

SCU Human Research Ethics Committee: Risk Assessment Guidelines and Matrix Prepared by Dr Liz Baker, with input from HREC members January 2019

The NHMRC's National Statement on Ethical Conduct in Human Research (2018 version) includes a thorough and helpful outline of the responsibilities of the researcher in relation to the assessment of risk (Chapter 2.1). Key points to note include:

- Application of the values in Section 1 [of the National Statement], in particular the value of beneficence, requires that risks of harm to research participants, and to others, be assessed.
- Researchers ... need to identify, gauge, minimise and manage any risks involved in their project.
- In designing a research project, researchers have an obligation to minimise the risks to participants, the researcher(s) and the university.
- 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.
- Human Research Ethics Committees, in reviewing research proposals, are required to make a judgement on whether risks are justified by potential benefits.

Note: The HREC is not risk-averse; the Committee's starting point is to always approve an application unless the potential for risk outweighs the potential benefits.

The HREC's assessment of the ethical acceptability of risks is based on the researcher:

- (a) identifying any potential of possible risks;
- (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.

A risk is a factor that will limit the capacity of the activity to achieve what it sets out to achieve.

Researchers are encouraged to carefully consider and declare any possible risks; this can be a powerful and enabling process. A risk that is often overlooked relates to the method chosen to undertake the research; if the method chosen won't work or achieve what it is expected to, this is an ethical risk, even if there is little or no apparent risk to any people involved. Harms caused by inappropriate methods include waste of funding, if it is a funded project, waste of participants time, efforts and goodwill and possibly reputation damage to the researcher.

Ethics risk assessment is different to, although sometimes overlaps with, Workplace Health and Safety risk. It is also different to the assessment of risk carried out by the University's legal office, whose primary concern is risk to the University, although the researcher is also responsible for ensuring that what they are proposing to do is lawful and in keeping with whatever contractual obligations they may have with funding bodies or partnering organisations.

Researchers also need to take into account that risk is multi-faceted and fluid; depending on the research it may need to be reassessed over the life of the research.

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.

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.

Research is '**negligible risk**' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is **no more than inconvenience**. **Inconvenience** includes things such as filling in a form, participating in a street survey, or giving up time to participate in research. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.

The greater the risks to participants in any research for which ethics 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.

The risk assessment applies to both participants and researchers, and will vary with research context. Examples:

- Swimming 500 meters: for the general population, this activity would be considered more than "low" or "negligible" risk. For members of a high school swim team, this activity could be considered "low" risk.
- Face-to-face survey of people in nightclubs: the researcher needs to consider physical risks to their own wellbeing, including threatened or actual violence, sexual harassment, and abuse.
- Blood glucose testing with a glucometer: hazards include:
 - for the participant: pain, infection, and injury;
 - for the researcher: possible exposure to blood/body fluids, or needle stick.If the participants are diabetics who conduct these tests on a daily basis this activity could be considered low risk. However, it would be considered more than low risk when a glucometer is used by a participant who does not perform this test as a function of their daily life.

Likelihood of each potential risk is assessed as:

- *Unlikely*: extremely rare risks, with almost no probability of occurring.
- *Seldom*: risks that are relatively uncommon but have a small chance of manifesting.
- *Occasional*: risks that are more typical, with about a 50/50 chance of taking place.
- *Likely*: risks that are highly likely to occur.
- *Definite*: risks that are almost certain to manifest.

Severity of each potential risk is assessed as:

- *Insignificant*: Risks that bring no real negative consequences or pose no significant threat;
- *Minor*: Risks that have a small potential for negative consequences but will not have a significantly negative impact;
- *Moderate*: Risks that could potentially bring negative consequences, posing a moderate threat;
- *Critical*: Risks with substantial negative consequences that will seriously affect the participants or researchers.
- *Catastrophic*: Risks with extreme negative consequences for participants or researchers.

Classifying Risk: Risk rankings combine impact and likelihood ratings:

- *Low*: The consequences of the risk are minor, and it is unlikely to occur. These types of risks are generally considered ‘everyday’ and acceptable.
- *Medium*: Somewhat likely to occur, these risks come with slightly more serious consequences. Generally considered ‘tolerable’ as long as minimisation and mitigation measures are outlined. As far as reasonably possible, the researcher should take steps to prevent medium risks from occurring in the first place.
- *High*: These are serious risks that both have significant consequences and are likely to occur. Active measures need to be in place to minimise / mitigate these risks. These risks would generally be considered unacceptable for human research proposals unless risk management measures are clearly defined and benefits of the research justify it.
- *Extreme*: Catastrophic risks that have severe consequences and are highly likely to occur. These risks are generally considered unacceptable for human research proposals.

The following matrix will help researchers to consider/decide the appropriate category for any risks they identify in their proposed research. If all potential risks fit into one of the Low categories, the research should be eligible for Expedited Ethics Approval. If not, a full Human Research Ethics Application (HREA) will be required.

Likelihood	Severity				
	Catastrophic	Critical	Moderate	Minor	Insignificant
Definite	Extreme	Extreme	Extreme	High	High
Likely	Extreme	Extreme	High	Medium	Medium
Occasional	Extreme	High	High	Medium	Low
Seldom	High	High	Medium	Low	Low
Unlikely	Medium	Medium	Low	Low	Low

Risk Management

Working through the potential risks to participants, researchers and others and assigning a rating to those risks enables the researchers to better plan how to minimise and manage them. A good way to do this is to firstly return to research design. Most declared risks can be limited through relatively simple design changes. Then, for the risks that remain relevant, the researcher's responsibility is to "establish the means for minimising the risks". The HREC's assessment has to take into account how the researcher has done this.

Some researchers may find the assessment table below useful when thinking about risk and assist them in assigning the appropriate rating to the risks they identify in their proposed research.

(Note: It is not mandatory that researchers complete this table; it is offered as a guide only).

