WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD.

MEMORANDUM

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

From: Chair, IRB # 4
Institutional Review Board

Date: 11/19/2013

Subject: Human Protocol: IRB00019384
Feasibility of Delivering a Quitline Based Smoking Cessation Intervention in Lung Cancer Patients Receiving Outpatient Treatment: A Pilot Study

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

This is to confirm for your record that the Institutional Review Board reviewed your progress report and consent form, containing compounded HIPAA authorization language, if applicable, for the above-named protocol. IRB approval was activated on 11/14/2013 and will expire on 11/13/2014. If the protocol is to remain active longer, a written request for renewal, together with a summary progress report, and a copy of the current consent form, if applicable, should be submitted to the Board at least one month prior to expiration.

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 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.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

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

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.

Richard Weinberg, M.D.

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