Adverse Event Reporting

Adverse Events (AEs)

An Adverse Event is defined by the NIH as: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

The IRB requires submission of an AE report form when the event is unexpected and related/possibly related to the research. Adverse events occurring on a study which satisfy these criteria must be submitted to the IRB within the timeline specified in the policy. Any death, which occurs while the subject is being treated on protocol or occurs within 30 days of completing research related interventions, must be reported immediately if it meets the reporting criteria.

For more information, please refer to HRPP policy 8.1

AEs will be submitted through the RSS system.

External Adverse Events

External Adverse Events are defined as: adverse events that occur at a site under external IRB oversight. External AEs are not reported to the IRB unless they require a change in protocol or revision of the consent document. These are not reported on an Adverse Event report form. The external AE report (i.e., IND Safety Report) is used as justification for the required changes.

External Adverse Device Effects (UADEs)

Unanticipated Adverse Device Effects (UADEs) are defined as: Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

External AEs for device studies must be reported to the IRB (in no case no later than 5 business days following PI notification from the sponsor that the event occurred) in accordance the requirements of 21 CFR 812.150(b)(1).

The PI should submit the report received from the sponsor along with any required Request for Change.

Once the status of a study is changed to “completed,” the IRB will no longer accept external UADE reports except under circumstances where the report involves important new risk information.

For more information, please refer to HRPP policy 8.1

For any questions, please email irbora@unmc.edu

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