MEMORANDUM

To:	Metro South Research Community		
Copies to:	Metro South Health Executive Directors, Divisional Chairs, Research Directors, and Research Managers		
From:	MSHREC Coordinator, Metro South Research	**Contact No:** Contact email:	(07) 3443 8047 MSH-Ethics@health.qld.gov.au
Subject:	Submission requirements for Metro South Human Research Ethics Committee (MSHREC)		
		Date:	19/10/2023

In an ongoing effort to reduce the administrative burden on our research community and enable efficiencies, the MSHREC would like to clarify the type of submissions that **do not require** ethical review. Section 5.1.37 of the NHMRC National Statement outlines that *"An institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review".* MSHREC continues to not require submissions which do not impact the ongoing ethical or scientific validity of a project.

While such changes/notifications do not require an individual submission, they can be listed in the next annual progress report for the project where the sponsor and/or research team feel is necessary.

Please see below a list of submissions that **do not** require ethical review:

- **Dear Investigator Letters (DIL)** that have no requirement for changes to Protocol or Participant Information and Consent Form (PICF).
- **Amendments to add additional investigators** that do not take a lead role in the project (e.g., lab staff, research assistants). Please note that the corresponding Research Governance Office (RGO) **may** need to be notified if the additional person has an impact on the ongoing site-specific acceptability (e.g., a contract change or budget change etc is required).
- **Amendments to study documents that are purely administrative (minor).** These should instead be noted on a study log by the Coordinating/Principal Investigator (CPI/PI) or Study Coordinator and can be submitted at a future date when an amendment that is more than administrative in nature is made.
- **Protocol deviations.** Whilst all protocol deviations need to be reported to the Sponsor, only those that are identified as serious or suspected need to be reported to the MSHREC as per NHMRC Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018).
- **Site-specific PICFs and other site-specific documents.** Only Master documents should be submitted to the HREC for multi-site projects approved under the National Mutual Acceptance (NMA) scheme. Site-specific versions are to be submitted to the corresponding RGO as part of the Site Specific Assessment (SSA), as per Section 3.4 of the QLD Health Research User Guide.

- **Notifications of changes to sponsor details**, such as name or address, that do not require updates to the study documents. However, all RGOs involved in the project will need to be notified of these changes.
- **Suspected Unexpected Serious Adverse Reactions (SUSAR) notifications and Serious Adverse Event (SAE) notifications*** Significant safety issues do not need to be reported unless they result in an Urgent Safety Measure (USM), an amendment to the study, or a temporary halt or early termination of a trial, as per Appendix 1 of the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods.

Please note: Items above marked with an Asterix (*) are still required where Metro South is the Sponsor of the study.

Maria Wojciechowski
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