



ACRIN Protocol 6673
SUMMARY OF CHANGES

February 26, 2008

Amendment # 3

The protocol was revised to clarify adverse event reporting logistics. Changes were made to the following places:

Cover Page

Amendment 3 and version date February 26, 2008, have been added.

15.7, Recording of Adverse Events, Page 291st paragraph, 2nd sentence: bold text added to “possibly, probably, or definitely”; “should be recorded” changed to “must be recorded”1st paragraph, 3rd sentence: “will also be recorded” changed to “must also be recorded”3rd paragraph, 2nd sentence: “will be reviewed” changed to “must be reviewed”4th paragraph, 3rd sentence: “should be followed” changed to “must be followed”4th paragraph, last sentence: “possibly related” changed to “possibly, probably, or definitely related”; “should be recorded” changed to “must be recorded”**15.8, Regulatory and Reporting Requirements of Adverse Events, Pages 29-31**15.8, 3rd paragraph, 1st sentence: part (b) re-written and reads, “completed AdEERS report faxed to both NCI/CIP (via TRI) and ACRIN within 10 days of knowledge along with an email confirming fax submission of the AdEERS report”15.8, 3rd paragraph, last sentence: “should be reported” changed to “must be reported”15.8.1, 1st sentence: “will be reported” changed to “must be reported”

15.8.1, Points 1-2: added and reads,

1. *Grade 1 Expected with an attribution of possible, probable, or definite must be reported by routine reporting procedures.*
2. *Grade 1 Unexpected AEs with an attribution of possible, probable, or definite must be reported within ten (10) days of first knowledge of the event. Routine reporting procedures also apply.*

all subsequent points appropriately renumbered

15.8.1, Points 3-4, 6-10: “an” added before “attribution”; bold text added to “possible, probable, or definite”; “will be reported” changed to “must be reported”

15.8.1, Point 5: “with an attribution of possible, probable, or definite” added

15.8.2, 1st sentence: “should be documented” changed to “must be documented”**15.9 Expedited Reporting to NCI and ACRIN, Page 31**

15.9.1: Re-written and reads,

Any serious adverse event (SAE) with an attribution of possible, probable or definite must be reported. Adverse event (AE) of lesser severity and an attribution of possible, probable or definite is reported on ACRIN AE case report forms and submitted with routine data submission. However, the following guidelines require a written report submitted within ten (10) days of the serious adverse event.

15.9.2: “should be reported” changed to “must be reported”

15.9.3: “an” added before “attribution”; bold text added to “possible, probable, or definite”; “will be reported” changed to “must be reported”

15.10 How to Report, Pages 31-32

15.10.1, 1st sentence: “CTCAE/CTC Archive” added parenthetically after “<http://ctep.info.nih.gov>”

15.10.2, 1st paragraph: TRI phone number corrected; “after hours” changed to “available Monday through Friday”; “and on weekends” added

15.10.2, 2nd paragraph: “, followed by an e-mail to CIPSAEReporting@tech-res.com confirming that the AdEERS report was faxed” added

15.10.3, 1st paragraph: “after hours” changed to “available Monday through Friday”; “and on weekends” added

15.10.3, 2nd paragraph: “should be sent” changed to “must be sent”; ACRIN fax number corrected

15.10.3, address information: “ACRIN 6673 AE Coordinator” changed to “ACRIN AE Coordinator”

15.10.4, last sentence: bolded; “local institution’s IRB” changed to “local IRB’s”

The following additional changes were made:

Appendix I, Study Chart, Pages 49-50

Within 2 weeks before the RFA treatment, 1st bullet: “and/or abdominal MRI scans” added

Month 18, 2nd bullet: “and chest” added