

RBWH Research Services Update

October 2019

Reminder

- All **new** clinical trials require you to submit evidence of Principal Investigator Good Clinical Practice certification with your Site Specific Assessment (SSA) application, please refer to the [MNHHS website for more information](#). If one has not been previously submitted to the RGO, please ensure you include in your next submission.
- [Ethics and Governance Clinics](#) – You or someone you know need assistance with ethics and SSA application(s)? Come to our Research Clinics! To book an appointment ring 3646 4301. For more information see our [website](#). <https://metronorth.health.qld.gov.au/research/ethics-and-governance/clinics>

Improvement processes

- **New** [SSA Checklist and Cover letter](#). The new checklist and cover letter will become mandatory for all new submission in 2020. The checklist has been updated and enables investigators to also use it as a cover letter for their SSA submission. Commercially-sponsored clinical trials can continue to use their own cover letter if it includes details of documents submitted, versions and dates.
- **New** [SSA Guidance Note](#). The SSA Guidance Note accompanies the SSA Checklist/Cover letter to assist researchers with SSA requirements.
- **Stay tuned** [Reporting adverse events](#) - we are working on internal process flows to improve the reporting of SAE's via ERM, particularly for clinical trials in relation to HREC and RGO requirements.
- Over the last two and a half months the RGO have processed a large back log of post authorisation amendments. We apologise for the delay. New amendments are now been processed within 10-15 working days.
- **ERM Acknowledgements** - The RGO will be using the Acknowledgment tile in ERM for our internal work flows. New submissions and amendments will be acknowledged in ERM, this will generate an automated ERM email. Further information and a more detailed email (request for information, authorisation etc) will then sent via our RBWH-RGO generic email.
- **New** [ERM Training and research user guides and videos](#)

Staffing

- As you may be aware in August, Rebekah Steele commenced as the new Research Governance Manager. In September we welcomed Monique Johnson to the Research Governance Office (RGO) as the Acting Administration Officer. Monique will be acting in this position while Janani is acting in the Research Support Officer role.

Contact Us

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