Appendix A

National Statement on Ethical Conduct in Human Research 2023

5.1.8 Institutions may establish their own processes for ethics review of research or use the review processes of another institution or external ethics review body.

5.1.9 When considering accepting the outcome of another institution's ethics review process, including the review of an overseas review body, institutions should follow the guidelines in Chapter 5.5.

5.1.10 All research should be assessed by an institution for its level of risk, in accordance with the guidance on risk provided in Chapter 2.1. This risk assessment can be conducted by a designated committee or an individual who has relevant experience and knowledge.

5.1.11 If a research project is assessed as having more than low risk, it must be reviewed by an HREC. The HREC review should include consideration of any proposed approaches to minimising or mitigating any risks associated with the research.

5.1.12 To enable efficient and proportionate review of lower risk research, institutions should establish processes or pathways for review of this research. Examples of such processes or pathways include, but are not limited to:

(a) review by a designated committee or person(s) within an institution;

(b) review by a sub-committee, Chair or Deputy Chair of an HREC

(c) review at departmental level by the head of department or a committee of peers; and

(d) a defined process that enables acceptance of a review process external to the institution (see Chapter 5.5).

5.1.13 Institutions that establish non-HREC pathways for ethics review of lower risk research, must have the resources and capacity to carry out such review competently and professionally.

5.1.14 Where institutions establish non-HREC pathways for ethics review of lower risk research, that review must:

(a) be carried out by people who are familiar with the National Statement and have an understanding of

(i) the ethical issues that can arise in the research under review;

(ii) issues associated with the collection, use and management of data and information in research (see Chapter 3.1, Element 4);

(iii) the privacy guidelines that may apply to the research under review;

(iv) other legal standards that may apply to the research under review, such as legislation relating to guardianship or use of human biospecimens;

(b) be informed by guidance provided in other sections of the National Statement;

(c) include clear criteria for referring review to an HREC where risk that is greater than low risk is identified during non-HREC review.