MEMORANDUM

To: Metro South Research Community

From: Sonia Hancock, Manager, Research Integrity and Compliance, Metro South Research, Metro South Health (MSH)

Contact No: (07) 3443 8046

Date: 17 November 2020

Subject: Study submission requirements for Metro South Research Governance Office

Dear Metro South Researchers

In an effort to reduce the administrative burden on our research community, the Metro South Research Governance Office (RGO) *no longer* requires submission of documents, which do not have an impact on ongoing site acceptability (see note below). Master Patient Information and Consent Forms (PICFs) and the Protocol may be requested for the initial Site Specific Assessment (SSA) review for information purposes only.

Documentation *no longer* required:

- Site specific PICFs
- *Dear Investigator Letters (DIL)
- *Independent Data Monitoring Committee (IDMC) outcome letters where study can continue as planned
- Suspected Unexpected Serious Adverse Reactions (SUSAR) notifications
- Serious Adverse Event (SAE) notifications
- Data Safety Update Reports (DSUR)
- Safety reports (including line listings)
- *Protocol deviations
- Research protocols/protocol amendments
- Investigator brochures/investigator brochure amendments
- Synopsis
- Case Study
- Curriculum Vitae

Please note:

- Items marked with an Asterix (*) are also **not** required by the MSH Human Research Ethics Committee (HREC) unless they have a bearing on the ongoing ethical and scientific validity of a study.
- This notice is not applicable to research projects being conducted under the Tele-Trials Model at this time.

If further clarification is required, please don't hesitate to contact the Metro South RGO on (07) 3443 8046 or MSH-RGO@health.qld.gov.au.

Sonia Hancock
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Note: Changes to site acceptability will include changes to financial, legal and risk implications.