



General Adverse Event Informational Sheet

Adverse Event Manual

The current version of the American College of Radiology Imaging Network (ACRIN) Adverse Event Manual (May 2008, v.4) is available from the ACRIN web site located within each protocol's dedicated web page as well as the Regulatory Resources' web page.

Adverse Event Reporting

Prompt reporting of all adverse events (AEs) is the responsibility of each principal investigator (PI) and/or investigator designee (e.g. clinical research associate and/or nurse engaged in clinical research). **It is the responsibility of the principal investigator (PI) to determine grade and attribution of each AE.**

All AEs and serious AEs (SAEs) will be documented in the study participant's chart and on AE case reporting forms (CRFs), in addition to meeting all study-specific reporting requirements of ACRIN, the National Cancer Institution's Cancer Imaging Program (NCI/CIP), and the policies of the local Institutional Review Board (IRB).

NOTE: Any study that includes pharmaceutical, commercial and/or investigational drugs or devices will have additional reporting requirements as defined in the study-specific protocol.

Routine reporting is defined as documentation of AEs on source documents. These source documents may include forms such as the ACRIN AE CRF and the AE Log. The AE Log is an optional source document that is available from the ACRIN web site, located within each protocol's dedicated web page as well as the Regulatory Resources' web page.

Routine reporting documents must be completed and submitted within thirty (30) working days of the first knowledge of an AE. The information from these source documents will be used to prepare bi-annual reports for review by the Data and Safety Monitoring Committee (DSMC), quarterly reports to Clinical Data Update System (CDUS), and the final study report.

Expedited reporting is defined as 1) immediate telephone notification of an SAE to NCI/CIP via TRI (Technical Resources International, Inc.) and to ACRIN within the specified timeframe outlined in the protocol and 2) the written completion of the NCI/CIP Adverse Event Expedited Reporting System (AdEERS) report. Routine reporting requirements also apply. Please note that any study that includes pharmaceutical, commercial and/or investigational drugs or devices will have additional reporting requirements as defined in the protocol.

Your local IRB may stipulate additional AE reporting based upon their review of the protocol. Please refer to your local IRB policies regarding reporting of AEs and SAEs.

Questions Regarding the Adverse Event Reporting Process?

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