



ACRIN 6684
MULTICENTER, PHASE II ASSESSMENT OF TUMOR HYPOXIA
IN GLIOBLASTOMA USING ¹⁸F-FLUOROMISONIDAZOLE
(FMISO) WITH PET AND MRI

SUMMARY OF CHANGES

January 24, 2012

Amendment # 7

This amendment introduces a new study co-chair to the trial, Dr. James Fink, and removes limitations on investigational agents from previous reference to anti-VEGF or PARP-inhibiting monotherapy only in addition to standard chemoradiotherapy/TMZ. With this amendment, potential participants may be scheduled for standard chemoradiotherapy alone or with any investigational agent.

Cover Page

Dr. James Fink has been added as a “Study Co-Chair”.

Dr. Mankoff is now listed as a “Co-Chair” for the trial.

Amendment 7 and version date January 24, 2012, have been added.

Table of Contents

Page numbers were adjusted to match the current version; reference to Appendix VI has been deleted.

Throughout

All reference to specific treatments (a single-anti-VEGF agent or PARP-inhibitor monotherapy) have been removed from the protocol with this amendment; reference to treatment requires standard chemotherapy/TMZ “alone or with an investigational agent”.

Revisions related to the therapeutic options for this amendment may be found on:

- Page 3: Schema Pages (Schema and Eligibility)
- Page 4: Section 1.0, 4th paragraph, 4th sentence
- Page 7: Previous-Sections 2.5 and 2.6 have been deleted; now-Section 2.5 has been revised to describe the reasoning behind opening the trial to additional therapeutic options
- Page 12: Section 6.0, 1st paragraph, 2nd sentence
- Page 12: Section 6.2.2
- Page 13: Section 6.3, 2nd paragraph, 1st sentence
- Pages 19 and 20: Section 9.1, 4th bullet and 2nd NOTE
- Page 20: Section 9.2, 1st paragraph, 1st sentence
- Page 57: Appendix I, Informed Consent Form Template, under “Standard medical procedures that are part of regular cancer care ...”, 1st bullet
- Page 58: Appendix I, Informed Consent Form Template, under “Standard medical procedures that are part of regular cancer care ...”, asterisk below bulleted list
- Appendix VI has been deleted

ADDITIONAL REVISIONS

Section 1.0, Abstract, Page 4

4th paragraph, 4th sentence: “predictive or” has been deleted.

Section 12.9.2, Recipients of e-AdEERS Reports, Page 43

Reference to Cornelia Tsikos has been deleted and reference to ACRIN 6684 has been added.