GUIDELINE: Risks and Benefits

**Benefit** is valued or desired outcome; an advantage.

**Risk** is the potential for a negative outcome or effect of the research. The *National Statement* considers a range of risks across physical, psychological, social, economic and legal domains. Risks are considered to occur on a spectrum of severity from inconvenience to harm:

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<th>Inconvenience</th>
<th>Discomfort</th>
<th>Harm</th>
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*Harm* is that which adversely affects the interests or welfare of an individual or a group (e.g. physical illness or injury, distress, pain, psychological disturbance, devaluation of personal worth and social disadvantage).

*Discomfort* is a negative accompaniment or effect of research, less serious than harm (e.g. minor side-effects of medication, anxiety induced by an interview).

*Inconvenience* is a minor negative accompaniment or effect of research, less serious than discomfort (e.g. giving up time to participate in research, filling in a form).

The assessment of whether the benefits of the research are balanced by any inconvenience, discomfort or potential harm to participants is central to the concept of ethical research. Ethical research is governed by the principles of justice, respect, beneficence and non-maleficence; essentially seeking to ensure that the research activity has valuable outcomes for individuals or communities and that the research participants’ rights are protected. Researchers must carefully assess and quantify the magnitude and probability of the risks to participants and the expected benefits to participants and others.

“*The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.*” (National Statement Chapter 1.6)

Sometimes researchers themselves may be subject to potential risks by conducting the research, for example by becoming distressed when interviewing those who have suffered trauma, and these potential risks should also be taken into consideration. A plan for managing any potential distress (which may, for example include a regular debriefing session with a supervisor or colleague) should be provided to the HREC with the ethics application.

**What are Risks?**

Burdens of research include not only risks but also the inconvenience or disruption to participants’ lives that may be caused by their participation. The National Statement identifies the following kinds of potential harms in research:

- “physical harms: including injury, illness, pain;
- *psychological harms:* including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;

social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;

economic harms: including the imposition of direct or indirect costs on participants;

legal harms: including discovery and prosecution of criminal conduct.

Where a person’s reactions exceed discomfort and become distress, they should be viewed as harms”. (National Statement, Chapter 2.1)

Risks to privacy should also be considered, for example in observational studies.

**Do the benefits justify the risks?**

“Research is ethically acceptable only when its potential benefits justify any risks involved in the research. Benefits of research may include, for example, gains in knowledge, insight and understanding, improved social welfare and individual wellbeing, and gains in skill or expertise for individual researchers, teams or institutions.

Some research may offer direct benefits to the research participants, their families, or particular group/s with whom they identify. Where this is the case, participants may be ready to assume a higher risk than otherwise. For example, people with cancer may be willing to accept research risks (such as treatment side-effects) that would be unacceptable to well people.” (National Statement, Chapter 2.1)

“Researchers are responsible for:
(a) designing the research to minimise the risks of harm or discomfort to participants;
(b) clarifying for participants the potential benefits and risks of the research; and
(c) the welfare of the participants in the research context.” (National Statement, Chapter 1.7)

When a research study involves risk of harm to participants, researchers must explain to the HREC how they propose to manage these risks and outline any strategies to mitigate them. For example, this may involve referral to counselling services. “……There should be clear protocols for dealing with distress that might be experienced by participants”. (National Statement, 3.1.12) Researchers working in a clinical setting should consult the guideline on Patient Recruitment.

**Minimising risks to non-participants**

Researchers should also consider the possible risks of discomfort or harm to those connected with participants. This may include the following situations:

- Where genetic results are being given to participants, which may impact the health of the individual or other relatives.
- Where a biography may include previously unknown information that could affect family and friends.
- Where research in a small community may lead to unfair discrimination or have effects on social cohesion, property values, or business investment.
Ways to minimise risks

- Provide complete information in the application regarding the experimental design and the scientific rationale underlying the proposed research, including the results of previous studies.
- Assemble a research team with sufficient expertise and experience to conduct the research.
- Ensure that the projected sample size is sufficient to yield useful results.
- Incorporate adequate safeguards into the research design such as an appropriate data safety monitoring plan, the presence of trained personnel who can respond to emergencies, and procedures to protect the confidentiality of the data (e.g., encryption, codes, and passwords).
- Ensure fully informed consent from all participants (where applicable).

Managing risks

When risks have been identified, gauged and minimised, and the research has been approved, the risks must then be managed. This requires that:

- researchers include, in their research design, mechanisms to deal adequately with any harms that occur; and
- a monitoring process is in place and carried out (see Chapter 5.5: Monitoring approved research in the National Statement).

The greater the risk to participants in any research for which ethical 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.

For more information please see Chapter 2.1 of the National Statement.