Data Monitoring Core Committee

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

(January 2015)

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.

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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 three year 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 three years, but this may be extended.

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
Associate Professor Katrina Sharples (Chair)	February 2006	June 2017	Biostatistician	Dunedin
Professor Tom Fleming			Consultant	USA
Dr Mark Jeffery	April 2009	April 2017	Clinical Trials	Christchurch
Professor Ngaire Kerse	March 2011	March 2016	Clinical Trials	Auckland
Professor Thomas Lumley	July 2012	July 2017	Biostatistician	Auckland
Professor John McCall	February 2009	February 2017	Clinical Trials	Dunedin
Associate Professor Andrew Moore	February 2006	December 2016	Ethicist	Dunedin
Dr Mark Webster	October 2012	October 2017	Cardiologist Consultant	Auckland

Secretary:	Ms Lana Lon
DMCC Quorum:	3
DMC Quorum:	3 DMCC members and the appropriate Augmented Member or members
Meetings per annum:	2 in-person meetings, with teleconferences as needed

Committee Fees and Allowances	Meeting fees and travel expenses for Committee members will be in accordance with standard HRC practice
Reports to:	HRC Council and HRC Ethics Committee
Established by:	HRC Board 1996
Reviewed:	February 2009 (this ToR)
Disbanded:	