

Gene Technology Advisory Committee

(September 2018)

Terms of Reference

The Gene Technology Advisory Committee (GTAC) is to review for the purposes of seeking an exemption under Section 30 of the Medicines Act (1981)* or as required by an approved ethics committee or the HRC or any of its committees for emerging clinical technologies such as:-

1. Proposals for clinical trials which include the introduction of nucleic acids (genetically manipulated or synthesized in the laboratory) or genetically manipulated microorganisms, viruses or cells into human subjects for the purpose of gene therapy, cell marking or cell therapy.
2. Proposals for clinical trials in which the introduction of nucleic acids (genetically manipulated or synthesized in the laboratory), or genetically manipulated microorganisms, viruses or cells is designed to stimulate an immune response against the subject's own cells, as in the treatment of certain cancers.
3. Proposals for clinical trials in which cells from animal species are transferred into humans for the purpose of disease treatment i.e. xenotransplantation.
4. Proposals for clinical trials in which human nucleic acids have been introduced into the genome of an animal species; including genetically manipulated microorganisms, for the purpose of developing products to be used for either disease prevention or treatment in human subjects.
5. Proposals for clinical trials involving vaccines in which nucleic acids (genetically manipulated or synthesized in the laboratory) or genetically manipulated microorganisms, viruses or cells have been introduced to stimulate an immune response to antigenic determinants of an infectious agent.

Membership composition

1. Up to eight members appointed on the recommendations of the Council, these individuals are responsible for proposal reviews.
2. The Chief Executive of the Health Research Council.

Process for appointment of committee members

The Chief Executive formally invites the proposed member (recommended by the Committee and supported by Council) to accept appointment to the Committee.

| Current Membership | Date Appointed | Expertise | Location |
|--|---|--|-----------------|
| Professor Ian Morison (Chair) | 9.1999 | Haematology/ Molecular genetics | Dunedin |
| Associate Professor Lynley Anderson | 10.2015 | Ethicist | Dunedin |
| Professor Ian Alexander | 10.2015 | Molecular medicine/Clinical genetics | Sydney |
| Professor Peter Browett | 09.2018 | Haematology | Auckland |
| Professor Stephen Chambers | 06.2009 | Infectious disease expert | Dunedin |
| Dr Jade Hollis-Moffatt | 10.2015 | Māori member | Dunedin |
| Professor Stephen Robertson | 02.2005 | Clinical Geneticist | Dunedin |
| Associate Professor Richard Robson | 08.2000 | Clinical trials and Chair of SCOTT | Christchurch |
| <i>Ex Officio Member</i> Professor Kath McPherson | 10.2015 | Chief Executive HRC | Auckland |
| Secretary: | Ms Lana Lon | | |
| Quorum: | 5 | | |
| Meetings per annum: | as required | | |
| Reports to: | Council | | |
| Established by: | Council – 1995, 1 st meeting 1 February 1996 | | |
| Reviewed: | October 2015 | | |
| Disbanded: | | | |