

SCOTT is a HRC committee, first founded in 1969, with Terms of Reference now based on the NZ Medicines Act 1981

Role:

1. To assess whether or not the proposed clinical trial of a medicine will provide clinically and scientifically useful information, particularly in relation to the safety and efficacy of the agent
2. To assess the ability of the trialists to conduct the trial
3. To attempt to improve trial design and the quality of clinical pharmacological research with particular respect to:
 - a) Power analysis and the need for trialists to satisfactorily justify their choice of numbers of subjects to be recruited to a trial
 - b) Efficacy and the need to establish criteria for clearly determining effectiveness of treatment
 - c) Toxicity
4. To review the merit of clinical trials submitted to the HRC for research funding when requested by the Chief Executive

Medicines Act 1981 Section 30

Process that a study sponsor or manufacturer must follow to obtain an exemption from Sections 20 and 24 of the Act for medicines required for use in clinical trials.

Also describes the obligations of the Sponsor:

- reporting adverse events
- progress of the study

An exemption is required for investigational and comparator medicines which:
are new chemical entities and/or
are new or different dose forms, delivery systems, or formulations of medicines, which do not have consent to market in NZ

Other requirements relating to New Zealand Health and Disability Ethics Committee relate to all clinical trials, regardless of whether they are trials that require approval under Section 30 of the Medicines Act.

The application and approval process for clinical trials under Section 30 of the Act is administered by Medsafe.

Approvals are issued by Medsafe under a delegation from the Director-General of Health.

All clinical trials in New Zealand are expected to be conducted in accordance with internationally accepted Good Clinical Practice standards.

Medsafe administers a self-certification scheme for clinical trial sites that have patients in residence

SCOTT considers applications and makes recommendations on whether trials should be approved.

Not usually included in SCOTT remit: bioequivalence studies (abbreviated approval), medical devices, trials using only approved medicines, trials with new organisms (GTAC)

Current Members of SCOTT:

Dr. Murray Barclay, Christchurch
Assoc Prof. Carl Burgess, Wellington
Dr. Stephen Duffull, Dunedin
Dr. Chris Frampton, Christchurch
Dr. Sisira Jayathissa, Wellington
Dr. Damian Pethica, Auckland
Dr. Richard Robson, Chair, Christchurch
Prof. Paul Smith, Dunedin
Mr. Trevor Speight, Auckland
Prof. Ian Tucker, Dunedin

SCOTT process

- Application lodged with SCOTT and MOH including application form, trial protocol, investigator brochure, CV's, information and consent forms
- Payment of \$6,525
- Application sent to 2 reviewers
- Return within 14 days
- Chairman independent review
- Chairman collates a response

SCOTT outcomes and timelines

Year 1 July-30 June	2011	2010	2009	2008
Number of applications	120	97	83	119
Mean time taken to review (days)	12.5	12.6	13.2	12.2
Recommended for:				
Approval without comment	92	77	53	93
Approval with comment	15	10	25	21
Trial not initially approved pending further clarification	12	8	4	3
Trial not approved	1	2	1	2

NZ Clinical Trials Showcase Sep 21st 2011
Standing Committee on Therapeutic Trials (SCOTT)

On-line information:

<http://www.medsafe.govt.nz/regulatory/clinicaltrials.asp>

<http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott>

<http://www.hrc.govt.nz/sites/default/files/SCOTT%20TOR.pdf>