Metro South Health

MEMORANDUM

To: MSH Research Community

Copies to: Metro South Research

From: A/Prof Scott Campbell, Chair **Contact No:** 3443 8047
Adj A/Prof Mary Boyde, Deputy Chair
Metro South HREC

Subject: Requests for a Waiver of Consent/Opt-out Approach in LNR Projects

Dear Metro South Researchers,

We are writing to you to provide an update on some recent changes made to the way in which the Metro South Health Human Research Ethics Committee (MSH HREC) reviews and grants a waiver of consent or opt-out method for participants in research studies.

Consent to participate in research must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. In certain circumstances, the requirement for consent may sometimes be justifiably waived if it meets the requirements as set out in 2.3.10 *of National Statement on Ethical Conduct in Human Research 2007 (updated 2018).* A waiver of consent or opt-out process can only be requested for research studies which carry no more than low risk to participants as per 2.3.6 and 2.3.10 (a) of the National Statement. When an HREC or, where appropriate, another review body grants a waiver of consent for research, research participants will typically not know that they, or perhaps their tissue or data, are involved in the research.

Across Australia, expectations regarding the level of scrutiny given to a waiver of consent request has been changing. It is now expected that a research ethics application which includes a request to waive the requirement of informed consent for participants is reviewed and approved by the *full membership* of the HREC as set out in 5.1.29 of the National Statement. This is a different interpretation of this policy. Previously it was understood to be acceptable for a waiver of consent to be reviewed and approved by the Low Risk sub-committee of the HREC which included three members selected from the full membership. This new interpretation also applies to the reviewing and granting of an opt-out approach as set out in Chapter 2.3 of the National Statement.

Given the high volume of applications currently received to each monthly meeting of the full HREC membership, it is not feasible to include all Low or Negligible Risk (LNR) applications on this agenda. This would result in longer turnaround times for lower risk research studies and would significantly impact the quality of review by the HREC members.

In response to recent guidance received from both the National Health and Medical Research Council (NHMRC) and Metro South Health Legal Unit regarding the above expectation, the MSH HREC has sought to develop a process which enables timely review of LNR research, whilst also meeting current compliance expectations.

Therefore, the MSH HREC has changed the review process of LNR applications as follows:

- If your LNR application includes a request for a waiver of consent or use of opt-out consent, the application will be circulated amongst all HREC members for specific consideration of the waiver/opt-out request following Low Risk sub-committee review. This will add approximately 1-2 weeks to the review timeline. Therefore, please allow 4-6 weeks for the entire review process and factor this into your research study planning. The formal ethical clearance letter will be issued once the waiver/opt-out request is endorsed by the full HREC.

Specific Considerations

- When designing your research studies ensure you give due consideration to choosing a methodology which enables the informed consent of your participants where practical, even when only accessing their data contained in medical records such as the iEMR. Extracting a patient's medical data makes them a participant in your study, even if you have no direct contact with them. The National Statement states that respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. The Australian Privacy Principles Guidelines contain further information about consent and the handling of personal information.

- Should your chosen research method require that informed consent be waived, please ensure you justify this by explicitly addressing the criteria for a waiver as set out in 2.3.10 of the National Statement in your answer to Q 2.2.8 of the HREA form. Alternatively, if it requires an opt-out methodology to be employed, please ensure your answer at Q2.2.7 of the HREA Form addresses the requirements of 2.3.6 of the National Statement. Applications which do not adequately address these questions may not proceed to ethical review and may be returned to the applicant for modification. This is to ensure a timely review of such applications when sent to the HREC.

For more information regarding any of the above, please contact the Metro South Research office on 3443 8047 or MSH-Ethics@health.qld.gov.au

Yours sincerely,

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Chair, Metro South HREC

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