AE

6654 Adverse Event Case Report Form

ACRIN Study #### **Case #**

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

All questions regarding Adverse Events should be directed to ACRIN Regulatory. All Adverse Events (AEs) and Serious Adverse Events (SAEs), as defined in the 6654 protocol, require routine reporting via this AE CRF within 30 days of the event. In addition, SAEs meeting the criteria for expedited reporting, as specified in the protocol, require (a) telephone report to both NCI and ACRIN within 24 hours of knowledge (deaths only); (b) AdEERS report faxed to both NCI and ACRIN within 10 days of knowledge; and (c) hard copy AdEERS mailed to NCI (only). Submit this form to ACRIN via mail or fax, (215) 717-0936.

	AE Description	AE Short Name CTCAE v3.0	CTCAE Grade	Attribution	1 = Expected 2 = Unexpected	AdEERS Submitted for SAEs	Action Taken	Outcome	Date of AE Onset and Resolution (mm-dd-yyyy) check box "on-going" if the AE is on-going at the time of report
			1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening or disabling 5 = Fatal	1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite		1=No 2=Yes	1 = None 2 = Medication Therapy 3 = Procedure 4 = Hospitalization 5 = Other	1 = Recovered 2 = Improved 3 = Ongoing 4 = Death 5 = Unknown	☐ On-going (X or √)
1									Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going
2									Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going
3									Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going

Comments:

☐	If there are more than 3 AEs for a given visit, check this box and use another AE Form. Page ___ of ___	**Investigator Signature**	**Date: ____ - ____ - 20____ (mm-dd-yyyy)**