



ACRIN Protocol 6657
SUMMARY OF CHANGES

March 8, 2010

Amendment # 6

In addition to routine updates to the protocol and Informed Consent Form to adhere to current NCI/CTEP language, a typo in the Schema, a typo in the Informed Consent Form, and a typo in Section 5.0 to specify that eligibility criteria will match that of the CALGB 150007 protocol, as intended throughout the course of the trial, have been corrected.

Cover Page

Amendment 6 and version date March 8, 2010, have been added.

Table of Contents

Page numbers were adjusted to match the current version.

Schema, Page 5

2nd table, specific to MRI time points, 4th column, 4th row: "Serum Sample" has been moved to the right to the 5th column, 4th row.

5.0 Eligibility Criteria, Page 17

1st paragraph, 1st sentence: has been revised to specify that "ACRIN 6657 eligibility criteria match that of CALGB Correlative Science trial 150007.

1st paragraph, 2nd sentence: has been deleted for reasons of repetition.

1st paragraph, now-2nd sentence: has been revised to read—"Patients with histologically-documented tumors per CALGB criteria that are at least 3 cm ...".

1st paragraph, now-3rd sentence: "(Type 1) or taxane ..." and "(Type 1 followed by Type 2)" have been added.

1st paragraph, new-4th sentence: "See Section 3.0 of the CALGB 150007 protocol for the complete eligibility description." has been added.

Section 5.1 header: has been moved to appear immediately above the 5.1.1 and 5.1.2 criteria specific to the ACRIN 6657 MRI Study.

9.0 Adverse Event Reporting, Page 46

Section 9.3, Adverse Event Grading, 1st paragraph, 1st sentence: "version 3.0" has been deleted and terminology has been revised to read—"CTEP Active version of the" CTCAE.

Appendix I Sample Informed Consent for Research Study, Pages 56-64

Page 56, 1st paragraph, 4th sentence: "Taking Part in Clinical Trials: What Cancer Patients Need to Know" has been updated to "Taking Part in Cancer Treatment Research Studies".

Page 58, under "Blood Samples", final sentence: "Type 1" has been deleted.