**SUMMARY OF CHANGES**
**Update: January 17, 2012**
***(Broadcast: January 17, 2012)***

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair:** Alan Pollack, MD, PhD, (305) 243-4916, APollack@med.miami.edu

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**RTOG 0534** has been updated as follows:

Dr. Wefel is the new Neuropsychology Co-Chair; his name and contact information has been inserted in place of Dr. Meyers' information in the following sections of the protocol:

- **Title Page**
- **Section 11.9**
- **Appendix VII** (Neurocognitive Battery)

**Section 11.8.1:** Dr. Bruner's e-mail address updated.

**SUMMARY OF CHANGES**
**Amendment 4: November 23, 2011**
***(Broadcast: January 17, 2012)***

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair:** Alan Pollack, MD, PhD, (305) 243-4916, APollack@med.miami.edu

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**RTOG 0534** has been amended as follows:

**Global:** All web links and related descriptions for sub-pages of the RTOG web site were updated.

**Title Page:** Dr. Balogh added as a study co-chair; Dr. Hunt added as Senior Statistician; contact information for Drs. Low and Bruner was updated; protocol document history table added per RTOG format.

**Eligibility Checklist:**

- Time "in days" inserted for questions 2, 7, 8, 17 on pages 1-2. These changes also have been included in **Sections 3.1 and 3.2**.
- Page 1, question 9, first bulleted item, "of the pelvis" inserted after "CT scan" and "MRI of the abdomen and pelvis" replaced with "MRI of the pelvis" for consistency with **Section 3.1.7.2**.
- Page 2, questions 17 and 18, clarifications regarding finasteride or dutasteride use were inserted, for consistency with **Sections 3.2.3 and 3.2.4**.
- Page 2, question 19, "prior to prostatectomy" replaced with "before or after prostatectomy".
- Page 2, question 23, addition of "superficial bladder cancer" within the last 5 years to the exclusion criteria, consistent with **Section 3.2.9**.
- Page 3, question 25 regarding RT dose was deleted. The subsequent questions were renumbered.

**Section 1.4:** Details regarding blood and urine collection were added to the end of the second paragraph.

**Section 2.2.10: "**Buffy coat cells" replaced with "whole blood", per RTOG Biospecimen Resource collection procedures.

**Section 3.1.7.2:** For clarity, "of the pelvis" inserted after "CT scan" and "a noncontrast CT is permitted if the patient is not a candidate for contrast" added.

**Sections 3.2.3 and 3.2.4:** Clarifications regarding finasteride or dutasteride use added.

**Section 3.2.5:** "Prior to prostatectomy" replaced with "before or after prostatectomy".

**Section 3.2.9:** Exclusion of patients with "superficial bladder cancer" within the last 5 years added.

**Section 4.2.2:** In the first sentence, "simulation" added after "non-contrast CT"; in the second sentence, "simulation or CT scan and MRI" was replaced with "simulation or MRI"..

**Section 5.2.2:** In the first sentence, "and/or" was replaced with "and".

**Section 5.3:** Regulatory pre-registration text added, per RTOG standard.

**Section 5.4:** The web support e-mail address was updated in the next to last paragraph.

**Section 6.0:** Timing clarifications ("+/- 1 week" replaced with "+/- 14 days"; "weeks and months" throughout replaced with "days") inserted for radiotherapy start at the beginning of the section (bold text) and at the beginning of Section 6.1.

**Sections 6.1, 6.3, 6.4.1-6.4.3, 6.5.4, 6.7, and 6.8:** Revised throughout for clarity regarding radiation therapy. In particular, the DVH criteria for the bladder and rectum were changed, replacing deviations with secondary variations because these have been very difficult to achieve, especially for Arm 3. It should be noted that prior studies never incorporated DVH criteria for the bladder, rectum and bowel. This study represents a significant advance in terms of acquiring data on these parameters that will be used to more clearly define such parameters in the future. It was premature to define deviations in this trial.

**Sections 6.4.3.1 and 6.4.3.2**: Revised the RTOG web site address for the Prostate Pelvic Lymph Node Contouring Atlas.

**Sections 6.6.1 and 6.8.1:** "RTQA" inserted in place of "The ITC" in the first sentence of each subsection.

**Section 6.6.3:** Deleted "for the axial and coronal planes (or multiple axial planes as outlined in QA Guidelines)" from the sentence.

**Section 7.0:** Timing clarification (+/- 2 weeks) inserted for short term androgen deprivation start at the beginning of the section (bold text).

**Sections 7.1.1 and 7.1.2**: Clarification added regarding the duration of antiandrogen and LHRH agonist treatment.

**Section 7.2.2:** "Trelstar" inserted after "Lupron".

**Sections 7.3.2 and 7.4.2:** In each section, the font of the next to last sentence (regarding termination of flutamide/bicalutamide) was bolded for clarity regarding drug administration timing.

**Section 7.7.1:** At the end of the first paragraph following "CTEP NCI Guidelines: Expedited Adverse Event Reporting Requirements", the date "January 2005" was replaced with "July 26, 2011".

**Section 10.3.1.2 and 10.3.1.3: "**Buffy coat" replaced with "whole blood", per RTOG Biospecimen Resource collection procedures; -20° C replaced with -80° C. Also, "buffy coat" was replaced with "whole blood" in **Sections 1.4, 2.2.10, 11.2.2.4, 11.3.5, and 13.1.2.15**.

**Section 10.3.1.3:** The DNA collection times in the collection summary table were reduced; timing clarifications (e.g., +/- 1 month; +/- 2 months) inserted for specimen collection in the summary table; specimen collection details updated per RTOG Biospecimen Resource procedures.

**Section 10.3.3:** The street address for the RTOG Biospecimen Resource was updated.

**Section 10.4:** The RTOG reimbursement text was updated. The updated text includes a web address for the Reimbursement and Case Credit Schedule located on the RTOG web site.

**Sections 11.2 and 11.3:** Timing clarifications inserted throughout for radiotherapy treatment start (+/- 2 weeks) and for assessments during follow-up (e.g., +/- 2 weeks; +/- 1 month).

**Section 11.2.2.4:** "Buffy coat" replaced with "whole blood", per RTOG Biospecimen Resource collection procedures.

**Section 11.3.5:** "Buffy coat cells" deleted.

**Section 12.2:** Under Preliminary Dosimetry Information,"C1, C3" removed from the digital data submission list.

**Section 13.1.2.15:** “Buffy coat cells” replaced with “whole blood”, per RTOG Biospecimen Resource collection procedures.

**Section 13.3:** Second paragraph, third sentence, deleted “double-secret”.

**Appendix I (Sample Consent):**
What side effects or risks can I expect from being in the study?

- “Increased long-term risk of developing diabetes” and “increased long-term risk of cardiovascular disease” were inserted in the list of “Rare and Possibly Serious” hormone therapy risks; a sentence regarding LHRH agonists was added.
- In the paragraph about reproductive risks, “nor donate sperm…or during the first 3 months after cessation of therapy” was inserted for consistency with the protocol (Section 7.4.3).

Will my medical information be kept private?

- Per NCI, the paragraph beginning “A description of this clinical trial will be available…” [new FDA language per 21 CFR 50.25(c)] and the “Note to Informed Consent Authors” were inserted to provide additional details to participants and the local institution.

About Using Tissue, Blood, and Urine for Research

- In the second paragraph under “About Using Tissue, Blood, and Urine for Research”, the web link for the tissue information sheet was updated.

Things to Think About

- Fourth paragraph, second sentence, “is” replaced with “are”.

Where can I get more information?

- The NCI’s TTY number is no longer in service and was deleted.

**Appendix VI (Biospecimen Collection Appendices):** Updated per current RTOG Biospecimen Resource procedures.

**SUMMARY OF CHANGES**
**Amendment 3: Version Date: December 23, 2010**
*(Broadcast: January 11, 2011)*

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair:** Alan Pollack, MD, PhD, (305) 243-4916, APollack@med.miami.edu

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**RTOG 0534** has been amended as follows:

As mandated by CTEP, CTCAE version 3.0 reporting requirements in **Section 7.7** of the protocol will be converted to CTCAE version 4 for grading of all adverse events reported via AdEERS beginning January 1, 2011. **All case report forms will continue to use CTCAE version 3.0.**

Note: REFERENCES to CTCAE, version 3.0, may remain in the protocol. These are appropriate, as treatment decision for patients enrolled on this study were based on that version.

Other Changes
**Section 7.7.3**: This section was amended as required by CTEP to instruct sites to report AML or MDS via AdEERS.

**SUMMARY OF CHANGES**
**Amendment 2: March 24, 2010**
*(Broadcast: April 20, 2010)*

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair:** Alan Pollack, MD, PhD, (305) 243-4916, APollack@med.miami.edu

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**RTOG 0534** has been amended as follows:

**Section 3.1.4**: Prostatectomy Gleason score revised from "8 or less" to "9 or less". Corresponding changes were made to the following sections of the protocol:

- Schema (stratification)
- "Patient Population" text on the Schema page
- Eligibility Checklist: Question 4 on page 1 and question 22 on page 3
- Section 13.2.1

**Section 3.1.7.2**: The CT scan or MRI of the abdomen was deleted; it is no longer a requirement for study entry. This assessment also was removed from the following sections of the protocol:

- **Appendix I (Sample Consent)**, under "What will happen if I take part in this research study/Before you begin the study"
- **Appendix II (Study Parameter Table)**

**Sections 3.2.5, 3.2.6, and 3.2.7**: Eligibility criteria added; the subsequent items were renumbered.

**Section 5.2**: For clarity, the sentence "Institutions that previously have been credentialed for one IMRT delivery technique…must repeat the credentialing process when they change to a different technology…." was added under the pre-registration requirements for the IMRT treatment approach.

**Section 6.0:** Revised in several subsections (6.4.1, 6.4.2, 6.4.3, 6.7.1, and 6.7.2) to clarify treatment planning and to update the compliance criteria scoring terminology to reflect the standard RTOG language.

**Section 12.2**: The reference to QA guidelines next to the T6 form and the ATC website address above the "note" at the bottom of the section were deleted.

**Appendix V (CTSU Logistics**): The ITC e-mail address was updated under

"Requirements for RTOG-0534 site registration" (second bullet).

**SUMMARY OF CHANGES**
**Update: October 22, 2009**
(Broadcast October 22, 2009)

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair:** Alan Pollack, MD, PhD, (305) 243-4916, APollack@med.miami.edu

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**RTOG 0534** has been updated as follows:

**Eligibility Checklist**: Question 25, the prescribed RT dose must be recorded in gray (Gy) rather than centigray (cGy) units.

**Section 3.1.3.1**: For clarity, "with or without a positive prostatectomy surgical margin" was added.

**Section 3.1.10**: The parenthetical notation regarding the requested serum testosterone value was added for clarity.

**Section 5.3.1**: The RTOG web support address in the next to the last paragraph was updated.

**Section 6.0**: For clarity, "(+/- 1 week)" was added following the treatment times specified. Also, "1.8 Gy per fraction" was added next to each treatment arm immediately above Section 6.1 and at the end of the "Dose Specifications" paragraph.

**Section 7.0**: In the paragraph immediately above Section 7.1, "(+/- 1 week)" was added following the treatment time specified for clarity.

**Section 10.3.2**: This section was added to the protocol to provide additional information to participating sites regarding the storage of biospecimens.

**Section 10.3.3**: "U.S. Postal Service" added to the mailing address for non-frozen specimens; "UPS" inserted in place of "DHL" in the Courier address for frozen specimens.

**Section 11.9**: The reference to "Section 11.9.4" corrected to "Section 11.9.5" immediately above the table.

**Section 12.1**: For patients in Arms 2 and 3, the "PQ" form is due to RTOG Headquarters 2 weeks prior to the start of radiation therapy. This data submission due date is included in Sections 11.2.1.1 and Appendix II of the protocol and was added to this section for consistency.

**Section 12.2**: The ATC web site address for the "Digital Data Submission Information" form was updated; the address is case-sensitive. The ITC e-mail address was updated.

**Appendix II**: The separate column, "Beta Amyloid Testing" was merged with the "Blood, urine for banking" column. Blood for beta amyloid testing is included in the blood collection for banking, if the patient consents to blood collection.

**Appendix III**: REFERENCES to the Karnofsky scale were deleted per RTOG standard for studies using the Zubrod scale.

**Appendix VI**: Updated per RTOG Biospecimen Resource standards for specimen collection and shipping.

**Appendix VII**: Revised to include additional information regarding neurocognitive certification. Corresponding changes were made to **Section 11.9.5**.

**SUMMARY OF CHANGES**
**Update: March 31, 2009**
*(Broadcast: March 31, 2009)*

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair:** Alan Pollack, MD, PhD, (305) 243-4916, APollack@med.miami.edu

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RTOG 0534 has been updated as follows:

**Neurocognitive testing optional for institutions**: Participation in the neurocognitive test battery is no longer mandatory for institutions. As a result, the following sections of the protocol were updated:

- Eligibility Checklist, page 4
- Sections 10.1, 11.2.1.3, 11.2.2.3, 11.3.6, 11.9.5, and 11.10

Institutions participating in the neurocognitive test battery must follow the certification process specified in the protocol.

Other changes to the protocol include:

**Eligibility Checklist**: Page 3, Item 24 regarding specification of pathology stage (stratification variable) was added. Specification of LHRH agonist planned duration is now Item 29.

**Section 4.2**: The text for pre-treatment tissue/blood/urine banking and the quality of life and neurocognitive assessments was removed from this section; these assessments are specified in Sections 10.0 and 11.0 of the protocol.

**Sections 10.3 and 10.4**: In accordance with RTOG Biospecimen Resource procedures, prostate tissue needle cores will not be collected; REFERENCES to the tissue cores were removed. As a result, Appendix VII (Specimen Plug Kit and Instructions) was deleted from the protocol and the remaining Appendices were renumbered. Also, the schedule for specimen collection was added to the table in 10.3.1.3.

**Appendix I (sample consent)**: Under "About Using Tissue, Blood, and Urine for Research", the web address for the information sheet on tissue research was updated.

**Appendix VII (Neurocognitive Battery)**: Question 4 was revised for clarity; RTOG will not provide translation of the assessments.

**SUMMARY OF CHANGES**
**Amendment 1: January 8, 2009**
*(Broadcast: March 31, 2009)*

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair:** Alan Pollack, MD, PhD, (305) 243-4916, APollack@med.miami.edu

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**RTOG 0534** has been amended as follows:

- PSA doubling time (PSADT) as an eligibility criterion and stratification variable was removed from the protocol. (PSA values will still be collected so that PSADT may be calculated later.) The following sections of the protocol were revised as a result:
  - Schema
  - Eligibility Checklist, pages 1 and 3
  - Section 1.1
  - Sections 3.1 and 3.2
  - Sections 13.2.1, 13.5.1, 13.5.2, 13.5.3, 13.5.4, 13.5.5, 13.5.6, and 13.7
  - REFERENCES: Revised throughout the protocol

- The required protocol entry PSA is now $\geq$ 0.1 and < 2.0 ng/mL. The following sections of the protocol were revised as a result:
  - Schema
  - Eligibility Checklist, pages 1 and 3
  - Section 3.1.2
  - Section 13.2.1

- Pathology stage (pT2 and margin negative vs. all others) was added as a stratification variable. The following sections of the protocol were revised as a result:
  - Schema
  - Sections 13.2.1, 13.5.1, 13.5.2, 13.5.3, 13.5.4, 13.5.5, 13.5.6, and 13.7

Other revisions to the protocol include:

**Title Page**: The contact information for Drs. Pollack and Bruner was updated.

ECOG has endorsed this study; the contact information for Dr. Whittington, the ECOG Co-Chair, was added.

- **Eligibility Checklist**:
- Page 1, "pN0" and "pNx" were added to the text.
- Page 1, Questions 2, 3, 7, 9, 10, and 12 were revised for consistency with changes made in Section 3.0.
- Page 3, Question 18 (medical oncologist) was deleted; it is not a requirement for the study.
- Pages 3-4, the following questions were added to the Checklist:

  24. Specify prescribed RT dose (_____ cGY)
  27. Specify LHRH agonist planned duration (4, 5, or 6 months)

- Page 3, the following was added to Question #25:

  If no, please specify the reason from the following:
  1. Patient refused due to illness
  2. Patient refused for other reason: specify _____
  3. Not approved by institutional IRB
  4. Tool not available in patient's language
  5. Other reason: specify_____

- Page 4, the question regarding health care data was deleted, as the RTOG Health Services Research and Outcomes (HSRO) Committee has decided not to routinely collect social security numbers for Medicare patients for the EQ-5D. Cost utility analysis will be done by means of modeling costs.

**Section 1.1**: Paragraphs 5 and 6 were added to include the rationale for the removal of PSA doubling time as a criterion for eligibility and stratification and the decrease in study entry PSA from $\geq$0.2 ng/mL to $\geq$0.1 ng/mL.

**Section 1.4**: The timing for specimen collection in the last paragraph was revised for consistency with other areas of the protocol.

**Section 2.2.4**: The phrase, "…and genomic (single nucleotide polymorphisms) patterns…" was added to this section for clarity of objective.

**Section 3.1.1.1**: Was revised to clarify that there is no time limit for the date of radical prostatectomy prior to protocol entry.

**Section 3.1.3.2**: Was revised to include margin negative patients.

**Section 3.1.7.1:** The time point for the digital rectal exam was changed to within 8 weeks prior to registration.

**Sections 3.1.7.2 and 3.1.7.3**: The timing for CT scan/MRI/bone scan was changed from 90 days prior to registration to 120 days prior to registration.

**Section 3.1.8**: The protocol entry hemoglobin value was changed to ≥ 10.0 g/dl.

**Section 3.1.10**: A required value (≥ 40% of the lower limit of normal) was added for serum total testosterone.

**Section 3.2.7.7**: The number for the protocol section referenced in parentheses was revised to 3.1.9, to be consistent with the numbering changes made to this section of the protocol.

**Section 4.1.2**: Was deleted from this section ("Required Pretreatment Evaluations") and moved to "Highly Recommended Pretreatment Evaluations" (Section 4.2.4).

**Section 4.2.1**: Buffy coat was included to be consistent with other sections of the protocol, e.g., Section 10.3.

**Section 6.3.1**:The requirement for a retrograde urethrogram or MRI was deleted because the inferior bladder beak or penile bulb are excellent anatomic landmarks for XRT planning which are now part of the consensus guidelines included in Section 6.4.

**Section 6.4.1.1**: Consensus definitions for the clinical target volume (CTV) were added to this section.

**Section 6.4.1.2**: For clarity, "for 3D-CRT technique" was added to the fourth sentence.

**Sections 6.4.3.1 and 6.4.3.2**: Atlases for the prostate bed CTV and lymph node CTV are now available on the RTOG website and are referenced in the protocol.

**Section 6.4.3.2**: The sentence, "Rotational IMRT treatments are permitted, as long as the constraints are met" was added to the paragraph for clarity.

**Sections 6.5.5, 6.5.6, and 6.7.2.2**: Minor changes were made to the text for clarity.

**Section 6.11**: The referenced section numbers were updated.

**Section 7.5**: Was deleted from the protocol, as the text is not applicable to this study.

**Sections 7.7.1 and 7.7.2**: The referenced section numbers were updated; the citation was updated in the first paragraph of Section 7.7.1, and "any adverse drug experience" was updated to "any adverse experience" in 7.7.2.

**Section 10.5**: The RTOG Patient Tissue Consent Frequently Asked Questions website address was updated.

**Sections 11.2 and 11.3**: Were revised to clarify the timing of patient assessments and to be consistent with Appendix I (sample consent) and Appendix II of the protocol.

**Section 11.9.5**: Was updated.

**Section 12.1**: The due dates for the follow-up form and the AUA SI were corrected for consistency with other areas of the protocol; the Neurocognitive form name and form abbreviation were updated.

**Section 12.2**: "DD" was added in parentheses next to "Preliminary Dosimetry Information".

**Section 13.4.2**: The Arm 3 hazard rate was corrected to 0.0051.

**Section 13.4.3**: The full definition of Schoenfeld's formula, which was typed incompletely, was included.

**Section 13.5.7**: All occurrences of the efficacy p-value of 0.002 were corrected to 0.001 for consistency with Section 13.2.2.

**REFERENCES**: Three new REFERENCES were added to the list; the reference numbers were revised in this section and throughout the protocol.

**Appendix I (sample consent)**:

- Under "Before you begin the study", a minor change was made to the final bulleted item for clarity.
- Under "After entering the study and prior to radiotherapy", a minor change was made to the text to clarify that the tests and procedures in that section are for patients on Arms 2 and 3 only.
- Under "During radiation therapy", a minor change was made to the final bulleted item for clarity.
- Under "When you are finished receiving radiation" and "How long will I be in the study?", the timing of patient assessments was revised for consistency with other areas of the protocol.
- Under "What side effects or risks can I expect from being in the study?", the following was added at the end of the paragraph for clarity: "The risks of side effects related to the radiation may be higher in group 3, which includes the treatment of the pelvic lymph nodes".
- Under "Risks and side effects related to the radiation therapy"
    - Likely: The risks were revised slightly.
    - Rare but serious: The phrase "such as a colostomy (bag for stool)" was added to the first bulleted item as an example of a procedure that might be required.
- Under "Risks and side effects related to the hormone therapy", potential risks were added under Likely, Less Likely, and Rare but serious.

- Under "Quality of Life study", the neurocognitive component of the study was separated to clarify that patients can participate in the QOL component of the study without taking part in the neurocognitive portion.
- Under "Quality of Life study", the paragraph describing the need for the social security number of patients for whom health care is covered at least in part by Medicare was deleted, as the RTOG Health Services Research and Outcomes (HSRO) Committee has decided not to routinely collect social security numbers for Medicare patients for the EQ-5D. Cost utility analysis will be done by means of modeling costs.
- Under "About using tissue, blood, and urine for research", the timing of patient assessments was revised for consistency with other areas of the protocol.

**Appendix II (Study Parameter Table)**: Was revised for consistency with Sections 3.0, 4.0, 11.0, and Appendix I of the protocol.

**Appendix IV**: Updated to include pathologic nodal staging.

**Appendix VIII (Neurocognitive Battery)**: The instructions to institutions were updated and Question 4 was added to allow for patient participation in the QOL component of the study even if they decline to participate in the neurocognitive portion of the study.

**SUMMARY OF CHANGES**
**Update: February 13, 2008**
(Broadcast 2/13/08)

**RTOG 0534**, "A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy"

**Study Chair**: Alan Pollack, MD, PhD, (215) 728-2940, alan.pollack@fccc.edu

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**RTOG 0534** has been updated as follows:

**Title page:** The acronym in the title was changed from "SPORT" to "SPPORT"; this change also was made in the title on the Schema page and on the first page of Appendix I, the sample consent.

**Index:** Appendix VIII, the PSA Doubling Time Worksheet, was deleted, and the subsequent appendix was renumbered appropriately.

**Section 3.1.5:** Since Appendix VIII, the PSA Doubling Time Worksheet, was deleted, instructions for calculating PSA Doubling Time were added to this section. No change to eligibility was made.

**Section 7.8:** The Adverse Event reporting guidelines were updated to current RTOG standard.

**Section 10.0:** The RTOG Tissue Bank has been relocated. The phrase, "RTOG Tissue Bank" was updated with the name of the new facility, "RTOG Biospecimen Resource" throughout this section. In addition, **Section 10.1** was updated with the location of the new facility, the University of California San Francisco, and contact information was provided for the RTOG Biospecimen Resource in **Section 10.3.2** and **Appendices VI and VII**.

**Section 10.3:**

- Consistent with the renumbering of the appendices on the Index page, in **Section 10.3.1.1**, Appendix V was changed to Appendix VI, and in **Section 10.3.1.2**, Appendix VI was changed to Appendix VII.
- **Section 11.9.5:** Consistent with the renumbering of appendices on the Index page, the reference to Appendix IX was changed to Appendix VIII.

**Section 12.2** was updated per current ITC digital data submission guidelines.

**Section 13.5.6:** The reference to Appendix II was deleted, as it was seen as unnecessary.

**Appendix II**, Study Parameter Table:

- In the pretreatment column, the word, "Recommended" was replaced by "If patient consents" for clarity for the following assessments: Alk phos, tissue for banking, blood, urine for banking, and beta amyloid.
- Under "Follow up After RT", in the "Annually thereafter" column, the phrase, "For 5 yrs post-RT" was added for clarity for the following assessments: blood, urine for banking and beta amyloid.
- Under "Long-term Follow up", an instruction, "As indicated in Sections 11.2 and 11.3", was added for clarity.

**Appendix V**, CTSU Logistics: At the request of the CTSU, hours of operation were changed from 8:00 am-8:00 pm to 9:00 am-5:30 pm Eastern Time in the following pages:

- Page 1, under "Address And Contact Information For RTOG-0415, CTSU Patient Registration";
- Page 2, under "CTSU Procedures for Patient Enrollment, #3".

**Appendix VIII**, Neurocognitive Battery: Consistent with the renumbering of appendices on the Index page, all REFERENCES to Appendix IX were changed to Appendix VIII. In addition, "NCI #" was added after "Institution Number/Name", and under "For Dr. Meyer's Use Only", the fax number was corrected.