Institutional process for ethical review of low and negligible risk research

1. Background

Metro North Hospital and Health Service (MNHHS) abides by the National Health and Medical Research Council (NHMRC) and related guidelines and relevant legislation on the review, conduct and monitoring of human research. The NHMRC *National Statement on Ethical Conduct in Human Research* (NS) details the different levels of risk that apply to human research, and sets out guidance by which institutions establish and utilise levels of ethical review, including by full Human Research Ethics Committee (HREC), based on that risk [NS Chapters 2.1; 5.1].

2. Ethical review mechanisms

2.1. The types of research requiring review by an HREC are given in NS 5.1.6:
"(a) all research that involves more than low risk;

(b) research falling under the following chapters (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review – see paragraphs 5.1.22 and 5.1.23):

Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations

Chapter 3.5: Human genetics,

Chapter 3.6: Human stem cells,

Chapter 4.1: Women who are pregnant and the human fetus,

Chapter 4.4: People highly dependent on medical care who may be unable to give consent,

Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness,

Chapter 4.7: Aboriginal and Torres Strait Islander Peoples,

and some categories of research falling under

Chapter 4.6: People who may be involved in illegal activities"

And NS 2.3.9:

"Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information."

2.2. Research that is considered by the institution to carry only low or negligible risk and does not encompass groups or types of research listed in NS 5.1.6(b) may be reviewed under alternative levels of ethical review than an HREC. These alternative levels should be established and

monitored by the institution [NS 5.1.7; 5.1.11; 5.1.18-5.1.21].

Research that is considered to carry negligible risk (no more than inconvenience) and **also** *"involves the use of existing collections of data or records that contain only non-identifiable data about human beings"* may be exempted from HREC review [NS 5.1.22(a) and (b)].

3. MNHHS Process for ethical review of low risk research

3.1. Submitting researchers will use the standard Queensland Health (QH) template for LNR research, available via the QH Online Forms website (https://au.ethicsform.org), ensuring a submission code is received on completion of the LNR form and the submission is thereby in a form to be uploaded to the QH Australian Research Ethics Database (AU-RED).

3.2. A valid submission includes the LNR form, a study protocol, recruitment material and additional tools to be used in the research.

3.3. The submission code provided via the online submission form, one (1) complete hardcopy and 1 complete electronic copy (on USB, disc [or via email for the RBWH only]) must be supplied to the HREC secretariat.

3.4. An assessment will be made by the HREC Coordinator and/or the HREC Chairperson or HREC delegate as to whether the project may be ethically reviewed at a level other than an HREC (2.1 above) or may qualify as exempt from ethical review on the basis that it conforms to NS 5.1.22 (a) and (b) or is not research [NS page 6].

3.5. If the application qualifies as low risk research, the HREC secretariat will distribute the submission to two reviewers, at least one of whom is an HREC member. Allocation will be based on the type of research and the expertise of the reviewer.

3.6. Neither of the reviewers should be involved and/or have a conflicting interest in the research to be reviewed. Any conflict of interest should be declared to the HREC secretariat as soon as possible after receipt of the submission by a reviewer so that a decision on further action may be taken.

3.7. A period of ten (10) working days is allotted for review, from the date the request, including research documents, are sent by the HREC secretariat. If a reviewer is unable to comply with this time-period, and a timely response within 2 weeks cannot be negotiated, or a conflict of interest is identified, an alternative reviewer will be approached by the HREC secretariat.

3.8. The review must be conducted in accordance with NS 5.1.19(a) (b) and (c), be informed by NS Sections 1, 3 and 4 and relevant privacy legislation. Reviewers are required to be familiar with the NS and other relevant human research ethics guidelines, legislation and policies relating to the conduct of research within MNHHS, and should have an understanding of ethical issues that can arise in the research under review.

3.9. If both reviewers recommend approval as LNR research, the HREC Chairperson will issue formal ethics approval for the project with the decision noted or ratified (in the case of a request for waiver of consent) at the next HREC meeting. The investigator should then finalise the Site

Specific Assessment submitted to the Research Governance Officer.

3.10. Where either or both the reviewers decide that the research does not meet the criteria for LNR research, the HREC office will advise the researcher about further steps required, such as full HREC review, including whether completion of the Human Research Ethics Application (HREA) is required.

3.11. The RBWH and TPCH HRECs report to the Executive Management Committee (RBWH) or Executive Director (TPCH) of each facility. Reporting for the previous calendar year shall coincide with the annual report to the NHMRC and include information on the number of LNR submissions and approvals and the time from submission to approval.

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