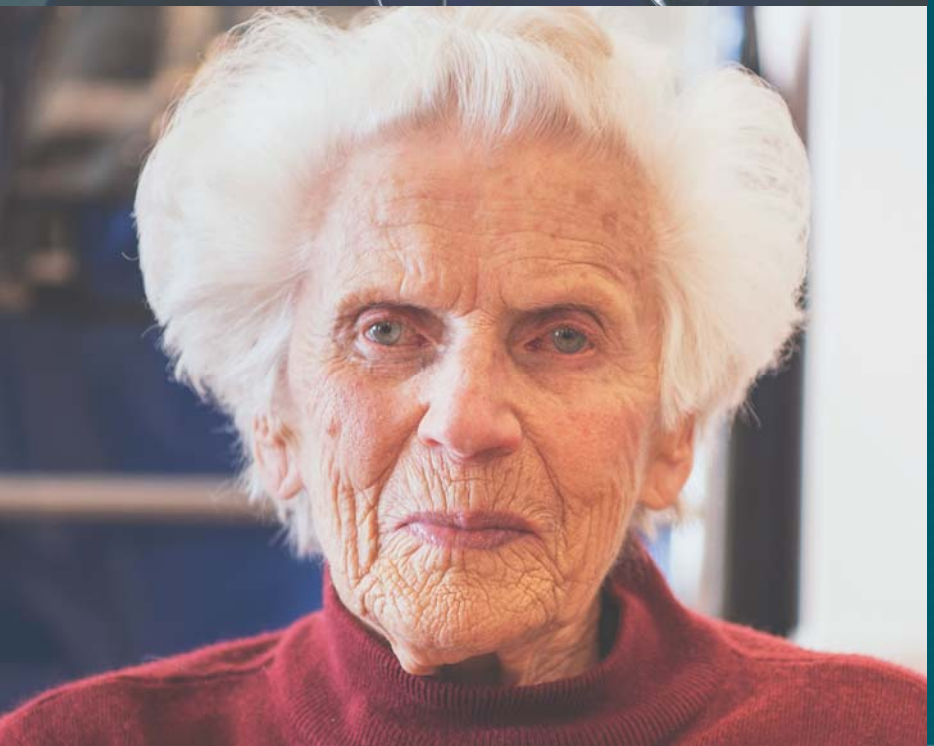

National Statement Training guide

Office for Research

Government of South Australia

Health
Southern Adelaide
Local Health Network

How well do you know you National Statement?

The National Statement on Ethical Conduct in Human Research ('National Statement') is intended for use by:

- Any researcher conducting research with human participants;
- Any member of an ethical review body reviewing that research;
- Those involved in research governance; and
- Potential research participants.

The National Statement articulates the four core principles of merit and integrity, beneficence, justice and respect that must be accorded to all participants in research.

Specific advice is provided with regard to benefits and risk, informed consent, privacy, methodologies and potential participant populations in specific chapters.

Guidance is also provided with regard to the appointment and operation of human research ethics committees, the conduct of ethical reviews, and the responsibilities of institutions.

Below is an overview of each section in the National Statement, followed by a quiz. This document is designed to guide you through the most common ethical issues to be considered, when planning an ethics application. It can also be used as guide to the relevant section of the National Statement, when you are not sure where to look.

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

Section 1:

This document articulates the four core principles of merit and integrity, beneficence, justice and respect that must be accorded to all participants in research.

Specific advice is provided with regard to benefits and risk, informed consent, privacy, methodologies and potential participant populations in specific chapters.

Guidance is also provided with regard to the appointment and operation of human research ethics committees, the conduct of ethical reviews, and the responsibilities of institutions.

While this document is not legally binding and state / federal polices can override it, The National Statement is the foundation guideline for ethical review of human research.

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
- Participant consent.

In regards to risk, researchers need to identify all possible risks, the likelihood of them occurring and the level of harm that may occur. They also need to minimise any risk to participants, and have a plan in place, should something go wrong.

The research benefit to participants must also justify any risks.

The HREC will assess the risk benefit ratio as part of their review.

Section 2.2 General requirements for consent

- Consent is more than just presenting the PICF to the potential participant and having them sign the consent form.
- 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.
- Consent may be expressed orally, electronically, in writing, implied (for example, return of a survey), or implying consent (remaining in a group, rather than leaving).
- If consent cannot be obtained by participants for the research project, a waiver of consent can be applied for addressing specific criteria, justifying why the waiver is appropriate to the HREC.

Other forms of consent are:

- Opt out - where the project is of such scale and significance that using explicit consent is neither practical nor feasible.
- Limited disclosure – not advising the participant they are in a research project until their participation has finished, avoiding bias in the results.

Section 3: Ethical considerations in the design, development, review and conduct of research

This section has very useful guidance on the ethical items you need to take into consideration when designing and writing your ethics application. It is broken up into 7 elements, and each element has key questions to help guide the application.

- Element 1: research scope, aims , themes, questions and methods
- Element 2: recruitment
- Element 3: consent
- Element 4: collection, use and management of data and information
- Element 5: Communication of research findings or results to participants
- Element 6: Dissemination of research findings or results to participants

- Element 7: After the project

Section 4: Ethical considerations specific to participants

In addition to the ethical considerations pertaining to all research participants, specific issues arise in the design, conduct and ethical review of research involving the categories of participants identified in this section.

The categories are:

- 4.1: Women who are pregnant and the human foetus
- 4.2: Children and young people
- 4.3: People in dependant or unequal relationships
- 4.4: People highly dependent on Medical care who may be unable to give consent
- 4.5: People with cognitive impairment, an intellectual disability, or a mental illness
- 4.6: People involved in illegal activities
- 4.7: Aboriginal and Torres Strait Islander people
- 4.8: People in other countries.

Section 5: Processes of research governance and ethical review

This Section sets out the processes by which institutions establish, conduct and oversee those different levels of ethical review, and includes the operations of Human Research Ethics Committees (HRECs). The section also describes other processes of research governance that must be in place if the ethical review of research is to be undertaken well.

The Australian Code for the Responsible Conduct of Research provides more comprehensive information such as:

- 5.1: Institutional responsibilities
- 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers
- 5.3: Minimising duplication of ethical review
- 5.4: Conflicts of interest
- 5.5: Monitoring approved research
- 5.6: Handling of complaints
- 5.7: Accountability

National Statement Quiz

Here are 20 questions to test your knowledge on the National Statement.

All answers can be found within the chapter provided with the question.

1. Is the purpose of the National Statement too:

   A. Give me a rough guideline on research, but I don't have to follow it.
   B. Make the participant feel better when they know I have used it.
   C. Make me feel better when I use it.
   D. Promote ethically good human research

   Answer: …….

2. Which one of these is not a value or principle for ethical research:

   A. Research merit and integrity
   B. Justice
   C. Beneficence
   D. Kindness

   Answer: …….

3. A low risk project is:

   A. A project that caused physical pain
   B. A project that causes emotional distress to the participant
   C. A project that causes mental anguish
   D. A project where the only foreseeable risk is one of discomfort

   Answer: …….

4. Research is ethically acceptable when…

   A. When the potential benefits justify any risks involved in the research
   B. Because my application is very well written
   C. the risks are higher than any potential benefit
   D. Because the participant agrees to take part in my research.

   Answer: …….

5. What are the 3 types of consent?

   A. Written, verbal and implied
   B. Direct, indirect and declined.
   C. Unanimous, freely given and simple consent
   D. I don't need participant consent

   Answer: …….

6. When is it considered appropriate to reimburse costs to participants?

   A. When parking and travel costs are incurred by their participation
   B. To make sure the participant agrees to consent
   C. To help them pay for their study medication
   D. To contribute towards their blood tests

   Answer: …….

7. A waiver consent can only be granted by:

   A. The chief investigator listed on the application
   B. The HREC
   C. The participant
   D. The CEO

   Answer: …….

8. Which below statement best describes opt out consent?

   A. Information is provided to the potential participant, and their consent is provided by contacting the researchers to verbally agree to be part of the research
   B. Information is provided to the potential participant, and their consent is presumed unless they take action to decline
   C. Information is provided to the potential participant, and consent is withdrawn by the participant, by writing a detailed explanation to the researcher.
   D. Information is provided to the potential participant via email only, and the potential participant emails back, confirming consent.

   Answer: …….

9. The recruitment strategy must be:

   A. Respectful of potential participant
   B. Respectful of culture, tradition and belief
   C. Voluntary
   D. All of the above

   Answer: …….

10. Should researchers adopt methods to reduce the risk identification during collection, analysis and storage of data?
    A. Yes
    B. No
    C. The data belongs to the researchers, so this doesn't apply
    D. Only if the participant asks for this to be done.

    Answer: …….

11. What is a data management plan?

    A. A rough outline of what will happen to the study data
    B. A plan that addresses the researcher's intentions of data analysis
    C. A detailed plan that addresses the researcher's intentions related to generation, collection, access, use, analysis, storage, retention, disposal, sharing and reuse of data
    D. A detailed plan that addresses the researcher's intentions to sell the data to third party.

    Answer: …….

12. Can data be shared with other researchers?

    A. No
    B. Yes, it's my data, so I can do whatever I like with it.
    C. Yes, providing there is a data management plan in place.
    D. No, once collected, data must never be shared.

    Answer: …….

13. Should research results be returned to the participants?

    A. Yes, providing the risk / benefit to participants has been considered
    B. Yes, providing an ethically defensible plan is in place
    C. Yes, if the participant has consented to receive the results.
    D. All of the above.

    Answer: …….

14. In regards to a child or young person being recruited into a research project

    A. They must participate, if their parent/guardian says so
    B. Children/young people should never be included in research
    C. Their refusal to participate must be respected, provided they have capacity to consent.
    D. Children / young people can only participate in data collection research.

    Answer: …….

15. If a participant has a pre-existing relationship with a researcher i.e. clinician / patient relationship, consent:

    A. Cannot be provided, and the participant cannot be part of the research.
    B. Consent should be obtained by an independent person to the participant i.e. research nurse.
    C. The researcher / clinician know what is best for the participant and can consent them.
    D. The participant must find a new clinician to be part of the research.

    Answer: …….

16. If a participant is unable to provide consent, as they highly dependent on medical care, the best consent process is:

    A. This type of participant should never be consented into research, as it is too risky.
    B. Third party consent can be obtained from a spouse / guardian / care giver.
    C. The treating clinician can consent the participant
    D. Consent is not required, as they are too sick to understand what is happening.

    Answer: …….

17. A potential participant with cognitive impairment, intellectual disability or a mental illness, can be consented into a research project:

    A. No, they are unable to provided informed consent, so cannot participate.
    B. Yes - they are entitled to participate in research and can provide consent if they have the capacity to do so.
    C. Yes, if they can physically sign their name, they can consent.
    D. No – they are too vulnerable to be research participants

    Answer: …….

18. Which statement is false in relation to a conflict of interest be placed?

    A. The researcher will declare they have a conflict of interest
    B. The conflict of interest will be assessed by the HREC or HREC Chair
    C. A researcher or HREC may decide to limit the researcher's participation in the research or in the deliberation about the research
    D. Conflicts are fine, particularly financial ones. They add more interest into a research project

    Answer: …….

19. What are some of the monitoring responsibilities of HRECs and/or institutions?

    A. Receiving progress reports from researchers
    B. Reviewing reports of serious adverse events occurring on site
    C. Ensuring that the requirements of project close out are met
    D. Reviewing the integrity of project data prior to publication
    E. A, B and C only

    Answer: …….

20. Whose responsibility is it to ensure all reports are submitted to the HREC?

    A. The HREC – they need to provide reminders to all researchers, their reports are due
    B. The coordinating principal investigator, who has overall responsibility for the research
    C. The admin officer – this should be part of their task list
    D. One of the co investigators listed on the application.

    Answer: …….

Bonus question:

21. What do HRECs focus on doing their review of a proposed clinical trial?

A. Records of researchers' completion of GCP training
B. Proposed recruitment strategies
C. Proposed mechanisms for storage of research data
D. Intellectual property clauses in the research agreement
E. B and C only
F. A, B and D only

Answer: ……

Quiz answers:

1 D

2 D

3 D

4 A

5 A

6 A

7 B

8 B

9 D

10 A

11 C

12 C

13 D

14 C

15 B

16 B

17 B

18 D

19 E

20 B

21 E

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