Responsibilities of the Sponsor-Investigator in MCRI-sponsored IITs: Safety Assessment, Documentation and Reporting

**Annual Safety Report**
- Provide to the HREC on the anniversary of the initial HREC approval

**Updated Reference Safety Information**
- e.g. IB, TGA-approved Product Information
- Provide to the HREC and Investigators as new information becomes available

**Ongoing safety review**
- Report USMs and other SSIs to approving HREC, TGA and other Site PIs within 72 hours and 15 calendar days, respectively, using process outlined below.

**Expedited safety report received from lead site or participating site**
- Sponsor-Investigator/delegate to undertake review within 24 hours of receipt/becoming aware of case

**SSI identified**
- USM instigated
- SAE, SAR, SUSAR
- SAE
- SAR
- SUSAR

**Report SUSARs to TGA and other Site PIs in accordance with process below**

- **TGA**
- Report to the Pharmacovigilance and Special Access branch via email to clinical.trials@health.gov.au

- **Site PIs**
- Forward copy of report provided to HREC

**Site PIs**
- Report local site SUSAR ≤ 24 hrs of receiving expedited safety report from site

**Note:** Site PI responsible for reporting to local RGO

**TGA**
- Report USMs and other SSIs to approving HREC, TGA and other Site PIs within 72 hours and 15 calendar days, respectively, using process outlined below.

**Report all SUSARs occurring in Australian participants to the TGA through the Adverse Event Management System (AEMS) portal or emailing either a Blue Card or CIOMS form to adr.reports@health.gov.au (Refer to SOP005 for further details)**
- For fatal/life threatening, report **immediately but no later than 7 calendar days after being made aware of the case**, with follow-up information within a further **8 calendar days**
- For all other SUSARs, report within **15 calendar days of becoming aware of the issue**