

# 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** → [Red dashed box: 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** → [Red dashed box]  
**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** → [Red dashed box]  
**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** → [Red dashed box]  
**no**

Does your study involve the use or disclosure of health information (as defined by the Health Information Privacy Code 1994)?  
**yes** → [Red dashed box]  
**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** → [Red dashed box]  
**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** → [Red dashed box]  
**no** para 28

Is your study a minimal risk observational study?  
**yes** → [Red dashed box]  
**no** paras 29, 30

Is your study an audit or related activity?  
**yes** → [Red dashed box]  
**no** para 31

Does your audit or related study involve the use, collection or storage of human tissue without consent?  
**yes** → [Red dashed box]  
**no**

Does a statutory exception to the need to gain informed consent apply to this use, collection or storage?  
**yes** → [Red dashed box]  
**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** → [Red dashed box]  
**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** → [Red dashed box]  
**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** → [Red dashed box]  
**no** para 33.2

Does your application involve the establishment or maintenance of a tissue bank?  
**yes** → [Red dashed box]  
**no** para 33.3