

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
- b) storage for future analysis
- c) analyses outside New Zealand
- d) analyses by individuals or organisations other than the study investigators

Yes

No

Yes

No

Yes

No

Yes

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.