

## Part 5: Use of Human Tissue

To be completed if the research involves collection of human tissue.  
 (See guidelines page 28 for definition.)

1.1 Provide details, eg, type, number of samples, total volume to be obtained.

1.2 Will consent, or has consent, been obtained?  
 If yes, proceed to 1.6

Yes       No

1.3 If consent is not able to be obtained for use of tissue, how consistent is the proposed use of tissue with the original consent for the use of the tissue?

1.4 State reasons why informed consent cannot be obtained or why it would not be desirable or possible to do so.

1.5 State the public good associated with continuing the research without the consent of the individual.

1.6 How was or will the tissue be obtained (including frequency and scope of consent that was or will be given)?

1.7 What are the current use(s) of the tissue and any intended or foreseeable future uses of that tissue (including the scope of consent that was or will be given) and why is it necessary?

1.8 If access is to be granted to third parties, how will that be done?

1.9 How will tissue be stored, eg, identified/ de-identified/anonymised, length of time, means of storage and labelling, security, the responsible individual or organisation?

1.10 How will the tissue be disposed or returned?

1.11 Is genetic analysis to be carried out (see also Part 6)?

1.12 Can the participant request the tissue to be withdrawn from the research? If so, how and at what point?

1.13 Will personal and health information or sensitive information be linked to the tissue? If yes, are procedures in place to recontact participants or their clinician to provide clinically relevant information if it arises.

1.14 What safeguards will be in place to ensure that the tissue will not be vulnerable to unethical use.

2. If there any additional safeguards in place not covered in 1.1–1.14 above please give details.

3. Will the human tissue involved in the research project be stored for later use in a future study? If yes, please give details.  Yes  No

Is this covered by distinct informed consent?  Yes  No

4. Will any human tissue samples or the information derived from them go out of New Zealand? If yes, complete the following questions.  Yes  No

4.1 If so to what organisation/s and how will they be transferred?

- 4.2 What governance structures, procedures and processes does this organisation have to ensure the participant's choices are respected ie storage facilities, control of access, appropriate disposal methods?

- 4.3 How will tissue be stored, eg, identified/de-identified/anonymised, length of time, means of storage and labelling, security, the responsible individual or organisation?  
(If different from 1.9.)

- 4.4 How long will the tissue and/or data be stored and what will happen at the end of this time?

- 4.5 If identified tissue and/or data is stored, will participants be able to request that their tissue be returned to New Zealand or request confirmation that their tissue and related information has been destroyed?

- 4.6 What appropriate ethical safeguards will be in place?

- 4.7 Will all future use of the tissue and the information derived from it be subject to review by an ethics committee approved by the New Zealand Health Research Council of New Zealand?  Yes  No

If **no**, provide confirmation from the organisation storing the tissue or the information derived from it, that it has protocols in place to ensure that any future use will have ethical and scientific review by a committee or institutional review board that conforms to the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences and World Health Organization 2002).