RTOG 0215, “Treatment Of Erectile Dysfunction In Patients Treated With Neoadjuvant Androgen Suppression and Radiotherapy for Prostate Cancer: Impact On Patient And Partner Quality Of Life”

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Bruner@fccc.edu

RTOG 0215 has been amended as follows:

Section 7.1.7: Information about ischemic optic neuropathy and potential loss of vision was added to the toxicity information for sildenafil. A corresponding addition was made to Appendix I, the sample consent, under “What Are the Risks of the Study?”.

Section 7.2 was amended to “Adverse Events”, and RTOG’s standard text was added.

Section 7.3: The NCI-mandated adverse event reporting requirements were added and Appendix III, which included the former guidelines, was deleted. The subsequent appendices were appropriately re-numbered on the Index page and throughout the protocol.

References: Citation number 51 was added, and the subsequent citations were appropriately re-numbered in references and throughout the protocol.

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: June 16, 2005

RTOG 0215, “Treatment Of Erectile Dysfunction In Patients Treated With Neoadjuvant Androgen Suppression and Radiotherapy for Prostate Cancer: Impact On Patient And Partner Quality Of Life”

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Bruner@fccc.edu

RTOG 0215 has been updated as follows:

Sections 5.1 and Appendix IX: The fax number for the RTOG Headquarters was corrected.

Section 7.1.5: The fax number for the CTSU Regulatory Office was corrected.

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

An updated protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: June 1, 2005

RTOG 0215, “Treatment Of Erectile Dysfunction In Patients Treated With Neoadjuvant Androgen Suppression and Radiotherapy for Prostate Cancer: Impact On Patient And Partner Quality Of Life”

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Bruner@fccc.edu

RTOG 0215 has been updated as follows:

Eligibility Checklist, page 4: In this demographic/operational portion of the checklist, question 22 was corrected to correspond to the Schema page, “Specify hormone therapy duration”.

Section 5.1: The fax number for the CTSU Regulatory Office was corrected.

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

An updated protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG 0215, “Treatment Of Erectile Dysfunction In Patients Treated With Neoadjuvant Androgen Suppression and Radiotherapy for Prostate Cancer: Impact On Patient And Partner Quality Of Life”

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Brunner@fccc.edu

RTOG 0215 has been amended as follows:

The patient selection criteria were amended to open the study to a cohort of patients similar to those enrolled on RTOG 99-10. The study now will be available to more patients and sites. The following sections were amended for this change:

- **Title page**: In the title, the phrase, “on RTOG 99-10”, was replaced with “With Neoadjuvant Androgen Suppression and Radiotherapy”. The title also was amended on the Schema page and on the first page of the consent in Appendix I.

- **Schema page**:
  - In the heading below “Schema” beginning “Sildenafil Study Schema begins…”, the phrase “on RTOG 99-10” was deleted.
  - The first stratification variable was amended to “Prior Use of Sildenafil after RT”. The third stratification variable was amended to “Hormonal Therapy Duration” (≤ 120 days vs. > 120 days).
  - In the paragraph below the Schema, “RTOG 99-01 protocol treatment” was replaced with “radiotherapy”.

- **Eligibility Checklist**:
  - **All pages**: In the heading, the parenthetical phrase, “if applicable” was added next to “RTOG 99-10 Case #”.
  - **Page 1**: Questions 1-7 were amended to correspond to changes in Section 3.1, and subsequent questions were appropriately renumbered. In question 11, “other than RTOG 99-10” was replaced with “other than one coordinated by RTOG”. Question 12 was amended for clarity.
  - **Page 2**: In question 15, “sildenafil” was added with “tadalafil” and “vardenafil” following “oral agents”. In the sub-question below question 16, “after RTOG 99-10 protocol treatment” was replaced with “after RT”. Questions 18 and 19 were added, and subsequent questions were appropriately renumbered. Question 20 was amended to correspond to changes in Section 3.2.
  - **Page 3 and 4**: Questions 19-21 were amended, and question 22 was
added to correspond to the Schema. Subsequent questions were appropriately renumbered.

- **Section 1.5.1.3**: In the third sentence, the phrase, “or similar to therapy prescribed in” was added prior to “RTOG 99-10”. In the eighth sentence, “total androgen suppression” was replaced with “radiotherapy and short-term androgen suppression”.

- **Section 3.1**: Sections 3.1.1 through 3.1.4 were amended; Sections 3.1.5 and 3.1.6 were added (and subsequent sections were appropriately renumbered).

- **Section 3.2**: The parenthetical phrase in Section 3.2.1 was amended. In Section 3.2.2, the parenthetical phrase, “AJCC Stage > 0”, was added after “invasive cancer”, and the phrase, “or a hematological malignancy (e.g. leukemia, lymphoma, myeloma)” was added. Sections 3.2.7 and 3.2.8 were added (and subsequent sections were appropriately renumbered). Section 3.2.9 was amended.

- **Sections 6.1, 9.0, and 11.1**, footnote “a” were amended.

- **Section 7.1.3**: In the second paragraph, the phrase “on RTOG 99-10” was deleted in the first sentence.

- **Section 13.2**: 
  - In Section 13.2.1, the phrase, “after RTOG 99-10 protocol treatment” was replaced with “after external radiotherapy”. The third stratification variable was amended to correspond to changes in the Schema.
  - Section 13.2.2 was amended.
  - The first two sentences of Section 13.2.3 were amended to reflect the total accrual of RTOG 99-10.
  - Section 13.2.3.1: In the sentence beginning, “In the revised design” was amended to correspond to changes in stratification variables on the Schema page, and the phrase, “prior to RTOG 99-10 protocol treatment” was replaced with “prior to external radiotherapy”.
  - Section 13.2.3.2 was added.
  - Section 13.3.2.1.1: In the sentence beginning, “In the revised design” was amended to correspond to changes in stratification variables on the Schema page, and the phrase, “prior to RTOG 99-10 protocol treatment” was replaced with “prior to external radiotherapy”.

**Other Changes**

**Schema page**: The “Eligibility” list was amended to the current RTOG standard, “Patient Population”.

**Section 7.1.5**: In the second paragraph, the fax number for RTOG Headquarters was corrected. In the fourth sentence, the phrase, “Upon receipt of the Shipment Form”, was replaced with “After randomization”.

**Section 11.2**: A note was added with information about administration of the assessments only to patients fluent in English.
Section 12.0: The address for RTOG Headquarters was updated.

Appendix IX: In the first paragraph, the fax number for CTSU was corrected. A line for providing the site e-mail address was added. The addresses for submission of completed forms were provided for U.S. and Canadian sites.

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: December 5, 2003

RTOG 0215, “Treatment Of Erectile Dysfunction In Patients Treated On RTOG 99-10 For Prostate Cancer: Impact On Patient And Partner Quality Of Life”

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Bruner@fccc.edu

RTOG 0215 has been updated as follows:

Appendices IV, V, VI, VII, VIII — “Sample” watermarks were added to these appendices for clarity. Institutions must submit data on protocol data forms rather than on appendices.

NOTE: This is an editorial/administrative change to the protocol. NCI 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/
RTOG 0215, Treatment Of Erectile Dysfunction In Patients Treated On RTOG 99-10 For Prostate Cancer: Impact On Patient And Partner Quality Of Life

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Bruner@fccc.edu

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

RTOG 0215 has been revised as follows:

Patients will be stratified by history of prior use of sildenafil after RTOG 99-10 protocol treatment (as well as by IIEF Question #1 Score and RTOG 99-10 Arm) rather than age. The Schema page under “Stratification” was revised for this change, and the following sections were added for this change: Eligibility Checklist, page 1, question 12 and page 3, question 21; Sections 4.2, 13.2.1, 13.2.3.1, and 13.3.2.1.1.

Patient eligibility was revised and clarified:

- The timeframe for patients’ completion of RT on RTOG 99-10 was revised in Section 3.1.3 to read, “Minimum of six months and maximum of 5 years”; corresponding changes were made on the Schema page, in the Eligibility Checklist, page 1, question 3, and in Sections 7.1.3 and 11.1, footnote “a”.

Patient ineligibility was revised and clarified:

- “Current use of any organic nitrate or need for prn nitrates”, was added as Section 3.2.4 and “use of any organic nitrate” was deleted from Section 3.2.5 (former Section 3.2.4); corresponding changes were made to the Eligibility list on the Schema page, to Question 10, page 1 of the Eligibility Checklist (subsequent questions were appropriately renumbered), and to Section 9.0;

- Section 3.2.5 — “Prior use of sildenafil”, was deleted, and “sildenafil” was added to the list of excluded therapies at study entry or throughout study treatment (former Section 3.2.4); changes were made in the following sections to correspond:

  - The Eligibility list on the Schema page;
  - Question 11, page 1 of the Eligibility Checklist;
  - Section 9.0;
  - Appendix I, the sample consent was revised to correspond: Under “What is
involved in the study”, two paragraphs below a title of “Both Treatments” were added, listing the excluded therapies and asking patients to agree to take only sildenafil/placebo during the study as a method to achieve erections.

Other Changes

Title page — Dr. Pisansky’s telephone number was updated.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: August 22, 2003

RTOG 0215, “Treatment Of Erectile Dysfunction In Patients Treated On RTOG 99-10 For Prostate Cancer: Impact On Patient And Partner Quality Of Life”

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Bruner@fccc.edu

RTOG 0215 has been updated as follows:

Section 5.1 — Sites in the U.S. will submit the Study Agent Shipment Form to the CTSU Regulatory Office versus RTOG Headquarters; this change also was made in Section 7.1.5 and Appendix IX.

Section 7.1.5 — Updated Biologics contact information

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/
RTOG 0215, “Treatment Of Erectile Dysfunction In Patients Treated On RTOG 99-10 For Prostate Cancer: Impact On Patient And Partner Quality Of Life”

Study Chair: Deborah Watkins Bruner, Ph.D., (215) 728-2967, D_Watkins-Bruner@fccc.edu

RTOG 0215 has been updated as follows:

Section 12.1 — The title of the F1 form was added; this is a correction, not an addition of a form.

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/