

AE**6654 Adverse Event
Case Report Form****ACRIN Study #####****Case #**

Place Label Here

Institution _____ Institution No. _____

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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, (225) 717-0606.

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)
		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	check box "on-going" if the AE is on-going at the time of report.
1								Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going
2								Start Date: ____ - ____ - 20____ Resolution Date: ____ - ____ - 20____ ☐ On-going
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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)		

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Michal Rosen-Zvi

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