For **Protocol Amendment #8 of RTOG 0126**, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT In Patients Treated For Localized Prostate Cancer

NCI/Local Protocol #: RTOG-0126/RTOG 0126

NCI Protocol Version Date: June 12, 2014       (Broadcast Date: August 4, 2014)

<table>
<thead>
<tr>
<th>Section</th>
<th>Change</th>
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<tbody>
<tr>
<td>13.4.5</td>
<td>New section added: “Revised Interim Futility Analysis Plan” – The original futility monitoring rule is very conservative and unlikely to lead to early stopping for lack of benefit during the planned full trial duration. A revised rule is provided that permits earlier determination that the trial will not result in a more favorable outcome for the experimental arm (i.e., futility) if the observed data support this conclusion. The reference list was updated to include the Freidlin, Korn &amp; Gray article (reference #78).</td>
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<tr>
<td>13.4.1</td>
<td>A few revisions were made to the 1st, 4th and 5th sentences of this section.</td>
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</table>

**Other revisions made to the protocol include:**

<table>
<thead>
<tr>
<th>Title page</th>
<th>Schema page 12.0 13.4.3</th>
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<tbody>
<tr>
<td>Due to the transition to the NCI National Clinical Trials Network (NCTN), “Radiation Therapy Oncology Group” and “RTOG Headquarters” were replaced with “NRG Oncology”. References to RTOG were modified as appropriate.</td>
<td></td>
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| Title page | Dr. Bruner’s contact information was updated. |
## Section Change

<table>
<thead>
<tr>
<th>Section</th>
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<tbody>
<tr>
<td>Appendix V (AE Reporting Guidelines)</td>
<td>As required by CTEP, references to the “Adverse Event Reporting System (AdEERS)” have been changed to “CTEP Adverse Event Reporting System (CTEP-AERS)” throughout these sections.</td>
</tr>
<tr>
<td>Title page</td>
<td>This Update Date was changed.</td>
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</table>
RTOG 0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, MD, MBA, (314) 362-8566, Michalski@radonc.wustl.edu

RTOG 0126 has been amended as follows:

As mandated by CTEP, CTC version 2.0 reporting requirements were converted to the CTCAE version 4.0. Changes were made to the following sections of the protocol:

- Section 6.12.4
- Appendix V (Adverse Event Reporting Guidelines): Sections B, D, and E

The following section was revised without the insertion of the NCI "CTCAE version 4.0" text because all patients on this trial have moved beyond the acute period and acute toxicities already have been documented using CTC, version 2.0:

- Section 6.12.3: "Acute (≤ 90 days from RT start) side effects of radiation therapy will be documented using the NCI Common Toxicity Criteria version 2.0" was revised to "Acute (≤ 90 days from RT start) side effects of radiation therapy were documented using the NCI Common Toxicity Criteria version 2.0".
RTOG 0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

RTOG 0126 has been updated as follows:

Section 10.3.3: Blood collection time points were added to the Specimen Collection Summary.
RTOG 0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

RTOG 0126 has been amended as follows:

Title Page: The Update Date was corrected.

Index: Appendix VIII and IX were added.

Eligibility Checklist: The page numbers of the checklist were renumbered.

Introduction

- Sections 1.6.1 and 1.6.2 were added to provide a rationale for the SNPs analysis. (pp. 4-5)
- The reference numbers in Section 1.7 were revised as a result of the addition of the REFERENCES in Sections 1.6.1 and 1.6.2. For example, reference 25 is now reference 44. (pp. 5-6)

Section 2.2.6: A translational research objective was added to the study. (p. 7)

Section 4.2.6: This section was added for consistency with Section 10.3. (p. 8)

Section 6.0

- Section 6.11 was added per current RTOG standard. (pp. 11-12)
- The original Sections 6.11 and 6.12 were renumbered 6.12 and 6.13. (p. 12)

Section 9.2: Patient use of Avodart (dutasteride) is not permitted while on study. (p. 12)

Section 10.0

- 10.2.1, 10.3.2, and 10.3.3: Were revised to include the collection and banking of specimens for translational research. (pp. 12-13)
- 10.3.4: The previous 10.3.3 is now 10.3.4. The contact information for LDS Hospital was updated. (pp. 13-14)
- 10.4.1: Was updated for consistency with the changes in Sections 1.0, 2.0, 4.0, and 10.0. (p. 14)
Section 11.0

- **11.1:** The rows, "tissue for banking" and "blood for banking" and the column "During Week 4 or 5 of RT" were added for consistency with Section 10.3. Note "l" was also added. (pp. 14-15)
- Reference numbers were revised as a result of the addition of REFERENCES to Section 1.0. For example, reference 39 is now reference 58. (pp. 15-16)

Section 12.2.1: The zip code for the Image-Guided Therapy Center (ITC) was corrected. (p. 17)

Section 13.0

- **13.1.2:** Consistent with Section 2.2.6, a translational research secondary endpoint was added. (p. 18)
- Reference numbers were revised as a result of the addition of REFERENCES to Section 1.0. For example, reference 49 is now reference 68. (pp. 18-20)

REFERENCES: REFERENCES 25-43 were added for consistency with Sections 1.6.1 and 1.6.2. The subsequent REFERENCES, previously REFERENCES 25-58, were renumbered, and are now REFERENCES 44-77. (pp. 24-27)

Consent (Appendix IB)*:
Under "Consent Form for Use of Tissue for Research"

- Blood" was added to the title and first subtitle of the section for consistency with Section 10.0. (p. 35)
- The third paragraph under "About Using Tissue and Blood for Research" was added to include banking of blood for future research. (p. 35)
- Under "Things to Think About" and "Benefits", blood was added after tissue for clarity. (pp. 35-36)
- Under "Making Your Choice", "blood" was added to statements 1, 2, and 3 for clarity; statement 4 was added to include the SNP analysis; and the original statement 4 is now statement 5. (p. 36)

*Tissue Consent: For currently enrolled patients, a separate, two-page consent form was developed regarding the addition of the SNPs translational research component to the study. (Separate document)

Appendixes VIII and IX: Instructions for tissue and blood collection were added. (pp. 62-64)
SUMMARY OF CHANGES

Update Date: May 11, 2006

RTOG 0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

RTOG 0126 has been updated as follows:

Title Page: The contact information for Mahul Amin, MD (pathology co-chair) was updated.

NOTE: This is an editorial/administrative change to the Protocol. NCI now requires that these changes be documented on the Protocol title page with the date of the update noted as "Update Date".

An updated Protocol is available (no password required) on the RTOG website: http://www.rtog.org
SUMMARY OF CHANGES
Amendment 5, Version Date: April 18, 2006

RTOG 0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

RTOG 0126 has been amended as follows:

Cover Page: Contact information for James Purdy, PhD and Deborah Watkins Bruner, RN, PhD were updated.

Eligibility Checklist - Page 1 of 2, Question #3: "Was the PSA done within a) 120 days prior to registration and prior to biopsy or b) within 120 days prior to registration and at least 10 days after prostate biopsy?" was deleted from the checklist because the eligibility requirement for this test was moved from Section 4.1 Evaluations Required for Eligibility section to Section 4.2 Other Pretreatment Evaluations. As a result of this deletion, all subsequent questions were renumbered.

Section 3.2.6: Use of "5-alpha-reductase (finasteride/dutasteride [Proscar])" was added to the beginning of the sentence to avoid ambiguity.

Section 4.1: Former Section 4.1.3, "Laboratory evaluations to include CBC, platelets, BUN, creatinine, testosterone, serum free PSA (if available), and prostatic specific antigen (PSA); PSA must be done a) within 120 days prior to registration and prior to biopsy or b) within 120 days prior to registration and at least 10 days after prostate biopsy" was deleted from Evaluation Required for Eligibility. As a result of this deletion, the subsequent sections were renumbered.

Section 4.1.3 (Formally Section 4.1.4): The word, "rectal" was added for clarity.

Section 4.2.5: "Laboratory evaluations to include CBC, platelets, BUN, creatinine, testosterone, serum free PSA (if available), and prostatic specific antigen (PSA); PSA must be done a) within 120 days prior to registration and prior to biopsy or b) within 120 days prior to registration and at least 10 days after prostate biopsy (Every effort should be made to obtain all serum PSA values obtained in the 1 year prior to treatment to allow for calculation of PSA kinetics).
The type of PSA assay (e.g., Abbott) should be recorded on the data forms" was replaced under Section 4.2 Other Pretreatment Evaluations, which no longer require these lab tests for trial eligibility.

Section 10.3.3: The contact information for central review and tissue submission (LDS Hospital in Utah) was changed to reflect the new mailing address, e-mail addresses and phone numbers.

Section 11.1: Superscript a: "Every effort should be made to obtain all serum PSA values obtained in the 1 year prior to treatment to allow for calculation of PSA kinetics" was added for clarity.

Section 12.1: "Long Term Follow-up Form (FF)" was deleted as RTOG is no longer requiring this form.

Section 12.2.1: Contact information for Image-Guided Therapy Center (ITC) was updated.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org
SUMMARY OF CHANGES

Update Date: November 24, 2004

RTOG 0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

Section 12.2 – added the link to the Advanced Technology Consortium website because the use of this website is encouraged for all advanced technology sub-groups.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date”, not as a revision.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org
SUMMARY OF CHANGES

Update Date: November 4, 2004

**RTOG 0126**, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

**Study Chair**: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

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Section 6.3.1 deleted because the urethrogram is *NOT* required as part of the “Treatment Planning Imaging and Localization Requirements.” This section was inadvertently added from a previous protocol. The remaining section was renumbered.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date”, not as a revision.

An updated protocol is available (no password required) on the RTOG website: [http://www.rtog.org](http://www.rtog.org)
SUMMARY OF CHANGES

Amendment 4, Version Date: October 18, 2004

RTOG 0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

The protocol has been re-designated RTOG 0126 (formerly RTOG P-0126). The letter “P” (for Prostate) that preceded the protocol number was deleted throughout the protocol to make the protocol designation consistent with current RTOG standards.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org
SUMMARY OF CHANGES

Amendment 3, Version Date: September 17, 2004

RTOG P-0126, A Phase III Randomized Study Of High Dose 3D-CRT/IMRT Versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

Study Chair: Jeff Michalski, M.D., M.B.A., (314) 362-8566, Michalski@radonc.wustl.edu

RTOG P-0126 has been amended as follows:

Title page: The mailing address and degrees for Dr. Michalski were changed to reflect current information.

Section 4.1.2: The phrase “Gleason pattern scores will be divided into 2-4 (well differentiated) and 5-7 (moderately differentiated)” was deleted.

Section 10.3.3: The e-mail address for central review and tissue submission was changed to reflect a new address.

Section 12.0 and Appendix VIIB: The mailing address for the American College of Radiology was changed to reflect a new address.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org
SUMMARY OF CHANGES

Revision 2, September 18, 2003

RTOG P-0126, A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT/IMRT VERSUS STANDARD DOSE 3D-CRT/IMRT IN PATIENTS TREATED FOR LOCALIZED PROSTATE CANCER

Study Chair: Jeff Michalski, M.D., (314) 362-85210 FAX# (314) 362-8521; Michalski@radonc.wustl.edu

IRB Review Requirements:
(   ) Full board review required
(X ) Expedited review allowed, however site IRB requirements take precedence
(   ) No review required

RTOG P-0126 has been revised to include IMRT as follows:

Title Page: The title of the study, as stated above, has been revised to include IMRT. The version date has changed to correspond with the date of this revision. The title was changed also on the Schema page and in Appendix IA for consistency.

Index: “IMRT” was deleted from the title of Appendix VI because Appendix VII “IMRT Quality Assurance Guidelines/Facility Questionnaire” was added.

Schema: The stratification “Radiation Modality, 1. 3D-CRT and 2. IMRT” was added. For Arms 1 and 2 “(ICRU prescription)” was replaced by “(minimum PTV prescription)” and “IMRT” was added. “Treatment is prescribed as a minimum to the planning target volume (PTV) to be delivered at a rate of 1.8 Gy/daily fraction. The PTV includes with margin a clinical target volume that encompasses the prostate and proximal seminal vesicles (see Section 6.0). A “cone-down” after 55.8 Gy to a planning target volume encompassing the prostate only will be optional for forward planned 3D-CRT.” replaced ”All patients will receive treatment to the prostate and seminal vesicles to 57.97 Gy, followed by a treatment volume reduction and prostate boost to the study dose. Treatments are prescribed to the ICRU reference point to be delivered at a rate of 1.87 Gy/daily fraction.” The rationale for this change is the growing availability of IMRT and its benefits in reducing normal tissue radiation dose has prompted many radiation oncologists to request the use of this modality on this clinical trial. To accommodate this modality the method of radiation dose prescription had to be changed because of the greater heterogeneity that accompanies IMRT treatment.
Eligibility on Schema Page: “No previous hormonal treatment (no finasteride or phytoestrogen preparation within 3 months prior to registration)” was rewritten for clarity. “Pretreatment evaluations must be completed as specified in Section 4.1” was added for clarification.

Eligibility Check: Question # 5 on page 1 was rewritten to include “and Gleason score 7” for consistency with the corresponding change in Section 4.1.5 and footnote c in Section 11.1. This change was made because the risk for bone metastases in patients with Gleason 6 and a PSA of 10-20 is too low to justify the cost of a bone scan.

On page 2, question # 21, “Specify Radiation Modality (3D-CRT or IMRT)” was added because IMRT has been added to study.

Introduction: The last three paragraphs of Section 1.5 Dose Selection were added for further clarification and as a result of adding IMRT. The last two sentences of the first paragraph in Section 1.7 Quality of Life were added for further clarification and in the last sentence of the last paragraph “and IMRT” was added per the addition of IMRT.

Section 2.1.1: This primary objective was rewritten to incorporate the addition of IMRT. It now reads “Determine whether 3D-CRT/IMRT to 79.2 Gy in 44 fractions will lead to improved overall survival in patients treated for prostate cancer compared to a group of patients treated with 3D-CRT/IMRT to 70.2 Gy in 39 fractions.”

Section 3.1.5: Reference to Section 4.0 was corrected to Section 4.1

Section 4.0: The requirement that protocol treatment begin within 2 weeks was changed to within 4 weeks of registration. This change was made to accommodate the waiting list that many of our committee and investigators face. Furthermore, allowing IMRT demands greater time to conduct quality assurance and quality control for this modality. The additional two weeks is not felt to be clinically detrimental.

Section 5.0 REGISTRATION PROCEDURES: Additional instructions were added to correspond with the addition of IMRT and the guidelines in Appendices VI and VII. Also, in Section 5.2 and Section 5.3 “registered” was changed to “randomized” for consistency.

Section 6.0 RADIATION THERAPY: “IMRT is allowed” was added. Sections 6.1.1, 6.1.2, and 6.1.2.1 were rewritten to incorporate IMRT and the treatment prescribed as a minimum to the PTV. IMRT creates more intra-target dose heterogeneity. As a result, the ICRU reference points that have been previously used for 3D CRT are rendered meaningless. In order to accommodate IMRT, the
radiation dose prescriptions had to be adjusted to explicitly state minimum dose and volume requirements for target volumes, as well as, maximum limits of dose heterogeneity.

Section 6.2.1: 10 MV was changed to 6 MV because with the use of IMRT energy plays a less significant role in radiation dose distribution, making 6MV appropriate for this protocol.

Sections 6.2.2, 6.2.3, and 6.9.1 were added to cross reference the QA Guidelines on the ITC website and in Appendices VI and VII. Therefore, the previous Section 6.2.2 was deleted.

Section 6.4.2: The CTV definition was amended to “CTV is the GTV plus the proximal bilateral seminal vesicles. Only in the first 1.0 centimeter of seminal vesicle tissue adjacent to the prostate shall be included in the clinical target volume. This 1.0 cm of seminal vesicles refers to both radial (in plane) and superior (out of plane) extent. If both prostate and seminal vesicle are visualized in the same CT slice, this seminal vesicle tissue will contribute to the 1.0 cm of tissue” for further clarification.

Section 6.4.5: The third sentence was changed and a fourth sentence added for clarity: “The bladder should be contoured from its base to the dome, and the rectum from the anus (at the level of the ischial tuberosities) for a length of 15 cm or to the rectosigmoid flexure. This generally is below the bottom of the sacroiliac joints” A table summarizing the naming of organs for submission of data to the ITC was added for clarification.

Section 6.5: Title changed from “3D treatment” to “Treatment Planning.”

Section 6.5.2: In the first sentence, second paragraph, “limits” was changed to “guidelines.” “Penile Bulb Mean dose less than or equal to 52.2 Gy” was added to the guideline table. A sentence was added to the end of the table footnote for clarity.

Section 6.6: A sentence was added to the end of the first paragraph for clarification of treatment verification.

Sections 6.7 and 6.8: These sections were rewritten to clarify ITC quality assurance procedures.

Section 6.9.3 Protocol Deviation: This section was changed from “95% of ICRU Reference Dose” to “Prescription“ isodose in each of the three bullets. In addition, in the first bullet, “100” was changed to “>98 %” and “appropriate” was deleted; in the second bullet “100” was changed to “98” % and “appropriate was deleted; in the third bullet, “appropriate” was deleted and “, or less than 100% of CTV” was added. These changes were made because the greater heterogeneity that
accompanies IMRT requires more explicit description of dose limits.

**Section 6.9.4:** The first part of the first sentence was changed to read: “Maximum dose to ≤ 2% of the PTV volume,” and the second sentence was added: “This maximum dose volume of the PTV must not be shared by an “Organ at Risk.” These changes were made to accommodate the use of IMRT and explicitly prevent high dose area to be within a normal organ.

**Section 10.3.2.3:** A typo in the word “include” was corrected.

**Section 10.3.3:** The email address for LDS Hospital was updated to ldhflinn@ihc.com

**Section 11.1:** Superscript k was added to the study parameter “Radionuclide bone scan” to correspond to the addition of footnote k, which was added for clarification. Superscript h was added to month 24 of “Functional Alterations due to Changes in Elimination [FA]” for clarity.

**Section 11.3.1:** The cross reference (See Section 12.1) was corrected to 11.1.

**Section 12.1:** “Functional Alterations due to Changes in Elimination [FA]” and “The Spitzer Quality of Life Index [SP]” will be collected “then every 6 months through year 5” after 6, 9, 12, 18, and 24 months for consistency with Section 13.4.4 of the protocol.

**Section 12.2.1:** The phone number for James A. Purdy, Ph.D. was corrected.

**Section 12.2.2:** The email address for digital data submission was changed.

**Section 13.2.1:** “and Radiation Modality: 3D-CRT vs. IMRT” was added to the first sentence to reflect the addition of this stratification to the protocol. In the last sentence, “or IMRT dose (79.2 Gy) and “or IMRT (70.2 Gy)” were added for consistency.

**Sections 13.2.2 and 13.4.4:** “/IMRT” was added to 3D-CRT in the first sentence of 13.2.2 and in two places in 13.4.4 for consistency.

**Section 13.6.1:** An “s” was added to variable; “and Radiation Modality” was added for consistency here and in **Section 13.6.2** as well.

**Appendix IA, Sample Consent:** Under Why Is This Study Being Done? “three dimensional (3D)” was deleted in three places. “Modern radiation therapy planning methods with 3-dimensional therapy or Intensity Modulated Radiation Therapy (IMRT) allow safer delivery of higher than conventional doses of radiation.” was added. In the second paragraph, “Both” and “and IMRT” were added to the first sentence and the end of the last sentence was changed to
“without increased toxicity.” “3D” was also deleted from the last sentence in this section.

Under “What Is Involved in the Study?” “or IMRT” was added to the first sentence under Treatment 1 and Treatment 2; in the last bullet “bowel habits,” was added and the text accompanying the table was changed to read “questionnaires numbers 2 and 3.”

Under What Are The Risks Of The Study? “3D” was deleted from the second to last sentence. Under Are There Benefits To Taking Part In The Study? “or IMRT” was added to the second sentence.

Under What Other Options Are There? “or IMRT” was added to the last sentence of first paragraph.

Under What Are The Costs? “3D” was deleted from the beginning of the first sentence.

**Appendix VIA:** A new (19 June 2003) edition of “3DCRT Quality Assurance Guidelines for RTOG P-0126” replaced the previous guidelines to establish credentialing requirements and quality assurance guidelines for institutions planning to participate in ATC supported protocols allowing 3DCRT. **Appendix VIB** is the corresponding “3DCRT Facility Questionnaire.”

**Appendix VIIA:** “IMRT Quality Assurance Guidelines for RTOG P-0126” were added to establish credentialing requirements and quality assurance guidelines for institutions planning to participate in ATC supported protocols allowing IMRT. **Appendix VIIB** is the corresponding “IMRT Facility Questionnaire.”
RTOG P-0126, A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT VERSUS STANDARD DOSE 3D-CRT IN PATIENTS TREATED FOR LOCALIZED PROSTATE CANCER

Study Chair: Jeff Michalski, M.D., (314) 362-85210 FAX# (314) 362-8521; Michalski@radonc.wustl.edu

RTOG P-0126 has been updated as follows:

The version date of Revision 1 has been corrected to August 23, 2002 throughout the protocol and the summary of changes to reflect the date that the protocol was submitted to CTEP (rather than the broadcast date of the revision).

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date”.
SUMMARY OF CHANGES

Revision 1, August 23, 2002

RTOG P-0126, A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT VERSUS STANDARD DOSE 3D-CRT IN PATIENTS TREATED FOR LOCALIZED PROSTATE CANCER

Study Chair: Jeff Michalski, M.D., (314) 362-85210 FAX# (314) 362-8521; Michalski@radonc.wustl.edu

IRB Review Requirements:
(   ) Full board review required
(X) Expedited review allowed
(   ) No review required

RTOG P-0126 has been revised as follows:

Title Page — Mahul Amin, M.D. has been added as Pathology study chair.

Schema — In the Eligibility list, the fifth bullet was corrected: “NX, NO” was deleted from “Clinically negative lymph nodes or histologically negative by nodal sampling or dissection” to correspond with Section 3.2.2.

Eligibility Checklist — Question 3 was revised for clarity; this clarification also was made in Section 4.1.3.

Section 6.6 — The second paragraph, concerning use of real-time ultrasound localization, was added.

Section 7.1, clarifying that neoadjuvant or adjuvant hormone therapy is NOT allowed on this study, was added.

Section 9.1, providing details regarding Subsequent Disease Progression, was added.

Section 10.0 was revised to clarify details of central review and collection of tissue for translational research; Section 10.3 was revised and Sections 10.4 and 10.5 were added to update Section 10 to the current RTOG standard.

Section 13.4.4 — The following sentence was added to clarify how data will be analyzed using the central review Gleason scores: “Secondary analyses of the
primary and secondary endpoints will be performed using the available Gleason scores from central review.”

**Appendix IA** — Under “Signature”, the name/signature of the person obtaining the consent was added to update the consent to RTOG standard.

**Appendix IB** was revised as follows:

- The first and second sentences were clarified: in the first sentence, “You have had or will have” replaced “You are going to have”; in the second sentence, “Your doctor has removed or will removed” replaced “Your doctor will remove”;
- Under “Making Your Choice”, the first sentence was added to update the consent to RTOG standard, and the subsequent sentences were appropriately renumbered;
- The participant and witness statements were added to update the consent to RTOG standard.

A revised protocol is available (no password required) on the RTOG website: [http://www.rtog.org](http://www.rtog.org)