Australian Government
Department of Defence
Defence Science and
Technology Organisation

CHIEF DEFENCE SCIENTIST INSTRUCTIONS

CDSI S&T 002 – DSTO HUMAN RESEARCH ETHICS APPROVAL PROCESS

Defence Science and Technology Organisation
Department of Defence
Canberra ACT 2600

15 April 2009

Issued with the authority of the Chief Defence Scientist in accordance with Defence Instruction (General) Admin 00-001 – The System of Defence Instructions.

Where there is inconsistency between any part or parts of this instruction and any Defence Instruction (General), any Defence Manual, any Departmental Instruction or the Defence Chief Executive Instructions, the provisions of the Defence Instruction (General), Defence Manual, Departmental Instruction or Chief Executive Instructions take precedence over the provisions contained in this instruction.

Important: Any direction given in these instructions constitutes a lawful and reasonable direction under the Australian Public Service Code of Conduct.

I.R. Sare
A/CDS

DOCUMENT ADMINISTRATION

New Instruction
CDSI S&T 002 – DSTO Human Research Ethics Approval Process

Sponsor
Deputy Chief Defence Scientist Platforms and Human Systems (DCDS PHS)

Cancellations
Nil

DSTO HUMAN RESEARCH ETHICS APPROVAL PROCESS

INTRODUCTION

1. As an organisation within the Australian Department of Defence, DSTO must ensure that all research involving humans or their data is subjected to appropriate ethical review and approval. This instruction describes DSTO's ethics review process established in compliance with the requirements of the Department of Defence and the National Health and Medical Research Council (NHMRC) under the NHMRC Act (1992). Details of the DSTO ethics review process are available on the Human Science Hub webpage: http://community.dsto.defence.gov.au/hubs/hs/Ethics/default.aspx.

SCOPE

2. This instruction applies to all DSTO staff involved in the planning, approval and conduct of research involving humans or their data. The nature of the research will dictate whether it requires prior approval by the Chief of Division, by the DSTO Ethics Review Panel or by the Australian Defence Human Research Ethics Committee (ADHREC). This instruction describes the responsibilities of Chiefs and their delegates to ensure appropriate ethical review and approval has been achieved and guides research staff in identifying the appropriate level of review. It also details the form, function and processes of the DSTO Ethics Review Panel.

BACKGROUND

3. Within the Australian Department of Defence, the authority to undertake research on humans and its ethical review is outlined in DI(G) ADMIN 24-3 *The Conduct of Human Research in Defence* and *Health Manual Volume 23, Human Research in Defence - Instructions for Researchers (2007).* These documents refer to the *National Statement on Ethical Conduct in Human Research* (hereafter termed the *National Statement*) in the determination of the requirement for ethical review. DSTO has an institutional responsibility to ensure that its research involving humans or their data is carried out in accordance with the *National Statement*.

POLICY STATEMENT

4. All DSTO researchers proposing to engage in research involving humans or their data must follow the process described in this instruction to ensure that their research proposal is ethically acceptable.

5. Chiefs of Division must ensure that this instruction is followed to ensure an appropriate level of ethical review and endorsement has been conducted prior to granting approval to proceed with research involving human participants or data.

DEFINITIONS

6. The following definitions apply in this instruction[1]:

a. **Human Research**. The *National Statement* (page 7) defines research 'to include at least investigation undertaken to gain knowledge or to train researchers'. The *National Statement* (page 8) defines human research as that 'conducted with or about people, on their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.'

A defining attribute of human research is that it is conducted for the purpose of research. Participation in work practices (eg, meetings, regular training) does not fall within the scope of human research unless the practice is not standard (eg, new techniques are being trialled). Conversely, observation of standard work practice for the purpose of research does fall within the scope of human research and requires ethical review. Materials research involving human participants also requires ethical review.

Ethical review is required in all cases where there is potential for infringement of basic ethical principles (respect, research merit and integrity, justice, and beneficence). For more information refer to sections 1 and 2 of the *National Statement* (reproduced in Annex G).

b. **Low Risk**. The *National Statement* (paragraph 2.1.6) defines low-risk human research as that 'where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.'

c. **Discomfort**. The *National Statement* (page 16) gives the following examples of discomfort: 'Less serious than harm is discomfort, which can involve body and/or mind. Discomforts include, for example, minor side-effects of medication, the discomforts relating to measuring blood pressure,

[1] Decisions about whether a research proposal is to be considered 'human research' and whether it is 'low risk' are not always clear cut. Where the potential exists for proposals to be considered to be 'human research', it is important that they are reviewed for ethics in accordance with the *National Statement*. The Chair of the DSTO Ethics Review Panel is available to assist in determining whether a particular proposal constitutes 'human research' and whether proposed 'human research' is above 'low-risk'.

and anxiety induced by an interview'. The *National Statement* (page 16) also gives examples of potential harms, which exceed discomfort.

IMPLEMENTATION

7. **DSTO Ethics Review Process**. Figure 1 illustrates the three decision points that determine whether research may be approved within the Division, or whether it requires review and approval from the DSTO Ethics Review Panel or by ADHREC, following Divisional endorsement.

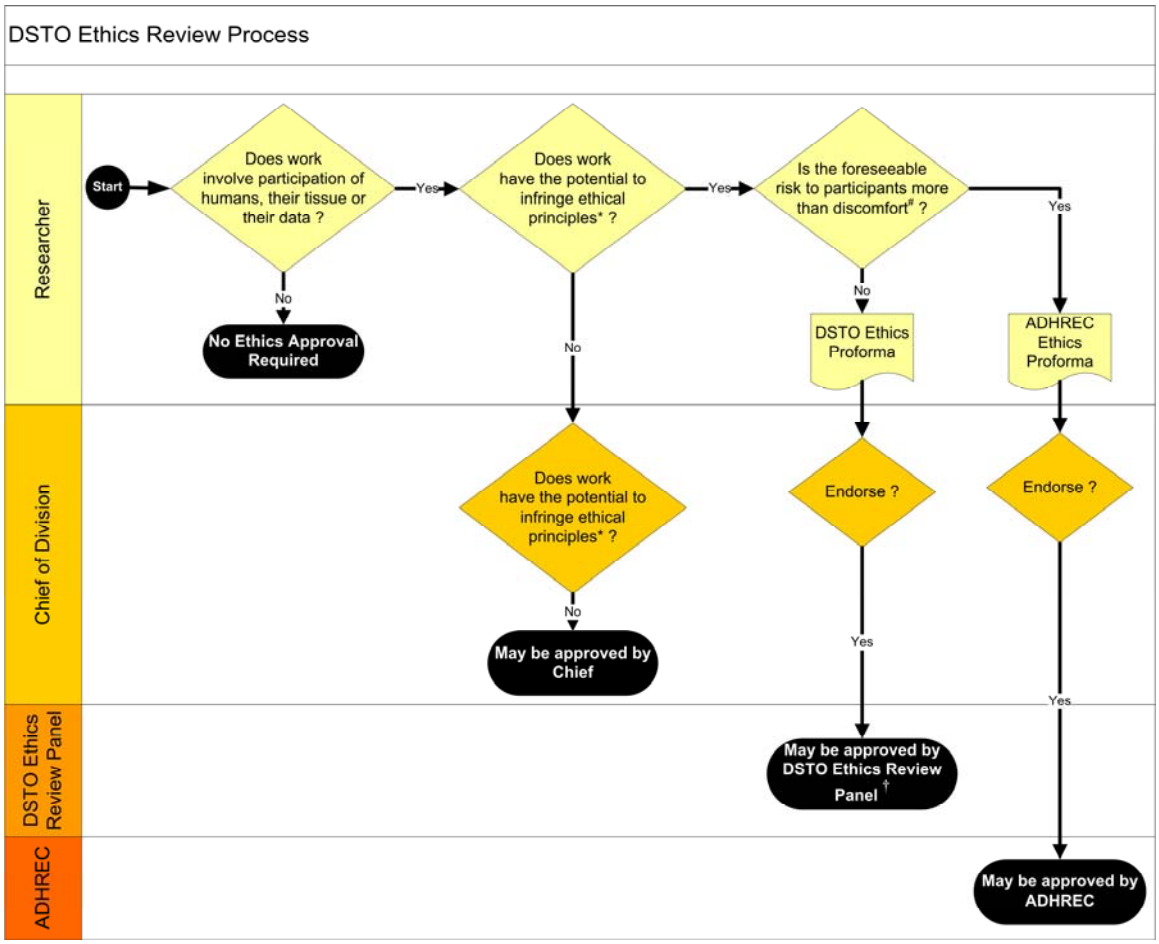

Figure 1. Ethics review process for DSTO research involving humans or their data.

* as defined in sections 1 and 2 of the *National Statement* (reproduced in Annex G)
# as defined in the *National Statement* (reproduced in paragraph 6c)
† a standing protocol may be agreed to cover commonly conducted low-risk human research

8. **Researcher**. Researchers should be familiar with the *National Statement*. Researchers must first assess their proposed activity against the *National Statement's* definition of human research (see paragraph 6a of this CDSI)[2]. An important consideration is whether there exists potential for the ethical principles outlined in the *National Statement* to be infringed. Activities judged not to constitute human research or not to infringe ethical principles may be reviewed and approved by the Chief of Division[3].

[2] The Chair of the DSTO Ethics Review Panel may be able to assist in this judgement.
[3]The Chief of Division, or their delegate, must ensure that human research is appropriately reviewed. Use of the proforma in Annex D is encouraged to facilitate record keeping and consideration of ethical issues.

However, it is important to ensure that the ethical principles outlined in the *National Statement* are adhered to.

Activities which may potentially infringe ethical principles must be reviewed by either the DSTO Ethics Review Panel or by ADHREC. Proposals that meet the criterion for low risk as defined in the *National Statement* (see paragraph 6b of this CDSI) may be submitted to the DSTO Ethics Review Panel using the proforma in Annex D. All other research involving humans or their data must be submitted to ADHREC[4].

9. **Chief of Division**. DI(G) ADMIN 24-3 (paragraph 11) states that 'Before human research is conducted in Defence, it is to be assessed by a properly constituted responsible Defence organisation to ensure that Defence research priorities are met, Defence resources are properly applied and the research is to be carried out using sound methodology'.

10. In cases where the Chief, or their delegate, judges that the proposed human research does not present the potential for infringement of ethical principles, the research may be approved without submission to the DSTO Ethics Review Panel. However, in approving this research the Chief takes full responsibility for ensuring that the research conforms to the ethical principles set out in the *National Statement.* General ethical considerations are reproduced in Annex G, but the *National Statement* should be consulted for specific guidance. The Chief, or delegate, must formally certify that there is no foreseeable potential for infringement of the ethical principles defined in the National Statement, that an auditable record of approved proposals will be kept and a copy forwarded to the DSTO Ethics Review Panel for information, and that they will monitor the research to ensure that these ethical principles are adhered to. It is recommended that Divisions use the proforma in Annex D to record and communicate this decision.

11. Where potential exists for infringement of ethical principles, proposals for conducting research involving humans or their data require formal endorsement by the relevant Chief, or delegate, and subsequent ethics approval by DSTO's Ethics Review Panel for low-risk research or by ADHREC for human research deemed to be above low risk. See Annex B for more detailed guidance to the Chief, or delegate.

12. Authorities and delegations follow the Divisional line management structure.

13. **DSTO's Ethics Review Panel**. The DSTO Ethics Review Panel is a non-HREC (Human Research Ethics Committee) panel whose principal role is to conduct ethical review of low-risk research. The DSTO Ethics Review Panel has been established to reduce the time and resource burdens of ethical review to a level commensurate with the assessed lower level of risk, whilst ensuring that NHMRC principles for ethical research are upheld. The DSTO Ethics Review Panel will consider research protocols submitted by DSTO staff for human research on three aspects:

- whether the research meets the criteria for low risk;
- whether safety and ethical issues have been addressed fully; and
- the soundness of the methodology.

See Annex C for the DSTO Ethics Review Panel's Terms of Reference.

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[4] Submissions to ADHREC must use their proforma, available at http://www.defence.gov.au/health/research/adhrec/i-adhrec.htm.

Where Divisions commonly conduct low-risk human research following a common methodology, the researcher may submit a protocol for consideration as a standing protocol. Details regarding the establishment, use, and review of standing protocols are set out in Annex A.

14. **Australian Defence Human Research Ethics Committee (ADHREC)**. ADHREC is a formally constituted Human Research Ethics Committee (HREC) that is authorised to review and approve protocols proposing human research, including those deemed to be higher than low-risk. Protocols submitted to ADHREC must use the ADHREC proforma [http://www.defence.gov.au/health/research/adhrec/i-adhrec.htm]. Protocols reviewed by the DSTO Ethics Review Panel are reported annually to ADHREC.

REFERENCES

Defence Instruction (General) Admin 24-3 *The Conduct of Human Research in Defence*. http://defweb.cbr.defence.gov.au/home/documents/DATA/ADFPUBS/DIG/GA24_03.PDF

Department of Defence (2007) *Health Manual Volume 23, Human Research in Defence - Instructions for Researchers.* http://defweb.cbr.defence.gov.au/home/documents/adfdocs/hlthman/hlthmanv23.htm

NHMRC (2007) *National Statement on Ethical Conduct in Human Research.* http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf

ANNEXES

A. Guidance for Researchers
B. Guidance for Chiefs
C. DSTO Ethics Review Panel Terms of Reference
D. Application to DSTO Ethics Review Panel Proforma
E. Information Sheet and Consent Form
F. DSTO Guidelines for Volunteers
G. *National Statement on Ethical Conduct in Human Research*, Section 1: Values and principles of ethical conduct (pp11-13), and Section 2: Themes in research ethics: risk and benefit, consent (pp 15-21 & 23-24)

ANNEX A

Guidance for Researchers

1. The following four documents contain information relevant to the conduct of human research in Defence. You should be familiar with them.
   - NHMRC (2007) *National Statement on Ethical Conduct in Human Research*
   - Department of Defence (2007) *Health Manual Volume 23 Human Research in Defence – Instructions for Researchers.*
   - Defence Instruction (General) ADMIN 24-3 *Conduct of Human Research in Defence*
   - NHMRC (2007) *Australian Code for the Responsible Conduct of Research*

2. For research where there is no potential for infringing the ethical principles outlined in the *National Statement* (reproduced in Annex G), ethical review and approval may be sought from the Chief of Division. However, the ethical principles in the *National Statement* must be adhered to. It is recommended that Divisions use the proforma in Annex D to record and communicate this decision.

3. For other human research where the anticipated risk to participants is low (see paragraph 6b of the CDSI), prepare the proforma provided in Annex D of this CDSI with reference to the *National Statement*. A standing protocol may be developed for low-risk research in which the activities are to be repeated many times. Any variations to methods must be detailed in the protocol. Completed applications should be submitted by email to the Chair of the DSTO Ethics Review Panel (HumanSciencesEthics@dsto.defence.gov.au) at least 2 weeks before a scheduled meeting of the panel.

4. For research involving more than low risk to participants, prepare the protocol in accordance with the ADHREC proforma (http://www.defence.gov.au/health/research/adhrec/i-adhrec.htm). It is important for researchers to pay attention to detail when preparing the protocol for ADHREC because poorly written submissions may cause undue delay in the approval process. While ADHREC is open to informal consultation should there be any issues in protocol preparation, advice may also be sought from the Chair of the DSTO Ethics Review Panel.

5. Submit the protocol to the relevant Chief of Division to obtain their endorsement. He/She will assess the proposal on the appropriateness of the research to Defence and its scientific merit and methodology.

6. When the Chief's endorsement has been obtained, the proposal should be submitted to the relevant ethics review body (DSTO Ethics Review Panel or ADHREC). It will assess the protocol in accordance with the *National Statement* on:
   (i) whether the research meets the criteria for low-risk research (DSTO Ethics Review Panel only);
   (ii) whether the ethical issues have been addressed; and
   (iii) the soundness of the methodology.

   Following review, the research team may be required to revise the protocol and resubmit.

7. Work may not proceed until approved by the appropriate ethics review body.

8. Researchers are required to seek approval for any changes to approved procedures.

9. If adverse events occur, researchers are required to immediately suspend the research and to inform the Chair of the approving ethics review body.

10. An annual report on the progress of the research is to be submitted to the approving ethics review body.

11. Complaints about the DSTO Ethics Review Panel's decisions or its conduct in reviewing research protocols should be directed to the Chair of the DSTO Ethics Review Panel in the first instance. The Panel is required to handle and resolve such complaints. If no resolution is achieved, the complainant will be advised to direct the complaint to the Chair of Human Sciences Hub.

12. A list of protocols reviewed by the DSTO Ethics Review Panel will be posted on the DSTO Human Sciences Hub website. This list will include the protocol title, the name of the lead researcher, the date of submission and the date of approval.

Important matters

When submitting the protocol ensure that the following issues are addressed:

1. Safety issues
   - The risks must be described and quantified, and measures to minimise the risks must be provided. See paragraph 4.12.g of Chapter 4 of *Health Manual Volume 23*.

2. Information and consent
   - It is important to ensure that the participants who are involved in the study have a good understanding of the investigation and their part in it. Prior to the study they should be provided with an information and consent sheet that contains details about the study in plain English including its benefits to Defence, their part in the study, the quantified risk of participating, the name of the investigators, etc. If they agree to participate, they should then sign the consent sheet. The template for the 'Information Sheet and Consent Form', copied and slightly modified from *Health Manual Volume 23*, is provided in Annex E. Please follow the instructions set out in *Health Manual Volume 23*, paragraph 4.12.

   - In the 'Information Sheet and Consent Form' the participant is advised that his or her 'participation in the study is entirely voluntary; there is no obligation to take part in the study and if the person chooses not to participate there will be no detriment to their career or future health care'. It should be stated that the participant may withdraw at any time without any adverse consequences. Researchers should be mindful of this statement and its intent, particularly when military personnel are used as participants. The military command structure should not be used as a means to pressure military personnel into volunteering. In addition there should be a statement indicating that participants are considered to be 'on duty'.

   - With regard to withdrawal from the activity, it should be explained whether the data that has been collected up to the point of withdrawal will or will not be used.

   - A statement of how the research will be monitored and the method of dissemination of research results should also be included in the 'Information Sheet and Consent Form'.

   - If applicable, the 'Information Sheet and Consent Form' should also include details about participant payment, funding sources and financial interests.

   - The 'Information Sheet and Consent Form' should also advise what services are provided if the participants are adversely affected by the activities.

   - If video clips and still images are to be used in reports and presentations, the participant's consent needs to be sought.

   - If interviews or group discussions are to be audio-taped, the participant's consent needs to be sought.

- Describe the means by which the data will be made non-identifiable and kept secure.

   - In addition to the 'Information Sheet and Consent Sheet', the participants should also be provided with the 'Guidelines for Volunteers'. These are provided in Annex F. The guidelines explain the participants' rights as volunteers.

3. DSTO conducts a significant amount of human research using qualitative methods (eg, interviews, focus groups etc.). This class of methods has particular ethical issues which are described in chapter 3.1 of the *National Statement*. If qualitative methods are proposed, it is important to fully address each of these issues in the proforma.

4. Ensure that the following documents are included in the application
   - Information Sheet and Consent Form (see Annex E)
   - Guidelines for volunteers (see Annex F)
   - Copies of questionnaires, survey questions and interview questions to be used
   - Copies of measuring instruments (scales)
   - Signed endorsement by Chief or delegate

ANNEX B

Guidance for Chiefs

1. Paragraph 11 of DI(G) ADMIN 24-3 *Conduct of Human Research in Defence* states that 'Before human research is conducted in Defence, it is to be assessed by a properly constituted responsible Defence organisation to ensure that Defence research priorities are met, Defence resources are properly applied and the research is to be carried out using sound methodology'.

2. To comply with this requirement, the proposal for conducting human research at DSTO requires a formal endorsement by the relevant Chief of Division or their delegate.

3. Please assess the submitted protocol in terms of whether the research:
    a. meets Defence requirement(s);
    b. is relevant to Defence;
    c. is appropriately resourced;
    d. has scientific merit; and
    e. employs sound methodology.

4. If the proposal is endorsed, sign the proforma and return it to the researchers for submission to the DSTO Ethics Review Panel, or ADHREC as appropriate.

5. In cases where the Chief, or delegate, judge that the proposed human research does not present the potential for infringement of ethical principles, the research may be approved without submission to the DSTO Ethics Review Panel. However, in approving this research the Chief takes full responsibility for ensuring that the research conforms to the *National Statement.* General ethical principles and considerations are reproduced in Annex G, but the *National Statement* should be consulted for specific guidance. The Chief, or delegate, must formally certify that there is no foreseeable potential for infringement of the ethical principles defined in the National Statement, that an auditable record of approved proposals will be kept and a copy forwarded to the DSTO Ethics Review Panel for information, and that they will monitor the research to ensure that these ethical principles are adhered to. It is recommended that Divisions use the proforma in Annex D to record and communicate this decision.

6. Where there exists the potential to infringe ethical principles, research proposals must first be endorsed by the Chief, or delegate, and subsequently approved by either the DSTO Ethics Review Panel (for low-risk research) or by ADHREC (for all other research).

ANNEX C

DSTO Ethics Review Panel
Terms of Reference

1. Introduction

As an organisation that conducts research involving humans and their data, DSTO needs to meet the following requirements specified by the *National Statement* (chapter 5.1)

- Institutions are required to ensure that human research is subjected to appropriate ethical review in accordance with the *National Statement*.
- Institutions may establish their own processes for ethical review of low-risk research in accordance with the *National Statement*, but these processes must be clearly documented and auditable.

DSTO has developed a process to ensure that human research is subjected to appropriate ethical review. The DSTO Ethics Review Panel plays a central role in this process.

2. Role

The DSTO Ethics Review Panel is a non-HREC (Human Research Ethics Committee) panel, whose principal role is to conduct ethical review of low-risk research. For research that involves more than low risk, ethical review is conducted by the Australian Defence Human Research Ethics Committee (ADHREC).

The DSTO Ethics Review Panel is to consider research protocols for human research on the following:

(i) whether the research meets the criteria for low risk;
(ii) whether safety and ethical issues have been addressed fully; and
(iii) the soundness of the methodology.

To minimise duplication of ethical review, where DSTO proposes to conduct research in collaboration with another institution, the panel will normally accept the ethical review by other panels if conducted in accordance with the *National Statement*. The exception is where the proposal involves research involving military personnel.

3. Assessment Criteria

The assessment of whether the research meets the low-risk criteria is based on the definition of low-risk research provided by the *National Statement* (paragraph 2.1.6).

> 'Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.'

Both physical and psychological discomfort must be included in the risk assessment. The risk associated with any procedure may depend on risk management strategies employed. When the participants are undertaking routine activities as part of their employment or training, it is important to consider whether there is any increased risk brought about by the research activities.

If the research is deemed to involve more than low risk, the researchers should be notified and directed to seek ethical approval through ADHREC.

For low-risk research, the DSTO Ethics Review Panel is required to assess whether safety and ethical issues have been addressed fully. Particular attention should be paid to

(i) informed consent;
(ii) quantification of risk;
(iii) confidentiality; and
(iv) voluntary participation.

The consideration of methodology issues include, but are not limited to the following:

(i) Is the method appropriate for achieving the study aims?
(ii) Is the design of the experiment or study sound?

(iii) Is the analysis method appropriate?
(iv) Is the method realistic in terms of resources and time frame?
(v) Has the issue of recruitment of participants been addressed?
(vi) Has the researcher supplied questionnaires, survey questions and interview questions?

DSTO conducts a significant amount of human research using qualitative methods (eg, interviews and focus groups). It is important to assess proposals using qualitative methods in accordance with chapter 3.1 of the *National Statement*.

4. Membership

The DSTO Ethics Review Panel consists of six members. The panel members are drawn from human researchers in different Divisions. The DSTO Ethics Review Panel will have additional members that may be called on when the need arises. Where a substantial proportion of the proposed research involves ADF personnel, the panel may consult an ADF representative as their advocate. The DSTO Ethics Review Panel may also invite a person or persons with specific expertise to assist with its deliberations.

It is expected that the Chair of the DSTO Ethics Review Panel will represent DSTO at the ADHREC meetings.

5. Competency

The DSTO Ethics Review Panel members must receive ethics training at least triennially. They must be familiar with the following documents:

- NHMRC (2007) *National Statement on Ethical Conduct in Human Research*
- Department of Defence (2007) *Health Manual Volume 23 Human Research in Defence – Instructions for Researchers.*
- Defence Instruction (General) ADMIN 24-3 *Conduct of Human Research in Defence*
- NHMRC (2007) *Australian Code for the Responsible Conduct of Research*

6. Procedure

(i) The DSTO Ethics Review Panel, using face-to-face, video and telephone conference methods as appropriate, meets on a monthly basis between February and November. When panel members cannot attend a meeting, the Chair should either ensure that those members have the opportunity to provide their opinion for consideration, and/or draw upon the additional members. The Chair of the panel will distribute proposed research protocols to the panel two weeks before each meeting. The Chair may call additional meetings if the need arises.

(ii) The Chair of the Panel will inform the researcher and Chief of the final decision. Any interim discussion requiring revisions of the protocol should not require involvement of the Chief.

(iii) The proposals, summary of discussion, and decisions made will be recorded and a copy kept in an electronic as well as hard-copy file. A list of protocols reviewed by the DSTO Ethics Review Panel will be posted on the DSTO Human Sciences Hub website. This list will include the protocol title, the name of the lead researcher, the date of submission and the date of approval.

(iv) The DSTO Ethics Review Panel will monitor the progress of approved research every 12 months through the submission of research progress reports. Although researchers have been informed of this requirement, the DSTO Ethics Review Panel may need to take steps to ensure that reports are received.

(v) The Chair of the DSTO Ethics Review Panel will provide a summary report of the proposals received and decisions made to the Human Sciences Hub Executive and to ADHREC.

7. Conflicts of interest

Members of the DSTO Ethics Review Panel should disclose any conflicts of interest with respect to proposed research. Conflicts of interest may be personal, professional or financial. Conflicts of interest will

be managed according to chapter 5.4 of the *National Statement*. For example, when a conflict of interest is declared, decisions may be made by the remainder of the panel.

8. Institutional responsibilities

- DSTO will ensure that the DSTO Ethics Review Panel is adequately resourced.
- DSTO will provide legal protection to the members of the DSTO Ethics Review Panel.
- The Human Sciences Hub Executive will monitor and report on progress of the DSTO low-risk ethical review process and will modify the process as necessary to maintain compliance with the *National Statement*. This assessment may involve documented experience of research participants.

9. Adverse effects and complaints

- The researchers are to be advised to immediately suspend the research if adverse effects occur, and report them to the Chair of the DSTO Ethics Review Panel. These events should be investigated by the DSTO Ethics Review Panel, the findings recorded and reported to the Chair of the Human Sciences Hub and ADHREC.
- Complaints by participants about researchers or the conduct of research should be directed to the Chair of the DSTO Ethics Review Panel in the first instance. The Panel is required to handle and resolve such complaints. If necessary, expert opinions may be sought to help resolve the issues.
- Complaints by researchers about the DSTO Ethics Review Panel's decisions or its conduct in reviewing research protocols should be directed to the Chair of the DSTO Ethics Review Panel in the first instance. The Panel is required to handle and resolve such complaints. If no resolution is achieved, the complainant will be advised to direct the complaint to the Chair of Human Sciences Hub.

ANNEX D

DSTO Ethics Application to Conduct Low-Risk Human Research

Project Title

Division | Task number:

Date of Submission | Duration of approval sought (up to 3 years)

Investigators

	Full Name	Division	Phone	Email
Lead (POC)				

(add rows if necessary)

Description of project (background, aims, method, analysis: maximum 1000 words)

Participants (refer to *National Statement* section 4)

From where do you intend to source participants?

Y☐ N☐ Are you selecting participants from a particular group (eg, male, ADF)?

Y☐ N☐ Will participants be paid or otherwise induced to participate?

Y☐ N☐ Will participants have any relationship (eg, subordinate) with the researchers?

Y☐ N☐ Does the research specifically target any of the following participant groups: pregnant women, children, people in unequal relationships, people with cognitive impairment, people who are not able to give consent, people involved in illegal activities, Aboriginal or Torres Strait islanders, or people from another country?

If YES to any of the above, describe the requirement and management of associated ethical issues.

Informed consent (refer to *National Statement* chapters 2.2, 2.3)

Y☐ N☐ Will you seek informed consent from participants? [If NO, describe the reasons why.]

Y☐ N☐ Is there a need to deceive participants?

Y☐ N☐ Will the research require covert observation?

If YES to either of the above, describe the reasons and debriefing process.

Risks and benefits (refer to *National Statement* chapter 2.1)

Y☐ N☐ Is there potential for physical or psychological discomfort of participants?

Y☐ N☐ Is there potential for physical or psychological harm to participants?

Y☐ N☐ Does the research address any topics that the participants might consider sensitive (eg, grief, illegal activity, gender identity)

Y☐ N☐ Are there any risks to researchers? [If YES please attach the DSTO safety case]

How will the research be monitored for adverse affects?

What services will be provided to any participants who are adversely affected by the research?

Who will benefit from the research and how will the benefits occur? (*Specifically address benefits to Defence*)

Describe all risks, their likelihood and mitigation.

Research methods (refer to *National Statement* section 3)

Y☐ N☐ Will the research use qualitative methods (interviews, focus groups etc.)?

Y☐ N☐ Will the research collect information for or from databanks?

Y☐ N☐ Will the research trial new clinical or non-clinical interventions or therapies?

Y☐ N☐ Will the research use tissue samples, genetics, or stem cells?

If YES to any of the above, describe the requirement and management of associated ethical issues

Privacy and confidentiality

Y☐ N☐ Will researchers have access to identifiable or potentially identifiable records not normally available to them?

Y☐ N☐ Is it possible that participants may be identified or that their data may be divulged without their consent during or after the research?

Y☐ N☐ Will it be necessary to make audio or video recordings of participants?

If YES to any of the above, describe how privacy will be ensured.

How will data be stored?

Conflicts of interest (refer to *National Statement* chapter 5.4)

Y☐ N☐ Is the research being funded outside of DSTO?

Y☐ N☐ Is the research being funded outside of Defence?

Y☐ N☐ Are there potential conflicts of interest (personal, professional, financial)?

If YES to any of the above, describe and include any relevant documentation.

Other approvals

Y☐ N☐ Are other organisations involved in the research?

Y☐ N☐ Has this research previously been submitted to or approved by another Human Research Ethics review body?

If YES to either of the above, please provide details.

Checklist *(materials to be included with this form)*

☐ Attached	Participant Information Sheet (in plain language)
☐ Attached	Participant Consent Form
☐ Attached	Guidelines for Volunteers
☐ Attached	Questionnaire and other materials (if applicable)

Resource Requirements *(estimate)*

DSTO	
ADF	
Other (specify)	
Participants	

Declaration of investigator(s)

If approved, I/we will conduct this research in accordance with this application, the *National Statement on Ethical Conduct of Human Research*, Defence Health Manual 23, and relevant privacy legislation. I/we will immediately advise the approving panel of any adverse outcomes from the research and will submit an annual report of progress to the approving panel.

Full Name	Signature	Date

(add rows if necessary)

Endorsement/Approval (circle one) of Chief of Division or their delegate

This research meets a Defence requirement, employs sound scientific methodology and estimated resources are appropriate. **In the case of approval**: I confirm that the research proposal does not have foreseeable potential for infringement of the ethical principles defined in the *National Statement*. I will keep a record of approved proposals and will forward a copy to the DSTO Ethics Review Panel for information. I will monitor the research to ensure that these ethical principles are adhered to.

Full Name	Signature	Date

DSTO Ethics Review Panel use only

Approval of DSTO low-risk human research ethics panel

Full Name	Signature	Date

Summary of discussion

ANNEX E

INFORMATION SHEET AND CONSENT FORM

INSERT NAME OF STUDY

Brief description of the Study. Cover why it is being done. It may be appropriate to paraphrase the aims of the study. Do not use jargon, and explain in a manner that a lay person can understand. If the research is being undertaken as part of a requirement to obtain qualifications, this must be indicated.

Your part in the Study. This section should include the following points:

- Participation in the study is entirely voluntary; there is no obligation to take part in the study, and if the person chooses not to participate there will be no detriment to their career or future health care;
- The participant has a right to withdraw at any time with no detriment to their career or to their future health care;
- The procedures to be followed and what is expected of the participant, including how much time will be required.

Risks of participating. Each of these must be laid out separately, described in full and quantified, no matter how trivial or remote they may seem. Risks are to be sufficiently emphasised and quantified, and the expression of the quantification should be positive not negative.

On duty. Where appropriate, include a statement that Australian Defence Force members will be considered 'on duty' during participation.

Statement of Privacy. Discuss how personal or attributed data is to be stored and handled; eg, stored under lock and key, investigators only have access, treated confidentially, anonymity preserved in reports or published articles. There is also to be a written assurance that any personal data collected will be used for the purpose of this study and no other, without the express permission of the participant.

Participant records. Where the study is a clinical trial, as per the NHMRC definition, a nominal roll of study participants will be provided to ADHREC for the sole purpose of facilitating the tracing of participants should anything untoward develop in the future that may be related to this study. This information will be stored in the protocol file, will only be accessible to the ADHREC Executive Secretary and may assist the future health care of individual study participants.

Other relevant human research ethics considerations. A statement addressing any ethical considerations should form part of the informed consent process. In addition to the considerations included in the application proforma, the *National Statement* requires the following information to be included: how the research will be monitored and the method of dissemination of research results, whether it will be possible to withdraw data if a participant withdraws before the activity is completed, funding sources, financial interests, payment to participants, and services provided should participants be adversely affected by the research.

Audio recording.

The following wording should be included here:

Audio recordings of interviews or group discussions may be made to enable the transcription of dialog. Please select and initial one of the following options

☐ I GIVE permission for the researchers to make audio recordings of my participation

☐ I DO NOT GIVE permission for the researchers to make audio recordings of my participation

Video/Still Images.

The following wording should be included here:

Video clips and still shots may be used for reports and presentations, therefore if these images are used you may be identifiable. Please select and initial one of the following options

☐ I GIVE permission for the researchers to use video clips or still shots which may identify me

☐ I GIVE permission for the researchers to use video clips, or still shots only where my face is de-pixelated

☐ I DO NOT GIVE permission for the researcher to use video clips or still shots that may identify me whether de-pixelated or not

Name the investigators. Provide details on how to contact the investigators if necessary, including telephone numbers where appropriate. The following statement should always be included here:

> Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers in person.
>
> Alternatively, you may contact the DSTO Ethics Review Panel or the DSTO Human Sciences Hub.
>
> Chair, DSTO Ethics Review Panel
> c/o Deputy Director Science & Technology PHS
> 506 Lorimer St
> Fishermans Bend VIC 3207
> Email: HumanSciencesEthics@dsto.defence.gov.au
>
> Chair, DSTO Human Sciences Hub
> c/o Deputy Director Science & Technology PHS
> 506 Lorimer St
> Fishermans Bend VIC 3207
> Telephone: (03) 9626 7835
> Fax: (03) 9626 7416
> Email: HumanSciencesHub@dsto.defence.gov.au
>
> Issues remaining following discussion with the DSTO Ethics Review Panel may be discussed with the Executive Secretary of the Australian Defence Human Research Ethics Committee.
>
> Executive Secretary
> Australian Defence Human Research Ethics Committee
> CP2–7–124
> Department of Defence
> CANBERRA ACT 2600
> Telephone: (02) 6266 3837
> Facsimile: (02) 6266 4982
> Email: ADHREC@defence.gov.au

CONSENT

I _____ give my consent to participate in the project described above on the following basis:

I have had explained to me the aims of this research project, how it will be conducted and my role in it.

I understand the risks involved as described above.

I am cooperating in this project on condition that:

- the information I provide will be kept confidential
- the information will be used only for this project
- the research results will be made available to me at my request and any published reports of this study will preserve my anonymity.

I understand that:

- there is no obligation to take part in this study,
- if I choose not to participate there will be no detriment to my career or future health care
- I am free to withdraw at any time with no detriment to my career or future health care

I have been given a copy of the information/consent sheet, signed by me and by the principal researcher (name) to keep.

[For clinical trials only] I understand that, as I am participating in a clinical trial, my name and regimental details (where applicable) will be provided to the Australian Defence Human Research Ethics Committee (ADHREC) in case I need to be traced at some time in the future. This information will be kept secure and will only be accessible to ADHREC for this purpose and none other.

I have also been given a copy of the *DSTO Guidelines for Volunteers*.

Participant

Full Name	Signature	Date

Researcher

Full Name	Signature	Date

Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers in person. Alternatively, you may contact the DSTO Ethics Review Panel at HumanSciencesEthics@dsto.defence.gov.au

ANNEX F

DSTO GUIDELINES FOR VOLUNTEERS

Thank you for taking part in DSTO Research. Your involvement is much appreciated. This pamphlet explains your rights as a volunteer.

DSTO ethics review process

- DSTO has developed an approval process for low-risk research to ensure that human research complies with the requirements of the NHMRC (2007) *National Statement on Ethical Conduct in Human Research* and the Department of Defence (2007) *Health Manual Volume 23 Human Research in Defence – Instructions for Researchers*.
- If you are told that the project has DSTO ethics approval, this means that the Chief of Division or the DSTO Ethics Review Panel has reviewed the research proposal and has agreed that the research is low-risk and is ethical. Ethical clearance through the Australian Defence Human Research Ethics Committee (ADHREC) is not required for low-risk research.
- DSTO approval does not imply any obligation on commanders to order or encourage their service personnel to participate or to release troops from their usual workplace to participate. Obviously, the use of any particular personnel must have clearance from their commanders but commanders should not use DSTO approval to pressure personnel into volunteering.

Voluntary participation

- As you are a volunteer for this research project, you are under **no obligation** to participate or continue to participate. You may withdraw from the project **at any time** without detriment to your military career or to your medical care.
- At no time must you feel pressured to participate or to continue if you do not wish to do so.
- If you do not wish to continue, it would be useful to the researcher to know why, but you are under no obligation to give reasons for not wanting to continue.

Informed consent

- Before commencing the project you will have been given an information sheet which explains the project, your role in it and any risks to which you may be exposed.
- You must be sure that you understand the information given to you and that you ask the researchers about anything of which you are not sure.
- If you are satisfied that you understand the information sheet and agree to participate, you should initial every page of the information sheet and keep a copy.
- Before you participate in the project you should also have been given a consent form to sign. You must be happy that the consent form is easy to understand and spells out what you are agreeing to. Again, you should keep a copy of the signed consent form.

Tracing of research participants

- **Clinical trials**. Media reports of human experimentation during times of conflict, eg WWII, Vietnam War, have raised the issue of being able to trace study participants, some time in the future, should any problems arise that may be related to the research conducted. To make this easier, ADHREC requires that the researcher provide a nominal roll of study participants for safekeeping by ADHREC, where the study is a clinical trial (eg. When the researchers are trialling a new treatment or device). For trials conducted by large Defence institutions like the Defence Science and Technology Organisation, the Submarine and Underwater Medicine Unit, the Army Malaria Institute, the Institute of Aviation Medicine or the Centre for Military and Veterans' Health, this roll is kept by them on ADHREC's behalf. We need to know who you are, only so that we can find you in the future, if there is any suggestion that the research may have been associated with the development of any health problems. Please note that a health study is not a clinical trial, and as such does not require the researcher to provide ADHREC with a nominal roll.

- This is consistent with current Occupational Health and Safety and Health Surveillance practices, and is encouraged under the NHMRC Guidelines.

- All ADHREC protocol files are secured in a locked filing cabinet and only the Secretariat has access to these. If you do need to be traced in the future, ADHREC will do this. ADHREC will not pass your contact information to a third party without your permission.

- These records will not be used to consider your medical employment standard or for compensation purposes.

Complaints

- If at any time during your participation in the project you are worried about how the project is being run or how you are being treated, then you should speak to the researchers.

- Alternatively, you can contact the Chair of the DSTO Ethics Review Panel, the Chair of the DSTO Human Sciences Hub, or the Executive Secretary of ADHREC. Contact details are:

  Chair, DSTO Ethics Review Panel
  c/o Deputy Director Science & Technology PHS
  506 Lorimer St
  Fishermans Bend VIC 3207
  Email: HumanSciencesEthics@dsto.defence.gov.au

  Chair, DSTO Human Sciences Hub
  c/o Deputy Director Science & Technology PHS
  506 Lorimer St
  Fishermans Bend VIC 3207
  Telephone: (03) 9626 7835
  Fax: (03) 9626 7416
  Email: HumanSciencesHub@dsto.defence.gov.au

  Executive Secretary
  Australian Defence Human Research Ethics Committee
  CP2–7–130
  Department of Defence
  CANBERRA ACT 2600
  Telephone: (02) 6266 3837
  Facsimile: (02) 6266 4982
  Email: ADHREC@defence.gov.au

SECTION 1: VALUES AND PRINCIPLES OF ETHICAL CONDUCT

INTRODUCTION

The relationship between researchers and research participants is the ground on which human research is conducted. The values set out in this section – respect for human beings, research merit and integrity, justice, and beneficence – help to shape that relationship as one of trust, mutual responsibility and ethical equality. For this reason, the National Statement speaks of research 'participants' rather than 'subjects'.

While these values have a long history, they are not the only values that could inform a document of this kind. Others include altruism, contributing to societal or community goals, and respect for cultural diversity, along with the values that inform *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003).

However, the values of respect, research merit and integrity, justice, and beneficence have become prominent in the ethics of human research in the past six decades, and they provide a substantial and flexible framework for principles to guide the design, review and conduct of such research. This National Statement is organised around these values, and the principles set out in paragraphs 1.1 to 1.13 give them practical expression.

Among these values, respect is central. It involves recognising that each human being has value in himself or herself, and that this value must inform all interaction between people. Such respect includes recognising the value of human autonomy – the capacity to determine one's own life and make one's own decisions. But respect goes further than this. It also involves providing for the protection of those with diminished or no autonomy, as well as empowering them where possible and protecting and helping people wherever it would be wrong not to do so.

Reference to these values throughout the National Statement serves as a constant reminder that, at all stages, human research requires ethical reflection that is informed by them. The order in which they are considered reflects the order in which ethical considerations commonly arise in human research.

Research merit and integrity are discussed first. Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable.

At a profound level, justice involves a regard for the human sameness that each person shares with every other. Human beings have a deep need to be treated in accordance with such justice, which includes distributive justice and procedural justice. In the research context, distributive justice will be expressed in the fair distribution of the benefits and burdens of research, and procedural justice in 'fair treatment' in the recruitment of participants and the review of research. While benefit to humankind is an important result of research, it also matters that benefits of research are achieved through just means, are distributed fairly, and involve no unjust burdens.

Researchers exercise beneficence in several ways: in assessing and taking account of the risks of harm and the potential benefits of research to participants and to the wider community; in being sensitive to the welfare and interests of people involved in their research; and in reflecting on the social and cultural implications of their work.

Respect for human beings is the common thread through all the discussions of ethical values. Turning to it as the final value is a reminder that it draws together all of the ethical deliberation that has preceded it.

The design, review and conduct of research must reflect each of these values.

GUIDELINES

Research merit and integrity

1.1 Research that has merit is:

(a) justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities;

(b) designed or developed using methods appropriate for achieving the aims of the proposal;

(c) based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of novel research for which there is little or no literature available, or research requiring a quick response to an unforeseen situation;

(d) designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results;

(e) conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research; and

(f) conducted using facilities and resources appropriate for the research.

1.2 Where prior peer review has judged that a project has research merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research.

1.3 Research that is conducted with integrity is carried out by researchers with a commitment to:

(a) searching for knowledge and understanding;

(b) following recognised principles of research conduct;

(c) conducting research honestly; and

(d) disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.

Justice

1.4 In research that is just:

(a) taking into account the scope and objectives of the proposed research, the selection, exclusion and inclusion of categories of research participants is fair, and is accurately described in the results of the research;

(b) the process of recruiting participants is fair;

(c) there is no unfair burden of participation in research on particular groups;

(d) there is fair distribution of the benefits of participation in research;

(e) there is no exploitation of participants in the conduct of research; and

(f) there is fair access to the benefits of research.

1.5 Research outcomes should be made accessible to research participants in a way that is timely and clear.

Beneficence

1.6 The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.

1.7 Researchers are responsible for:

(a) designing the research to minimise the risks of harm or discomfort to participants;

(b) clarifying for participants the potential benefits and risks of the research; and

(c) the welfare of the participants in the research context.

1.8 Where there are no likely benefits to participants, the risk to participants should be lower than would be ethically acceptable where there are such likely benefits.

1.9 Where the risks to participants are no longer justified by the potential benefits of the research, the research must be suspended to allow time to consider whether it should be discontinued or at least modified. This decision may require consultation between researchers, participants, the relevant ethical review body, and the institution. The review body must be notified promptly of such suspension, and of any decisions following it (see paragraphs 5.5.6 to 5.5.9, page 91–92).

Respect

1.10 Respect for human beings is a recognition of their intrinsic value. In human research, this recognition includes abiding by the values of research merit and integrity, justice and beneficence. Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.

1.11 Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities. Any specific agreements made with the participants or the community should be fulfilled.

1.12 Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

1.13 Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary.

Application of these values and principles

Research, like everyday life, often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong. In such circumstances, it is important that all those involved in research and its review bring a heightened ethical awareness to their thinking and decision-making. The National Statement is intended to contribute to the development of such awareness.

This National Statement does not exhaust the ethical discussion of human research. There are, for example, many other specialised ethical guidelines and codes of practice for specific areas of research. Where these are consistent with this National Statement, they should be used to supplement it when this is necessary for the ethical review of a research proposal.

These ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.

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SECTION 2: THEMES IN RESEARCH ETHICS: RISK AND BENEFIT, CONSENT

Two themes must always be considered in human research: the risks and benefits of research, and participants' consent. For this reason, the two themes are brought together in this section, before discussion in the following sections of ethical considerations specific to different research methods and categories of participants.

CHAPTER 2.1: RISK AND BENEFIT

INTRODUCTION

The conduct of research in Australia is characterised by high ethical and scientific standards, and the dangers to participants have been few. The continued promotion of ethically good human research – the purpose of this National Statement – will help to maintain these standards.

Application of the values in Section 1, in particular the value of beneficence, requires that risks of harm to research participants, and to others, be assessed. Research will be ethically acceptable only if its potential benefits justify those risks.

While this chapter provides guidance on the assessment of risk, such assessment inevitably involves the exercise of judgment.

What is risk?

A risk is a potential for harm, discomfort or inconvenience (discussed below). It involves:

- the likelihood that a harm (or discomfort or inconvenience) will occur; and
- the severity of the harm, including its consequences.

Assessment of risk

Assessment of risks involves:

- identifying any risks;
- gauging their probability and severity;
- assessing the extent to which they can be minimised;
- determining whether they are justified by the potential benefits of the research; and
- determining how they can be managed.

Assessment of risks engages:

- researchers, who need to identify, gauge, minimise and manage any risks involved in their project;
- institutions, in deciding the appropriate level of ethical review for research projects;
- Human Ethics Research Committees (HRECs) and other ethical review bodies (see paragraph 5.1.7, page 78), in reviewing research proposals and making judgements on whether risks are justified by potential benefits; and
- participants' perceptions of risks and benefits. These perceptions are a factor to be considered by review bodies in deciding whether the risks are justified by the benefits.

Harm, discomfort and inconvenience

Research may lead to harms, discomforts and/or inconveniences for participants and/or others.

No list of harms can be exhaustive, but one helpful classification identifies the following kinds of potential harms in research[3]:

- physical harms: including injury, illness, pain;
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
- social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
- economic harms: including the imposition of direct or indirect costs on participants;
- legal harms: including discovery and prosecution of criminal conduct.

Less serious than harm is discomfort, which can involve body and/or mind. Discomforts include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.

Less serious again is inconvenience. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

[3] Adapted from National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants, Bethesda, 2001 pp.71–72

Examples of risks to non-participants include the risk of distress for a participant's family member identified with a serious genetic disorder, the possible effects of a biography on family or friends, or infectious disease risks to the community. Some social research may carry wider social or economic risks; for example, research in a small community into attitudes to specific subpopulations may lead to unfair discrimination or have effects on social cohesion, property values, or business investment.

Harms that may arise from research misconduct or fraud, and harms to members of research teams from other forms of misconduct (for example, harassment or bullying) are addressed primarily in the *Australian code for the responsible conduct of research*. These forms of misconduct may, of course, also lead to potential harms to participants.

Low risk and negligible risk research

The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

Requirements for the ethical review of low risk research and negligible risk research are set out in paragraphs 5.1.18 to 5.1.23, page 79.

Gauging risk

Gauging risk involves taking into account:

- the kinds of harm, discomfort or inconvenience that may occur;
- the likelihood of these occurring; and
- the severity of any harm that may occur.

These judgements should be based on the available evidence. The evidence may be quantitative or qualitative. In either case, the process needs to be transparent and defensible.

For those gauging the severity of the harm, the choices, experience, perceptions, values and vulnerabilities of different populations of participants will be relevant.

Minimising risk

In designing a research project, researchers have an obligation to minimise the risks to participants. Minimising risk involves an assessment of the research aims, their importance, and the methods by which they can be achieved.

Where a researcher or review body judges that the level of risk in a research proposal is not justified by the benefits, either the research aims or the methods by which they are to be achieved, or both, will need to be reconsidered if the research is to proceed.

Do the benefits justify the risks?

Research is ethically acceptable only when its potential benefits justify any risks involved in the research.

Benefits of research may include, for example, gains in knowledge, insight and understanding, improved social welfare and individual wellbeing, and gains in skill or expertise for individual researchers, teams or institutions.

Some research may offer direct benefits to the research participants, their families, or particular group/s with whom they identify. Where this is the case, participants may be ready to assume a higher risk than otherwise. For example, people with cancer may be willing to accept research risks (such as treatment side-effects) that would be unacceptable to well people. Those ethically reviewing research should take such willingness into account in deciding whether the potential benefits of the research justify the risks involved.

For ethical review bodies, there can be a profound tension between the obligation on the one hand to give maximum scope to participants' freedom to accept risk, and on the other to see that research is conducted in a way that is beneficent and minimises harm.

Managing risks

When risks have been identified, gauged and minimised, and the research has been approved, the risks must then be managed. This requires that:

- researchers include, in their research design, mechanisms to deal adequately with any harms that occur; and
- a monitoring process is in place and carried out (*see Chapter 5.5: Monitoring approved research*, page 91–92).

The greater the risk to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

GUIDELINES

2.1.1 Institutions that choose to establish levels of ethical review other than by HREC for research that carries low or negligible risk (see paragraphs 5.1.18 to 5.1.23, page 79) should use this chapter (i.e. Chapter 2.1) to inform their identification of the level of risk.

2.1.2 Risks to research participants are ethically acceptable only if they are justified by the potential benefits of the research.

2.1.3 Steps to arriving at a judgement on the ethical acceptability of risks should include:

(a) identifying the risks, if any;

(b) assessing the likelihood and severity of the risks;

(c) identifying whom (participants and/or others) the risks may affect;

(d) establishing the means for minimising the risks;

(e) identifying the potential benefits; and

(f) identifying to whom benefits are likely to accrue.

2.1.4 In determining the existence, likelihood and severity of risks, researchers and those reviewing the research should base their assessments on the available evidence, whether qualitative or quantitative. They should consider whether to seek advice from others who have experience with the same methodology, population and research domain.

2.1.5 In considering whether the potential benefits of the research justify the risks involved, those reviewing research should take into account any willingness by participant populations to assume greater risks because of the potential benefits to them, their families, or groups to which they belong.

2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.

2.1.8 The greater the risks to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

CHAPTER 2.2: GENERAL REQUIREMENTS FOR CONSENT

INTRODUCTION

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

What is needed to satisfy these conditions depends on the nature of the project, and may be affected by the requirements of the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted.

Variations of these conditions may be ethically justified for some research. Respect for human beings must, however, always be shown in any alternative arrangements for deciding whether potential participants are to enter the research.

It should be noted that a person's consent to participate in research may not be sufficient to justify his or her participation.

This chapter provides guidelines on the requirement for consent. *Chapter 2.3: Qualifying or waiving conditions for consent* then discusses and provides guidelines on conditions under which the requirement may be qualified or waived.

GUIDELINES

2.2.1 The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. For qualifications of this principle, see *Chapter 2.3: Qualifying or waiving conditions for consent,* page 23.

2.2.2 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.

2.2.3 This information must be presented in ways suitable to each participant (see paragraph 5.2.16, page 84).

2.2.4 The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.

2.2.5 Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on:

(a) the nature, complexity and level of risk of the research; and

(b) the participant's personal and cultural circumstances.

2.2.6 Information on the following matters should also be communicated to participants. Except where the information in specific sub-paragraphs below is also deemed necessary for a person's voluntary decision to participate,

it should be kept distinct from the information described in paragraphs 2.2.1 and 2.2.2:

(a) any alternatives to participation;

(b) how the research will be monitored;

(c) provision of services to participants adversely affected by the research;

(d) contact details of a person to receive complaints;

(e) contact details of the researchers;

(f) how privacy and confidentiality will be protected;

(g) the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data;

(h) the amounts and sources of funding for the research;

(i) financial or other relevant declarations of interests of researchers, sponsors or institutions;

(j) any payments to participants;

(k) the likelihood and form of dissemination of the research results, including publication;

(l) any expected benefits to the wider community;

(m) any other relevant information, including research-specific information required under other chapters of this National Statement.

2.2.7 Whether or not participants will be identified, research should be designed so that each participant's voluntary decision to participate will be clearly established.

Renegotiating consent

2.2.8 In some research, consent may need to be renegotiated or confirmed from time to time, especially where projects are complex or long-running, or participants are vulnerable. Research participants should be told if there are changes to the terms to which they originally agreed, and given the opportunity to continue their participation or withdraw (see paragraphs 5.2.16 and 5.2.17, page 84).

Coercion and pressure

2.2.9 No person should be subject to coercion or pressure in deciding whether to participate. Even where there is no overt coercion or pressure, consent might reflect deference to the researcher's perceived position of power, or to someone else's wishes. Here as always, a person should be included as a participant only if his or her consent is voluntary.

Reimbursing participants

2.2.10 It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.

2.2.11 Decisions about payment or reimbursement in kind, whether to participants or their community, should take into account the customs and practices of the community in which the research is to be conducted.

Where others need to be involved in participation decisions

2.2.12 Where a potential participant lacks the capacity to consent, a person or appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information and decide whether he or she will participate. That decision must not be contrary to the person's best interests. Researchers should bear

in mind that the capacity to consent may fluctuate, and even without that capacity people may have some understanding of the research and the benefits and burdens of their participation. For implications of these factors, see *Chapter 4.2: Children and young people*, *Chapter 4.4: People highly dependent on medical care who may be unable to give consent*, and *Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness*.

2.2.13 Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research.

Consent to future use of data and tissue in research

2.2.14 Consent may be:

(a) 'specific': limited to the specific project under consideration;

(b) 'extended': given for the use of data or tissue in future research projects that are:

(i) an extension of, or closely related to, the original project; or

(ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);

(c) 'unspecified': given for the use of data or tissue in any future research.

The necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent (see paragraph 2.2.2).

2.2.15 Extended or unspecified consent may sometimes need to include permission to enter the original data or tissue into a databank or tissuebank (see paragraph 3.2.9, page 31).

2.2.16 When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.

2.2.17 Subsequent reliance, in a research proposal, on existing unspecified consent should describe the terms of that unspecified consent.

2.2.18 Data or tissue additional to those covered by the original extended or unspecified consent will sometimes be needed for research. Consent for access to such additional data or tissue must be sought from potential participants unless the need for this consent is waived by an ethical review body.

Declining to consent and withdrawing consent

2.2.19 People who elect not to participate in a research project need not give any reason for their decision. Researchers should do what they can to see that people who decline to participate will suffer no disadvantage as a result of their decision.

2.2.20 Participants are entitled to withdraw from the research at any stage. Before consenting to involvement in the research, participants should be informed about any consequences of such withdrawal.

[p 22 – Deliberately Blank]

CHAPTER 2.3: QUALIFYING OR WAIVING CONDITIONS FOR CONSENT

INTRODUCTION

Consent to participate in research must be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

The requirement for consent may sometimes be justifiably waived. In this case research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.

'Limited disclosure' to participants of the aims and/or methods of research may also sometimes be justifiable. This is because in some human research (for example, in the study of behaviour), the aims of the research cannot be achieved if those aims and/or the research method are fully disclosed to participants.

Research involving limited disclosure covers a spectrum, from simply not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants. Examples along the spectrum include: observation in public spaces of everyday behaviour; covert observation, for example of the hand-washing behaviour of hospital employees; undisclosed role-playing by a researcher to investigate participants' responses; telling participants the aim of the research is one thing when it is in fact quite different. At the beginning of that spectrum (for instance, observation in public spaces), limited disclosure research shades into research for which waiver of consent might be sought.

GUIDELINES

Limited disclosure

2.3.1 Where limited disclosure does not involve active concealment or planned deception, ethical review bodies may approve research provided researchers can demonstrate that:

(a) there are no suitable alternatives involving fuller disclosure by which the aims of the research can be achieved;

(b) the potential benefits of the research are sufficient to justify both the limited disclosure to participants and any risk to the community's trust in research and researchers;

(c) the research involves no more than low risk to participants (see paragraph 2.1.6, page 18), and the limited disclosure is unlikely to affect participants adversely;

(d) the precise extent of the limited disclosure is defined;

(e) whenever possible and appropriate, after their participation has ended, participants will be:

(i) provided with information about the aims of the research and an explanation of why the omission or alteration was necessary; and

(ii) offered the opportunity to withdraw any data or tissue provided by them.

2.3.2 Where limited disclosure involves active concealment or explicit deception, and the research does not aim to expose illegal activity, researchers should in addition demonstrate that:

(a) participants will not be exposed to an increased risk of harm as a result of the concealment or deception;

(b) a full explanation, both of the real aims and/or methods of the research, and also of why the concealment or deception was necessary, will subsequently be made available to participants; and

(c) there is no known or likely reason for thinking that participants would not have consented if they had been fully aware of what the research involved.

2.3.3 Where research involving limited disclosure aims to expose illegal activity (see paragraph 4.6.1, page 67), the adverse effects on those whose illegal activity is exposed must be justified by the value of the exposure.

2.3.4 Only a Human Ethics Research Committee (HREC) can review and approve research that:

(a) involves active concealment or planned deception; or

(b) aims to expose illegal activity.

Waiver

2.3.5 Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.

2.3.6 Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

(a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants;

(b) the benefits from the research justify any risks of harm associated with not seeking consent;

(c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);

(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;

(e) there is sufficient protection of their privacy;

(f) there is an adequate plan to protect the confidentiality of data;

(g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, *via* a disease-specific website or regional news media);

(h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;

(i) the waiver is not prohibited by State, federal, or international law.

2.3.7 Before deciding to waive the requirement for consent in the case of research aiming to expose illegal activity, an HREC must be satisfied that:

(a) the value of exposing the illegal activity justifies the adverse effects on the people exposed (see paragraph 4.6.1, page 67);

(b) there is sufficient protection of their privacy;

(c) there is sufficient protection of the confidentiality of data; and

(d) the waiver is not otherwise prohibited by State, federal, or international law.

2.3.8 Given the importance of maintaining public confidence in the research process, it is the responsibility of each institution to make publicly accessible (for example in annual reports) summary descriptions of all its research projects for which consent has been waived under paragraphs 2.3.6 and 2.3.7. Waiver decisions under paragraph 2.3.7 should not be made publicly accessible until the research has been completed.