UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

AEs and SAEs – when do they need to be reported to the IRB?

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.

Helpful Reminders:

It is the responsibility of the PI to have a process in place with the clinical team to make sure they are aware of any AEs/SAEs that occur at our site. This is true of Sponsored or Investigator Initiated studies.

It is the responsibility of the clinical team to keep track of any AEs/SAEs that occur throughout the life of a research study. The best way to do this is by keeping an AE/SAE log.

It is the combined responsibility of the PI/Clinical team to follow the protocol specific guidelines in sponsor reporting of AEs/SAEs.

It is the combined responsibility of the PI/Clinical team to notify AR IMRegulatory of any AEs/SAEs that require immediate IRB submission.

Keeping a log will:

- Allow the clinical team to document that the PI is aware of all AEs/SAEs that occurred at our site by collecting their signature on the log periodically.
- Allow the clinical team to show the sponsor's monitor/auditor that we are aware of the AEs/SAEs that occurred, even if they are 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!