What is Serious Adverse Event (SAE) reconciliation?

The SAE reconciliation process is an iterative process and occurs multiple times during a study. The process compares key safety data in the sponsor's safety database with the clinical trial database. This allows for identification a discrepancy between databases, determining whether a discrepancy is acceptable or not, and if acceptable, documenting the discrepancy. For example, a discrepancy can be:

- An SAE present in one database but missing in the other one

- Inconsistent SAE data between the databases (e.g., grade, attribution)

- Missing SAE data in one of the databases

- Mismatched SAE preferred term

The process used by the sponsor includes:

- Comparing of SAE data in the clinical trial database and the safety database

- Reviewing any noted discrepancies

- Resolving the discrepancies

- Making the necessary adjustments to the safety database

If the sponsor identifies any discrepancies, they will contact the research team (e.g., PI, study coordinator).

For CCR-held IND's, please review OSRO SOP 301-S02 *Serious Adverse Event Reconciliation.*

So, what is the research site's responsibility in SAE reconciliation?

All AEs submitted as SAEs need to have the same AE term, grade and attribution on both the SAE form and the routine AE CRF. This will help to keep the data submitted to the sponsor's databases the same. If additional AEs are included in the report, those need to be on the AE CRF. Tips to assist with this process:

- Research Nurse should send SAE reports including follow-ups to Data Manager and ensure CRIS documentation supports the SAE.

- Data Manager will use CRIS as the main source first and if discrepancies exist between source and SAE report, DM will follow up with the Research Nurse.