

How to Assess the Level of Risk

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

Categories of Potential Risks

The [National Statement on Ethical Conduct in Human Research](#) (2007 - updated 2018) categorises potential risks to research participants as follows:

1. Harms such as pain (including physical, psychological, social, economic and legal harms, and the devaluation of personal worth)
2. Discomforts (such as the measurement of blood pressure or anxiety induced by an interview). If discomfort becomes distress, then it is considered to be harm.
3. Inconveniences (such as filling in a form)

Please review [Section 2: Themes in research ethics: Risk and benefit, consent](#) in the National Statement, to assess the potential risks of your research proposal. Suitable justification matched against the National Statement will be required for the decision made regarding the level of risk.

Levels of Risk

The ethical review of research takes into account the varying level of risk to which participants are exposed: **Negligible risk:** Research in which 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).

The National Statement allows research to be exempted from ethical review if it is both (a) negligible risk research and (b) involves existing collections of non-identifiable data (NS 5.1.22 b). Your project may also be outside the scope of the HREC (Tasmania) if it does not involve human participation in research ([When is approval needed?](#)). Please remember that human research is broadly defined to include, for example, researchers having access to existing patient records for purposes other than normal clinical practice.

Low risk: 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 (NS 2.1).

- **All research involving more than low risk must be reviewed by an HREC (that is, by the full committee).**
- **Please note that requests involving a waiver of consent for the use of personal information in medical research, or personal health information, may only be approved by an HREC.**