Terms of Reference of the Standing Committee on Therapeutic Trials (SCOTT)

Version 0.4 Proposed draft for public consultation

Proposed to come into effect on 1 January 2025 *[Date to be confirmed following public consultation].*

Contents

1. Introduction

1.1. The Health Research Council of New Zealand (the **HRC**) is a Crown entity established under s 5 of the Health Research Council Act 1990 (the **HRC Act**).

1.2. The HRC is the Crown's primary funder of health research in New Zealand.

1.3. The HRC Act sets out the primary functions of the HRC, its two research committees (the Biomedical Research Committee and the Public Health Research Committee), the Māori Health Committee and the Ethics Committee.

1.4. The HRC's functions include making recommendations to the Director-General of Health (the **Director-General**) under s 30 of the Medicines 1981 (the **Medicines Act**) for the approval of clinical trials involving medicines in New Zealand. In practice this function applies to clinical trials of new medicines, including pharmacokinetic, bioequivalence and first-in-human (**FIH**) studies.

1.5. The New Zealand Medicines and Medical Devices Safety Authority (**Medsafe**) administers the process for approval of clinical trials under s 30 of the Medicines Act on behalf of the Director-General.

1.6. Medsafe produces guidelines to help interpret the requirements of the Medicines Act: the "Guideline on the Regulation of Therapeutic Products in New Zealand – Clinical Trials – regulatory approval and good clinical practice requirements" (the **Medsafe Guideline**) is periodically reviewed and updated by Medsafe as necessary.

1.7. The Medsafe Guideline explains the application and approval process for clinical trials under s 30 of the Medicines Act. This process includes the HRC considering an application and providing a recommendation to the Director-General.

1.8. The HRC has established the Standing Committee on Therapeutic Trials (**SCOTT**) to fulfil this review and recommendation function under the Medicines Act. The Guideline is relevant to SCOTT functions.

2. Purpose

2.1. The purpose of these Terms of Reference is to set out the functions, responsibilities and standard operating procedures of SCOTT.

2.2. These Terms of Reference set out principles and are not intended to cover every eventuality. They should be interpreted purposively to allow SCOTT to adapt its processes to the demands of the applications received.

3. Commencement

3.1. These Terms of Reference come into force on 1 January 2025. *[Date to be confirmed after public consultation].*

4. Functions of SCOTT

4.1. The primary function of SCOTT is to assess applications for clinical trials of medicines (**applications**) on behalf of the HRC so the HRC can recommend to the

Director-General whether such trials should be approved under s 30 of the Medicines Act.

4.2. In performing its functions SCOTT may assess any aspect of an application's proposed trial, including but not limited to the following considerations.

4.2.1. Assessing whether the proposed trial is likely to:

- provide benefits that justify the risks to trial participants;
- provide clinically and scientifically useful information.

4.2.2. Assessing whether the persons proposed to conduct the trial (the **investigators**) have the capacity to safely and effectively conduct the trial having regard to:

- the investigators' experience and qualifications relevant to the conduct of clinical trials;
- the suitability of the proposed trial site (including staffing and physical facilities; monitoring and quality assurance procedures; emergency and local hospital arrangements).

4.2.3. Assessing whether the proposed trial is likely to provide clinically and scientifically useful information, having regard to:

- the rationale for the trial;
- the trial design;
- the number of subjects to be recruited;
- mitigation of risks of toxicity or harm resulting from the administration of the investigational medicinal product;
- the criteria for determining efficacy of the investigational medicinal product, where this is one of the trial's aims.

4.3. SCOTT's functions do not include assessment of whether a proposed trial meets established ethical standards. This assessment shall be addressed by a separate ethics approval process.

4.4. After assessing an application in accordance with the operating procedures in section 8, SCOTT's function is to recommend that the proposed trial is:

4.4.1. approved; or

4.4.2. approved with improvements suggested; or

4.4.3. not approved until improvements are made; or

4.4.4. not approved, with reasons.

4.5. The HRC will consider the recommendation provided by the SCOTT regarding the proposed clinical trial and, when complete, provide it to the Director-General pursuant to s 30 of the Medicines Act.

4.6. SCOTT shall assess each application within a sufficient period of time to allow HRC to provide a recommendation to the Director-General, and the Director-General to determine the outcome for the application, within 45 days of receipt (as provided for in s 30(4) of the Medicines Act). This time limit of 45 days does not include periods during which further information is required from the applicant.

5. Membership of SCOTT

5.1. Membership of SCOTT

5.1.1. Members of SCOTT are appointed by the HRC in accordance with section 6.

5.1.2. SCOTT shall comprise of up to 30 individual members who each have the necessary qualifications, expertise and experience to assess applications and make appropriate recommendations.

5.1.3. The membership of SCOTT shall include the following positions to be appointed in accordance with section 6:

- a Chair;
- Panel Chairs;
- Members.

5.2. Secretariat

5.2.1. The HRC shall provide secretariat support to SCOTT, through suitably qualified and appointed HRC staff (the **Secretariat**).

5.2.2. The Secretariat shall adhere to all HRC employment expectations.

5.3. Knowledge and capability

5.3.1. SCOTT Members shall have qualifications, scientific knowledge, clinical trial and/or clinical experience to provide suitable expertise to assess applications and make recommendations.

5.3.2. Appropriate knowledge and experience includes but is not limited to:

- knowledge of pharmacology, toxicology and formulation science relevant to substances proposed to be administered to humans in clinical trials;
- clinical trial design expertise sufficient to assess whether the protocol for a proposed trial will provide information that will answer the research questions;
- experience in the conduct of clinical trials relevant to mitigation of risk to participants;
- knowledge and experience of the design and conduct of clinical trials in New Zealand, including specific New Zealand populations such as Māori;

- knowledge and experience of the regulation of clinical trials, including applicable international guidelines and best practice; and

- knowledge of pharmacogenomics (being the study of how genes affect response to medicines) in a New Zealand context.

5.3.3. Members should be representative of a breadth of social, personal, medical and cultural experiences.

5.3.4. Membership should reflect HRC's support of the Crown's commitment to be a good partner under Te Tiriti o Waitangi.

5.4. Members in Development

5.4.1. SCOTT shall foster a development pathway that builds Member capability and experience in matters relevant to its functions.

5.4.2. SCOTT is expected to include and encourage Members in Development to engage in SCOTT activities prior to considering an appointment to SCOTT.

5.4.3. Members in Development do not count towards the maximum number of individual Members of SCOTT.

5.4.4. Members in Development may be assigned to a Panel to consider an application and contribute to the assessment of an application. However, their participation shall not count towards:

- the required number of Members assigned to that Panel; nor

- the Panel Chair's recommendation on an application.

5.4.5. Members in Development should expect to participate in the assessment of at least 4 applications covering a range of categories, before being considered for appointment as a Member in accordance with section 6.

5.4.6. Members in Development shall be remunerated for any applications they review according to the same fees as Members.

6. Appointment of Members, Chair and Panels

6.1. Members

6.1.1. SCOTT Members shall be appointed by the HRC for a two year term.

6.1.2. Members are appointed as follows:

- Potential Members may be identified for appointment by any Member, by the Secretariat, or through an open recruitment process.

- Potential Members may express interest in appointment directly to SCOTT by emailing the Secretariat at SCOTT@hrc.govt.nz.

- The qualifications, experience and capability of potential Members shall be considered against the needs of SCOTT at any time by the SCOTT Chair and the HRC.

- If the potential Member is assessed as being suitable for appointment, the individual may be appointed directly or invited to join as a Member in Development.

- Members in Development are required to contribute to a minimum number of application assessments in that role pursuant to section 5.4.5 prior to being considered for appointment as a Member.

- The HRC will formally confirm the appointment of a Member to SCOTT and communicate this to SCOTT in writing.

6.1.3. Members are appointed for an initial term of two years with possible renewal of four further two-year terms. The maximum total combined, continuous term for a Member is ten years.

6.1.4. Any time spent as a Member in Development does not count towards the initial two year term.

6.1.5. After a stand-down period of two years, any former Member is eligible for reappointment.

6.2. SCOTT Chair

6.2.1. The SCOTT Chair shall be appointed by the HRC for a three year term.

6.2.2. The SCOTT Chair shall be appointed as follows:

- The HRC shall seek nominations for the position of SCOTT Chair from Members at SCOTT's Annual General Meeting or otherwise in advance of the end of the current Chair's term.

- Any Member may nominate themselves or any other existing Member to be considered for appointment as SCOTT Chair, with the agreement of the nominee. Nominations should include a written rationale for the nominee's suitability to the role.

- The HRC shall consider all nominations and may at its discretion consider other persons, including members not nominated.

- Upon selecting its preferred SCOTT Chair, the HRC shall invite that individual to become the SCOTT Chair for a term.

- Upon the SCOTT Chair's acceptance of the role, the HRC will confirm the appointment in writing and communicate the appointment to SCOTT.

6.2.3. The SCOTT Chair shall be appointed for an initial term of three years with possible renewal of two further three-year terms. The maximum total combined, continuous term for the SCOTT Chair is nine years.

6.2.4. After a stand-down period of three years, any former SCOTT Chair is

eligible for reappointment.

6.2.5. Any transitional arrangements between an outgoing and incoming SCOTT Chair will be determined by the HRC.

6.3. Panel Chairs

6.3.1. SCOTT Panel Chairs shall be Members who are suitably trained and experienced to act as the Panel Chair in accordance with the responsibilities described in section 7.2 and section 8.

6.3.2. Panel Chairs shall be appointed by the HRC from among Members.

6.3.3. Each Panel Chair shall be appointed as follows:

- Any Member (including the SCOTT Chair) may express an interest in becoming a Panel Chair. Expressions of interest may be actively sought by the HRC from time to time.
- The SCOTT Chair and Secretariat shall provide training and support to Panel Chairs to ensure they understand their role, responsibilities and procedures.
- The HRC will formally confirm the appointment of a Panel Chair and communicate this to SCOTT in writing.

6.3.4. Panel Chairs shall be appointed for an initial term of three years, with a possible renewal of two further three-year terms. The maximum total combined, continuous term for a Panel Chair is nine years.

6.3.5. After a stand-down period of three years, any former Panel Chair is eligible for reappointment.

6.4. Panels

6.4.1. Each application shall be considered by a Panel (comprising a Panel Chair and Members) in accordance with the procedures in section 8.

6.5. Termination of membership

6.5.1. Members of SCOTT (including the SCOTT Chair and Panel Chairs) are expected to serve in their position for the duration of their term of appointment.

6.5.2. An individual's membership of SCOTT (whether as a Member, SCOTT Chair or Panel Chair) may be terminated prior to the completion of the Member's term by the Member or HRC for any reason, on the giving of not less than two calendar months' written notice.

7. Roles and responsibilities

7.1. SCOTT Chair

7.1.1. The SCOTT Chair is responsible to the HRC for the performance of SCOTT.

7.1.2. The SCOTT Chair is responsible for:

- providing guidance and leadership to SCOTT Members on awareness and comprehension of relevant national and international standards and good practice guidelines;
- ensuring Members understand SCOTT's functions and their individual responsibilities;
- reporting to the HRC on SCOTT's activities and matters relevant to its functions;
- ensuring Members are kept updated with academic, clinical or technical developments relevant to SCOTT's functions;
- approving the content and updating of guides, checklists, templates, training materials and documentation relevant to SCOTT's functions;
- assisting the HRC to train Members in Development and potential Panel Chairs;
- mentoring Members in Development and potential Panel Chairs;
- facilitating open, fair discussion among Members and ensuring that SCOTT decisions are reached effectively; and
- approving agendas and minutes of SCOTT meetings and pursuing action items as appropriate.

7.1.3. The SCOTT Chair's responsibilities may be temporarily delegated to another Member as required.

- Any delegation must be in writing, to a named Member, for a period not exceeding two calendar months, and communicated in writing to the HRC.
- If for any reason the SCOTT Chair cannot authorise a delegation, the HRC may delegate on the SCOTT Chair's behalf.

7.2. Panel Chairs

7.2.1. A Panel Chair is responsible for providing to the HRC the recommendation on the application assigned to that Panel.

7.2.2. The Panel Chair is responsible for:

- approving the appointment of Members to the Panel as recommended by the Secretariat pursuant to section 8;
- the management of any conflicts of interest declared by panel Members in relation to each application, supported by the Secretariat;
- determining the deadline for the assessments of an application by Panel Members;

- assessing the application alongside other Panel Members;
- considering Panel Members' assessments of the application and discussing those assessments with them as required;
- preparing the final recommendation on an application and submitting this in a timely manner to the HRC; and
- facilitating the Panel's response to any questions raised by the HRC. Medsafe or the Director-General in relation to an application.

7.3. Members

7.3.1. Each Member (including the SCOTT Chair and Panel Chairs) is responsible for ensuring that SCOTT carries out its functions in an effective, efficient and timely manner.

7.3.2. Each Member is required to act at all times in accordance with:

- these Terms of Reference;
- any operating procedures, guides or other documentation relevant to SCOTT's functions;
- any instructions or guidance provided by the Chair, Panel Chair, Secretariat or HRC; and
- any other obligations imposed as a matter of law.

7.3.3. Each Member shall assess every application assigned to the Member in an expert, independent and impartial manner and adhere to any timeframes specified by the Panel Chair and/or Secretariat.

7.4. Secretariat

7.4.1. The Secretariat shall support the SCOTT Chair in ensuring the effective, efficient and timely operation of SCOTT.

7.4.2. The Secretariat is responsible for:

- Reviewing and categorising each new application received by SCOTT and promptly allocating it to an appropriate SCOTT Panel (including Panel Chair and Members) for assessment under sections 7.4.3 – 7.45.
- maintaining records of SCOTT's activities and ensuring these are stored in accordance with HRC protocols;
- maintaining a register of interests declared by Members under section 10;
- liaising on behalf of SCOTT with the Director-General, Medsafe and HRC as required;
- organising SCOTT's Annual General Meeting, training sessions (including the Annual Training Day) and any other related activities

necessary to fulfil SCOTT's functions;

- circulating materials including agendas, notes and minutes of HRC and SCOTT meetings to ensure that matters relevant to SCOTT are identified and that decisions are documented;
- communicating with Members, HRC and other third parties about SCOTT's activities as required;
- any other administrative tasks necessary for the efficient, effective and timely operation of SCOTT.

7.4.3. The Secretariat shall review each new application received by SCOTT and:

- categorise it in accordance with section 8; and
- promptly allocate it to an appropriate SCOTT Panel (including Panel Chair and Members) for assessment.

7.4.4. In assigning an application to an appropriate Panel Chair and Members, the Secretariat will:

- take into account the interests of those individuals as declared under section 10;
- consider whether any of these interests is, or could be perceived as, a conflict of interest in relation to the application; and
- if a potential conflict of interest is identified, follow the procedures set out in section 10 and the HRC Management of Interest policy.

7.4.5. In assigning an application, the Secretariat will also:

- consider the suitability of the proposed Panel (including Panel Chair and Members) to ensure the Panel has sufficient knowledge and capability to assess the application;
- consider the availability and workload of the proposed Panel Chair and Members to ensure applications are distributed evenly between Members and can be determined in a timely manner;
- establish and communicate the timeline by which the Panel Chair and Members must complete their assessment to ensure HRC can make a recommendation in accordance with the timeframe set out in section 4.

7.4.6. The Secretariat remains an employee of the HRC while carrying out these responsibilities.

8. Operating procedures

8.1. Operating procedures

8.1.1. Each assessment of an application received by SCOTT after the commencement of these Terms of Reference will be conducted in accordance with the operating procedures set out in this section.

8.1.2. Applications for clinical trials assessing bioequivalence of an investigational medicinal product with an active pharmaceutical ingredient that is already approved for use in New Zealand (**bioequivalence studies**), have been deemed approved by SCOTT and recommended by HRC to Medsafe without review of individual applications. These applications are managed by Medsafe according to an abbreviated process as described in the Medsafe Guideline and SCOTT review is not required unless specifically requested by Medsafe.

8.1.3. Each new application received by HRC for review by SCOTT will be categorised by the Secretariat, and confirmed by the Panel assigned the application, as one of the following:

- **Standard Clinical Trial**; or
- **First-In-Human (FIH) Clinical Trial**; or
- **Low-Risk Clinical Trial**; or
- **Non-Standard Clinical Trial**.

8.1.4. After assessing the application in accordance with the operating procedures in this section 8, the Panel will recommend to the Secretariat that the proposed trial is:

- approved; or
- approved with improvements suggested; or
- not approved until improvements are made; or
- not approved, with reasons.

8.2. New applications for Standard clinical trials

8.2.1. A Standard clinical trial is a trial that is neither a FIH administration of a specific investigational medicinal product, nor categorised as either Low Risk or Non-Standard for other reasons determined by SCOTT.

8.2.2. A Standard clinical trial application shall be reviewed by a Panel of three Members (excluding Members in Development) comprising a Panel Chair and two Members. Members in Development may also be assigned to the Panel but will not count towards the total of three Members required.

8.2.3. The Panel Chair and Panel Members will be selected by the HRC following consideration of relevant expertise, availability and screening for potential conflicts of interest.

8.2.4. Each Panel Member shall independently assess an application for a Standard clinical trial against a checklist approved by the SCOTT Chair

for use for such applications.

- The checklist will be developed by SCOTT to guide assessments.
- The checklist will be informed by the Medsafe Guideline and other international clinical trial guidance as identified by SCOTT and Medsafe from time to time.

8.2.5. Each Panel Member shall complete his or her assessment by providing:

- a recommendation of the type set out in section 4.4; and
- a summary of any suggestions, requests for further information or concerns identified during the assessment.

8.2.6. Each Panel Member will provide his or her assessment in writing to the Secretariat within 10 days of appointment to the Panel and receipt of the application materials.

8.2.7. The Secretariat shall distribute the assessments to the Panel Chair within 3 days.

8.2.8. The Panel Chair shall consider the Member assessments and determine the Panel recommendation regarding the application. In arriving at this determination, the Panel Chair may:

- discuss an application with Panel Members to clarify areas of detail, agreement, or disagreement between Members;
- make a recommendation that differs from the majority of Panel Members;
- formulate the Panel's recommendation on the application, including any suggestions, requests for further information or concerns regarding the application.

8.2.9. The Panel Chair shall provide the Panel's recommendation to the Secretariat and HRC within 7 days of receiving Panel Members' assessments.

- That recommendation shall be formatted according to a template approved by the SCOTT Chair and suitable for communication to the HRC and Medsafe (on behalf of the Director-General).

8.2.10. The HRC shall provide the Panel's recommendation and Panel Member assessments (including completed checklists) to Medsafe to inform the Director-General's decision regarding the application. The time period ending with the provision of the Director-General's decision to the applicant, is expected to be within 45 days from application submission (as required by s 30 of the Medicines Act), excluding periods during which further information is required from the applicant.

8.3. New applications for First-in-Human Clinical Trials

8.3.1. A FIH Clinical Trial is a trial that will administer a specific investigational medicinal product to humans for the first time.

8.3.2. As FIH Clinical Trials pose greater risks to the safety of trial participants, the procedure for assessing such applications is the procedure for Standard Clinical Trials, modified as follows:

- Applications for FIH Clinical Trials will be assessed by a Panel of four Members (excluding Members in Development), comprising a Panel Chair and three other Members.
- The Panel will include at least one Member who has experience in management of risk to participants in the operation of FIH Clinical Trials.
- Each Panel Member shall independently assess an application for a FIH Clinical Trial against a checklist approved by the SCOTT Chair for use for such FIH applications.
    - The checklist will be developed by SCOTT to guide assessments.
    - The checklist will be informed by the Medsafe Guideline and other international clinical practice guidance as identified by SCOTT and Medsafe from time to time.

8.4. New applications for Low Risk Clinical Trials

8.4.1. A Low Risk clinical trial is:

- **A clinical trial of an investigational medicinal product that is a food product (including dietary supplements)** presented in a form and dosage that is consistent with common use as a food or dietary supplement for prospective participants (noting that common use should not exclude any participant groups such as persons under 18, pregnant or breastfeeding persons, or persons with health conditions);

  or

- **A Phase 4 clinical trial** (being a clinical trial to study the benefits and side effects caused over time by the investigational medicinal product after it has been approved as a medicine by a national jurisdiction);

  or

- **A Phase 3 clinical trial that is an open-labelled long-term extension study** (being a clinical trial where participants take the active form of the investigational medicinal product without a placebo, because the randomised (blinded) portion of the trial has been completed and the investigational medicinal product was found to have the potential for benefit);

  or

- **A Phase 3 clinical trial** (being a trial to test the safety and benefits of the investigational medicinal product compared with an existing treatment) **for which the investigational medicinal product has**

been approved for use in UK[1], EU[2], USA[3], or Australia, unless trial participants include persons who are under 18 years of age, pregnant, or breastfeeding or producing breastmilk, in which case the application must be categorised as Standard.

- or **A Phase 3 clinical trial** (being a trial to test the safety and benefits of the investigational medicinal product compared with an existing treatment) **for which the trial protocol has already been approved in the UK, EU, or USA**, unless trial participants include persons who are under 18 years of age, pregnant, or breastfeeding or producing breastmilk, in which case the application must be categorised as Standard.

8.4.2. In all cases evidence of the application's proposed clinical trial falling into one of the above cases must be supplied by the applicant to Medsafe.

8.4.3. As Low Risk Clinical Trials pose lower risks to the safety of trial participants, the procedure for assessing such applications is the procedure for Standard Clinical Trials, modified as follows:

- Applications for Low Risk clinical trials will be assessed by a Panel of a Panel Chair.
- The Panel Chair may include in the Panel one additional Member if deemed necessary by the Panel Chair to provide technical expertise or experience relevant to the trial.

8.5. New applications identified as Non-Standard

8.5.1. The Secretariat, the SCOTT Chair or a Panel Chair may at any point identify an application as Non-Standard, in circumstances where the operating procedures for Standard, FIH and/or Low Risk clinical trial assessment will not satisfactorily provide the Panel with the information required to make a recommendation.

8.5.2. An application may be Non-Standard if:

- The proposed trial is at a newly established facility or by a newly established organisation;
- The proposed trial raises issues of technical or clinical complexity, or high risk to participants;
- Aspects of the proposed trial raise questions that cannot be answered on the basis of the application or are outside the combined expertise of Members able to be assigned to a Panel; or
- A conflict of interest arises which prevents the formation of an unconflicted Panel and SCOTT is required to modify the operating procedures for Standard clinical trials to manage that conflict of

[1] UK = United Kingdom: Medicines and Healthcare products Regulatory Agency (**MHRA**)
[2] EU = European Union: European Medicines Agency (**EMA**)
[3] USA = United States of America: Food and Drug Administration (**FDA**)

interest.

8.5.3. If an application is identified as Non-Standard, the Secretariat shall, as soon as practicable:

- Discuss the matter with the application's Panel Chair (or if there is no Panel Chair, with the SCOTT Chair);
- Notify Medsafe (on behalf of the Director-General) that SCOTT will need to modify the operating procedures for Standard clinical trials to provide a recommendation.

8.5.4. The Secretariat will work with Medsafe and the Panel Chair (or if there is no Panel Chair, with the SCOTT Chair) to modify the operating procedure for Standard clinical trials for each Non-Standard application. Modifications to the procedure may include, but would not be limited to, the following:

- modifications to the Standard clinical trial or FIH clinical trial checklists;
- interviews with personnel named in the application;
- visits to the proposed clinical trial site facility named in the application to ascertain the suitability of the site to safely operate the trial;
- consultation of external parties to provide expert advice on matters outside the combined expertise of SCOTT Members available for the Panel, following the provisions for external engagement in section 9.4;
- requirement for additional supporting evidence;
- modifications to decision-making procedures such as the holding of Panel meetings to facilitate evaluation and consensus decision-making; and
- modifications to the time in which the Panel Chair must provide the Panel's recommendation to the Secretariat and HRC after receiving Panel Members' assessments.

8.5.5. In cases of Non-Standard applications that require modifications to the Standard operating procedure:

- The Secretariat is responsible for supporting the Panel Chair and/or the SCOTT Chair with respect to the formulation and implementation of agreed modifications.
- The Secretariat is responsible for communicating the agreed modifications to Medsafe.
- Medsafe is responsible for communicating the agreed modifications to the applicant.

8.6. Post Approval Form Applications

8.6.1. A Post Approval Form (**PAF**) application is an application submitted to Medsafe by an applicant whose clinical trial application has previously been approved, but who proposes changes to the operation of the trial and seeks approval of those changes.

8.6.2. Medsafe may request a recommendation from the HRC as to whether a PAF application should be approved, and in these circumstances the Secretariat will refer the matter to SCOTT.

8.6.3. A PAF application requiring a recommendation from SCOTT will ordinarily be assigned to and assessed by the Chair of the Panel that reviewed the original application.

- If the original Panel Chair is no longer available or suitable to carry out the PAF review, the Secretariat will reassign the PAF application to another Panel Chair.

- The Panel Chair may request approval from the Secretariat to consult with Members of the Panel that reviewed the original application or may request that another Member also assess the PAF application to inform the Panel Chair's recommendation.

- The Secretariat will screen for potential conflicts of interest associated with the PAF application prior to assigning that application to a new Panel Chair or approving consultation with new Panel Members.

8.6.4. The Panel Chair shall provide a recommendation in writing on whether the PAF application should be approved to the Secretariat and the HRC within 5 working days of the Panel Chair accepting the assignment. to the

- That recommendation shall be formatted according to a template approved by the SCOTT Chair and suitable for communication to the HRC and Medsafe (on behalf of the Director-General).

8.6.5. The HRC shall provide the recommendation to Medsafe (on behalf of the Director-General).

9. Meetings and engagement

9.1. Annual General Meeting

9.1.1. SCOTT will hold an Annual General Meeting at which all Members and Members in Development are expected to attend.

9.1.2. The purpose of the Annual General Meeting is to consider:

- a summary of the year's work and any changes or trends relative to previous years;

- a strategy for managing future workload, including Member recruitment and reappointment;

- training needs of Members and a strategy for meeting those needs;
- topics of interest including national and international developments that impact SCOTT operations;
- any changes required to these Terms of Reference and/or operational practices to enable the effective and efficient fulfilment of SCOTT's functions.
- The draft annual report in accordance with section 12.

9.1.3. The Annual General Meeting will be attended by members of the HRC including the Secretariat and the HRC Chair or Chief Executive (or delegate).

9.1.4. The Annual General Meeting will be attended by a representative of Medsafe's Medical Director.

9.1.5. Third parties may be invited to attend the Annual General Meeting as required.

9.2. Training Meeting

9.2.1. SCOTT shall hold an annual training day on a date to be determined by the Secretariat in consultation with the SCOTT Chair.

9.2.2. The purpose of the training day is for experts in relevant fields to provide training to SCOTT Members and Members in Development on matters relevant to SCOTT's functions.

9.3. Panel meetings

9.3.1. The operating procedures for Standard clinical trials do not require a Panel considering a clinical trial application to meet.

9.3.2. A Panel Chair may request a discussion with one or more Panel Members to assist with the Panel Chair's recommendation on an application. Such discussions are not considered to be additional tasks for the purposes of remuneration.

9.3.3. Discussions between the Panel Chair and individual Panel Members do not require minutes.

9.3.4. A clinical trial application requiring a Panel meeting to facilitate decision-making may be considered a Non-Standard Application as described in section 8.

9.4. External engagement

9.4.1. SCOTT may, with the approval of the HRC, engage with or consult any third party who SCOTT considers can assist it to perform its functions. This may include seeking or sharing advice with other regulatory, technical and advisory committees, or individuals or organisations that hold knowledge or information that would be of use to SCOTT in the performance of its functions.

9.4.2. All engagement between SCOTT and third parties will be initiated and overseen by the Secretariat to preserve the integrity of decision-making, ensure confidentiality and manage potential conflicts of interest.

9.4.3. The HRC and the Secretariat will provide advice and other support to SCOTT (including seeking authorisation from Medsafe and the applicant where required) regarding the engagement of or consultation with third parties.

10. Management of interests

10.1. Governing principles

10.1.1. HRC and SCOTT are committed to maintaining the integrity of SCOTT's decision-making processes and the confidence of all parties affected by SCOTT decisions.

10.1.2. All Members and Members in Development shall bring an open and impartial mind to their consideration of an application for approval of a clinical trial and in otherwise carrying out SCOTT's functions.

10.1.3. SCOTT is bound by the HRC Management of Interest Policy.

- The HRC Management of Interest Policy shall be provided to Members and Members in Development as part of their training materials.
- In the event of a conflict between these Terms of Reference and the HRC Management of Interest Policy, the terms of the latter will prevail.
- If the HRC Management of Interest Policy is revised, these Terms of Reference shall also be reviewed and revised copies of each document provided to Members as required.

10.2. SCOTT interests register

10.2.1. A conflict of interest arises where the duties or responsibilities of a Member (or Member in Development) as part of a Panel assessing an application could be affected by some other interest or duty that Member may have.

10.2.2. All Members (including Panel Chair and Chair) and Members in Development must disclose to the Secretariat information about their financial and non-financial interests prior to confirmation of their appointment or re-appointment.

- A financial interest might arise from, for example, ownership of a business or land, or a paid contract or employed role.
- A non-financial interest might arise from, for example, a family relationship or friendship, an academic connection or position, or another close professional or personal relationship.

10.2.3. The HRC shall provide a template for Members and Members in Development to disclose their financial and non-financial interests to SCOTT, and retain this information on an interests register to be managed by the Secretariat.

- The SCOTT interests register must be kept current.
- The SCOTT interests register is subject to the Official Information Act 1981, but the privacy interests of Members and Members in Development will be preserved as much as possible under that legislation.
- All Members and Members in Development must disclose their interests to the HRC Secretariat annually or more frequently in the case of a potential new interest.
- The Secretariat will maintain the interests register throughout each Member's term(s) and for the period following as required by the HRC's Management of Interest Policy and other policies related to confidential information.
- The Secretariat shall keep records of previous versions of the interests register and the time period in which each was utilised.

10.3. Potential conflicts of interests in Panel assignments

10.3.1. The Secretariat will assign a Panel Chair and other Members to assess a clinical trial application only after screening each Member for potential conflicts of interest in connection with that application.

10.3.2. A financial or non-financial interest will give rise to a conflict of interest if a fair-minded observer would reasonably think that the Member might not bring an impartial mind to that individual's assessment of the application in question or fulfilment of any other SCOTT function.

10.3.3. Conflicts of interest may arise for SCOTT Members in relation to a particular application particularly by interests that arise from the proposed trial methodology, the applicant for the trial being affiliated with a colleague or a competitor to the Member, or through relationships with personnel involved with the trial.

10.3.4. When the HRC receives a request from Medsafe to assess a clinical trial application, the Secretariat shall screen the information provided by the applicant against Members' disclosures on the SCOTT interests register.

- If the Secretariat does not identify a potential conflict of interest, it shall provide relevant information about the application to each potential Panel Member (including Members in Development where applicable) and invite that Member to disclose any other potential conflict of interest.
- If the HRC does identify a potential conflict of interest, it may seek further information from the Member to better assess the potential conflict of interest.

10.3.5. No Member shall be assigned to a Panel if the HRC determines that Member has a conflict of interest in relation to a particular application.

10.3.6. The Secretariat shall make the final determination on whether a Member has a conflict of interest.

10.3.7. Only those Members assigned to a Panel in respect of an application will be provided with access to the application materials.

11. Remuneration

11.1.1. Remuneration for SCOTT Members (including the SCOTT Chair and Panel Chairs) and Members in Development will be provided according to the HRC's Letter of Remuneration for Services Provided by SCOTT (the **Remuneration Letter**).

11.1.2. Fees payable to Members by the HRC for contributing to the assessment of applications are fixed fees per application according to application type and Member role as set out in the Remuneration Letter.

11.1.3. Fees for meetings, ad-hoc or non-standard activities requested of SCOTT members by the HRC from time to time will be remunerated based on time commitment and role, at day rates set out in the Remuneration Letter. Reasonable costs of travel for members carrying out SCOTT activities will be reimbursed by the HRC.

11.1.4. The SCOTT Chair's responsibilities (section 7.1) include duties that may be expected to occur throughout a period of appointment and are in addition to consideration of applications or attendance at meetings. Remuneration for these duties will be provided to the SCOTT Chair at a per annum rate, additional to fees for consideration of applications and attendance at meetings.

12. Reporting and accountability

12.1.1. SCOTT is accountable to the HRC for the delivery of the functions set out in these Terms of Reference.

12.1.2. SCOTT shall provide an annual written report to the HRC on SCOTT's performance and activities, consistent with any guidance and templates provided by the HRC.

- The report is intended to support the effective and efficient delivery of SCOTT's functions by identifying and communicating matters that may need attention by SCOTT and/or the HRC.
- A draft of the report shall be prepared by the Secretariat and SCOTT Chair in advance of the Annual General Meeting for consideration and approval by Members.
- The HRC shall provide feedback to SCOTT on its report within two months of its delivery.

12.1.3. Both the HRC and the SCOTT Chair may at any time request a meeting

to discuss any matter relevant to the delivery of SCOTT's functions.

13. Confidentiality and storage of information

13.1.1. All material submitted by an applicant in support of a clinical trial application will be considered confidential to SCOTT and the HRC.

13.1.2. Such material and the information contained therein will not be shared by SCOTT Members with any persons outside the Panel assessing the application without the written approval of the Secretariat or, if required as a matter of law, without notification to the Secretariat.

13.1.3. Documents relating to SCOTT's assessment of applications will be stored by the HRC according to its policies and procedures for the management of confidential information and evidence of decision-making.

13.1.4. SCOTT Panel Members will access application materials in Medsafe's online application portal.

13.1.5. Panel Members will not print or save any application materials to digital drives (or similar) except for the purpose of carrying out their assessment.

- Any materials printed by Members must be destroyed following appropriate methods for disposal of confidential documents (e.g. shredding or disposal by authorised organisations) within 48 hours of completing their duties for a particular Panel.
- Any materials saved to digital drives by Members must be deleted within 48 hours of completing their duties for a particular Panel.

14. Review

14.1.1. The HRC shall review these Terms of Reference at least once every three years after the commencement date. That review shall be undertaken in consultation with SCOTT and Medsafe.

14.1.2. These Terms of Reference may be revoked by the HRC.

15. Transitional arrangements

15.1. Membership and roles

15.1.1. Members appointed to SCOTT, and Members appointed as a Panel Chair, prior to the commencement of these Terms of Reference shall continue to be appointed and are deemed to have started their first term as a Member (or Panel Chair) on the commencement date in section 3.

15.1.2. The SCOTT Chair appointed prior to the commencement of these Terms of Reference shall continue as SCOTT Chair and is deemed to have started their first term as SCOTT Chair on the commencement date in

section 3.

15.1.3. Members appointed prior to the commencement of these Terms of Reference and who do not wish to have their appointments continued afterwards must advise the SCOTT Chair as soon as possible.

15.2. Standard operating procedures

15.2.1. The HRC may determine that any standard operating procedure in section 8 shall come into force prior to the commencement date in section 3.

15.3. Other matters

15.3.1. Any other transitional requirements may be adopted by the HRC prior to the commencement date in section 3.