SUMMARY OF CHANGES
Amendment 7, Version Date: March 24, 2010
Broadcast: 4/6/10

RTOG 0214, "A Phase III Comparison of Prophylactic Cranial Irradiation Versus Observation in Patients With Locally Advanced Non-Small Cell Lung Cancer"

Study Chair: Elizabeth Gore, M.D.; (414) 805-4465; FAX (414) 805-4369; egore@radonc.mcw.edu

As mandated by CTEP, RTOG 0214 has been amended to replace CTC version 2.0 with the CTEP Active Version of CTCAE. Changes were made to the following sections:

- Section 6.4.1
- Appendix V: Sections "B", "D", and "E"
SUMMARY OF CHANGES
Amendment 6, Version Date: October 1, 2007

RTOG 0214, "A Phase III Comparison of Prophylactic Cranial Irradiation Versus Observation in Patients With Locally Advanced Non-Small Cell Lung Cancer"

Study Chair: Elizabeth Gore, M.D.; (414) 805-4465; FAX (414) 805-4369; egore@radonc.mcw.edu

RTOG 0214 has been amended as follows:

Title page: Dr. Gore's e-mail address was updated.

Appendix I, the sample consent: At the request of the Central IRB, under "What are my rights as a participant?", the second sentence of the first paragraph was amended to read, "Choosing not to take part in this study or leaving the study will not result in any penalty or loss of benefits."

Appendix VII: At the request of the Cancer Trials Support Unit (CTSU), the hours of "Patient Registration" (2nd column of the table) were amended to "9:00 AM-5:30 PM".
SUMMARY OF CHANGES
Amendment 5, Version Date: January 24, 2007

RTOG 0214, "A Phase III Comparison of Prophylactic Cranial Irradiation Versus Observation in Patients With Locally Advanced Non-Small Cell Lung Cancer"

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

At the request of the Cancer Trials Support Unit (CTSU), RTOG 0214 has been amended as follows:

Title page: The statement at the bottom of the page regarding Cooperative Group members who are not affiliated with RTOG was deleted, and text was added to the subsequent page.

Appendix VII: All prior CTSU logistics text was deleted and was replaced with new CTSU logistics.
RTOG 0214, A Phase III Comparison of Prophylactic Cranial Irradiation Versus Observation in Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0214 has been amended as follows:

At CIRB's request, a change was made to the section titled "What Are the Risks of the Study?" in the Informed Consent. "Memory loss and behavioral change" was moved from the list of "Very Likely" brain irradiation side effects to the "Less Likely, But Serious" list. The parenthetical phrase "(This risk may be permanent because it is a potential effect associated with brain irradiation.)" was added after "Memory loss and behavioral change."

A amended protocol is available (no password required) on the RTOG web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: May 24, 2005

RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0214 has been updated:

Schema page, Eligibility Checklist page 1, Question #10, and Section 3.2.4: The words “a primary” were added to the text as follows: “that have progression free, disease free, or overall survival as a primary endpoint”.

A updated protocol is available (no password required) on the RTOG web site, http://www.rtog.org
SUMMARY OF CHANGES
Amendment 3, Version Date: February 28, 2005

RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0214 has been amended as follows:

An ineligibility criterion was amended to make the study available to patients who also are participating in other phase III studies: Section 3.2.4 was amended to specify that patients may not be entered on other phase III trials “that have progression free, disease free, or overall survival as an endpoint”. Corresponding changes were made to the Eligibility list on the Schema page and to Question 10, page 1 of the Eligibility Checklist.

The designation for the supplemental quality of life questionnaire, “BCM20”, was corrected to “BN20” in the following sections: 1.2.5, 4.0, 11.1, 11.2, 11.3, and 12.1.

Section 12.0: The address for RTOG Headquarters was updated.

Appendix VII, At CTSU’s request, the following changes were made:

- Under “CTSU Procedures for Patient Enrollment”: the hours for faxing forms to the CTSU Patient Registrar were amended and a phrase was added after “the CTSU will contact the RTOG”; 
- Under “All CTSU report forms and data must be sent to”, the fax number was deleted.

A amended protocol is available (no password required) on the RTOG web site, http://www.rtog.org
RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0214 has been updated as follows:

Title Page — The telephone number for Benjamin Movsas, M.D. has been corrected to 313-916-5188.

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: September 30, 2004

RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0214 has been updated as follows:

Title Page — The contact information for Benjamin Movsas, M.D. has been updated.

Appendix VII — The following CTSU information was updated:

- Under “For patient enrollments:” added “[For CTSU patient enrollments that must be completed within approximately one hour or other extenuating circumstances, call 301-704-2376. Please use the 1-888-462-3009 number for ALL other CTSU patient enrollments.]”
- Under “For patient eligibility or treatment-related questions” changed contact to “RTOG Headquarters (215-574-3214).”
- At the end of the paragraph “All other questions…”, added “the CTSU Help Desk at:”
- Under “REGISTRATION/RANDOMIZATION”, the CTSU patient registration hours were changed to 8:00 to 5:00.
- Under “Requirements for RTOG-0214 site registration:” deleted “IRB-approved consent form.”
- Under “Requirements for patient enrollment on RTOG-0214”, added “CTSU registrars will confirm investigator eligibility and review enrollment documents for completeness, but cannot confirm patient eligibility.”

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
Revision 2, Version Date: December 9, 2003

RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

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

RTOG 0214 has been revised as follows:

Eligibility was revised to allow patients to be enrolled directly after radiation or surgery and go on to get systemic therapy after the Prophylactic Cranial Irradiation (PCI). The following sections were revised to reflect these changes: the Eligibility list on the Schema page; Question 1, page 1 of the Eligibility Checklist; Sections 3.1.1 and 9.0.

At the request of the Cancer Trials Support Unit (CTSU), the following sections were revised:

- **Title page** — The sentence at the bottom of the page was revised to read, “All Cooperative Group members who are not affiliated with RTOG…”
- **Appendix VII** — The boxed text at the top of page 1; the times PMB is available in the first paragraph of “Registration/Randomization”; the paragraph under “Requirements for patient enrollment”; the bullets under “Data Submission”; the boxed text under the Westat address on page 2; and the “Adverse Event Reporting section were revised.

Other Changes

Question 5, page 2 of the Eligibility Checklist and the text under Section 12.0 were updated to RTOG standard.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0214 has been updated as follows:

Title Page — The 800 telephone number for RTOG Headquarters has been corrected to 1-800-227-5463, ext. 4189.

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
Revision 1, Version Date: June 24, 2003

RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

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

Assessment of quality of life has been added to RTOG 0214. The following sections were revised for this change:

- **Title page** — Dr. Movsas was added as the quality of life study chair;
- **Section 1.2.4** — “Quality of Life” was deleted from the title of this section;
- **Section 1.2.5**，“Quality of Life”，was added, and the subsequent section was appropriately renumbered;
- **Sections 4.5, 11.1, and 11.2.3** were revised to include the quality of life assessments;
- **Section 11.3** was added, and the subsequent section appropriately renumbered;
- **Section 12.1** — The quality of life assessments and the schedule of these assessments were added;
- **Sections 13.2.1 and 13.5.3** were revised;
- **References** — Numbers 39-56 and 68-71 were added, and prior references were renumbered appropriately in this section and in the body of the protocol;
- **Appendix I**, the sample consent — The last bulleted item under “What Is Involved In The Study” was revised to reflect the addition of the quality of life assessments

Other changes:
**Title page** — Dr. Choy was added as a co-chair for radiation oncology.

At the request of the Central IRB and CTSU, **Appendix I** was revised as follows:

- At the top of the first page, the boxed CTSU text was deleted;
- Under “What about confidentiality?” in the 2nd paragraph, CTSU was briefly defined.

At the request of the Cancer Trials Support Unit (CTSU), **Appendix VII** was revised as follows:
• The CTSU contact information for submission of registration documents was updated;
• Under “Registration/Randomization”:
  o Two sentences were added to the first paragraph, and the remainder of the paragraph beginning with “Each CTSU investigator…” was made into a separate paragraph;
• Under “Requirements for RTOG-0214 site registration”:
  o In the 2nd bullet, the words, “RT version” were deleted;
  o In the 3rd bullet, the parenthetical phrase, “(NOTE: Radiation therapy facilities must participate in the RPC monitoring program to participate in studies sponsored by the CTSU.)”, was added;
  o The 5th bullet, Personnel Contact List, was deleted;
• Under “CTSU Procedures for Patient Enrollment” section, the last paragraph was revised;
• Under “Data Submission”, the boxed text, “A CTSU Data Transmittal Form…”, was revised;
• Under “Special Materials or Substudies”, the “Neuropsychological Testing / Quality of Life (QOL)” section was revised;
• The heading, “Adverse Event (AE) Reporting” was capitalized, and the last sentence of paragraph 1 of this section was revised;

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/
SUMMARY OF CHANGES
Update Date: November 8, 2002

RTOG 0214, A Phase III Comparison Of Prophylactic Cranial Irradiation Versus Observation In Patients With Locally Advanced Non-Small Cell Lung Cancer

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

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

The following cooperative groups have endorsed RTOG 0214 through the Cancer Trials Support Unit (CTSU): The National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), The North Central Cancer Treatment Group (NCCTG), and The Southwest Oncology Group (SWOG). The co-chairs for each group have been added to the protocol title page.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page as “Update Date”, not as a revision. IRB review is not required; however, this change must be reported to site IRBs.

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