



**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**

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

**5.0 Eligibility Criteria, Page 17**

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

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

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

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

1<sup>st</sup> paragraph, new-4<sup>th</sup> 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, 1<sup>st</sup> paragraph, 1<sup>st</sup> 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, 1<sup>st</sup> paragraph, 4<sup>th</sup> 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.