



National Statement on Ethical Conduct in Human Research and ethical review and research involving only low or negligible risk

Introduction

The National Statement authorises institutions to establish processes for dealing with low risk and to decide whether to exempt negligible risk research from review. This fact sheet clarifies the options that institutions may choose. Before any human research proposal begins and full funding is released, a judgment must be made by the institution that the requirements of the National Statement are satisfied and it is ethically acceptable. (NS p.8)

What is low risk in human research?

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. (NS 2.1.6)

What is discomfort?

The National Statement describes discomfort as "less serious than harm...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." (NS p.16)

What processes of ethics review can apply to research involving only low risk?

Institutions can have low risk research ethically reviewed by an HREC or by other non-HREC procedures that they establish.

The National Statement authorises institutions to establish non-HREC processes of ethical review for low risk research provided that:

- (a) those processes meet the conditions set out in paragraphs 5.1.18, 5.1.19 and 5.1.21. Examples of such procedures are offered in paragraph 5.1.20, and
- (b) institutions fulfil the requirements for establishment, monitoring, assessment and audit of review procedures set out in paragraphs 5.1.10 – 5.1.17

What Is Negligible Risk In Human Research?

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. (NS 2.1.7)

What Is Inconvenience?

Inconvenience is less serious than discomfort. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research (NS p.16).

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What Processes of Ethics Review Can Apply To Research Involving Only Negligible Risk?

Institutions can have negligible risk research ethically reviewed by an HREC or by other non-HREC procedures that they establish.

Where research involves

- only 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. (NS 5.1.22(b)).

“Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirement of this national Statement and is ethically acceptable” (NS 5.1.23)

Institutions should also have in place an auditing process to confirm that research is being exempted from review in accordance with the criteria in paragraphs 5.1.22 – 5.1.23 (NS 5.1.17(b))

The following chart contains a hypothetical example of the processes that could be implemented by an institution that has chosen to develop ethical review procedures for low and negligible risk research.

PROCESSES FOR LOW RISK AND NEGLIGIBLE RISK ETHICAL REVIEW

The National Statement authorises institutions to establish processes for dealing with low risk and to decide whether to exempt certain negligible risk research from review. The following flow chart explains the processes developed by a particular HREC (not the NHMRC) and is provided here to assist institutions in developing their own suitable path for processing a research protocol.

