Responsibilities of Site PIs in MCRI-sponsored IITs: Safety Assessment, Documentation and Reporting

SSI reported by Sponsor-Investigator to Site PI

Adverse Event (AE) in local participant

Review must be expedited if suspected to meet definition of SAE or SUSAR to facilitate reporting to Sponsor-Investigator within 24 hours

Site PI/delegate to undertake review

USM instigated at site

Is event serious?

YES → SAE

NO → Non-serious AE

Is event related to IP?

YES → SAR

NO

Is event related to IP?

YES → Adverse Reaction

NO → Adverse Event

Is event unexpected as per RSI?

NO → SAE / SAR

YES → SUSAR

Report and document non-serious AEs/AEs using process outlined below

Document in source notes

Document in CRF if required by protocol

Report and document SAEs (including SARs), SUSARs, SSIs and USMs using process below

Document SAEs, SARs and SUSARs in source notes and CRF

If required by protocol, report non-serious AEs/ARs that require expedited reporting to the Sponsor-Investigator using the trial-specific Expedited Safety Report Form and within protocol-specified timeframe

End of process

Report *SAEs, SARs, SUSARs and USMs to the Sponsor-Investigator within 24 hours of becoming aware of event using trial-specific Expedited Safety Report Form
*The protocol may specify types of SAEs that do not require expedited reporting

Forward copy of safety report and REG Acknowledgement to the Sponsor-Investigator

File copy of safety report and REG acknowledgement in ISF

Report SSIs, local SUSARs and USMs to local Research Governance Office within 72 hours of becoming aware of event using locally-approved process

End of process