

Office of Research

INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Kathryn Weaver, Ph.D.

PHS - Social Sciences

From: Chair, Institutional Review Board

Date: 11/14/2012

Subject: Human Protocol: IRB00019384

Feasibility of Delivering a Quitline Based Smoking Cessation Intervention in Lung

Cancer Patients Receiving Outpatient Treatment: A Pilot Study

Sponsor Title: Amendment 3

Study Documents:

Protocol Version: 99211 Am 3 Protocol wo tracking; Informed Consent Version: 99211 Am 3 Consent wo tracking (approved); Advertisements: 99211 Am 3 Flyer Approved; Other Documents: Appendix 10 Letter from MD Usual Care Group, Appendix 10 Week 6 Booklet Usual Care, Appendix 11 Benefits of Quiting Smoking Quitline Group, Appendix 11 Letter from MD Quitline Group, Appendix 11 Nicotine Replacement Diary, Appendix 11 Week 6 Booklet Quitline Group, Appendix 13 Telephone Contact Form, Appendix 14 18 Wek Encouragement Letter, Appendix 15 Early Withdraw Form, Appendix 16 Declined Form, Appendix 6 Alcohol Use ID Test, Appendix 7 Baseline Booklet, Appendix 8 - Week 12 Booklet, Appendix 9 - Week 24 Booklet

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

Protocol:

- 1. Title Page: Added amendment 1 and 2 dates, NCI version date 10/31/12 added, removed "Lung" from the protocol title
- 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 enrollment
- 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

Consent:

- 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"

Flyer updated to reflect new disease sites.

This application indicates that advertising materials will be used for research purposes. Please consult with Creative Communications to ensure the appropriate visual identity is put forth.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

Richard Weinberg, M.D.