

Part 6: Genetic Section

To be completed if the research involves products made by genetic modification, genetic analysis or clinical genetics.

1. Have you read, and does your research comply with, the Guidelines *Ethical Considerations Relating to Research in Human Genetics*? Yes No

Applicant responses to these questions may initiate a request from the Ethics Committee for more detailed information.

2. Will the study involve administration of any products that include the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory)? Yes No

Refer to Appendix 2 in the Guidelines.

3. If yes to 2, has approval from GTAC been obtained? Yes No

If yes, please describe.

4. Is ERMA approval required/obtained? Yes No

5. Information on samples:

5.1 Is tissue or body fluid samples for genetic analysis to be taken for:

(Tick all boxes which apply)

- | | | | | |
|--|--------------------------|-----|--------------------------|----|
| a) immediate analysis | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| b) storage for future analysis | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| c) analyses outside New Zealand | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| d) analyses by individuals or organisations other than the study investigators | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

5.2 Describe processes for storage and disposal of samples taken for genetic analyses.

5.3 Up to what point would withdrawal of the sample or the data at the request of the participant be possible?

6. Is personal and health information from individuals and genetic analysis to be linked?

Yes No

If yes, please describe how confidentiality will be assured.

7. Are samples to be obtained from Māori?

Yes No

If yes, please describe any relevant issues additional to section 5.1.

8. Will the study involve participant contact with a clinical geneticist?

Yes No

If yes, please provide:

- the name of the clinical geneticist(s) who have agreed to be involved, and
- describe the purpose.

9. Will participants be advised of any individual results?

Yes No

If yes, please detail the process for advising results, including provision of genetic counselling if appropriate.

If no, explain why not.