

**CCCWF CCOP RESEARCH BASE
PROTOCOL AMENDMENT CHANGE FORM**

Study Title: Feasibility of Delivering a Quitline Based Smoking Cessation Intervention in Cancer Patients Receiving Outpatient Treatment: A Pilot Study

Protocol #: 99211

Date of Submission to IRB: 11/7/12

IRB Number: 00019384

IRB Approval Date: 11/14/12

Principal Investigator: Kathryn Weaver

Protocol Amendment # 3

Brief description of each change in the study protocol and rational. (Additional pages may be used as needed):

1. Title Page: Added amendment 1 and 2 dates, NCI version date 10/31/12 added, removed "Lung" from the protocol title, added amendment 3 and date to footer
2. Schema: Updated first inclusion criteria reading "AJCC Stages(all histologies.)"
3. Removed "lung" in Sections 1, 1.1, 1.2.2, 2.2, 7.2, 7.8, 12.1
4. Section 1.2: 2: updated to read "FACT-G and for lung cancer patients only the FACT-L other concerns questions and"
5. Sections 2.1-3 entire sections and references updated
6. Section 3.1: updated to read "to lung, breast...and cervical"
7. Section 3.3: updated to "All lung breast...and cervical cancer" and added to first paragraph "6 months whichever is most recent."; second paragraph added "AJCC Stages...histologies."
8. Section 4.1.1: Updated to read "AJCC Stages...histologies."
9. Section 4.1.5: Deleted ECOG and replaced with KPS 70-100
10. Section 7.1 #2: Added paragraph concerning Quitline enrolment
11. Section 7.2: Updated references and FACT-G, FACT-L and EORTC paragraphs and bullet points
12. Section 7.9: Added footnote F

Consent Form Changes

Brief description of each change in the consent form and rational.

1. Introduction: deleted "lung" in first and third paragraphs
2. Why is this study being done? deleted "lung" in first and third paragraphs
3. Changed version number to "3"

Appendices Changes

Brief description of each change in the appendices.

1. Each appendix updated to reflect disease site changes.

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