pro forma and other supporting documentation for submission of new applications is available on the DHRC website[5].

1.25 Research proposals are to be clear and comprehensive and written in plain language. All technical terms and acronyms are to be explained in plain language and technical jargon is to be avoided. Participant Information and Consent Forms (PICFs) are to be in plain language that is easy to understand and phrased in a manner appropriate for the study cohort.

1.26 The Principal Investigator is to ensure that all relevant documents are attached including, but not limited to PICFs, surveys/questionnaires, letters of invitation and recruitment materials (including website content, newspaper advertisements etc) and previous PICFs for proposals that are requesting to use data obtained under a previously approved study.

1.27 Researchers are encouraged to submit protocol applications as early as possible. Completed applications are to be submitted electronically to health.research@defence.gov.au.

[5] Directorate Health Research Coordination Website

http://www.defence.gov.au/health/shc/ddhrc/adhrec/HealthResearchForms.asp

Student research

1.28 In considering approval of PhD or other student research, the JHC-LREP requires the first listed Principal Investigator to be the primary supervisor of the student researcher, as they have overall responsibility for the conduct of the research.

1.29 Applications involving student researchers are to ensure that the mechanisms in place for supervision of their research are clearly articulated to meet the requirements under section 3 of the 'Australian Code for the Responsible Conduct of Research'[6] (the Code).

Conflicts of interest

1.30 A researcher is to disclose any actual or potential conflicts of interest, including financial or other interest of affiliation, that bears on the research at the time of the application or as they arise during the active life cycle of the research project.

Resubmissions

1.31 A resubmission may consist of a revised protocol, supporting documentation or provision of further information. Resubmissions may require review by the Chair and reviewing panel members or may be reviewed by the Chair or the Secretariat.

Amendments to existing protocols

1.32 Prior to implementation of any amendments to an approved protocol, the Principal Investigator must seek ethical approval of the amendment from the JHC-LREP. A Request for Amendment Form is to be submitted along with any relevant supporting documentation (eg copies of surveys, updated PICFs, curriculum vitae for any additional research personnel). The request for amendment is to be signed by the first listed Principal Investigator as they have overall responsibility for the conduct of the research.

1.33 When submitting a request for amendment/s it is important that the Principal Investigator ensures that dates and version control numbers are updated on all relevant documentation. Failure to update these may delay approval of the amendment.

Researcher contact details

1.34 To facilitate the management of research protocols and correspondence, researchers are to ensure that they provide contact details to the Directorate Health Research Coordination. Any change in contact details should be notified promptly to health.research@defence.gov.au.

ON DUTY

1.35 Defence personnel should be considered 'on duty' when participating in research.

---

[6] Australian Code for the Responsible Conduct of Research

https://www.nhmrc.gov.au/guidelines-publications/r39

PAYMENTS TO RESEARCH PARTICIPANTS, INVESTIGATORS, DEPARTMENTS AND INSTITUTIONS

Research participants

1.36 Defence personnel should be considered ‘on duty’ when participating in research.

1.37 Consideration may be given to incentive payments for civilian cohorts on a case-by-case basis. Payment of money or incentives of any kind should not result in pressure on individuals to consent to participate. The use of lottery-style incentive payments will not be supported.

Investigators, departments and institutions

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

1.39 All remuneration should be paid into a fund used to finance the execution of the study and should be administered under a formal contractual arrangement that is open to scrutiny.

1.40 Payments on a per capita basis pose a problem because they raise the possibility of a conflict between the clinical responsibilities of a researcher and their financial gain. A researcher is to disclose the amounts, sources or potential sources of funding in any research proposal and, following approval of the proposal, any subsequent funding sources.

RECRUITMENT OF PARTICIPANTS

Consent

1.41 A person’s decision to participate in research must be voluntary and based on sufficient information and an adequate understanding of the proposed research and the implications of participation. Consideration also needs to be given to the consent process to ensure that it is free from coercion.

1.42 The National Statement[7] section 2.2.6 outlines the information that must be communicated to potential participants. This information must be presented in ways suitable to each participant, although it will most often take the shape of a PICF. The PICF template is available on the DHRC website[8].

Guidelines for volunteers

1.43 The JHC-LREP has developed a set of Guidelines for Volunteers, informing them of their rights and of the panel’s role and responsibilities. Each participant is to be given a copy of these guidelines to keep. The guidelines are available on the DHRC website.

---

[7] National Statement on Ethical Conduct in Human Research

https://www.nhmrc.gov.au/guidelines-publications/e72

[8] Directorate Health Research Coordination website

http://www.defence.gov.au/health/shc/ddhrc/research/healthresearch.asp#LowRisk

RESEARCH DATA

Future use of data

1.44 It is essential that when drafting both the ethics application and the consent documentation that researchers give adequate consideration to the future use of data in research (see National Statement sections 2.2.14 – 2.2.18).

Data matching/data linkage

1.45 Researchers should inform the panel if they intend to link or match data from other sources, what the other sources are, and what data is going to be obtained from the other sources. The ability for individuals to be identified from matched or linked data should be a consideration in all ethics applications to the JHC-LREP.

Retention of materials and research data

1.46 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, the 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. Additionally, if the research has community or heritage value the data should be retained permanently.

1.47 Research documents created by Defence research institutions are Commonwealth records and are to be managed in accordance with the Archives Act 1983[9] (the Archives Act) and the Records Management Policy Manual [10] (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 [11] (the Privacy Act), the Archives Act and other appropriate legislation.

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

1.49 Unauthorised access and/or use of data by a person for a purpose other than that indicated in the approved protocol and permitted under the Privacy Act is strictly prohibited.

1.50 At the completion of the approved research, data must be returned, stored or destroyed in accordance with approved protocols, the Archives Act and any contractual requirements.

---

[9] Archives Act 1983 http://www.austlii.edu.au/au/legis/cth/consol_act/aa198398/

[10] Records Management Policy Manual

http://intranet.defence.gov.au/home/documents/data/DEFPUBS/DEPTMAN/RECMAN/RECMAN.pdf

[11] Privacy act 1988 http://www.austlii.edu.au/au/legis/cth/consol_act/pa1988108/

PRINCIPAL INVESTIGATORS ASSURANCE

1.51 All Principal Investigators are to sign and return a Principal Investigators' Assurance prior to commencing the research project.

MONITORING

1.52 The JHC-LREP will monitor approved protocols during the active lifespan of the project. This includes low or negligible risk health and medical research protocols that were previously approved by the Australian Defence Human Research Ethics Committee (or the Australian Defence Medical Ethics Committee). Researchers are responsible for providing scheduled (eg Progress and Final Reports) and for cause reports (eg Adverse and Serious Adverse Event Reports) to ethical review bodies in accordance with National Statement[12] Chapter 5.5. Paragraphs 1.60 – 1.66 outline the requirements for submission of progress reports, adverse and serious adverse event reports, notification of deviations from approved protocols and submission of final reports to the JHC-LREP. Reporting templates are available on the DHRC website[13].

Progress reports

1.53 The Principal Investigator is required to submit an annual progress report for the lifespan of the project. Details on when the reports are due will be provided in the correspondence provided when ethical approval has been granted. The report is to be signed by the first listed Principal Investigator as they have overall responsibility for the conduct of the research.

1.54 For all active research protocols, the Secretariat will email a reminder to the Principal Investigator regarding the submission of the progress report approximately one month prior to the due date.

1.55 Upon receipt of a progress report, the Secretariat will send the report to the Chair for review. The Chair will review the protocol file against the information contained in the report and will either request further information or advise that no further action is required.

1.56 In the event that a progress report is not received by the due date, the Secretariat will email the Principal Investigator and, where relevant, the point of contact, to advise them that the progress report for their project is overdue, and that the matter of non-compliance will be reported to the Chair.

1.57 Failure to submit a progress report may result in ethical approval being withdrawn.

---

[12] National Statement on Ethical Conduct in Human Research

https://www.nhmrc.gov.au/guidelines-publications/e72

[13] Directorate Health Research Coordination website

http://www.defence.gov.au/health/shc/ddhrc/research/healthresearch.asp#LowRisk

Audits

1.58 The JHC-LREP or their delegate may conduct random inspections of research sites and review their study documentation. A summary of the outcome of the audit will be provided to the Principal Investigator, the panel and where appropriate, the research sponsor.

1.59 Additionally, desktop audits of protocol files will be conducted periodically to ensure completeness of applications and compliance with the approved protocol and any conditions of ethical approval. Where the audit raises areas for concern the Chair, or their delegate, may request further information until the matter is resolved.

Adverse and Serious Adverse Event Reports

1.60 Researchers have a significant responsibility in monitoring research as they are in the best position to observe any adverse events or unexpected outcomes. A report detailing the event details and the implications for the research is to be submitted to the JHC-LREP within 72 hours for serious adverse events and 30 days for adverse events.

1.61 Researchers should also be cognisant of the requirements to notify those who have provided research governance authorisation (research sponsors and those who have granted command approval) for research involving recruitment of Defence personnel in accordance with the Defence Human and Animal Research Manual (pending).

1.62 Upon receipt of an adverse or serious adverse event report, the report will be forwarded to the Chair, who shall determine the appropriate course of action which may include:

a. notation of the occurrence

b. increased monitoring of the project

c. request for amendment to the protocol or supporting documentation

d. a request for additional information

e. suspension of ethical approval

f. termination of ethical approval.

1.63 Where appropriate, additional advice may be sought from other panel members, subject matter experts or the Departments of Defence and Veterans' Affairs Human Research Ethics Committee in order to facilitate a considered review of the notification.

1.64 The Principal Investigator will receive written advice of the outcome of the review of the event/s and the appropriate course of action.

Deviations from approved protocols

1.65 Any deviations from the approved protocol must be notified to the panel as soon as possible and documented in the protocols progress and final reports.

Final reports

1.66 In accordance with the National Statement[14] section 5.5.5 researchers are required to submit a final report at the completion or abandonment of their project.

1.67 Failure to submit a final report will result in a notation made on the file indicating non-compliance with monitoring obligations and advice of non-compliance being sent to the research sponsor/s and/or head of organisation/s.

1.68 Upon receipt of a final report, the report will be reviewed by the Chair on behalf of the panel. Where necessary additional information will be requested prior to closure of the file.

WITHDRAWAL OF ETHICAL APPROVAL

1.69 Where the JHC-LREP has deemed that circumstances have arisen that prevent ongoing ethical approval of the research project being maintained, it may recommend that ethical approval be withdrawn. Circumstances for this decision may include, but are not limited to:

a. deviation from the approved protocol

b. failure to comply with the conditions of ethical approval

c. failure to submit a progress report

d. receipt of a complaint where significant concerns about the ongoing ethicality of a project have been raised

e. notification of an adverse or serious adverse or serious adverse event.

1.70 In such circumstances the committee will inform the Principal Investigator, the investigator's home institution and, where appropriate, the relevant Departmental sponsor/s and commander/s responsible for Defence personnel who are participating in the research. The decision to withdraw ethical approval and any circumstances under which ethical approval may be reinstated is to be in writing.

FINALISATION OF FILES

1.71 Protocol files will be finalised when a research project is completed, abandoned, withdrawn or when no correspondence has been received from the researchers within the preceding 12 months. Finalisation means that the protocol is removed from the active protocol list and no further action is taken by the Secretariat regarding that file. Researchers will be notified in writing when a file is finalised. If the researcher wishes to resume the project at a later date, the file may be reactivated upon agreement from the Chair. In the case of no correspondence having been received for 12 months, a finalisation letter will be sent to the researcher at the last known address and a letter will be sent to the Departmental sponsor/s and/or commander/s responsible for the study participants (where appropriate).

[14] National Statement on Ethical Conduct in Human Research

https://www.nhmrc.gov.au/guidelines-publications/e72

DISSEMINATION OF RESEARCH OUTCOMES

1.72 Researchers may wish to publicly present research findings or publish articles in journals or other publishing forms. This may include submissions as a thesis or treatise, based on information acquired through approved human research involving Defence personnel and/or resources.

1.73 Researchers are required to obtain approval of the research findings from the relevant sponsor/s. The sponsor/s must be a senior commander or manager of a rank/APS classification no lower than one Star /SES Band 1. In instances where a Defence sponsor was not required advice should be sought from the Directorate of Health Research Coordination. Review of the findings may also require review and advice from other relevant areas, where appropriate.

1.74 Researchers should submit the article and/or abstracts of verbal presentations that are to be published and/or presented to the relevant one Star/SES Band 1, noting that this does not include the verbal presentation per se. If there is a request for copies of slides or other visual aids used in a verbal presentation, the researcher is to provide them.

1.75 Where Defence has approved a draft manuscript and that manuscript is subsequently amended prior to publication, the amended manuscript is to be re-submitted for Defence approval.

1.76 In accordance with the Defence Security Manual[15], no classified material is to be included in any manuscript which is to be published as open source material. Defence retains the right to prohibit or otherwise place conditions on the publication of a submitted manuscript.

1.77 All publications should include the following in the body of the manuscript:

a. a detailed statement on relevant ethical approvals

b. an acknowledgment of the use of Defence resources and personnel where appropriate

c. a disclaimer stating that the opinions expressed therein are those of the author/s and do not necessarily reflect those of Defence or reflect requirements under extant policy.

1.78 A copy of the final document is to be provided to the Secretariat for inclusion on the protocol file. This should include advice on who cleared the document.

COMPLAINTS OR CONCERNS

1.79 Participants are to be advised of points of contact for complaints or concerns about a research project. This is to include a contact/s on the research team and indicate that they alternatively may wish to contact the Director Defence Health Research (refer to the PICF template for further details).

1.80 The Principal Investigator is to advise the JHC-LREP within 72 hours of any complaints that might affect the continued ethical acceptability of the project. In

---

[15] Defence Security Manual

http://intranet.defence.gov.au/dsa/dsm/

addition to this, a summary of any complaints received is to be provided to the JHC-LREP in the projects Progress Reports.

1.81 Complaints regarding the conduct of research are to be submitted to the Director Defence Health Research for consideration and resolution.

1.82 Where a complaint is made against a researcher, or against the way in which a study is being conducted it may be necessary to suspend the research pending resolution of the complaint. Depending on the nature of the complaint, it may also be necessary to withdraw ethical approval from the project temporarily until the matter is resolved, or permanently if significant problems are identified.

1.83 Where a complaint arises from a researcher regarding the consideration of their research protocol by the panel, they should contact the Chair in writing with details of the complaint. The Chair will endeavour to resolve any issues raised. A decision will be made based on all evidence received, including any response submitted by the researcher.

1.84 Where a complaint arises regarding the conduct of the panel, the Chair is the initial point of contact for the complaint. Where appropriate, the complaint will be directed to the Director General Strategic Health Coordination.

1.85 The Directorate of Health Research Coordination will maintain a complaints register for audit purposes

ANNEX 1A

DEFINITIONS

Adverse event	An untoward occurrence.
Amendment	Where the principal investigator proposes changes to a previously approved protocol.
Conflict of interest (in research)	Where a person's individual interests or responsibilities have the potential to influence the carrying out of their institutional role or professional obligation in research; or where an institution's interest or responsibilities have the potential to influence the carrying out of its research obligations.
Consent (in research)	A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research.
Data	Pieces of information.
Ethical review	The review of research by a Human Research Ethics Committee or other body.
Ethics (in research)	The concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.
Evaluation	An activity where the primary purpose is to monitor, evaluate or improve the quality of said activity.
Human Research	Research which is conducted with or about people, their data or tissue.
Low risk research	Research in which the only foreseeable risk is one of discomfort.
Monitoring (in research)	The process of verifying that the conduct of the research conforms to the approved proposal.
Negligible risk research	Research in which there is no foreseeable risk or harm or discomfort, and any foreseeable risk is of inconvenience only.
New application (in research)	Where a research proposal has not been considered by the ethical review body 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.
Participant (in research)	Anyone who is the subject of research.

Principal Investigator	The researcher(s) with primary responsibility for a research project including the preparation, conduct, and administration of the research, the associated funding, cooperative agreements, training, supervision, and delegation of any related tasks in compliance with applicable laws, regulations and institutional policy governing the conduct of human research.
Publication (in research)	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 but does not include any publication that is brought into existence for the dominant purpose of seeking financial gain or commercial benefit.
Quality assurance	An activity where the primary purpose is to monitor, evaluate or improve the quality of said activity.
Research	Includes at least investigation undertaken to gain knowledge and understanding or train researchers.
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.
Resubmission	Where a research proposal was previously submitted to the ethical review body and was not approved and revised documentation is subsequently submitted for consideration.
Risk (in research)	The function of the magnitude of harm and the probability that it will occur.
Serious Adverse Event	Any untoward medical occurrence that results in death; is life-threatening; requires in-patient hospitalisation or prolongations of existing hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; or is a medically important event or reaction.
Sponsor (in research)	A senior commander or manager of no lower rank / APS classification than a one Star / Senior Executive Service Band 1 who takes responsibility for initiation, authorisation/approval/endorsement, management and/or financing of research.