RESEARCH

RATIONALE/ PURPOSE

The Northland District Health Board (Northland DHB) recognises the importance of research as a scientific basis for clinical practice. As a result of research, patient care may be improved by development of new methods of treatment, theories and solutions to problems. In order to protect patients from undue risk and deprivation of personal rights and dignity, ethical approval and informed consent are required.

POLICY STATEMENT

All research conducted in the Northland DHB must be conducted with the knowledge of the Northland DHB and must meet all the requirements of the Health and Disability Ethics Committees (HDECs) from which approval may have been obtained, including all stipulations regarding informed consent.

SCOPE

All health and disability research must comply with established ethical standards. The Health and Disability Ethics Committees (HDECs) check that proposed health and disability research meets or exceeds established ethical standards determined by the National Ethics Advisory Committee (NEAC). These ethical standards are contained in:

- Ethical Guidelines for Observational Studies
- Ethical Guidelines for Intervention Studies.

These standards apply to **all** health and disability research, regardless of whether HDEC review is required for that research.

Not all health and disability research requires HDEC review. The complete definition of the scope of HDEC review is contained at section 3 of the SOPs for HDECs. View the summary flowchart on Page 3.

A study is likely to require HDEC review if it involves:

- **Human participants** recruited in their capacity as:
  - consumers of health or disability support services, or
  - relatives or caregivers of such consumers, or
  - volunteers in clinical trials; or
- **Human tissue**; or
- **Health information**.

DEFINITIONS

A systematic investigation designed to develop or contribute to knowledge. Research may include the evaluation of clinical practice to determine its safety and efficacy.

METHOD

1. Whether a research proposal requires HDEC approval or not, a locality assessment must be undertaken to review all research conducted at Northland District Health Board. Locality Assessments will consider resource implications, suitability of the local researcher and research environment, and cultural issues.

2. A Locality Assessment meeting will include the Chief Medical Officer, a representative of the Maori Health Directorate, and the researcher; the meeting is organised by the Chief Medical Officer.

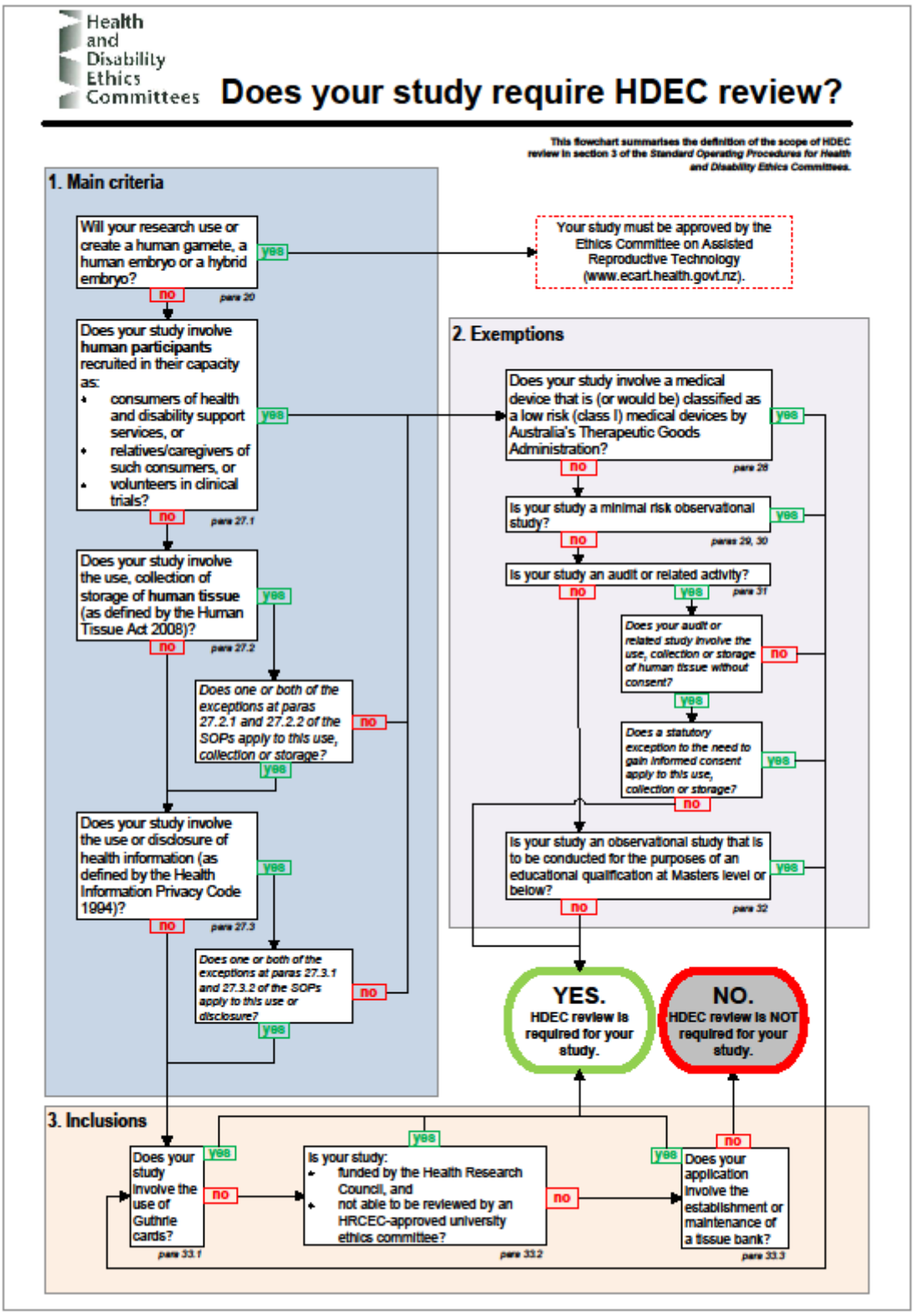
3. Prior to the locality assessment meeting, the research proposal and any other relevant information (participant and other consents, information sheets, questionnaires, approvals, etc) should be submitted to the Chief Medical Officer for review and distribution to those attending the locality assessment meeting.

4. No research project can be undertaken until it has received locality assessment approval from the Chief Medical Officer. The research should be performed according to the proposal approved by the Locality Assessment. The researchers must adhere at all times to the proposal's stipulations regarding consent procedures, cultural sensitivity and provision of information to participants.

5. The Chief Medical Officer will keep a database of all research activities at Northland DHB and the researcher should provide a report to the CMO outlining the outcome of the research.

References:

- Code of Health & Disability Services Consumers' Rights 1996, Right 6 & 9
- Health & Disability Ethics Committees http://ethics.health.govt.nz/ethical-standards-health-and-disability-research


Health and Disability Ethics Committees
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
no
para 27.1
Does your study involve the use, collection of storage of human tissue (as defined by the Human Tissue Act 2008)?
yes
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?
no
yes
Does your study involve the use or disclosure of health information (as defined by the Health Information Privacy Code 1994)?
yes
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?
no
yes
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
no
para 28
Is your study a minimal risk observational study?
yes
no
paras 29, 30
Is your study an audit or related activity?
no
yes
para 31
Does your audit or related study involve the use, collection or storage of human tissue without consent?
no
yes
Does a statutory exception to the need to gain informed consent apply to this use, collection or storage?
yes
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
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
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
no
para 33.2
Does your application involve the establishment or maintenance of a tissue bank?
yes
no
para 33.3