Health
South Western Sydney
Local Health District

Research and Ethics Office
Leadership · Quality · Governance
Locked Bag 7103, LIVERPOOL BC, NSW, 1871
Phone: 02 8738 8304
Facsimile: 02 8738 8310
http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

South Western Sydney Local Health District acknowledges the traditional owners of this land.

Clinical Trial Monitoring and Safety

NSW Health's Safety Monitoring and Reporting for Clinical Trials Conducted in NSW public health organisations policy directive applies to all clinical trials conducted within public health organisations in NSW.

The policy, released on 27 October 2017, outlines the safety monitoring and reporting requirements for trials involving investigational medicinal products or investigational medical devices (referred to as therapeutic good trials) and also the safety monitoring and reporting requirements for trials involving other types of intervention (referred to as non-therapeutic goods trials).

Please see the NSW Health Medical Research – Clinical Trial Monitoring and Safety website for resources, forms, information and FAQs at:
https://www.medicalresearch.nsw.gov.au/clinical-trial-safety-monitoring/

The new policy can be found at:
http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_039.pdf

What changes to reporting requirements have been made?
Fewer reports are required, and all safety reporting to the HREC and/or RGO is the responsibility of the sponsor of the trial.

HRECs will no longer receive: Single case AEs, SAE/SARs and SUSARs* or device/non-therapeutic good trial equivalents or six monthly line listings.
***Note:** If a SAE/SAR/SUSAR meets the definition of an SSI, it will be reported to the HREC/RGO through that reporting mechanism.

HRECs will receive: all significant safety issues via the submission of **Significant Safety Issue Notification Form found under resources and forms at: https://www.medicalresearch.nsw.gov.au/clinical-trial-safety-monitoring/)**, annual safety reports and investigator's brochure updates. Annual Safety reports can be reported in the Annual Progress Report, on the sponsor's template or in the form of the most recently updated Investigator's Brochure or DSUR/DSMB report.

Research Governance Office's will no longer receive: Single case AEs, SAE/SARs and external SUSARs* or device/non-therapeutic good equivalents or six monthly line listings.

Research Governance Office: As per the guidelines listed above the only submissions to be made to the Research Governance Office are as below. Please note lead HREC approval letters for these kinds of submissions are not required to be sent to the local governance office.

- Significant Safety Issues reported as USMs via the Significant Safety Issue Notification Form found under **resources and forms at**: https://www.medicalresearch.nsw.gov.au/clinical-trial-safety-monitoring/, as amendments or as a temporary halt/early termination of a trial.
- SUSARs arising from the site please complete the Local SUSAR/USADE/URSAE Notification Form found under **resources and forms at**: https://www.medicalresearch.nsw.gov.au/clinical-trial-safety-monitoring/

Where the sponsor is another entity- for example, a University, you should seek guidance from that institution. It is likely that the delegation will be to the Principal Investigator.