AEs and SAEs – Sponsor reporting vs. IRB reporting

If you are working on an Industry sponsored study the protocol should give guidance on AE/SAE reporting **to the sponsor**. It is important to report AEs/SAEs to the sponsor, allowing them the information required to process and analyze all data from all sites participating in their trial. The onus is on the sponsor to assess the implications and significance of AE/SAE reporting from all sites, and based on aggregate analysis, determine if an AE/SAE is an **unanticipated problem** requiring IRB reporting for a multi-site study.

**Are AE/SAEs IRB reportable when they happen at our site? Answer: Yes and No.**

If you can answer yes to **ALL THREE** of the following questions concerning an AE/SAE at our site, then it **IS** IRB reportable:

- **Is the event unanticipated AND serious?**
- **Was the event possibly/probably related to the study?**
- **Did the STUDY RELATED event increase risks to the patient or others?**

If you answered **YES to ALL THREE** of these questions, notify your regulatory CRP and they will provide a form for you to complete with the AE/SAE details they will need to report it to the IRB of record. If you can answer **NO to ANY** of these questions, you will still want to note it on an AE/SAE log, but it is **NOT** IRB reportable.

**ARS IM Regulatory has developed an AE/SAE log template that is available to help you track all study AEs/SAEs as well as recognize if they are IRB reportable. We also have an AE/SAE Reporting Form to be used to provide to your Regulatory CRP if an AE/SAE is IRB reportable. For more information, please contact us!**

If you have any questions, please do not hesitate to reach out to: IMRegulatory@uc.edu

**For more information, please click:** Tools and Templates

Thank you!