



## ACRIN 6678

### SUMMARY OF CHANGES

August 17, 2010

Amendment # 5 + Administrative Update

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**This brief amendment removes two Eligibility Criteria restrictions related to Group C (specifying that they apply to only Groups A and B) and the required RECIST imaging for Group C. One clarifying item has been added to the Informed Consent Form Template for Group B, as well.**

#### **Cover Page**

Amendment 5, version date August 13, 2010, and Administrative Update completed August 17, 2010, have been added.

#### **Table of Contents**

Page numbers were adjusted to match the current version.

#### **Section 5.1.5, Inclusion Criteria, Page 26**

**“(Groups A and B ONLY)”** has been added; Group C may include potential participants regardless of ECOG performance status score.

#### **Section 5.2.5, Exclusion Criteria, Page 27**

**“(Groups A and B ONLY)”** has been added; prior malignancy no longer excludes a participant from joining the trial as a participant in Group C.

#### **Section 8.0.4, CT Scans, Page 31**

Under “Diagnostic CT”, 1<sup>st</sup> sentence: “for Groups A and B only” has been added as an Administrative Update to further clarify that Group C does not require repeat RECIST scans at baseline.

#### **Section 8.5.1, Imaging Visit C1: Pre-Treatment, Page 37**

Final paragraph: The paragraph describing repeat CT scan for RECIST has been deleted; no additional RECIST CT scan is necessary for Group C participants.

#### **Section 8.9.3, Group C Study Procedures Table, Page 46**

2<sup>nd</sup> footnote below table: “... or a diagnostic CT will need to be scheduled if results are unavailable for verification” has been deleted.

#### **Appendix I, Informed Consent Form Template for Group B, Page 88**

1<sup>st</sup> paragraph appearing under “Time Required”, 5<sup>th</sup> sentence: “(post-cycle 2 of chemotherapy)” has been added for clarification.