

Risk Mitigation and Management

What is Risk?

A risk is a potential for harm, discomfort or inconvenience. It involves:

- the likelihood that a harm (or discomfort or inconvenience) will occur; and
- the severity of the harm, including its consequences

Assessment of Risk

Involves:

- identifying any risks;
- gauging their probability and severity;
- assessing the extent to which they can be minimised;
- determining whether they are justified by the potential benefits of the research; and
- determining how they can be managed.

Engages:

- researchers, who need to identify, gauge, minimise and manage any risks involved in their project;
- institutions, in deciding the appropriate level of ethical review for research projects;
- Human Research Ethics Committees (HRECs) and other ethical review bodies, in reviewing research proposals and making judgements on whether risks are justified by potential benefits; and
- participants' perceptions of risks and benefits. These perceptions are a factor to be considered by review bodies in deciding whether the risks are justified by the benefits.

[National Statement on Ethical Conduct in Research 2007 \(updated 2023\) Page 12 – or section 2](#)

Consideration of the different types of harm:

As per the requirements of the NHMRC Human Research Ethics Application (HREA), consideration should be given as to whether any of the following types of harm might occur in your research and the likelihood, severity and consequence of those harms occurring:

- physical harm
- psychological harm
- disclosure of sensitive personal information
- exposure of illegal activity
- economic harm
- discrimination, stigma or other social harm
- devaluation or harassment
- familial distress
- harm to any member of a vulnerable population (see [National Statement Section 4](#))
- reputational harm
- consider whether your research is likely to result in discomfort or inconvenience and how this might occur.

Include risks to and burdens on participants, researchers and third parties (individuals or groups).

Consider the multiple levels of personal relationships that may arise during research (especially in ethnographic research or research using the participant-observation or other observational methods) and their impact upon participants, researchers and third parties.

Consider whether there are any concerns that might be relevant to the research project regarding political or institutional sensitivities.

Consider whether any combination of methods being used in this research might lead to additional risks.

Risk Mitigation & Management Matrix

Depending on many factors such as the design of your research, scope, interventions, participant groups etc. there may be other risks to consider.

Please Note: These are **examples** only.

Risk Examples	What to Consider	Possible Mitigation & Management
Interview/focus group time	<ul style="list-style-type: none">▪ Participants age/health/ability/attention span▪ Travel time taken to attend interview▪ Building/location access▪ Length of interview/focus group	<ul style="list-style-type: none">▪ Ensure participants have a break▪ Split sessions (different days etc.)▪ Offer different engagement platforms
Accessing medical records	<ul style="list-style-type: none">▪ Privacy legislation▪ Who will have access?▪ Safeguarding/management of data	<ul style="list-style-type: none">▪ Ensure that the research team is aware of current privacy legislation▪ Only those on the research team have access to records.▪ Ensure data custodian has provided approval for access to data for research purposes▪ Protocols in place to ensure only the applicable records are accessed▪ De-identification of data▪ Ensuring sufficient data management is in place to safeguard collected data.
Discussing sensitive/distressing topics with participants	<ul style="list-style-type: none">▪ The age and ability of the participant▪ Consider optional support person▪ Provision of contact information for support agencies▪ Depending on the targeted participant group, topics could be considered more	<ul style="list-style-type: none">▪ Consider whether it is appropriate to have someone on the research team that can provide specialist advice and support to the participant. i.e. has had previous experience or is experienced and/or school councillor availability

	<p>distressing/sensitive to some individuals</p> <ul style="list-style-type: none"> Researcher becomes distressed? 	<ul style="list-style-type: none"> Ensure there are relevant support services in place and that the participants have access to these services. Ensure the support service is relevant to the participant and age group. Ensure it is clear to participants they can withdraw at any point from the study In addition, ensure it is also clear to participants whether they can withdraw their data (how and at what point).
Participants under orders	<ul style="list-style-type: none"> Legislative requirements i.e. define participant approval process 	<ul style="list-style-type: none"> Children who may be under an order that are unable to participate due to legislation, ensure they do not feel discriminated against.
Research involving physical activities	<ul style="list-style-type: none"> Age and ability of participant Current health status Medical conditions Consideration of hidden medical conditions 	<ul style="list-style-type: none"> Ensure the inclusion/exclusion criteria is appropriate If required, ensure there is someone on the research team that is trained in first aid or has medical training Ensure that the researchers have appropriate training with the activity.
Incidental findings	<ul style="list-style-type: none"> Tests undertaken could uncover a potential illness or diagnosis Disclosure of Illegal activities Mandatory reporting obligations Professional reporting obligations 	<ul style="list-style-type: none"> If applicable (i.e. genomic), a 'return of results' plan is in place i.e. NS 3.3.17 & 3.3.32 Research team is aware of any reporting requirements and that a plan is in place to manage this. Ensure participants have consented to the research with knowledge of possible reporting (i.e. police).