Identifying low / negligible risk projects

The *National Statement on Ethical Conduct in Human Research* (section 2) defines low-risk as "research in which the only foreseeable risk is one of discomfort." Negligible risk is defined as "research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience." Research where the risk for participants is more than discomfort is not low-risk.

Beyond this, risk can be very difficult to define.

Risk is primarily an assessment of the harm that participants, researchers, or the university may be exposed to. Risk depends as much on the expertise of the researcher as it does on the content and context of the research. For instance, a simple project which involves measuring a person's height, weight etc and collecting a urine sample is regarded as low or negligible risk in a medical setting, whereas it may be higher risk in a non-medical setting. A psychologist using standard assessment instruments, a social researcher asking basic interview questions or an education researcher observing normal classroom practice, are also usually regarded as low-risk. Sometimes activities such as these can be higher risk. This is because the assessment of risk also depends on a number of wider factors such as:

- who is taking the measures and what level of training and expertise the person has
- what will be done with the information once collected
- whether individuals will be identifiable or whether only aggregate data will be used
- who will have access to the information that has been collected

There are no simple measures of risk that cover all situations. Risk is a judgment inherent in the overall context of research. Different people interpret harm and risk in different ways.

The HREC considers many types of harm / risk as part of its deliberations eg: physical, social, psychological, spiritual, privacy infringement, reputation, economic and others. Each is considered from the perspective of participants, researchers, the university and the public. The principles undergirding these considerations are in Section 2 of the *National Statement*.

In order to assist the HREC in its deliberations, projects are organised into two broad categories – higher and lower risk. Lower risk projects can be expedited through a sub-committee system and do not need to be reviewed by the whole committee. Higher risk projects will be reviewed by the full HREC.

The following is a list of areas considered to be higher risk. Applications in these areas will generally be reviewed by the full HREC. Researchers can assist the HREC and the speed of review by clearly identifying the level/s of risk inherent in proposed research.

Research that will usually be reviewed by the full HREC includes:

- Use of Databanks where individuals are identifiable (3.2)
- Interventions and therapies (eg psychological interventions or clinical therapies). Or research involving any physically invasive procedure (eg blood or body fluid collection, exercise regimens or physical examination), and which is not part of ordinary clinical management (3.3)
- Use of human tissue samples (3.4)
- Human Genetics or human genetic samples (3.5)
- Use of Human stem cells (3.6)
- Research with women who are pregnant (4.1)
- Research with the human foetus (4.1)
- Research with children and young people (4.2) other than in normal school activities research

- Research with people in dependent or unequal relationships (4.3)
- Research with people highly dependent on medical care or people unable to give consent (4.4)
- Research with people with a cognitive impairment, intellectual disability or mental illness (4.5)
- Research with people who may be involved in illegal activities (4.6)
- Research with Aboriginal and Torres Strait Islander people (4.7)
- Research conducted in other countries (4.8)

- Research on potentially sensitive or contentious issues (eg 2.1.5, 2.1.8)
- Research which places undue pressure or coercion on participants (2.2.9)
- Research where consent is not entirely voluntary or where participants may be unable or incapable of giving voluntary informed consent (2.2.12)
- Research where there is concealment, deception, partial disclosure or covert observation (2.3.1, 2.3.2)
- Research which collects or discloses personal information in a way that might involve a breach of a National Privacy Principle (as defined by the Commonwealth Privacy Act 1988)
- Research where there is any payment, gift or inducement, other than a reasonable reimbursement of participants for their participation (2.2.10, 2.2.11)
- Research which identifies people as belonging to a specific group (eg racial, sexual, socio-economic) *and* which may expose the person/group to discrimination or misrepresentation (2.1)
- Research which collects information, the disclosure of which outside the research could place participants at risk of criminal prosecution or civil liability or be damaging to their financial standing, employability, professional or personal relationships (4.6)
- Research which utilises any form of passive consent (2.3.1)
- Research which collects, uses or discloses information which may identify individuals but which is collected or used without their consent (2.3.5 – 2.3.8)
- Research where there are possible conflicts of interest e.g. a researcher is a member of or has a previous association with an organisation being studied; or a researcher has or has previously had the illness or condition being studied (5.4)
- Research using techniques such as questionnaires, interviews or surveys, where irrespective of the recording of the individual's identity, it might reasonably be expected that embarrassment, or psychological or spiritual harm could be caused to the participants (3.1)
- Research which causes or is likely to cause physical pain beyond mild discomfort (1.6 – 1.9)