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PROCEDURES FOR ASSESSMENT OF RISK IN RESEARCH PROPOSALS

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Purpose and Scope

The purpose of this document is to specify procedures for risk assessment of research proposals submitted to the Excelsia College Human Research Ethics Committee (HREC) for ethical approval. Assessment of risk balances the nature and degree of risk to all associated with the proposed research with potential benefits of the research, as specified in the National Statement (2007, updated 2013, chapter 2.1).

Responsibility

- Assessment of risk will be carried out by the Risk Assessment sub-committee of the HREC comprising the Chair, one current researcher, and one counsellor or lay person.

Categories and Definitions of Level of Risk

- The Risk Assessment sub-committee will assess the level of risk related to every research proposal using three categories: negligible risk, low risk, and greater than low risk.
- Negligible risk is defined as research where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.
- Low risk is defined as research where the only foreseeable risk is one of discomfort.
- Greater than low risk is defined as research where the risk, even if unlikely, is more serious than discomfort (National Statement 2.1.6 - 2.1.7).

Steps in Consideration of Risk

The Risk Assessment sub-committee will take steps to (a) identify the risks, if any; (b) assess the likelihood and severity of the risks, and c) identify whom (participants and/ or others) the risks may affect. In assessing the existence, likelihood, and severity of risks the Risk Assessment sub-committee will use available evidence from similar research domains. In the assessment of risk the sub-committee will consider participants’ perceptions of risks and benefits.

Review According to Level of Risk

- Negligible risk. Examples of research that might be considered negligible risk include research on collections of non-identifiable data, research where the only foreseeable risk is inconvenience, such as anonymous interviews or questionnaires requesting information about non-personal, factual data or opinion. Proposals deemed to be of negligible risk will then be reviewed in full by the Risk Assessment sub-committee.
- Low risk. Examples of research that might be considered low risk (where the only foreseeable risk is discomfort) include studies involving minor physical discomfort such as the monitoring of blood pressure, and studies occasioning minor emotional discomfort such as low levels of anxiety induced by an interview. Proposals deemed to be of low risk will also then be reviewed in full by the Risk Assessment sub-committee. In particular, the way the researcher plans to minimise participants’ discomfort will be evaluated.
• Greater than low risk. Research that involves risk greater than discomfort is likely to occasion harm. Examples of research that may occasion harm include the following from the National Statement (p 16):
  a. physical harms: including injury, illness, pain;
  b. 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;
  c. devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
  d. 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;
  e. economic harms: including the imposition of direct or indirect costs on participants;
  f. legal harms: including discovery and prosecution of criminal conduct.
  g. other harms: such as harm to participants’ families, harm to a small community as a result of inquiries into a particular sub-group, or harm resulting from research misconduct.

All research deemed as having greater than low risk for those involved will be referred to the full HREC for full risk assessment. In these cases the HREC will require researchers to weigh the risks against the potential benefits of the research, indicate those for whom benefits and risks will accrue, propose mechanisms to minimise risk, and develop a plan to monitor and manage the risks. Indicators of risk minimisation and risk management provisions will be evaluated, such as whether the researcher is providing participants with full information about potential risks, informing participants of their right to withdraw at any time, debriefing participants and providing referrals in the event of felt harm. After a complete risk assessment, the full HREC will then provide a comprehensive ethical review of proposals deemed to be greater than low risk.