

Data Monitoring Core Committee

(July 2020)

Terms of Reference

1. The primary function of the Health Research Council ('HRC') Data Monitoring Core Committee ('DMCC') is to ensure trials which require data and safety monitoring are adequately monitored. Specific settings include trials where interim analysis of safety and efficacy are considered essential to ensure the safety of trial participants (such as early trials of high risk treatments) and trials in vulnerable populations. Trials may be appropriate for data and safety monitoring for other reasons such as:
 - (a) Trials with a potentially large public health impact; and
 - (b) Trials where study integrity could be enhanced by the independence of the DMC.
2. To independently review the grant applications of clinical trials, innovative treatment evaluation or community intervention studies submitted to the HRC for research funding, when requested by the Chief Executive and make recommendations regarding issues relevant to monitoring which may include comments on trial design and organisation.
3. To evaluate, advise and contribute to Independent or International Data Monitoring Committees on those trials funded or co-funded by the HRC. This may be particularly appropriate where there is:
 - (a) A large New Zealand cohort; and/or
 - (b) Significant contribution to funding by the HRC; and/or
 - (c) Minor New Zealand representation on the DMC; and/or
 - (d) Inexperience in monitoring data and safety in the proposed DMC.
4. To monitor and provide recommendations for trials not funded by the HRC in exceptional circumstances (such as significant involvement of researchers or patients in New Zealand) or in cases which benefit public good.
5. To contribute to the current field of knowledge in monitoring and protocol review by:
 - (a) Apprenticeship and mentoring of DMCC members with appropriate expertise but without monitoring experience; and
 - (b) Providing information and education regarding protocol development, current data and safety monitoring processes and Good Clinical Practice.

Membership Composition

Up to eight members appointed on the recommendation of the HRC. Membership expertise must include a biostatistician, an ethicist and two clinicians or health professionals, one with strong clinical trial experience. Membership should include members who have varied professional interests in order to minimise conflict of

interest. Also, membership should reflect apprenticeship positions for members with appropriate expertise, but with little experience monitoring clinical trials. The Chief Executive of the Health Research Council is an ex officio member of the DMCC.

Data Monitoring Committees

For each trial monitored, a Data Monitoring Committee ('DMC') will be established, which requires a minimum DMCC membership of 4, with each area of expertise represented. The DMC may additionally appoint up to 2 Augmented Members who are specialists in the field of the clinical trial. The Chair of the DMCC formally invites any new augmented members recommended by the DMCC and membership will be confirmed by the Chief Executive of the HRC. Trial DMC members do not become DMCC members and will be released once the monitoring of the trial is complete.

Term of Office

Term of office is an initial five-year period, with a five years extension at the discretion of the Council. Members of a Data Monitoring Committee specific to a clinical trial may retain their membership in the DMC after their end of term in the DMCC until the end of the clinical trial and this will be at the discretion of the Chair of the DMCC. Term of office for the Chair is five years plus five years.

Process for Appointment of Committee Members

The Chief Executive formally invites the proposed member recommended by the Committee and confirmed by HRC.

Current Membership	Date Appointed	End of Term	Expertise	Location
Professor Thomas Lumley (Chair from June 2019)	Jul 2012	Jul 2022	Biostatistician	Auckland
Professor Tim Dare	Oct 2019	Sep 2024	Ethicist	Auckland
Professor Ngaire Kerse	Mar 2011	Mar 2021	Clinical Trials	Auckland
Professor Dr Suetonia Palmer	Apr 2020	Apr 2025	Clinician	Christchurch
Dr Mark Webster	Oct 2012	Oct 2022	Cardiologist Consultant	Auckland
Dr Yalu Wen	Nov 2018	Nov 2023	Biostatistician	Auckland
Associate Professor Conroy Wong	Oct 2016	Oct 2021	Consultant Specialist Physician	Auckland

Secretary:	Ms Lana Lon
DMCC Quorum:	Four
DMC Quorum:	Four DMCC members and the appropriate Augmented Member or members
Meetings per annum:	Two in-person meetings, with teleconferences as needed