

ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

CHRISTUS HEALTH IRB

DEFINITION OF ADVERSE EVENT

- ▶ Adverse event (AE) means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related (21 CFR 312.32(a)). An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Definition of Serious Adverse Event

- ▶ An AE is considered “serious” (SAE) if, in the view of either the investigator or sponsor, it results in any of the following:
 - ▶ Death
 - ▶ Is considered Life-threatening
 - ▶ Results in Hospitalization or Prolongation of hospitalization
 - ▶ Results in a disability or permanent damage
 - ▶ Causes a congenital anomaly or birth defect
 - ▶ Requires or Required intervention to prevent permanent impairment or damage
 - ▶ Other Important medical event

REPORTING ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

- ▶ The PI or designee collect AEs and SAEs from subject histories, interviews, medical records, assessments, test results, other medical providers, family and friends (as applicable).
- ▶ The PI is responsible to assign severity, seriousness, relationship, and if applicable, the unexpected nature of AEs and SAEs identified from the subject's medical records. This safety information is then reported to the sponsor according to the protocol.
- ▶ The sponsor and the IRB will define the criteria and the prescribed time frames for AEs and SAEs that require Prompt Reporting.
 - ▶ The Sponsor shall describe their requirements in the protocol.
 - ▶ The IRB explains their processes in the IRB policies.

REPORTING ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

- ▶ In cases of Investigator-Initiated Trials, where the investigator is also the Sponsor, safety reporting should be submitted to the Food and Drug Administration (FDA) in accordance with federal regulations (21 CFR 312.32 (C)(V)).
- ▶ AEs and SAEs requiring Prompt Reporting are submitted to the IRB of record, unless otherwise stated.
- ▶ Any internal AE or SAE that is *serious, related, and unexpected* should be reported promptly to the CHRISTUS Health IRB.
- ▶ All internal events resulting in suspension of the research protocol or *death* or significant disability to a CHRISTUS Health study subject, regardless of the IRB of record, shall be reported to the CHRISTUS Health IRB within 24 hours of identification of the death or within 10 days of awareness of all SAEs (other than death).

REPORTING ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

Other tips:

- ▶ Record in the source document and on the CRF
- ▶ If you become aware of an AE or SAE discuss it as soon as possible with the investigator
- ▶ Ensure the information on the AE or SAE is captured during every subject's visit
- ▶ If an unexpected, related, and/or SAE occurs, the investigator must report it immediately to both the sponsor and the IRB of record according to their SOPs and Guidelines.

REPORTING TIMELINES

Investigator's obligations:

TO THE IRB

- ▶ All serious, unexpected and *related to the study* will be reported to the IRB in a timely manner but no later than 10 days from the time the investigator becomes aware of the event.
- ▶ **All** deaths must be reported as SAEs and must be reported within 24 hours of discovery to the CHRISTUS Health IRB, regardless if the CHRISTUS Health IRB is the IRB of record.

TO THE SPONSOR

- ▶ SAE's must be reported to the sponsor via the case form within 24 hours of discovery or as per instructions in the protocol.
 - ▶ The sponsor must then report the SAE to the FDA.

Serious Adverse Events – updated submission form within iRIS

- ▶ Modifications:
 - ▶ Report Type
 - ▶ Removed Related, Possibly Related, Not Related & Unknown
 - ▶ Event Type
 - ▶ Added Related Adverse Event
 - ▶ Description of Serious Adverse Event
 - ▶ The question was modified from 1 long question to 3 shorter questions.
 - ▶ The section titled, Grade was removed
 - ▶ The section titled, Study Medications was removed

**Thank You For Your
Time!!**