WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Kathryn Weaver, Ph.D.
PHS - Social Sciences

From: Assistant Director, Institutional Review Board

Date: 7/16/2012

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 2

Study Documents:
Protocol Version: 99211 Am 2 Protocol without tracking; Informed Consent Version: 99211 Am 2 Consent Form (approved); Advertisements: Smoking Cessation Flyer 99211; 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:

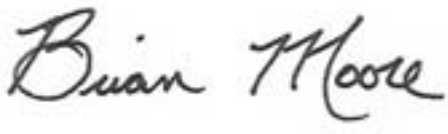
Protocol:
Title Page: Added amendment 1 and 2 dates
Table of Contents: Removed “18. Flyer” from list
Section 4.1: Added note “Patients who decline…included on this form.” as reminder to utilize form
Section 4.2.2: Added “(Patients that discontinue use of these type drugs within 7 days are eligible.)” for clarification
Section 7.9: Added Decline Form at Screening
Section 8.1: Updated first sentence to read “At least one CRA at each site”
Section 11.1: Removed Data Management Schedule table and reference made to Data Submission Checklist appendix.
Footer: Removed “Initial” and added “Amendment 2”
Consent:
Clarified "What is Involved in the Study" for Usual Care Group
Changed Version number to 2
Appendices:

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

Patient appendices uploaded to eIRB.

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA autorization will be sought. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

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.



Brian Moore