

Does your study require HDEC review?

This flowchart summarises the definition of the scope of HDEC review in section 3 of the *Standard Operating Procedures for Health and Disability Ethics Committees*.

1. Main criteria

Will your research use or create a human gamete, a human embryo or a hybrid embryo?
yes → **Your study must be approved by the Ethics Committee on Assisted Reproductive Technology (www.ecart.health.govt.nz).**
no para 20

Does your study involve human participants recruited in their capacity as:
 • consumers of health and disability support services, or
 • relatives/caregivers of such consumers, or
 • volunteers in clinical trials?
yes → **Your study must be approved by the Ethics Committee on Assisted Reproductive Technology (www.ecart.health.govt.nz).**
no para 27.1

Does your study involve the use, collection or storage of human tissue (as defined by the Human Tissue Act 2008)?
yes → **Your study must be approved by the Ethics Committee on Assisted Reproductive Technology (www.ecart.health.govt.nz).**
no para 27.2

Does one or both of the exceptions at paras 27.2.1 and 27.2.2 of the SOPs apply to this use, collection or storage?
yes → **Your study must be approved by the Ethics Committee on Assisted Reproductive Technology (www.ecart.health.govt.nz).**
no

Does your study involve the use or disclosure of health information (as defined by the Health Information Privacy Code 1994)?
yes → **Your study must be approved by the Ethics Committee on Assisted Reproductive Technology (www.ecart.health.govt.nz).**
no para 27.3

Does one or both of the exceptions at paras 27.3.1 and 27.3.2 of the SOPs apply to this use or disclosure?
yes → **Your study must be approved by the Ethics Committee on Assisted Reproductive Technology (www.ecart.health.govt.nz).**
no

2. Exemptions

Does your study involve a medical device that is (or would be) classified as a low risk (class I) medical devices by Australia's Therapeutic Goods Administration?
yes → **YES. HDEC review is required for your study.**
no para 28

Is your study a minimal risk observational study?
yes → **YES. HDEC review is required for your study.**
no paras 29, 30

Is your study an audit or related activity?
yes → **YES. HDEC review is required for your study.**
no para 31

Does your audit or related study involve the use, collection or storage of human tissue without consent?
yes → **YES. HDEC review is required for your study.**
no

Does a statutory exception to the need to gain informed consent apply to this use, collection or storage?
yes → **YES. HDEC review is required for your study.**
no

Is your study an observational study that is to be conducted for the purposes of an educational qualification at Masters level or below?
yes → **YES. HDEC review is required for your study.**
no para 32

YES. HDEC review is required for your study.

NO. HDEC review is NOT required for your study.

3. Inclusions

Does your study involve the use of Guthrie cards?
yes → **YES. HDEC review is required for your study.**
no para 33.1

Is your study:
 • funded by the Health Research Council, and
 • not able to be reviewed by an HRCEC-approved university ethics committee?
yes → **YES. HDEC review is required for your study.**
no para 33.2

Does your application involve the establishment or maintenance of a tissue bank?
yes → **YES. HDEC review is required for your study.**
no para 33.3