



# National Statement on Ethical Conduct in Human Research

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## Objectives of session

- To identify some key features
  - focus on institutional responsibility
  - flexible risk-related levels of ethical review processes
  - communication, shared responsibility for review
  - structure of relationship among values principles and guidelines
- To identify strengths, issues of interpretation & of implementation in specific chapters.

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## Outline of address

- Process of National Statement revision
- Content outline
- Preamble, Purpose, Scope & Limits
- Ethics and law & legal status
- Institutional responsibilities
- Levels of ethical review processes
- Communication, shared responsibility for review
- Structure of relationship among values, principles and guidelines

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### National Statement - revision process

- Under NHMRC policy, 1999 NS due for revision in 2004
- ToR for Working Party December 2003
- Working party of NHMRC (AHEC), ARC and AV-CC June 2004
- First consultation draft December 2004
- 178 submissions - about 1000 pages
- Second consultation draft – January 2006
- 186 submissions - 1120 pages

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### National Statement - revision process

- With approval of ARC, AV-CC & AHEC, NHMRC Council approved March 2007
- Final version tabled in Federal Parliament 28 March 2007
- Institutions to report against it from 1 January 2008
- Transition period for information, promotion and preparation for institutional compliance
- National roll-out information sessions August/September 2007

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### Continuing promotion & review

- Planning on-going FAQ process of feedback & advice
- Future review & revision to be based on feedback
- Revision of chapters or sections as needed
- 18 - 24 months interval - Canadian model
- Loose-leaf binding

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## National Statement - content

User guide  
 Preamble  
 Purpose, Scope and Limits  
 Sections:

- 1 Values and principles of ethical conduct
- 2 Themes in research ethics: risk and consent
- 3 Ethical considerations specific to research methods or fields
- 4 Ethical considerations specific to participants
- 5 Processes of research governance and ethical review

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## National Statement - Preamble

Brief historical context  
 Ethical background  
 Historical context of ethics & of research ethics  
 Ethical justification for national guidelines  
 Research governance

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## National Statement - purpose

To promote ethically good research, i.e.

- research in which participants are accorded the respect and protection that is due to them, and
- fostering research that is of benefit to the community (p.7)

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### Scope - research

- Broad definition of research – see p.7
- Drawn from the UK Research Assessment Exercise (2005)
- Same as used in the Australian Code for Responsible Conduct of Research, (NHMRC, ARC, UA, 2007)

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### Scope - human research

Human research = research that involves humans through:

- surveys, interviews etc
- psychological, physiological or medical testing
- being observed
- use of personal documents
- collection or use of tissue samples
- access to their information

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### Limits - ethics and law

- Australian law governs research through statutes, common law and contracts
- Advice about compliance with legal obligations not in scope of NS
- Some Commonwealth legislation specific to research is identified – not State/Territory laws
- Responsibilities in NS intended to be consistent with international human rights instruments Australia has ratified
- Responsibility of institutions and researchers to be aware of relevant legal obligations

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### Legal status of National Statement

- Issue of NS fulfils NHMRC statutory obligation to issue ethical guidelines on medical research involving humans
- Also provides guidelines for all human research
- No intrinsic legal force from Parliament tabling
- Legal status by reference, e.g. Therapeutics Goods Act
- Contractual force by public research funding agreements
- Conformity may be required as institutional policy
- Probable source of standard of reasonable care in ethical conduct & review of human research

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### Institutional responsibilities

- Governance of research
- Minimising duplication of ethical review
- Managing conflicts of interest
- Monitoring approved research
- Handling complaints
- Specific to types of research
- Ethical review of human research

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### Institutional responsibilities

- On matters of ethical review, 1999 National Statement focus on HRECs
- Lacked clear & consistent recognition of function of HRECs in institutional structures
- May have contributed to lack of clarity in accountability
- Where relevant, revised version recognises institutional context in order to:
  - redress the existing lack of clarity
  - facilitate flexible risk related review, and
  - emphasise ethics review part of research governance

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## Research governance

Institutions to see that human research:

- meets Australian code for the responsible conduct of research (NHMRC, ARC, UA 2007)
- meets scholarly standards
- ethically reviewed, monitored under NS, using own or another review process
- conducted by researchers with experience, qualifications, understand risks to self & participants; can conscientiously withdraw

Clear, documented & accessible procedures for governance and ethical review

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## Minimising duplication of ethical review

Institutional responsibility to adopt review process that eliminates unnecessary duplication

Institutions that regularly share research, agree on single review body

If use another review body:

- local relevant factors & information
- scientific review
- monitoring
- discontinuance
- procedures to avoid duplication

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## Conflicts of interest

Institutions establish transparent processes to identify & manage Col's involving institutions, researchers, review bodies

**Institutional Col's:**

institutions notify review body and vice versa

**Researchers' Col:**

disclosure and/or modify conduct; ethical basis to not disclose nature of Col

**Review body Col:**

disclose, manage by e.g. exclusion

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## Monitoring approved research

Institutions' ultimate responsibility to monitor

Mechanisms related to risk

Researchers:

- report & deal with adverse events etc
- notify review body of mechanisms
- report progress regularly & early discontinuation

Review bodies may use reports to require modification or implement suspension process

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## Suspension of research

If review body has reason to believe participants' welfare compromised:

- seek to establish whether to withdraw approval
- treat researchers & others fairly

Where approval withdrawn by review body:

- inform institution, researcher, participants
- institution to see researcher suspends
- research not resume unless:
  - researcher shows will not compromise welfare
  - research modification ethically reviewed/approved

Urgent suspension of research by institution

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## Handling complaints

**Complaints about research/researchers:**

Institutions to:

- identify accessible person to receive
- establish procedures for handling, seeking to resolve
- if "research misconduct", as per Code: others by institutional processes

**Complaints about review bodies:**

- institutional procedures for receiving, handling, seeking to resolve
- default access to person external to review body

Institutions identify external person/agency for complaints not resolved

Publicise procedures

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## Specific institutional responsibilities

**Clinical research**

- Investigation of innovative interventions (3.3.1)
- Monitoring commensurate with risk, size & complexity
  - mechanisms for reporting & reviewing SAES, ADRs, SUSARs and device events
  - DSMB for large trial & access for HREC
  - local trial, person with suitable expertise to advise HREC about SAEs (3.3.20)
- Sponsors have made insurance & indemnity arrangements (3.3.24)
- Arrangement to compensate participant for harm from negligence (3.3.25)

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## Specific institutional responsibilities (cont)

**Human tissue samples**

- policy for collection, storage, use & disposal of human tissue used in research (3.4.1)

**Waiver of consent**

- make publicly accessible summary descriptions of research projects for which consent has been waived (2.3.8)

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## Levels of ethical review

Levels of review related to the risk involved in research

Chapter 2.1 contains discussion, guidance on risk assessment and ethical acceptability of risk

Distinguishes:

- More than low risk = foreseeable risk more than discomfort
- Low risk = only foreseeable risk is discomfort
- Negligible risk = no foreseeable risk of harm or discomfort & any foreseeable risk no more than inconvenience

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**All reviewable human research with risks**

More than low risk  
HREC

No more than low risk  
HREC or non-HREC

Negligible risk  
May be exempted

Existing collections of non-identifiable data

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**Review of research with more than low risk**

Institutions that establish HRECs should ensure:

- sufficient resources & set & publicize ToR
- members have relevant expertise/experience, inducted, trained & disclosed
- access to necessary expertise
- review is thorough, expeditious
- decisions transparent, consistent, communicated
- conflicts of interest managed
- good HREC-researcher communication
- workload does not compromise quality or timeliness
- meets NS (5.1.24 – 5.1.28)

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**HREC membership - changes**

- As far as possible, equal men & women; one third non-institutional
- Chair's responsibilities not compromise NS compliance,
- Pastoral community role
- Lawyer, where possible not institution's
- At least 2 current relevant research experience.
- Pools of inducted members
- Where possible, one or more experienced in ethical reflection, decision making.
- Appointment: open, individuals not representatives, consider review every 3 years. (5.1.29 – 5.1.35)

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## HREC meetings

- Arranged to enable attendance of at least one core member in each category
- Decisions to be informed by exchange of opinions from at least minimum membership
  - at face to face meeting (ideally) or
  - chair satisfied that views of absent members received and considered. (5.2.28 - 5.2.31)

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## Review of research with no more than low risk

Institutions to ensure that non-HREC review level:

- based on NS values & principles
- follows accessible criteria for levels of review based on NS 2.1
- monitored to ensure sufficient participant protection
- regularly assessed to ensure continuing NS compliance, using participant experience,
- subject to review if emerging ethical issues warrant
- the subject of regular accessible reports
- audited to confirm research review meets criteria. (5.1.10 – 5.1.17)

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## Review of research with no more than low risk (cont)

- has resources & capacity to conduct review competently & professionally
- conducted by people familiar with NS & understand how ethical issues can arise in such research
- be informed by relevant parts of NS sections 1, 2, 3 & 4
- takes account of researchers' judgment of review level
- have regard to privacy regulation.(5.1.18-5.1.19)
- examples of review procedures in 5.1.20

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### Review of research with no more than negligible risk

- Institutions may have negligible risk research ethically reviewed by non-HREC procedures or an HREC.
- Where research involves
  - no more than negligible risk,
  - **and**
  - the use of existing collections of data or records that contain only non-identifiable data about human beings,
 institutions can choose to exempt that research from ethical review. (5.1.22)
- Decision to exempt = determination that the research meets NS & is ethically acceptable.(5.1.23)

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### Review of research with no more than negligible risk

- Institutions to have auditing process to confirm that research is being exempted from review in accordance with the criteria in paragraphs 5.1.22 – 5.1.23 (N.S. 5.1.17(b))
- Researchers to maintain auditable record of any research exempted from ethical review under 5.1.22 & 5.1.23(5.2.9)

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### Legal responsibility & review procedures

Institutions

- to provide assurance of legal protection to all involved in ethical review for liabilities arising in bona fide conduct of review duties. (5.1.9)
- to ensure non-HREC levels have good working procedures (5.2.1)

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### Communication, shared responsibility in ethics review

Institutions encourage open communication & shared commitment by promoting

- awareness of NS among researchers
- ready accessibility of review bodies and staff to researchers (5.2.13)

Review bodies should

- encourage informal communication
- resolve differences in face to face meetings (5.2.14)

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### Communication, shared responsibility in ethics review

Review bodies

- may invite researchers to attend & researchers may request
- to clearly communicate decisions
- approval and rejection in writing (email)
- reasons for amendments or rejection & linked to NS (5.2.22)

Permits reliance on other, consistent guidelines – p.13

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### Structure of the NS

Four values used to shape relationship between researchers and participants:

- Research merit and integrity
- Justice
- Beneficence
- Respect for human beings

Apply to all human research  
Used to organize the substantive content of NS  
Principles & guidelines expressed in these values

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### Structure of the NS

Each value is

- Described in Introduction to chapter 1 – pp. 11-12
- Reflected in general principles in chapter 1 – pp. 12-13
- Reflected in specific guidelines in most chapters

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### Structure of the NS – example 1

*Specific guideline that:*

“3.3.3 Researchers should show that:  
(a)the research is directed to answering a specific question or questions”

*reflects general principle that:*

“1.1 research that has merit is  
(a)justifiable by its potential benefit . . .”

*and expresses value that . .*

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### Structure of the NS – example 1

“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.” (p.11)

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### Structure of the NS – example 2

*Specific guideline that:*

“4.3.4 People in (dependent relationships) are vulnerable to being over-researched because of the relative ease of access to them as research populations. Researchers should take account of this vulnerability in deciding whether to seek out members of these populations as research participants.”

*reflects the general principle that*

“1.4 In research that is just:

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

*and expresses the value that*

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### Structure of the NS – example 2

“Justice involves a regard for the human sameness that each person shares with every other.” (p.11)

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### Structure of the NS – example 3

*Description of value of beneficence:*

“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;” (p.11)

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**Structure of the NS – example 3**

*reflects general principle that:*  
 “1.7 Researchers are responsible for:  
 (a) designing research to minimise the risks of harm or discomfort to participants”  
*and*  
*expressed in specific guideline that:*  
 “3.1.11 Where possible, participants should be informed about any potential to be identified in results of research even if identifiers, such as name and address, are removed.”

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**Structure of the NS – example 4**

*Description of value of respect:*  
 “recognising that each human being has value in himself or herself, and that this value must inform all interaction between people.” (p.11)

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**Structure of the NS – example 4**

*Reflected in general principle that:*  
 “1.10 respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.”  
*And in specific guideline that:*  
 “4.2.6 researchers should be attentive to the developmental level of children and young people when engaging them in understand the nature and likely outcomes of research.”

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**Questions?**

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**Small group discussion**

What are the strengths of this chapter?  
What questions of interpretation arise?  
What challenges does the implementation of this chapter present to :

- researchers?
- HRECs and review bodies?
- institutions?

Feedback from each table: a strength, a question and a challenge  
Feedback collected (blue forms), available for future sessions and from NHMRC website  
Beginning of conversation & review process.

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