Standing Committee on Therapeutic Trials

Health Research Council of New Zealand
Te Kaunihera Rangahau Hauora o Aotearoa

(December 2017)

Terms of Reference

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 triallists 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 triallists 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 Council for research funding when requested by the Chief Executive (Refer to HRC Council minutes April 1993).

Membership Composition

1) Up to seven members appointed on the recommendation of the Council, these individuals are responsible for proposal reviews.
2) The Chief Executive of the Health Research Council.
3) A biostatistician be included, not as a full-time member, but as someone to consult as appropriate.
4) A representative to be appointed on the recommendation of the Pharmaceutical Society of New Zealand.
5) A nominee of the Ministry of Health attends the AGM for liaison purposes.

Process for Appointment of Committee Members

The Chief Executive formally invites the proposed member recommended by the Committee and confirmed by Council (Refer to Executive minutes August 1992).

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Current Membership	Date Appointed	Location
Associate Professor Richard Robson (Chair)	10.1990	Christchurch
Clinical Professor Murray Barclay	09.1999	Christchurch
Emeritus Professor Carl Burgess	06.1998	Wellington
Dr Matthew Dawes	01.2013	Auckland
Professor Stephen Duffull	10.2009	Dunedin
Professor Chris Frampton	09.1997	Christchurch
Dr Sisira Jayathissa	10.2009	Wellington
Dr Damian Pethica	10.2003	Auckland
Professor Paul Smith	09.1997	Dunedin
Mr Trevor Speight	1993	Auckland
Professor Ian Tucker	08.1992	Dunedin
Dr Chris Wynne	01.2013	Christchurch
Ex Officio Members		
Chief Executive, HRC	05.2007	Auckland
Dr Alexander Bolotovski	05.2007	Wellington

Quorum: 5
Meetings per annum: 1

Committee Fees and Allowances

Meeting fees and travel expenses for Committee members in accordance with standard practice. For each trial assessment members receive an allowance of $320, and the Chair $400.

Ministry of Health Payment

HRC receives from the Ministry of Health $2590.00 GST exclusive per trial.

The fees for two or more clinical trial applications received at the same time for the same product will be:

> full fee for the first trial application - half of the full fee for each of the extra applications.

In such cases, payment to SCOTT will be $2590 for the first trial application, $1295.20 for each additional application (Refer Variation 1 of the Agreement for services provided by the HRC pursuant to Section 30 of the Medicines Act 1981 dated 31 May 2012 (dated 1 May 2015)).

The suggested fee structure for reimbursement to SCOTT assessors was approved for one year with a report back to the Council concerning the number of applicants reviewed by each assessor in the period 1 September 1991 to 31 August 1992 (Refer to HRC Council minutes November 1991).

Explanatory Notes

Operates under Section 30 of the Medicines Act* to assess clinical trial applications on behalf of the Director-General of Health (see Terms of Reference 1 - 3 above). The SCOTT acts on an advisory committee to the Ministry of Health, with delegated authority from the HRC. This is essential in order to expedite the process of assessment of clinical trial protocols to meet the time frame required under the Medicines Act.

Where appropriate SCOTT reviews clinical trials submitted to the HRC for funding, providing assessment in areas not necessarily addressed by the Referees and Assessing Committees. Each application is reviewed by three assessors, one of whom is the SCOTT Chair, who also prepares the report (Refer Dr Colin Geary's letter, 11 February 1992).

Council recommended that the Research Committees develop a process to determine which clinical trials are sent to the HRC for funding are sent to SCOTT and to make recommendations on the issues of remuneration for their review (Refer to HRC Council minutes December 1992).

Reports to:	Council and MoH
Established by:	25-26 November 1991
Reviewed:	September 1994
Disbanded:	

**Note: Terms of Reference to be reviewed after the Trans-Tasman Review of Clinical Trials*