Austin Health a member of: Melbourne Academic Centre for Health

Ethics Risk Level Definitions

High risk research

High risk research is research in which there is any possibility of harms greater than discomfort, or research which is ineligible for low or negligible risk review (*National Statement on Ethical Conduct in Human Research (2007), Chapter 2.1*). Most clinical interventional research involving drugs or devices is high risk.

Potential harms in research may include:

- *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

Low and negligible risk research

Low risk research is 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. *Negligible risk research* is research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience (*National Statement on Ethical Conduct in Human Research (2007), Chapter 2.1*).

Discomfort can involve the 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. Where a person's reactions exceed discomfort and become distress, they should be viewed as harms. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

Negligible risk research generally aims to establish new knowledge about a disease by review of information that has already been collected and is stored at the local site only, or by collection of information via surveys or interviews.

There are a number of populations that may be vulnerable or require special consideration due to the circumstances and context of the research. Research involving these groups may not be eligible for low or negligible risk review, and should be assessed with reference to the National Statement on Ethical Conduct in Human Research (2007) and the Health Records Act 2001 (Vic) – Statutory

Guidelines on Research, and in collaboration with the Research Office, prior to submitting a low or negligible risk application.

Waiver of consent

A waiver of consent may be requested for a project that satisfies all required criteria as listed in the National Statement on Ethical Conduct in Human Research (2007), Chapter 2.3.10. A request for waiver of consent must be submitted for full HREC review via the high risk research submission process. Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. It is recommended that requests are discussed with the Research Office prior to submission.