ACRIN Adverse Event Log

Institution Number: ______________________________ Investigator Name: ______________________________

ACRIN Protocol Number: __________ Case Number: __________ Patient Initials: __________ Date: __________

Adverse Events: ☐ None

Adverse Events	**Start Date** mm/dd/yy	**Stop Date** mm/dd/yy: check box "on-going" if the AE is on-going at the time of report	**Type of AE**	**Serious Criteria*** **AdEERS Submitted**		**Intensity/ Grade** (Please √ one) **To be completed by the PI**	**Attribution** (Please √ one) **To be completed by the PI**	**Action Taken**	**Outcome**	**PI Initials/ Date**
				Yes*	**No**					
		☐ On-going	☐ Expected ☐ Unexpected	☐	☐	☐ Mild/1 ☐ Moderate/2 ☐ Severe/3 ☐ Life-threatening or Disabling/4 ☐ Death/5	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication Therapy ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown	
		☐ On-going	☐ Expected ☐ Unexpected	☐	☐	☐ Mild/1 ☐ Moderate/2 ☐ Severe/3 ☐ Life-threatening or Disabling/4 ☐ Death/5	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication Therapy ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown	
		☐ On-going	☐ Expected ☐ Unexpected	☐	☐	☐ Mild/1 ☐ Moderate/2 ☐ Severe/3 ☐ Life-threatening or Disabling/4 ☐ Death/5	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication Therapy ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown	
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Comments: ____

(Specify AE) ____

*All Serious AEs that are fatal, life-threatening, requires inpatient hospitalization or prolongation of an existing hospitalization, and results in persistent or significant disability or incapacity require an expedited adverse event reporting within via telephone 24 hours of knowledge of the event and submission of report within ten (10) working days of knowledge of the event.

American College of Radiology

Investigator Signature: ______________________________ Date: ____________________

Case Number: ________ Patient Initials: _______

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