REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

Protocol Deviations – what do I do with them?

Deviations from a study protocol are going to happen. How do I know if they need reported to the IRB?

If you are working on a sponsored study, it's likely that the sponsor will want to be notified of most, if not all, deviations that occur. **However, not all deviations are reportable to the IRB.**

If you can answer yes to **any** of the following questions concerning a protocol deviation, that deviation **IS** IRB reportable:

- ✓ ***Did the deviation increase risk to the patient or cause changes to the Informed Consent or protocol?***
- ✓ ***Did you deviate from the protocol to eliminate an immediate hazard to the patient?***
- ✓ ***Is this deviation serious or continued (happening multiple times) non-compliance?***
- ✓ ***Could this deviation compromise the integrity of the study?***
- ✓ ***Is this deviation a consent violation?***

If you answered **YES** to **ANY** of these questions, notify your regulatory CRP and they will provide a form for you to complete with the deviation details they will need to report it to the IRB of record.

If you can answer **NO** to **ALL** of these questions, you will still want to note it on a deviation 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 deviations 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 deviations that occur throughout the life of a research study. The best way to do this is by keeping a deviation log.

It is the combined responsibility of the PI/Clinical team to notify ARS IM Regulatory of any reportable deviations immediately, and to provide the deviation log for IRB submission with the continuing review.

Keeping a log will:

- ➢ Allow the clinical team to document that the PI is aware of all deviations 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 deviations that occurred, even if they are not IRB reportable.
- ➢ Allow the study team to recognize if there is continued non-compliance at our site that does need reported to the IRB.
- ➢ Provide documentation to your regulatory team of any deviations that occurred to submit as needed with the Continuing Review.

ARS IM Regulatory has developed a deviation log template that is available to help you track all study deviations, as well as recognize if they are IRB reportable. We also have a Deviation Form to be used to provide to your Regulatory CRP if a Deviation 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!