Terms of Reference of the Data Monitoring Core Committee (DMCC)

(August 2022)

1. Introduction

1.1 In 1996, the HRC funded two trials meeting the criteria for requiring an independent Data Monitoring Committee (DMC). In order to fulfil this monitoring function, the Council established the Data and Safety Monitoring Board in 1996. Subsequently the name of the committee was changed to the Data Monitoring Core Committee (DMCC).

1.2 The primary function of the DMCC is to ensure HRC funded trials which require data and safety monitoring are adequately monitored.

1.3 Criteria for trials that require data and safety monitoring :

(a) Early trials of high-risk treatments;
(b) Trials in vulnerable populations;
(c) Trials with a potentially large public health impact;
(d) Trials where study integrity could be enhanced by the independence of the DMC;
(e) Trials with risk of, potentially life-threatening or disabling complications;
(f) The intervention is novel and there is very limited information on clinical safety;
(g) Where prior information of the trial raises concern regarding potential serious adverse events;
(h) Studies carried out in emergency settings; and
(i) Other trials where independent monitoring is international best practice.

2. Responsibilities of the DMCC

Responsibilities of the DMCC include:

2.1 If requested by the Chief Executive, independently review grant applications of clinical trials, innovative treatment evaluation or community intervention studies submitted to the HRC and make recommendations regarding issues relevant to monitoring which may include comments on trial design and organisation.

2.2 Reviewing the monitoring plans for trials funded by the HRC and provide advice to the HRC on whether the plans meet best international practice.

2.3 Constituting a trial-specific Data Monitoring Committee (DMC) for any trial funded by the HRC where this is appropriate and is requested/agreed by the investigators.

2.4 Evaluating, advising, and contributing 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.

2.5 Contributing 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.

3. Composition, membership, and meetings

3.1. Membership of the DMCC shall be appointed by the Council upon recommendation by the DMCC and will comprise of seven members. The term of membership of DMCC members shall be for a period of five years with possible one-off renewal for a further five-year term.

3.2. The Chair of the DMCC will be appointed by the Council. The Chair will be appointed for a period of five years with possible one-off renewal for a further five-year term, regardless of the term served by the appointed Chair as an ordinary member of the Committee. The total combined term is up to a maximum of 15 years.

3.3. Membership expertise must include a biostatistician, an ethicist and two clinicians or health professionals, one with strong clinical trial experience. Membership should aim for diversity and inclusiveness as well as including members who have varied professional interests in order to minimise conflict of interest.

3.4. The DMCC may include up to 2 associate members. These positions are for promising younger academic researchers, who are not yet experienced in running and monitoring larger clinical trials. Associate members have no voting rights, and are appointed for a term of up to 2 years with no renewal.

3.5. A DMCC meeting shall be held at least once a year to decide which HRC funded trials from the general annual funding round require monitoring. Prior to this annual DMCC meeting, the Chair reviews all funded research to identify the clinical trials to be included in the discussion at the meeting.

3.6. Apart from the general annual funding round, throughout the year, the Chair will review the funding decisions from the Council and identify if any HRC funded research is a clinical trial which needs the DMCC to consider monitoring.

3.7. The Chair of the DMCC may call a special meeting of the DMCC if so requested by any member of the committee or the Chief Executive of the HRC.

3.8. A quorum shall comprise of at least half plus one of current DMCC members (e.g. if there are 6 current members of the committee, the quorum will be half of 6 (3) plus 1 = 4).

3.9. For each trial monitored by the DMCC, a trial- specific DMC will be established:

3.9.1. The trial DMC will have a minimum of four DMCC members, with each area of expertise represented.
3.9.2. The DMC may appoint up to two additional members who are specialists in the field and independent of the trial to provide necessary trial-specific expertise. The Chair of the DMCC formally invites any additional members recommended by the DMCC or the principal investigators of the trial to participate in the DMC and membership is confirmed by the Chief Executive of the HRC.
3.9.3. Trial DMC members do not become DMCC members and will be released once the monitoring of the trial is complete.
3.9.4. Members of the DMCC who are also members of a trial-specific DMC, 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.
3.9.5. Trial DMC meetings shall be held at least twice a year and may occur through face-to-face or other communication means.
3.9.6. A quorum of the trial DMC for each meeting shall comprise of at least half plus one of DMC members.
3.9.7. The proceedings of all trial DMC meetings will be minuted by an appointed secretary.

3.10. The proceedings of all meetings of the DMCC will be minuted by an appointed secretary.

4. Reporting to the Council

4.1 The draft minutes of all DMCC meetings shall be included in the Council agenda.

5. Review of the DMCC

5.1 The Chair of the DMCC shall ensure that the DMCC undertakes a self-review of its objectives and activities every two years.

5.2 The review shall be tabled with the Council for discussion and formal adoption.