

Expedited Adverse Event Reporting Instructions

Adverse Event Expedited Reporting Instructions: By Telephone

For serious adverse events (SAEs) that require 24-hour notification as outlined in the study-specific protocol, please call the following numbers to report the event:

1. TRI – SAE dedicated phone line at: 301-897-1704

- The TRI - SAE dedicated phone line is staffed Monday through Friday from 7:30am – 7:30pm.
- SAEs may be reported via voicemail during off hours.
- A TRI contact for AE/SAE reporting will return your call within 24 hours.

The following details are mandatory when reporting SAEs, so please collect this information and have it available prior to calling TRI:

- Your contact information including:
 - Name
 - Telephone number and e-mail address
- Your institution's name or ID number
- Protocol title and number
- Participant's case number and initials
- Principal investigator's name and telephone number
- Date and time of the SAE
- Date and time you learned of the SAE
- Brief description of the SAE
- A statement regarding the principal investigator's (PI's) determination of the grade and attribution of the event

2. ACRIN – SAE dedicated phone line at: 215-717-2763

- The ACRIN – SAE dedicated phone line is staffed from Monday through Friday 8:30am – 4:30pm.
- SAEs may also be reported via voice mail during off hours.
- An ACRIN contact for AE/SAE reporting will return your call within 24 business hours.

The following details are mandatory when reporting SAEs, so please collect this information and have it available prior to calling ACRIN:

- Your contact information including:
 - Name
 - Telephone number and e-mail address
- Institution's name or Institution's number
- Protocol number
- Participant's case number
- Date and time of the SAE
- Date and time you learned of the SAE
- Brief description of the SAE
- PI's determination of the grade and attribution of the event

IMPORTANT: After calling the TRI - and ACRIN - SAE 24-hour phone notification lines, complete an “Adverse Event Expedited Report (AdEERS)—Single Agent v4.0” form (see AdEERS reporting instructions on the next page).

Submitting an AdEERS Report: Paper and Electronic Submission

After completing the telephone notifications of SAEs, an AdEERS form must also be submitted. A completed AdEERS should be submitted within ten (10) working days or ten (10) calendar days of first knowledge of the AE (Please refer to the protocol for specific reporting requirements).

AdEERS for Imaging Trials: Paper Submission

Some information routinely included in AdEERS forms is not applicable to imaging trials, specifically the: “Course Information” (question # 4) and “Protocol Agent” (question # 10) sections. These questions should be omitted. Therefore, you MUST submit a paper copy of the AdEERS report because the electronically submitted reports are not accepted with omissions.

AdEERS for Imaging Trials with IND Agent(s): Electronic Submission

For imaging trials with IND agent(s), the AdEERS report can be submitted electronically. Please find the AdEERS application on the NCI/CTEP web page at: <http://ctep.cancer.gov/reporting/adeers.html>.

Completing an AdEERS Report

The NCI/CIP “Adverse Event Expedited Report (AdEERS)—Single Agent v4.0”, is accessible at: http://ctep.cancer.gov/forms/34-AdEERSv4_SAT.pdf. You can also access the “Adverse Event Expedited Report (AdEERS)—Single Agent v4.0” document from the ACRIN web site. You will find an electronic copy within each protocol-specific web page and the Regulatory Resources’ web page.

Need Assistance Completing an AdEERS Report?

A TRI representative can assist you with the completion of the AdEERS report through the AdEERSMD help line at: 301-897-7497.

AdEERS Submission Requirements

1. Fax the completed AdEERS report to both TRI and ACRIN at:
 - TRI Fax Number: 301-897-7402
 - ACRIN Fax Number: 215-940-8819
2. Email TRI to notify them of the fax submission at: CIPSAEReporting@tech-res.com
3. Mail the original, signed copy of the completed AdEERS report to ACRIN Headquarters:
American College of Radiology Imaging Network
Attn: ACRIN AE Coordinator
1818 Market Street, Suite 1600
Philadelphia, PA 19103
4. Please refer to your local IRB’s policies regarding the reporting of AEs, SAEs and the submission of the appropriate paperwork to your institution.

Questions Regarding the Adverse Event Reporting Process?

Please Contact:

Cornelia (Lia) Tsikos
ACRIN AE Coordinator
Phone: (215) 574-3236
E-mail: ctsikos@phila.acr.org

Maria Oh
ACRIN Director of Protocol Development and
Regulatory Compliance (PDRC)
Phone: (215) 574-3160
E-mail: moh@phila.acr.org