RTOG 0612, Investigating Markers of Radiation Outcome in Patients With Intermediate-Risk Prostate Cancer Using DNA Microarray Analysis: An RTOG Pilot Study

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RTOG 0612 has been amended as follows:

Title Page: The contact information for the Principal Investigator, Dr. Chakravarti, was updated.

Section 13.5: The sentence beginning, "If we proceed to aim 13.1.2.1.." was corrected.
SUMMARY OF CHANGES
Update Date: July 2, 2009
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RTOG 0612, Investigating Markers of Radiation Outcome in Patients With Intermediate-Risk Prostate Cancer Using DNA Microarray Analysis: An RTOG Pilot Study

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RTOG 0612 has been updated as follows:

References to the "RTOG Tissue Bank" and contact information for "LDS Hospital" were replaced with the "RTOG Biospecimen Resource" name and contact information in the following sections of the protocol:

• Section 10.0
• Section 12.0
• Appendix II (Specimen Collection Instructions)

Appendix I (Sample Consent): Under "Who can answer my questions about the study?", the web site address for the information sheet, "How is Tissue Used for Research", was updated.
RTOG 0612, Investigating Markers of Radiation Outcome in Patients With Intermediate-Risk Prostate Cancer Using DNA Microarray Analysis: An RTOG Pilot Study

Study Chair: Arnab Chakravarti, MD; (617) 724-1159; FAX (617) 726-209

RTOG 0612 has been updated as follows:

For increased clarity, all terminology referring to normal tissue was changed to benign tissue. Changes were made to following sections:

- Section 1.0: Third paragraph, third-to-last sentence
- Section 10.3.6: Second sentence
- Section 10.4.2: Third paragraph, last sentence
- Section 10.4.3: Second-to-last sentence
- Section 10.4.5: Fourth sentence
- Section 13.2: First sentence and Table 1, first column
- Section 13.3.2: Third sentence
- Section 13.6 Stage 1, second paragraph, first sentence; Stage 2, last sentence; Stage 3 last sentence
- Section 13.6.2.1: First sentence
- Section 13.6.2.2: First sentence
- Section 13.6.2.3: First sentence

All references to Emory University were changed to Cedars-Sinai Medical Center, because Dr. Amin has moved from Emory to Cedars-Sinai. Changes were made to the following sections:

- Section 10.3.5: Second sentence
- Section 10.3.6: First sentence
- Appendix I/Sample Consent: "What will happen if I take part in this research study?"/first paragraph, last sentence; second paragraph, last sentence

Other Changes

Eligibility Checklist, Page 1: Question 5 was added to correspond with Section 3.1.5. Patients who have received neoadjuvant hormonal therapy are not eligible for this trial.

Eligibility Checklist, Page 2: To conform with the set elements of RTOG's current database, the following changes were made:

- Question 11: Gender was added as the new question 11, and all subsequent questions were renumbered.
• Question 16 (former question 15): "Calendar base date" has replaced "treatment start date"
• Question 17: Randomization/registration date was added as the new question 17, and all subsequent questions were renumbered.
• Question 18 (former question 16): "Cancer research" has replaced "non-prostate cancer oncology research"

Section 10.4.3: The second sentence was modified to clarify that paired matched benign tissue will be examined.

Section 10.4.5: The fourth sentence was modified to reflect the fact that a common reference design will be employed.

Section 13.5: The seventh and eighth sentences were modified to reflect that this tissue will be collected from both arms if the feasibility (primary endpoint) of this study is successfully addressed.

Section 13.6.2.1: The wording in the first sentence was modified for increased clarity.

Section 13.6.2.2: The wording in the first sentence was modified for increased clarity.

Section 13.6.3: CDUS information was added based on NCI's current analysis plan.

Appendix II/Specimen Collection Instructions: In the last section, contact information for the Tissue Bank was updated.