

## Metro North Office of Research

This document outlines the institutional process for ethical review of low and negligible risk research by the Metro North Health A and Metro North Health B Human Research Ethics Committee's (HREC).

### Background

Metro North Health 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].

At Metro North Health (MNH) Low/Negligible Risk (LNR) projects are reviewed out-of-session and can be submitted at any time for review; this is called the 'Low/Negligible Risk Review Pathway'. These projects are reviewed out-of-session and can be submitted at anytime.

- Determining the [review pathway \(LNR Checklist\)](#)

### Process for ethical review

1. Submitting researchers will use the Human Research Ethics Application (HREA) available via Ethics Review
2. Manager (ERM) for submission of a low or negligible risk research application. At Q4.5 on the HREA, please choose 'Low risk review pathway'.
3. A valid submission includes the HREA, a study protocol and any recruitment material/additional tools that will be used in the research.
4. An assessment will be made by the HREC Delegate as to whether the project may be ethically reviewed via the low risk pathway; greater than low risk or if the project qualifies as a quality initiative and exempt from ethical review.
5. If the application qualifies as low risk research, the application will be distributed to 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.
6. Neither of the reviewers should be involved and/or have a conflicting interest in the research to be reviewed.
7. The review must be conducted in accordance with NS 5.1.19(a) (b) and (c), be informed by NS Sections 1, 3 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 MNH and should have an understanding of ethical issues that can arise in the research under review.
8. The HREC Chairperson will issue formal ethics approval for the project with the decision noted or ratified (in the case of a request for a waiver of consent) at the next HREC meeting. The investigator should then finalise the Site-Specific Assessment for research governance approval.
9. Where it is determined that a project does not meet the criteria for LNR research, the HREC office will advise the researcher about further steps required, such as full HREC review.