AUCKLAND DHB – Research Review Committee (RRC)

Terms of Reference v3 (May 2021)

1. Purpose

1.1 To function as a sub-committee of the ADHB Research Governance Committee advising the CMO and SLT 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 AUCKLAND DHB.

1.3 To provide peer oversight and expert advice to enable the organisation to achieve AUCKLAND DHB 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 contribute to and promote the development and implementation of the AUCKLAND DHB research strategy.

1.6 To provide a conduit for the accountability of researchers via the Research Governance Committee and SLT.

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

2. Objectives

2.1 To contribute to the oversight of research at ADHB

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

2.3 To advise the AUCKLAND DHB Charitable Trust (A+ 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 "National Standards for Health and Disability Research and Quality Improvement", 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 AUCKLAND DHB 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 of New Zealand.

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

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 Research Governance Committee 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 AUCKLAND DHB 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 interventional studies eligible for the expedited ethics review pathway.

3.4 High risk research includes, but is not limited to, first in human and phase 1 trials and other interventional studies that involve high dependency patients.

3.5 Research involving AUCKLAND DHB is defined from either a) involvement of AUCKLAND DHB patients, and b) involvement of AUCKLAND DHB staff. Therefore RRC approval is required a) for any research activity involving AUCKLAND DHB patients, whereby information held by AUCKLAND DHB about patients is sought. RRC approval is required if b) AUCKLAND DHB staff are participating in the research activity, as part of or as a consequence of their AUCKLAND DHB employment, or otherwise have contact with patients or access to their information for research purposes when acting in their capacity as an AUCKLAND DHB staff member. When AUCKLAND DHB is not a site (locality) but the research is introduced to a patient by AUCKLAND DHB staff on

AUCKLAND DHB premises, or during any activity relating to the patient's care by AUCKLAND DHB, 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, 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 RRC Chair
- At least 10 members with a mix of quantitative and qualitative research expertise.
- Manager AUCKLAND DHB Research Office [ex officio]

In attendance

- Secretarial/administrative support

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.

7. Secretariat

7.1 Secretariat support will be provided by the AUCKLAND DHB Research Office.

7.2 Preparation and presentation of papers, agendas and minutes will follow standard AUCKLAND DHB 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 AUCKLAND DHB 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 AUCKLAND DHB and make recommendations to the Executive Leadership Team, 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 designate research projects to be listed on a high risk register and will review Serious Adverse Events reports at the monthly meeting (see Appendix 1).

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 AUCKLAND DHB.

10.7 The Committee will review issues of research misconduct and recommend action according to the AUCKLAND DHB Policy and Procedures to the Research Governance Committee.

10.8 The Committee will report research accomplishments, innovations, risks, issues and recommendations via AUCKLAND DHB CMO to the CEO/Board.

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

10.10

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 AUCKLAND DHB 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.

Appendix 1. High Risk Register

Once the Research Review Committee (RRC) deems that a project is to be added to the High Risk Registry, the A+ number, HDEC number, PI, ADHB approval date, HDEC expiry date and project title will be entered in the High Risk Registry spread sheet. The criteria for a project being added to the High Risk Registry varies from an increased risk to the patient, the already vulnerable nature of the patients, the project involving first in human procedures, devices or drugs.

The week the Research Review Committee agenda is being prepared, an email will be sent to the nominated coordinators asking for any new recruits or Severe Adverse Events (SAEs) to be reported[1]. Any new recruits will be noted separately in the spreadsheet as well as a running total of recruits.

If there are any SAEs reported, a copy of the ADHB SAE report form will be sent back to the coordinator to be filled out. New SAEs will be designed with an * until it can be determined by the RRC if the SAE is a direct result of the trial or due to some other reason (i.e. disease progression). Any SAE determined to not be related to the trial will continue to be designated with an * in the total SAE column of the spreadsheet.

Compliance

Monthly reportage is a requirement to maintain ADHB institutional approval. In extreme cases of non-reporting or insufficient reportage, ADHB approval may be temporarily withdrawn until a satisfactory resolution can be reached. The Research Office will facilitate any resolution to minimise any disruptions

Removal from the High Risk Registry

Projects will be removed from the High Risk Registry once recruitment has been completed and all follow up visits have been completed. At this point, normal procedures for the closing of studies will commence and reportage will not be necessary.

[1] Major SAEs considered to be linked to research participation must be notified within 24 hours to the CMO and Research Office manager.