

**Ethics Committee on Assisted Reproductive Technology
Application Form for Ethics Approval of a Research Project**

This application form is only valid for 'human reproductive research' which is defined in the Human Assisted Reproductive Technology (HART) Act 2004 as 'research that uses or creates a human gamete, a human embryo, or a hybrid embryo'. Research that does not fall within this category should seek approval from a Health and Disability Ethics Committee.

Please note:

- All sections of the application are to be word processed - text boxes for answers will expand as you type.
- All headings are to be included in your application. If you consider a section or part of a section does not apply to your proposal, please explain why.
- Additional relevant information that the headings do not allow for may be appended.
- Copies of information and consent forms for participants are to be attached. These should be consistent with the information provided in the application.
- Please use plain English.

Completed applications are to be sent to:

Secretariat
Ethics Committee on Assisted Reproductive Technology
PO Box 5013
WELLINGTON

PART ONE: General Information

1. Project title.

2. Name, address, telephone, and fax number of principal researcher.

3. Principal researcher's relevant qualifications and experience.

4. Names and relevant qualifications and experience of all researchers involved in the project.

5. Names and relevant qualifications of any researchers who are involved in any part of the project to gain training in a particular technique (include details of the technique).

6. List any other ethics committees to which this project has been submitted and attach their letter of approval where available.

7. Location of the project.

8. Proposed starting date of the project.

9. Proposed finishing date of the project.

10. Give a brief summary of the study.

PART TWO: Project Details

11. Describe the hypothesis/research question(s).

12. Describe the specific aims of the project.

13. Explain the scientific basis of the project.

14. Give the name of a person or organisation that has scientifically assessed this project. A copy of the report should be attached.

15. Explain the protocols and procedures involved. Identify those that are new in terms of their use in this project and describe, with references to literature, their tested use in other countries. Identify the procedures that are experimental, and refer to relevant literature.

16. Explain your understanding of the legal implications of the project for all those involved.

17. Provide, in summary form, a literature review, including details of references and documentation of all data referred to in support of this application.

PART THREE: Participants

18. State the number of participants you intend to recruit.

19. Describe how potential participants will be identified.

20. Describe how participants will be recruited.

21. Describe where and when potential participants will be approached.

22. State who will make the initial approach to potential participants.

23. Is there any special relationship between the participants and the researchers?
(eg. doctor/patient)

24. Describe the inclusion/exclusion criteria for participation in the project. (Do not include identifying information)

25. If randomisation is used, describe how this will be done.

Form updated 26/05/06

26. Explain counselling arrangements for participants, including professional training of counsellors, their availability before, during, and after the project, and fees and arrangements for payment of these.

PART FOUR: Consent

27. By whom, and how, will the project be explained to potential participants?

28. When and where will the explanation be given? (Include the information sheet for participants with your application)

29. Will a competent interpreter be available, if required?

30. How much time will be allowed for the potential participant to decide about taking part?

31. Will the participants be capable of giving consent themselves?

32. In what form (written or oral) will consent be obtained? (Include a copy of the written consent form with your application)

33. Are participants in clinical trials to be provided with a card confirming their participation, medication and contact phone number of the principle investigator?

PART FIVE: Study Design

34. Describe the study design.

35. State how many visits of participants this project will involve. Give also an estimate of total time involved for participants.

36. Describe any methods for obtaining information. Attach questionnaires and interview guidelines.

37. Who will carry out the research procedures?

38. Where will the research procedures take place?

39. If human specimens (for example, gametes or embryos) are to be obtained, state type, use, access to, frequency, number of samples, total volume, means of storage and labelling, length of proposed storage, and method of disposal. Describe how they are to be obtained, and the consent to be sought in relation to their use. Explain what you propose to do with human specimens of any kind that are extraneous to the project, and the consent to be sought.

40. Will data or other information be stored for later use in a future study? If yes, explain how.

Form updated 26/05/06

41. State whether samples will be transported out of New Zealand. If so, where, and for what purpose?

PART SIX: Risks and Benefits

42. Explain the benefits of the project to research participants taking part.

43. Explain the physical and psychological risks and/or side affects to participants or third parties. Describe what action will be taken to minimise any such risks or side effects.

44. Give details of monitoring arrangements for the project. Describe what arrangements will be made for monitoring and detecting adverse outcomes.

45. Describe any drugs to be used, including side-effects, availability, responsibility for costs, indemnity arrangements for participants in case of injury, misadventure, etc. (You are responsible for negotiating indemnity cover with drug companies)

46. Describe in detail any radioactive materials to be used, including dose estimates and risk estimates.

47. Describe the indemnity cover available to participants and the researcher, excluding that in relation to drugs, in case of injury, etc.

PART SEVEN: Expected Outcomes or Impacts of Research

48. Describe the potential significance of this project for improved healthcare.

49. Describe the potential significance of this project for the advancement of knowledge.

50. Give details of how you intend to disseminate the findings from the project, including information to be given to participants.

51. Is it intended to inform the participants GP of individual results of the investigations, and their participation, if the participant consents?

PART EIGHT: Genetics

52. Does this research involve any gene or genetic studies?

53. Does the proposed research study involve the use of products made by genetic modification, analyses of DNA, or clinical genetics?

54. Are tissue or body fluid samples for DNA analysis to be taken for:

(a) immediate analysis;

(b) storage for future analyses;

(c) analyses outside New Zealand;

(d) analyses by individuals or organisations other than the study investigators.

55. Describe processes for storage and disposal of samples taken for DNA analyses.

56. Up to what point would withdrawal of the sample or the data (at the request of the participant) be possible?

57. Is personal and health information from individuals and DNA analysis to be linked? If yes, please describe how confidentiality will be assured.

58. Will the study involve participant contact with a clinical geneticist? If yes, please provide the name of the clinical geneticist, and describe the purpose of their involvement.

59. Will provision be made where appropriate for genetic counselling? If yes, please describe the process.

PART NINE: Budget and Use of Resources

60. How will the project be funded?

61. Does the researcher, the host department or the host institution, have any financial interest in the outcome of this research?

62. Will the researcher personally receive payment according to the number of participants recruited, or a lump sum payment, or any other benefit to conduct the study?

63. What other research studies is the lead investigator currently involved with?

64. Does the study involve the use of healthcare resources? If yes, please specify.

65. What effect will this use of resources have on waiting list times for patients? i.e. for diagnostic tests or for standard treatments.

66. Will there be any financial cost to the participant? Give examples, including travel.

67. Will any payments be made to participants or will they gain materially in other ways from participating in the project? If yes, please supply details.

PART TEN: Ethical and Cultural Issues

68. Explain what you consider to be ethical issues involved in the project, including any potential conflicts of interest. Include in your explanation how you have addressed these ethical issues.

69. Explain how you have addressed cultural issues, including issues pertinent to the Treaty of Waitangi, in relation to all aspects of the research project.

PART ELEVEN: Confidentiality

70. Provide details of arrangements for the protection of information, using these headings:

(a) Record keeping.

(b) Procedures for ensuring confidentiality of the records that are kept.

(c) Access to records:

(i) by the individual subject of the record.

(ii) by researchers involved in the project.

(iii) by third parties (if any).

(d) Storage of records.

(e) Retention of the records (including details as to whether records will be retained in a form in which individuals can be identified).

PART TWELVE: Declaration by Principal Researcher

Please read and sign this declaration:

The information supplied in this application is, to the best of my knowledge and belief, accurate. I understand that if the protocol for this project changes in any way I must inform the ethics committee that has formally been assigned oversight of such projects.

Signature of Principal Researcher: _____

Date: _____

The information requested in this application is for the purposes of the Ethics Committee on Assisted Reproductive Technology, which is considering your application for ethics approval. The Committee will endeavour to maintain confidentiality of this information in accordance with the Privacy Act 1993. This may result in disclosure of information for a purpose or a directly related purpose with which this application is concerned but is limited in terms of the Official Information Act.

Checklist of Information to be included with the Application

- Information sheets for participants
- Consent forms for participants
- Scientific evaluation report