31 May 2024 - Public Consultation Brief – SCOTT Terms of Reference

For stakeholders and public providing feedback on the draft Terms of Reference proposed by the Health Research Council of New Zealand (HRC) for its Standing Committee on Therapeutic Trials (SCOTT).

Introduction

The HRC established SCOTT in 1991 to deliver part of the HRC's function under section 30 of the Medicines Act 1981. The HRC is now seeking stakeholder and public feedback on new draft Terms of Reference for SCOTT.

The draft Terms of Reference propose substantial changes to the way in which SCOTT functions, including how SCOTT formulates recommendations on behalf of the HRC to provide to the Director-General of Health regarding applications for approval of clinical trials of new medicines in New Zealand under section 30 of the Medicines Act.

Objectives of reform

The draft Terms of Reference aim to apply principles of modern regulatory practice to SCOTT's decision-making and achieve the following.

- Clarify the broad principles and considerations that govern SCOTT decisions on whether to recommend approval of a clinical trial to the Director-General of Health (noting that these are intended to dovetail with substantive guidelines issued by Medsafe as delegate of the Director-General of Health).
- Streamline SCOTT decisions on low-risk applications and devote more resource to applications where this is justified by risk, complexity or technical expertise required.
- Respond to the current regulatory workload (in terms of volume and type of applications for approval of clinical trials) and continue to provide recommendations to inform the Director-General of Health's decision on each application within 45 days.
- Provide for rational resourcing of SCOTT functions.
- Provide for ongoing SCOTT membership, ensuring there are sufficient members with the technical expertise and experience to competently and efficiently assess the types of clinical trial applications received.
- Provide for a secretariat to SCOTT, ensuring that clinical trial applications are appropriately classified (in terms of complexity), allocated to qualified SCOTT members for consideration, and that any conflicts of interest are identified and managed.

HRC's goal is that the draft Terms of Reference will come into effect on **1 January 2025.**

Summary of impact of reform

Key changes proposed by the draft Terms of Reference include:

- Changes to how SCOTT is constituted as a committee including expansion of membership, clarification of expertise requirements, roles and responsibilities, and the introduction of terms and practices related to appointments.
- Formal provision by HRC of Secretariat support to SCOTT, including allocation of applications to panels for assessment and management of conflicts of interest.
- Changes to categorisation of applications for approval of clinical trials and provision for varied decision-making processes by SCOTT panels for arriving at a recommendation to the

Director-General of Health, depending on the risks and complexity of the proposed trial. This new categorisation of applications is summarised in the following table.

Category	Description*	Recommendation Process*	Terms of Reference section(s)
Deemed approvable	Trial of bioequivalence to IMP** already approved in NZ	Recommended as approvable without SCOTT review of individual applications	8.1.2
Standard	All trials that do not meet criteria for other categories	Recommendation by a SCOTT Panel Chair, supported by two members	8.2
First-In-Human	Phase 1 trials proposing to administer an IMP** in humans for the first time	Recommendation by a SCOTT Panel Chair, supported by three members	8.3
Low-Risk	Food products, Phase 4, Phase 3 OLEs,*** Phase 3 IMP** or protocol approved internationally****	Recommendation by a SCOTT Panel Chair	8.4
Non-Standard	Any trial that SCOTT or HRC deem to require a modified recommendation process	Customised case-by-case SCOTT assessment	8.5

**Descriptions included here are highly abbreviated. Detailed descriptions of inclusion and exclusion criteria for each category, and associated process for SCOTT to arrive at a recommendation regarding approval, can be found in the indicated section of the draft Terms of Reference.*

*** Investigational Medicinal Product*

**** Open-labelled Long-term Extension study*

*****Phase 3 clinical trials for which the IMP or protocol has been approved by one of the international jurisdictions identified in the Terms of Reference section 8.4.1.*

Please note that, as part of implementing the proposed new categorisation of applications for approval of clinical trials summarised above, the HRC is likely to request improvements to the application system administered by Medsafe. This is likely to involve changes to the application form to enable Medsafe, the HRC and SCOTT to allocate each application into one of the above categories and assign it to an appropriate SCOTT panel that has been screened for conflicts of interest. Applicants will need to supply all information pertinent to this initial assessment in a format that can be considered without sharing the full application.

Feedback requested

The HRC is seeking feedback from stakeholders with an interest in the conduct and regulation of clinical trials of new medicines in New Zealand, and from the public, who have an interest as the potential beneficiaries and participants of clinical trials of new medicines in New Zealand.

Submissions are welcomed on all aspects of the draft Terms of Reference. Feedback on the matters referred to in the '**Summary of impact of reform**' section above would be of particular

value in ensuring that the regulatory process is well-tailored to the benefits and risks of clinical trials that propose to recruit participants within New Zealand.

How the consultation process will be managed

Submissions should be made in writing by 12 July 2024 and uploaded (as a Word or PDF file) via the HRC's website at https://hrc.govt.nz/news-and-events/have-your-say-how-hrcs-standing-committee-therapeutic-trials-runs. Any questions about the submission process may be directed to SCOTT@hrc.govt.nz, or by contacting Hannah Neale, Integrity & Regulatory Portfolio Manager at (09) 303 5221.

All submissions will be considered by the HRC with a view to identifying opportunities to improve SCOTT's processes, procedures, and principles as specified within the Terms of Reference. The HRC's goal is to adopt the Terms of Reference by November 2024, to take effect on 1 January 2025.

The HRC is committed to transparency and following adoption of the Terms of Reference will proactively release all submissions as official information. Should any submitter wish to submit confidential information, this should be clearly indicated in a separate section of the submission. The HRC will withhold or redact such indicated confidential information when releasing the submission publicly only to the extent permitted by the Official Information Act 1982.

Following the close of the consultation period, the HRC will consult with Medsafe (as delegate of the Director-General of Health) and current members of SCOTT on any substantive changes proposed to the draft Terms of Reference as the result of submissions received. The HRC will seek to appropriately balance the needs of the public and stakeholders prior to approving a final version of the Terms of Reference.

Once the Terms of Reference are adopted by the HRC, they will be published on the HRC website, and transition / implementation will commence.