# Genetic Technology Advisory Committee approval

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.

(a) Proposals for clinical trials which include the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated microorganisms, viruses or cells into human subjects for the purpose of gene therapy or cell marking.

(b) Proposals for clinical trials in which the introduction of nucleic acids (genetically manipulated or synthesised 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.

(c) Proposals for clinical trials in which nucleic acids either from or within cells from animal species are transferred into humans for the purpose of disease treatment i.e. xeno-transplantation.

(d) 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.

(e) Proposals for clinical trials involving vaccines in which nucleic acids (genetically manipulated or synthesised 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.

The definition of medicine given in Section 3 of the Medicines Act 1981 is "any substance or article that is manufactured, imported, sold or supplied wholly or principally - for administering to one or more human beings for a therapeutic purpose".

Section 4 defines a therapeutic purpose as:

(a) treating or preventing disease; or

(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition, or

(c) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily and whether by reducing or postponing, or increasing or accelerating the operation of that function, or in any other way.

If the "medicine" is to be used for the sole purpose of obtaining clinical and scientific information, the investigator will be required to seek permission for its use under Section 30 "Exemption for Clinical Trial" of the Medicines Act (1981). Approval under Section 30 is given by the Director-General of Health on the recommendation of the HRC.

For pharmaceutical-type medicines, the recommendation to the Director-General of Health is made by SCOTT.

## *1. Application process for GTAC approval*

To make an application, the applicant must complete and sign the "Application for approval of a clinical trial under Section 30 of the Medicines Act 1981 form" (see *Forms and templates* available at Medsafe). The applicant seeking an approval under Section 30 of the Medicines Act will also be required to lodge a fee per application payable to Medsafe (for a list of current fees, see *Schedule of fees* available at Medsafe). In the case of public good research, this may be waived by the Director-General of Health on the recommendation of the HRC.

The application will be reviewed by GTAC which will provide the Director-General of Health with its recommendation as to whether the trial be approved.

If a proposal involves materials which originate from the USA, the investigator will be required to meet the regulatory requirements of the Food and Drug Administration (FDA) to obtain an export certificate. The Director-General of Health will not give approval for a Section 30 exemption until the appropriate documentation has been received and has been approved by the Ministry of Health.

Approval from an approved ethics committee cannot be sought until the Director-General of Health has received a recommendation from GTAC that the trial under review be approved.

When the Director-General of Health has received recommendations for approval from GTAC and an approved ethics committee, written approval for an exemption under Section 30 of the Medicines Act (1981)may be given. Only then can the investigator proceed with the trial. Investigators should also ensure that they meet all the requirements of their host institutions with respect to making applications to gain approval from GTAC, relevant ethics committees, bio-safety committees and Environmental Protection Authority.

See the following website for more information on Application for approval of a clinical trial under section 30 of the Medicines Act:
http://www.medsafe.govt.nz/regulatory/guidelines.asp#Part11.

## *2. Criteria for GTAC approval*

GTAC will review applications to establish whether:

(a) there is adequate scientific evidence from laboratory and experimental studies in animals to allow a trial in humans to proceed;

(b) the proposed trial will provide a clinical benefit and scientifically useful information particularly in relation to safety and efficacy;

(c) there is adequate information on the safety and toxicity of the materials to allow them to be used in a trial in humans;

(d) the investigators have the qualifications, experience and track record to conduct the proposed trial;

(e) the investigators have conducted appropriate risk assessment of their proposed procedures.

GTAC will provide the Director-General of Health with a written report and a recommendation as to whether the proposed study should be approved, declined or deferred.