SUMMARY OF CHANGES  
Amendment 3: August 17, 2011  
(Broadcast August 25, 2011)

RTOG 0417, “A Phase II Study of Bevacizumab in Combination with Definitive Radiotherapy and Cisplatin Chemotherapy in Untreated Patients with Locally Advanced Cervical Carcinoma”

Study Chair: Tracey Schefter, MD; (720) 848-0116/Fax# (720) 848-0222; tracey.schefter@uc.denver.edu

RTOG 0417 has been amended as follows:

As mandated by CTEP, this study will utilize CTCAE version 4.0 for AdEERS reporting of adverse events beginning October 1, 2011. Related changes were made to Section 7.7.

All AE reporting on the study 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
Global: All weblinks and related descriptions to sub-pages of the RTOG website were updated.

Title Page: The email address was updated for the RTOG statistician; the Document Version History table was added per current RTOG standard

Section 7.7.3: Text referring to AML/MDS paper report forms has been removed since AdEERS will now be used for reporting AML or MDS and additional notification to CTEP is no longer required. Instructions for submitting a hard copy of the report, including the RTOG HQ address, have also been deleted per current RTOG standard.
RTOG 0417, "A Phase II Study of Bevacizumab in Combination with Definitive Radiotherapy and Cisplatin Chemotherapy in Untreated Patients with Locally Advanced Cervical Carcinoma"

Study Chair: Tracey Schefter, MD; (720) 848-0116/Fax# (720) 848-0222; tracey.schefter@uchsc.edu

RTOG 0417 has been updated as follows:

Section 3.2.22: "> 350 cells/mm³" was corrected to "less than 350 cells/mm³" for consistency with question 32 of the Eligibility Checklist.

Section 11.1: "Creatinine, total bilirubin, AST and/or ALT, calcium" row was corrected to "Creatinine, total bilirubin, AST and ALT, calcium" for consistency with Section 3.1.4.

Section 13.4.5: RTOG Data Safety Monitoring Board information was added per current RTOG standard. All subsequent sections were appropriately renumbered.

Appendix II: In the Zubrod scale 4 description, "or" was deleted after "bed" because it was included in error.
SUMMARY OF CHANGES
Amendment #2, Version Date: August 27, 2008
(Broadcast 9/18/08)

RTOG 0417, "A Phase II Study of Bevacizumab in Combination with Definitive Radiotherapy and Cisplatin Chemotherapy in Untreated Patients with Locally Advanced Cervical Carcinoma"

Study Chair: Tracey Schefter, MD; (720) 848-0116/Fax# (720) 848-0222; tracey.schefter@uchsc.edu

RTOG 0417 has been amended as follows:

Title Page: Contact information was updated for Dr. Kwon, Dr. Schefter, and RTOG Headquarters. The RTOG statistician for this study, Kathryn Winter, was added per current RTOG standard.

Eligibility Checklist, question 10, page 1: "of the pelvis" was added after the second use of MRI for consistency with Section 3.1.8.

Eligibility Checklist, question 25, page 2: The spelling of thromboembolic was corrected.

Eligibility Checklist, signature line, page 3: Wording was updated for web registration.

At NCI's request, information was deleted from the following sections that indicated that the bevacizumab supplied for the study is intended for clinical use only and is not the commercially available Avastin:

- Section 1.4, 1st paragraph, last 3 sentences
- Section 7.1.5, last 3 sentences
- Appendix I, Why is this study being done, last 2 sentences

Section 3.1.2: The timeframe for cervical biopsy was eliminated because it was deemed unnecessary. The corresponding change was made to the Eligibility Checklist and to Section 11.1.

Sections 3.1.6, 3.17, and 3.1.8: The timing for pre-treatment chest x-rays, CTs, MRIs, and PET-CTs was changed from 6 to 8 weeks because the 8-week timeframe was deemed sufficient for screening purposes. Corresponding changes were made to the Eligibility Checklist and to Section 11.1.

Section 3.2.6: "for" was deleted before "carcinoma" for increased clarity.

Section 3.2.8: "with external beam" was deleted after "irradiation" for increased clarity.
The corresponding change was made to the Eligibility Checklist.

Section 3.2.16: "fine needle aspirations or cores biopsies within 7 days prior to treatment start" was eliminated because it conflicts with tissue biopsy parameters elsewhere in the protocol. The corresponding change was made to the Eligibility Checklist.

Section 3.2.18: The criterion was rewritten for increased clarity and accuracy and reads, "Patients with a history of any type of fistula (vesicovaginal, gastrointestinal, etc.) or gastrointestinal perforation." The corresponding change was made to the Eligibility Checklist.

Section 3.2.22: Because invasive cervical cancer is an AIDS-defining illness based on the current CDC definition of AIDS. the criterion was rewritten to state that patients who are known to be HIV positive are excluded unless they have a CD4 count of > 350 cells/mm³. The corresponding change was made to the Eligibility Checklist.

Section 4.2.1, 1st sentence: "but not mandatory" was added parenthetically for emphasis.

Section 5.1.1.1: The numbering was corrected from 5.1.2.

Section 5.1.2: Regulatory Pre-Registration Requirements were added per current RTOG standard.

Section 6.3: The second sentence was corrected to indicate that images will be submitted to RPC not RTOG Headquarters.

Section 6.4.1.2, last section: Planning information was added for Stage IIIA/IIIB with lower third vaginal involvement.

Section 6.4.3.2, 1st sentence: "to avoid overlap with brachytherapy" was added parenthetically for increased clarity.

Section 6.4.5.3, 2nd sentence: Recommendations were added for patients with lower third vaginal involvement.

Section 6.4.5.3, last sentence: "or poor anatomy (obliterated fornices)" was added for increased accuracy.

Section 6.4.6.5: "or at the level of the flange if no ovoids are used" was added for increased accuracy.

Section 6.4.6.9, last bullet: The entire bullet ("mid pelvic isodose curve") was deleted because it is not applicable to the study.

Section 7.1.5, 2nd bullet: 16 mL was corrected from 4 mL.
Section 7.1.13: The updated CAEPR for bevacizumab (NSC 704865) version 1.2, June 19, 2007, replaced the previous CAEPR.

Section 7.2

- 1st and 2nd sentences: Provisions were added for starting cisplatin and radiation on a Monday, Tuesday, or Wednesday, because Monday-only starts are too rigid.
- 3rd and 4th sentences: These statements were rewritten for increased clarity and accuracy and read, "Cisplatin will be given weekly with external beam radiation therapy and once with LDR brachytherapy for a total of six doses. When given with LDR brachytherapy it should be administered after the applicators are placed."

Section 7.4.1, table, 5th-to-last row: "Fistula" was qualified as "ANY fistula (GI or other)" for increased clarity.

Section 7.4.2, table, bilirubin and ALT: In the last column, "above threshold" was corrected to "below threshold."

The following AE Reporting Sections were modified per current RTOG standard:

- Section 7.7, last paragraph: Added
- Section 7.7.1, last 2 paragraphs: Revised
- Section 7.7.2: Revised
- Section 7.8: Added

Section 8.0:

- In the 1st paragraph, the last 2 sentences were combined and revised for consistency with similar statements elsewhere in the protocol. The statement reads, "In addition, see Section 10.1 concerning optional biopsies for biological correlative studies."
- The 2nd two paragraphs were added to account for potential healing/bleeding problems connected with surgical procedures during protocol treatment. Planned hysterectomy is not permitted and salvage hysterectomy is not permitted sooner than 8 weeks after completion of chemoradiation. Unrelated elective surgery is not permitted sooner than 8 weeks after the last bevacizumab dose.

Section 9.4.1: Revised to indicate that any protocol pump inhibitor is acceptable.

Section 10:

- The RTOG Tissue Bank has been renamed the RTOG Biospecimen Resource and has moved from LDS Hospital to the University of California San Francisco. This section was updated accordingly throughout. Appropriate changes were also made in Appendix IX.
Sections 10.0/Tissue Specimen Submission, 2nd sentence; 10.3.3; and 10.8.3: Optional collection of plasma and buffy coat was added.

Section 10.1: The 1st paragraph was rewritten because patients are not necessarily being asked to consent to two additional biopsies. The statement now reads, "For consenting patients, tissue from two biopsies for biological correlative studies will be obtained: one prior to treatment; and one at the time of first brachytherapy. (For tissue banking purposes, the biopsy performed for tissue diagnosis may be combined with the pretreatment biopsy.)" Corresponding changes were made to Appendix I.

Sections 10.2 and 10.3: Performance of RNA profiling and DNA SNP and methylation studies was added as the 2nd sentence of both sections.

Section 10.3.1: Collection at mid-treatment was added as the 3rd bullet. A corresponding change was also made in Appendix I, Consent for Use of Tissue, Blood and urine for research/ About using blood for research.

Section 10.4.1 and 10.8.3: Logistics for urine collection were updated. Corresponding changes were also made in Appendix IX.

Section 10.7: Reimbursement was updated per current RTOG standard.

Section 10.8: The link to the RTOG Patient Tissue Consent Frequently Asked Questions was updated.

Section 11.1

- 1st row:
- 3rd column: "& radioactive insertions" for consistency with the rest of the protocol
- Former 6th column: "During last wk of CRT" was deleted because it was included in error.
- 4th row/pelvic exam: Exam requirements were added 4-6 wks post RT and at all 4 subsequent follow-up times (up to yr 2, yr 3, yrs 4-5, and > 5 yrs).
- Last 4 rows: Optional banking studies (tissue, blood, and urine) were added per current RTOG standard.
- Footnote lettering: Reorganized due to the deletion of a timeframe for diagnostic biopsy (see above).
- Footnote d: "and then" was added before "annually" because it was inadvertently missing.

Appendix I

- **Risks Associated with Bevacizumab:** The entire section was updated for consistency with the updated CAEPR and for consistency with recent RTOG trials incorporating bevacizumab.
- **During Follow-up, 1st bullet:** "4-6 weeks after the completion of radiation" was added for consistency with Section 11.1.
- **During Follow-up, 7th bullet:** "every 3 months for the first 2 years, then every 4 months for the 3rd year, every 6 months for the next 2 years, then annually" was added for consistency with Section 11.1.
- **Consent Form for Use of Tissue, Blood and Urine for Research:** The first 3 paragraphs were revised to clarify: (1) that patients may not yet have had a diagnostic biopsy; and (2) that patients are being asked to consent to one or two additional biopsy, depending on the timing and quantity of the diagnostic biopsy.

**Appendix VII:** Under Brachytherapy Dose, 2nd bullet, the vaginal surface dose was changed from 140% to 140-200%, to allow for institutional variability.
SUMMARY OF CHANGES
Amendment #2, Version Date: August 26, 2008
(Broadcast 9/18/08)

RTOG 0417, "A Phase II Study of Bevacizumab in Combination with Definitive Radiotherapy and Cisplatin Chemotherapy in Untreated Patients with Locally Advanced Cervical Carcinoma"

Study Chair: Tracey Schefter, MD; (720) 848-0116/Fax# (720) 848-0222; tracey.schefter@uchsc.edu

RTOG 0417 has been amended as follows:

Title Page: Contact information was updated for Dr. Kwon, Dr. Schefter, and RTOG Headquarters. The RTOG statistician for this study, Kathryn Winter, was added per current RTOG standard.

Eligibility Checklist, question 10, page 1: "of the pelvis" was added after the second use of MRI for consistency with Section 3.1.8.

Eligibility Checklist, question 25, page 2: The spelling of thromboembolic was corrected.

Eligibility Checklist, signature line, page 3: Wording was updated for web registration.

At NCI's request, information was deleted from the following sections that indicated that the bevacizumab supplied for the study is intended for clinical use only and is not the commercially available Avastin:

- Section 1.4, 1st paragraph, last 3 sentences
- Section 7.1.5, last 3 sentences
- Appendix I, Why is this study being done, last 2 sentences

Section 3.1.2: The timeframe for cervical biopsy was eliminated because it was deemed unnecessary. The corresponding change was made to the Eligibility Checklist and to Section 11.1.

Sections 3.1.6, 3.17, and 3.1.8: The timing for pre-treatment chest x-rays, CTs, MRIs, and PET-CTs was changed from 6 to 8 weeks because the 8-week timeframe was deemed sufficient for screening purposes. Corresponding changes were made to the Eligibility Checklist and to Section 11.1.

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Section 6.3: The second sentence was corrected to indicate that images will be submitted to RPC not RTOG Headquarters.

Section 6.4.1.2, last section: Planning information was added for Stage IIIA/IIIB with lower third vaginal involvement.

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- **Section 7.7.2:** Revised
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- In the 1st paragraph, the last 2 sentences were combined and revised for consistency with similar statements elsewhere in the protocol. The statement reads, "In addition, see Section 10.1 concerning optional biopsies for biological correlative studies."
- The 2nd two paragraphs were added to account for potential healing/bleeding problems connected with surgical procedures during protocol treatment. Planned hysterectomy is not permitted and salvage hysterectomy is not permitted sooner than 8 weeks after completion of chemoradiation. Unrelated elective surgery is not permitted sooner than 8 weeks after the last bevacizumab dose.

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Section 10.7: Reimbursement was updated per current RTOG standard.

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Appendix I

- **Risks Associated with Bevacizumab:** The entire section was updated for consistency with the updated CAEPR and for consistency with recent RTOG trials incorporating bevacizumab.
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• **During Follow-up, 7th bullet:** "every 3 months for the first 2 years, then every 4 months for the 3rd year, every 6 months for the next 2 years, then annually" was added for consistency with Section 11.1.

• **Consent Form for Use of Tissue, Blood and Urine for Research:** The first 3 paragraphs were revised to clarify: (1) that patients may not yet have had a diagnostic biopsy; and (2) that patients are being asked to consent to one or two additional biopsy, depending on the timing and quantity of the diagnostic biopsy.

**Appendix VII:** Under Brachytherapy Dose, 2nd bullet, the vaginal surface dose was changed from 140% to 140-200%, to allow for institutional variability.
SUMMARY OF CHANGES

Amendment #1, Version Date: May 11, 2007

RTOG 0417, "A Phase II Study of Bevacizumab in Combination with Definitive Radiotherapy and Cisplatin Chemotherapy in Untreated Patients with Locally Advanced Cervical Carcinoma"

Study Chair: Tracey Schefter, MD; (720) 848-0116/Fax# (720) 848-0222; tracey.schefter@uchsc.edu

RTOG 0417 has been amended as follows:

In response to NCI's 3/23/07 safety report, the risk of neutropenia was clarified. Changes were made to the following sections:

- **Section 1.5**: The last paragraph was added.
- **Appendix I** (sample consent): The paragraph titled "Risks Associated With Bevacizumab When Combined With Chemotherapy" was added.

The specimen collection timeframes in the following sections were corrected, so that all collection timeframes are consistent with each other:

- **Section 1.2**, last 2 paragraphs
- **Section 4.2.1**
- **Section 8.0, 2\(^{nd}\) sentence**
- **Section 10.2 1\(^{st}\) sentence**
- **Section 10.3, 1\(^{st}\) sentence**
- **Section 10.3.1**
- **Section 10.4.2**
- **Section 10.8.3, 1st column, last 2 rows**
- **Appendix I/Consent Form for Use of Tissue, Blood and Urine for Research: About Using Blood for Research, bulleted text**
- **Appendix I/Consent Form for Use of Tissue, Blood and Urine for Research: About Using Urine for Research, bulleted text**

In addition, the following other changes were made:

**Title Page**: The Study Chair heading was added per RTOG standard, and contact information was updated for Dr. Kwon.

**Schema**: "Total of 3 doses" was added parenthetically on the schema page for increased clarity.

**Section 1.4**
• The 3rd paragraph was added to clarify the possible mechanism of improving results with chemoradiation.
• The last sentence of the 6th paragraph was added to state the issue that no dose is considered standard.
• The last paragraph was added to provide literature justification for the choice of drug dose (10 mg/kg).
• All REFERENCES were appropriately adjusted within the text and reference list.

Section 3.1.1.1: Added for increased clarity.

Section 5.1.1: In the first sentence, "institutions that" was changed to "physicians who" for increased clarity.

Section 5.1.2: In the third sentence, "treatment media and films" was changed to "treatment media and images for CT-based planning" to more accurately describe submission requirements.

Section 6.2: To update the treatment technique, "and a minimum source to skin distance of 80 cm" was deleted from the first sentence and "Isocentric technique will be used" was added as the second sentence.

Section 6.3: The second sentence was reworded (1) to clarify that the supine position is acceptable per institutional standard and/or if the patient cannot tolerate the prone position, and (2) to clarify that an empty bladder is acceptable if the patient cannot tolerate a full bladder.

Section 6.4: The last sentence was added to clarify that heterogeneity correction must be turned off, in order to keep the protocol consistent with previous trials.

Section 6.4.3.2: In the second-to-last sentence, +/- 5% was added to provide an acceptable dose range.

Section 6.4.2: The last two sentences were added for increased clarity.

Section 6.4.5.1: First sentence added for increased clarity.

Section 6.4.5.2: Instructions concerning HDR brachytherapy were clarified as follows:

• In the second sentence, "at least one insertion" was changed to "one insertion";
• The third sentence was deleted because chemotherapy and HDR may be given on the same days;
• In the fourth sentence, "could" was changed to "can"; and
• The final sentence was added because no more than 2 HDR treatments may be given per week.
Section 6.4.6.5: "As demarcated by the opaque packing" was added parenthetically for increased clarity.

Section 6.4.6.6: The last sentence was added for increased clarity.

Section 6.5: In the third sentence, "treatment media and films" was changed to "treatment media and images for CT-based planning" to more accurately describe submission requirements.

Section 7.1.8: Preparation instructions were modified per NCI's 8/4/06 notice to investigators regarding the simplification of bevacizumab preparation.

Section 11.1: The calendar for pelvic exams was corrected to reflect that pelvic exams will not be performed weekly during chemoradiation. This correction was also made to Appendix I (sample consent) in the second bullet under "During Chemotherapy, External Radiation Treatment, and Radioactive Insertions."

Section 11.1: Reference to footnote f was deleted because there is no corresponding footnote f text.

Section 12.2: In item lines 1, 5, and 7, "films" was changed to "images" and an asterisk indicating "CT on disc preferred" was added to more accurately describe submission requirements.

Appendix VII (High Dose Rate Intracavitary Brachytherapy Guidelines):

- Under "Schedule," in the first bullet, first sentence, week 2 was added parenthetically for increased clarity.
- Under "Dose Specifications, "x-rays" was changed to "images" to more accurately describe submission requirements.
- Under "Dose Specifications," in the first bullet, the last 2 sentences were added parenthetically for increased clarity.
- Under "Dose Specifications," in the last bullet, 2nd sentence, "applicator" was changed to "packing" for increased clarity.
- Under "Brachytherapy Dose," in the parenthetical statements before the bulleted text: (1) 60.0 Gy was corrected to 30.0 Gy; (2) "6 Gy per fraction" was added for increased clarity.
- Under "Brachytherapy Dose," the last 2 sentences of the 3rd bullet were added for increased clarity.
- Under "Dose Specifications, "x-rays" was changed to "images" to more accurately describe submission requirements.
SUMMARY OF CHANGES

Update Date: August 31, 2006

RTOG 0417, "A Phase II Study of Bevacizumab in Combination with Definitive Radiotherapy and Cisplatin Chemotherapy in Untreated Patients with Locally Advanced Cervical Carcinoma"

Study Chair: Tracey Schefter, MD; (720) 848-0116/Fax# (720) 848-0222; tracey.schefter@uchsc.edu

RTOG 0417 has been updated as follows:

The specimen collection timeframes in the following sections were corrected from 4-6 weeks to 4-8 weeks post-radiation, so that all collection timeframes are consistent with each other:

- Section 10.4.2
- Section 10.8.3: 1st column, last 2 rows
- Appendix I/Consent Form for Use of Tissue, Blood and Urine for Research: About Using Blood for Research, 3rd bullet
- Appendix I/Consent Form for Use of Tissue, Blood and Urine for Research: About Using Urine for Research, 4th bullet

In addition, changes were made to the following sections:

Section 5.1.1: (1) For increased accuracy, references to the Facility Inventory and the RTOG Implant Quality Assurance Guidelines were deleted. (2) Reference to the ATC website was corrected to the RPC website.

Section 6.5: (1) References to the protocol compliance form were corrected to the RTOG Gynecological Brachytherapy Compliance Form. (2) References to the ATC website were corrected to the RPC website.

Section 12.2: (1) The RT Prescription (Protocol Treatment Form/T2) was deleted because it is not being collected for this study. (2) Reference to the Intracavitary Dose Form was corrected to the Gynecological Brachytherapy Compliance Form (19).
SUMMARY OF CHANGES

Update Date: August 11, 2006

RTOG 0417, "A Phase II Study of Bevacizumab in Combination with Definitive Radiotherapy and Cisplatin Chemotherapy in Untreated Patients with Locally Advanced Cervical Carcinoma"

Study Chair: Tracey Schefter, MD; (720) 848-0116/Fax# (720) 848-0222; tracey.schefter@uchsc.edu

RTOG 0417 has been updated as follows:

Sections 10.1.5, 10.2.2.3, 10.3.6.2, 10.4.3, and Appendix IX: Contact information for LDS Hospital was updated.

Section 12.1: The AE form was deleted because this information will be collected on the TF and F1.