RTOG 0841, Efficiency of Screening for Depression in Cancer Patients Receiving Radiotherapy

Study Chair: Lynne I. Wagner, PhD; 312-503-3529; lwagner@northwestern.edu

RTOG 0841 has been revised as follows:

The patient interviews now will be conducted by interviewers from Northwestern University only. Accordingly, references to the University of Pennsylvania have been removed from the following sections of the protocol, and the phrase, “interviewers who are supervised by study investigators” has been added before “Northwestern University”:

- Section 1.4.2
- Section 3.3
- Section 11.2.2, second and third paragraphs
- Section 12.1, under “Summary of Data Submission/Participant Data”, text denoted by an asterisk (*)
- Appendix I (Sample Consent), under “What will happen if I take part in this research study/If you are selected…, the bulleted text beginning, “The interviews will be conducted…”
- Appendix I (Sample Consent), under “Will my medical information be kept private”, third paragraph beginning, “Organizations that may look at and/or copy your medical records…”
- Appendix II (Study Parameter Table), the text denoted by an asterisk (*)

Title Page: Dr. Shook has been added as the Senior Statistician for the study. The “Note” at the top of the page has been revised from “Note: This study is limited to CCOP institutions only until January 2011” to “Note: This study is limited to CCOP institutions only”.
RTOG 0841, Efficiency of Screening for Depression in Cancer Patients Receiving Radiotherapy

Study Chair: Lynne I. Wagner, PhD; 312-503-3529; lwagner@northwestern.edu

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RTOG 0841 has been updated as follows:

**Title Page:** This study is limited to CCOP institutions only until January 2011. A "note" regarding the limited participation was added to the page.

**Appendix I (Sample Consent):** For clarity, under "What will happen if I take part in this research study/During the research study…", the first bulleted item, "If you are not selected for the full study, your participation ends after filling out the brief questionnaires" was moved to the bottom of the list immediately above the paragraph beginning, "If your responses to the questionnaire…". Also, the text was revised slightly to clarify when study participation ends for patients that will not be asked to participate in the telephone interviews component of the study.
RTOG 0841, Efficiency Of Screening For Depression In Cancer Patients Receiving Radiotherapy

Study Chair: Lynne I. Wagner, PhD; 312-503-3529; lwagner@northwestern.edu

RTOG 0841 has been updated as follows:

Section 1.1.1: In the final paragraph of the Section, a minor revision was made to the wording of the SCID module: Module I was updated to Module A.

Section 5.2: Was updated with subsection numbers 5.2.1.1, 5.2.1.2, and 5.2.1.3. In the fifth sentence of Section 5.2.1.1, a "0" was added at the end of the fax number. In Section 5.2.1.3, instructions to sites were added regarding completion of the "0841 Application to Participate" prior to registration of the first patient on study.

Section 5.2.3: The RTOG Headquarters fax number was added in the last paragraph.

Section 11.2.3.3: The Modules of the Structured Clinical Interview for Diagnosis (SCID) are posted on the RTOG website, next to the protocol. This change was included at the end of the section.

Appendix IV (Interviews):

- The Modules of the Structured Clinical Interview for Diagnosis (SCID) being used in this study were removed from the Appendices and placed next to the protocol on the RTOG website. Additional instructions to the SCID interviewers were added to the title page of Appendix IV, which specifies the sections of the SCID the interviewers will use.
- The Perceived Barriers to Psychological Treatment (PBPT) questionnaire was inserted into the Appendix.

Appendix VI (Psychosocial Care Referral List):

- "RTOG" was added before "Institution Number", for clarity. Also, spaces for entering the "Institution Name" and "NCI Code" were added for RTOG Headquarters tracking purposes.
- Instructions for completion of the 0841 Application to Participate were added at the bottom of the Appendix.

Appendix VII (Description of Psychosocial Care Services):
- "RTOG" was added before "Institution Number", for clarity. Also, spaces for entering the "Institution Name" and "NCI Code" were added for RTOG Headquarters tracking purposes.
- Instructions for completion of the 0841 Application to Participate were added at the bottom of the appendix.
- For all response choices, "check" was replaced with "circle". This option best fits the design format of the Appendix.

**Appendix VIII (Patient Consultation Log):** Added to capture the number of patients that are offered, but decline to participate in the study. Member sites are required to document this information and submit it to RTOG Headquarters at the time of study closure to accrual.
RTOG 0841 has been revised as follows:

Title Page: Dr. Wagner's contact information was updated.

Schema: The text was replaced with a chart.

Section 1.0

- The following sections were revised to cite relevant research to support modifications to our secondary objectives (see Section 2.0 below). The Rationale and Justification for the study have been revised to reflect the revised secondary study objectives: 1.1.1 and 1.1.2 1.2 1.3.1 and 1.3.2 1.4

- **Section 1.4.2:** "Northwestern University" was inserted next to the "University of Pennsylvania" in the first sentence. Telephone interviewers at both universities will be responsible for administering and submitting the specified questionnaires.

- Procedures for assessing and managing suicidal ideation, risk of self-harm, and/or imminent risk of suicide have been revised for clarity of implementation. The following sections of the protocol were revised as a result:

- **Section 1.5.2:** In the second sentence of the third paragraph, "or doctoral level" was added for consistency with the protocol. In the fourth paragraph, the first sentence beginning, "In addition to the potential risks described above...." and the sentence beginning, "If this occurs, research staff have the responsibility....", in the middle of the paragraph were added. Other sentences in the paragraph were revised. The first sentence in the fifth paragraph was deleted.

- **Appendix V (Safety Plan):** Includes procedures for emergent risk and non-emergent risk plan implementation and corresponding documentation requirements.

- The reference numbers were revised throughout the section, beginning in Section 1.1.1 with reference #13.

Section 2.0
• **Section 2.2.1:** This secondary objective was revised from, "Establish the rates of major depression identified through diagnostic telephone interviews" to "Establish the rates of major depression and other mood disorders (bipolar, dysthymic, and adjustment) identified through diagnostic telephone interviews based on the standard SCID scoring and Endicott criteria", to clarify how the clinical diagnosis of depression will be determined.

• **Section 2.2.2:** The National Comprehensive Cancer Network Distress Thermometer (NCCN-DT) has been added as a component of patient assessment.

• **Section 2.2.4:** "Characterize the availability of psychosocial services at participating institutions using the Description of Psychosocial Care Services interview" was added as an explicit secondary objective of the study. The Description of Psychosocial Care Services interview is not a new component of the study. The subsequent objectives were renumbered.

• **Section 2.2.7:** This secondary objective was revised from, "Establish nature and adequacy of existing care, patient preferences, and treatment availability and barriers to depression treatment utilization for patients identified with major depression using the Assessment of Mental Health Services and Barriers to Care" to "Determine barriers to psychosocial treatment and acceptability and patient interest in telephone-based and internet-based psychosocial interventions", to reflect the new questionnaire, the Perceived Barriers to Psychological Treatment (PBPT), which replaces the Assessment of Mental Health Services and Barriers to Care questionnaire.

**Section 3.1.9:** For clarity, "but who are not currently receiving psychotherapy or pharmacotherapy for depression at screening" was deleted from the eligibility criterion.

**Section 5.0**

• **Section 5.2.1:** The section, "Institution Certification", was added in the beginning to provide institutions with details for submission of information regarding mental health care providers within the member institution and in the community at the time of study activation. In the previous version of the protocol (Amendment #1), the text in this section was included under the heading "Section 5.2.2, RTOG Member Site Responsibilities". The following sections were renumbered.

• **Section 5.2.2:** The first sentence under "Online Registration" was revised.

• **Section 5.2.3:** The text from the first paragraph was moved to Section 5.2.1 (see above). The NCCN-DT questionnaire was included in the second sentence for consistency with protocol objectives. In the second paragraph, "or other mood disorders" was added in the first sentence. The final paragraph was added to include information about the Patient Consultation Log, which institutions will complete to track the number of patients seen in clinic that decline to participate in the trial. **Section 11.0**

• **Sections 11.2.1, 11.2.2, and 11.2.3:** Revised for clarity regarding recruitment procedures and the Stage I (Screening), Stage II (Diagnostic Telephone Interview), and Stage III (Follow-up Interview) protocol processes and to include REFERENCES to the NCCN-DT questionnaire.
sections 11.2 and 11.3: Revised to include information regarding two new patient questionnaires—the National Comprehensive Cancer Network Distress Thermometer (NCCN-DT) and the Perceived Barriers to Psychological Treatment (PBPT)—and additional interview questions have been added to the study for patient completion. The Perceived Barriers to Psychological Treatment (PBPT) questionnaire replaces the Assessment of Mental Health Services and Barriers to Care questionnaire. The additional interview questions (Patient Interest in Psychosocial Intervention Modalities) are included in Appendix IV.

Section 11.3.1.4: Revised to include the use of the Endicott criteria for scoring of the Structured Clinical Interview for DSM-IV (SCID).

The reference numbers were revised throughout the section, and the section numbers were renumbered where appropriate.

Section 12.1

Revised to include data submission due dates for the new questionnaires [the National Comprehensive Cancer Network Distress Thermometer (NCCN-DT), the Perceived Barriers to Psychological Treatment (PBPT) and Patient Interest in Psychosocial Intervention]. Also, the Patient Consultation Log and the HSQ (QL form) have been added to this section.

The due date for data submission was added next to the HSCL-25 (HP) and the PHQ-9/PHQ-2 (PQ) forms.

"Northwestern University" was inserted next to the "University of Pennsylvania" at the end of the section. Telephone interviewers at both universities will be responsible for administering and submitting the specified questionnaires.

Section 13.0

Section 13.1: The study endpoints have been updated as necessary to remain consistent with the revised study objectives in Section 2.0.

Section 13.3: The reference numbers were revised.

Section 13.4.2: In the next to the last sentence of the paragraph, "master's-level or" was inserted before "doctoral-level" for consistency with the protocol.

Section 13.4.3.1: The phrase, "and other mood disorders" was added in the first sentence, for consistency with the revision to Section 2.2.1.

Section 13.4.3.2: The NCCN-DT was included in the listing of the screening questionnaires for consistency with the revision to Section 2.2.2.

Section 13.4.3.4: The second and last sentences were revised to correspond with the revised secondary study objectives.

REFERENCES: The reference list was revised to include the new REFERENCES (ref #s 13-14, 21-23, 25-26, and 49) cited in Sections 1.0 and 11.0 of the protocol. REFERENCES (previously numbered) #46-54 were deleted from the protocol. The reference numbers were updated accordingly throughout the protocol.

Appendix I (Sample Consent):
Under "What will happen if I take part in this research study/If you are selected for the full study…", the approximate time frame for completion of the interview was revised from "between 10 and 45 minutes" to "approximately 1 hour".

Under "What will happen if I take part in this research study/If you are selected for the full study…", Northwestern University was added after the University of Pennsylvania in the first bulleted item. The telephone interviews will be conducted by interviewers from both universities.

**Appendix II (Study Parameter Table):** Revised to include the NCCN-DT and the PBPT and Patient Interest in Psychosocial Intervention questionnaires.

**Appendix IV (Interviews):** Revised per modifications to Sections 1.0, 2.0, 11.0, and 13.0 of the protocol.

**Appendix V (Safety Plan):** Revised to include procedures for emergent risk and non-emergent risk plan implementation and corresponding documentation requirements.
SUMMARY OF CHANGES
Amendment 1: December 7, 2009
(Broadcast July 1, 2010)

RTOG 0841, Efficiency Of Screening For Depression In Cancer Patients Receiving Radiotherapy

Study Chair: Lynne I. Wagner, PhD; 312-695-6946; lwagner@northwestern.edu

RTOG 0841 has been revised as follows:

Title Page: Dr. Wagner is the new Principal Investigator for the study. Dr. Small was added as Radiation Oncology Co-Chair. Dr. Pajak’s e-mail address was updated.

Index: Revised per the changes made within the protocol.

Schema: Revised for clarity regarding study assessment procedures.

Sections 1.1.2, 1.2, 1.4, and 1.5.2: Revised to address concerns regarding screening procedure details, such as instructions for participating institutions on ensuring patient safety in the event of risk of self-harm or suicidal ideation; and to include information regarding the addition of the psychosocial services questionnaire (Appendix VII) that institutions will need to complete at study activation. The questionnaire is designed to elicit information from individual institutions regarding their current level of psychosocial programming services.

Section 1.1.1: In the second paragraph, the acronym for the SCID was spelled out.

Section 1.4.1: The reference to adverse event (AE) reporting was deleted; AE reporting is not a component of this trial.

Section 2.0: The tertiary objectives in Section 2.3 were revised and integrated into Section 2.2 as these objectives are no longer exploratory.

- 2.1: "Definitive or palliative radiotherapy" was added to the primary objective for clarity.
- 2.2.5: "Describe correlates of distress and major depression" was revised to "Correlate both depressive symptoms and major depression" for clarity.
- 2.2.6: "Establish nature and adequacy of existing care, patient preferences, and treatment availability and barriers to depression treatment utilization for depressed cancer patients using the Assessment of Mental Health Services and Barriers to Care" was revised to "Establish nature and adequacy of existing care, patient preferences, and treatment availability and barriers to depression..."
treatment utilization for patients identified with major depression using the Assessment of Mental Health Services and Barriers to Care" for clarity.

- **2.2.8** "Examine differences in study objectives based on institution characteristics with regard to existing psychosocial services that are provided on-site and integrated in cancer care" was added as a secondary objective.

**Section 3.1.9**: The phrase, "and who are" in the middle of the section was revised to "but who are not".

**Section 5.0**

**5.2.1**: The RTOG web support address was updated.

**5.2.2**: Was added; this text was moved from Section 1.4.1.

**Section 11.0**

- **11.2**: Revised for clarity and to provide additional detail regarding the procedures for the Stage I Screening, the Stage II Diagnostic Telephone Interviews, and the Stage III Follow-up Interviews.
- **11.3**: Revised in several areas to include REFERENCES to Appendix IV (Interview Questionnaires).
- **11.3.1.1**: In the first sentence, "screener" was replaced with "screening tool".
- **11.3.2.1**: In the next to the last sentence, the acronym for AHCPR was spelled out.
- **11.3.5**: Was added to provide information about the Description of Psychosocial Care Services questionnaire (Appendix VII) that must be completed by institutions at the time of study activation.
- **11.4**: Revised to include information about the Stage II Evaluation (telephone interview) and subsequent follow-up for select participants.

**Section 12.0**

- The "RTOG Member Site Data" table was added to include the due dates for the Psychosocial Care Referral List (Appendix VI) and the Description of Psychosocial Care Services (Appendix VII).
- Collection times for the Emergent Risk and Non-Emergent Risk Incident forms (if applicable) were added.
- The timing for submission of the A5, I1, HP, PQ, and QL forms was revised from "within 2 weeks after registration" to "within 1 week after registration". The timing for submission of the SCID and the Assessment of Mental Health Services and Barriers to Care was revised from "within 2 weeks after registration" to within 4 weeks after registration". The latter change also was made to the Study Parameter Table in Appendix II.
- The note indicated with an asterisk at the bottom of the section was revised for clarity.

**Section 13.0**
13.1: The study endpoints were revised per the changes made to the study objectives in Section 2.0.

13.2: Revised for clarity regarding the acceptability and efficiency of the Stage I Screening procedure and to include the sampling and the analysis plan for the patients who screen negative for depressive symptoms.

13.3: The first paragraph regarding waiting room screenings was revised.

13.4: The analysis plan was revised for clarity. It now includes the new study component involving patients who screen negative for depressive symptoms. The total number of patients registered remains the same. However, the anticipated number of patients receiving a diagnostic interview and subsequently the anticipated number of patients diagnosed with major depression has changed because a sample of patients who screen negative for depressive symptoms now will be interviewed. REFERENCES to the PHQ-2 questionnaire have been clarified to more accurately reflect that the PHQ-2 is not a separate questionnaire but consists of the 2 mood disturbance items on the PHQ-9.

13.5: Interim reports for this study will contain information about accrual per RTOG member site with regard to the Description of Psychosocial Care Services (Appendix VII). The section was revised to include this information.

13.6: The last sentence was revised to include, "and by institution psychosocial care services".

REFERENCES: One reference was inserted into Sections 1.2 and 11.3.5. As a result, REFERENCES 19-56 (now 20-57) were revised in the protocol and the reference list. REFERENCES 57-59 were deleted.

Appendix I (Sample Consent)

- Under "What will happen if I take part in this research study?", the second sentence of the first paragraph following the bulleted items, beginning, "If your responses to the questionnaire…", was revised from "With your consent, your treating physician will be contacted" to "Your treating physician and/or RTOG principal investigator at the institution where you are being treated will be contacted…".
- Under "Will my medical information be kept private?", the third paragraph beginning "Some interviews will be audio-taped…" was deleted; the interviews will not be audiotaped.
- The Principal Investigator's institution, Northwestern University, was added to the list of organizations that may look at and/or copy medical records for research, quality assurance, and data analysis.

Appendix IV (Interviews)

- The Hopkins Symptom Checklist (HSCL-25), the Patient Health Questionnaire (PHQ-9, PHQ-2), and the Health Status Questionnaire (HSQ) were removed from the appendixes; these questionnaires were developed into case report forms that
will be available on the RTOG web site. The remaining appendixes were renumbered.

- At the top of the Assessment of Mental Health Services and Barriers to Care questionnaire, "Subject ID #" was changed to "Case #" to be consistent with RTOG data capture procedures.

**Appendix V** (Safety Plan): The Emergent and Non-Emergent Risk Incident Report was divided into two separate reports, the Emergent Risk Incident Report and the Non-Emergent Risk Incident Report.

**Appendix VI** (Psychosocial Care Referral List): Added to capture information from participating institutions regarding psychosocial care providers on-site and within the community.

**Appendix VII** (Description of Psychosocial Care Services): Added to capture information regarding screening processes and the availability of mental health services at individual institutions.
SUMMARY OF CHANGES
Update: May 28, 2009
(Broadcast 5/28/09)

RTOG 0841, Efficiency Of Screening For Depression In Cancer Patients Receiving Radiotherapy

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RTOG 0841 has been updated as follows:

**Title Page, Schema Page, Appendix I:** The protocol title was revised from "Efficiency Of Screening For Depression In A Mixed Sample of Cancer Patients" to "Efficiency Of Screening For Depression In Cancer Patients Receiving Radiotherapy" to clarify that accrual is open to any cancer patient undergoing radiation treatment.

**Title Page:** "Outcomes" and "CCOP" were added before "Co-Chair" for Drs. Bruner and Kirshner, respectively.

**Sections 1.4 and 13.3:** The sentence, "Member Sites will receive CCOP credit for each participant screened, as determined by the NCI" was deleted.

**Section 2.1:** The wording of the primary objective was revised to clarify that accrual is open to all RTOG institutions and to any cancer patient undergoing radiation treatment.

**Section 5.1.1:** The second bulleted item was updated with current RTOG standard regulatory text.

**Appendix I:** The following changes were made at the recommendation of the American College of Radiology Institutional Review Board:

- Under "What will happen if I take part in this research study/During the research study" the text beginning, "Before you begin the research study…" was deleted. Reviewing the patient's medical records prior to study entry is not necessary for this protocol.
- "Study doctor" was replaced with "research associate", as research associates will likely have the most contact with participants.

**Appendices III to VI:** Page numbers were added at the bottom of each page.

**Note:** These are editorial/administrative changes to the protocol. NCI requires that these changes be documented on the protocol title page as "Update Date."