ADHB – Research Review Committee (RRC)
Terms of Reference

1. PURPOSE

1.1 To function as a sub-committee of the Clinical Leadership Group advising the CEO and Board on research and contracts particularly in areas of innovation, quality, risk and approvals.

1.2 To act as a scientific advisory committee and review and approve or delegate approval of all research that involves the ADHB.

1.3 To provide peer oversight and expert advice to enable the organisation to achieve ADHB goals of supporting and promoting high quality research. The Committee will have an advisory role on ways of encouraging more research activity in the organisation.

1.4 To identify areas of potential growth in high quality research and to promote mechanisms to stimulate appropriate research programmes in such areas.

1.5 To oversee and promote the development and implementation of the ADHB research strategy.

1.6 To provide a conduit for the accountability of researchers via the Clinical Leadership Group, CEO and the Board.

1.7 To establish a subcommittee (if necessary) to review research applications.

2. OBJECTIVES

2.1 To establish and maintain a system of oversight that maximizes the quality of research and minimizes its risks.

2.2 To review and approve all research project for scientific merit and institutional appropriateness.

2.3 To advise the ADHB Charitable Trust on the relative priority of approved research projects.

2.4 To ensure that all research conducted adheres to a) the ethical standards according to the National Ethics Advisory Committee's "Ethical Guidelines for Interventional Studies" and "Ethical Guidelines for Observational Studies", b) to National Standards and Codes of Practice and c) all regulatory and legislative requirements (e.g. Medsafe, NRL, ERMA, GTAC).

2.5 To ensure all research is conducted in ADHB according to Board Policy and Procedure and the current versions of the Good Clinical Research Practice Guidelines, Declaration of Helsinki and relevant Guidelines for Researchers developed by the Health Research Council.

2.6 To promote visibility and transparency of research activity within the ADHB.

2.7 To offer an independent analysis of research where proposer or management support for a proposal conflicts.

2.8 To provide an independent review of outstanding research issues and provide a report of issues to the Clinical Leadership Group where required.

2.9 To provide advice to the organisation on research matters with appropriate consultation with colleagues, researchers and staff when appropriate.

3. DEFINITIONS

3.1 A research project is defined as any scientific study (either investigational or observational). Full committee review is required for all clinical trial research projects when ADHB is a study site (locality) and all research projects deemed more than low risk, but including low risk studies requiring financial support and a budget. Otherwise, low risk research can be reviewed outside the committee on delegated authority.

3.2 All research, irrespective of funding status, is included under these Terms of Reference

3.3 Low risk research under these Terms of Reference is defined as any research project for which full review by a Health and Disability Ethics Committee is not required (refer MoH *Standard Operating Procedures for Health and Disability Ethics Committees 2012*), but excludes clinical trial research eligible for the expedited ethics review pathway. Low risk research includes minimal risk observational research and audit and related activity as defined in the National Ethics Advisory Committee's *Ethical Guidelines for Observational Studies 2006* (11.12 – 11.17).

3.4 Research involving ADHB is defined from either a) involvement of ADHB patients, and b) involvement of ADHB staff. Therefore RRC approval is required a) for any research activity involving ADHB patients, whereby information held by ADHB about patients is sought. RRC approval is required if b) ADHB staff are participating in the research activity, as part of or as a consequence of their ADHB employment, or otherwise have contact with patients or access to their information for research purposes when acting in their capacity as an ADHB staff member. When ADHB is not a site (locality) but the research is introduced to a patient by ADHB staff on ADHB premises, or during any activity relating to the patient's care by ADHB, RRC may note rather than review the research at their discretion.

4. CHAIRPERSON

4.1 The Chair shall be appointed by the Chief Medical Officer (CMO) annually.

5. MEMBERSHIP

There shall be at least 10 members in addition to the Chair and CMO, all with proven research histories. Each member will be appointed for three years with reappointment for a subsequent term at the direction of the CMO.

- The Chief Medical Officer (CMO) or designate
- The RRC Chair
- At least 10 members with a mix of quantitative and qualitative research expertise.
- Manager ADHB Research Office *[ex officio]*

In attendance

- Secretarial/administrative support
- Trustee of the ADHB Charitable Trust

6. APPOINTMENT PROCESS

6.1 Nominations will be sought and appointment will be made by the RRC Chair for a 3 year term, up to two terms.

6.2 In the case of the ADHB Charitable Trust attendance will be at the direction of Trust Chair.

7. SECRETARIAT

7.1 Secretariat support will be provided by the ADHB Research Office.

7.2 Preparation and presentation of papers, agendas and minutes will follow standard ADHB format.

8. PROCEDURE

8.1 The RRC will meet monthly and as required.

8.2 A quorum will be five members with at least three experienced in research

8.3 Members will attend meetings having read the associated papers and research matters as appropriate.

8.4 Decisions will be made on a consensus basis.

8.5 Late applications can be accepted after the agenda closing date, at the discretion of the Chair, with relevant materials being presented by the Chair at the monthly meeting.

9. Accountability

9.1 Perform functions in good faith, honestly and impartially and avoid situations which may compromise the integrity of, or external confidence in, the RRC processes.

9.2 Feedback on scientific review and the decision to support or decline an application will be provided to the applicant within two working days of the RRC meeting.

9.3 The Committee will seek advice related to research issues (e.g. legal, scientific) as appropriate.

10. ACTIVITIES

10.1 The Committee will review all research projects submitted to it for scientific merit and rigor and establish procedures for ranking applications that are subsequently submitted to the A+ Trust.

Decisions to support applications need, at a minimum, to demonstrate the following characteristics:

- Evidence of scientific rigor (this can be shown through previous external scientific review (i.e. HRC, Collaborative Group review))
- Consistent with ADHB policies, goals and objectives
- Complies with all current regulations, standards, guidelines and ethical approval processes

10.2 The Committee will review and respond to issues and concerns brought to its attention, regarding research being proposed or undertaken within the ADHB and make recommendations to the Clinical Leadership Group, the specific Department Clinical Director/Leader, the Research Office and/or the researcher as appropriate.

10.3 The Committee will consider any appeal when management approval for research has been declined and make a recommendation for action.

10.4 The Committee will consider any appeal when applications for funding support have initially been declined and make a recommendation for action to the A+ Trust and the Researcher.

10.5 The Committee will seek outside advice related to research issues (e.g. legal, scientific) as appropriate.

10.6 The Committee will advise management on declared Conflict of Interest related to research projects undertaken within the ADHB.

10.7 The Committee will review issues of misconduct and other behaviours and recommend action according to the ADHB Policy and Procedures to the Clinical Leadership Group.

10.8 The Committee will report research accomplishments, innovations, risks, issues and recommendations via ADHB Clinical Leadership Group to the CEO/Board.

10.9 The Committee will receive a quarterly report (presented by the Research Office Manager) on research within the ADHB.

11. Dual Interest

11.1 If a member of the committee has an interest in any proposal, they shall declare a dual interest (as per ADHB Conflict of Interest Policy) and withdraw

(if deemed appropriate by the Committee), from the discussion and decision making for that particular research project or projects.