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

Adverse Event (AE) in local participant

Site PI/delegate to undertake review

Is event serious?

NO

Non-serious AE

Is event related to IP?

YES

Adverse Reaction

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

NO

Adverse Event

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

Is event related to IP?

YES

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

NO

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

Document in source notes

Document in CRF if required by protocol

End of process

SAE

Is event related to IP?

YES

SAR

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

NO

SAE

Is event unexpected as per RSI?

YES

SUSAR

Document SAEs, SARs and SUSARs in source notes and CRF

NO

SAR

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

End of process

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

USM instigated at site

SSI reported by Sponsor-Investigator to Site PI