MEMORANDUM

To: Suzanne Danhauer, Ph.D.
PHS-Social Sciences

From: Chair, IRB # 5
Institutional Review Board

Date: 1/15/2015

Subject: Human Protocol: IRB00025539
Reducing Lung Cancer Survivors' Anxiety (RELAX)
Amendment 2 for IRB Study #IRB00025539

Study Documents:
Protocol Version: RELAX Protocol 12-29-14 - Clean.docx; Informed Consent Version: RELAX Am 2 Consent wo tracking (approved); Investigator's Brochure: What is Resperate; Other Documents: Appendix 1 - Data Submission Checklist, Appendix 10 - PROMIS Fatigue, Appendix 11 - Activities Form, Appendix 12 - Six Minute Walk, Appendix 13 - Visual Analogue Scale, Appendix 14 - Device Instructions for Coordinators, Appendix 15 - Device Instructions for Participants, Appendix 16 - Intervention Feedback, Appendix 17 - Patient Decline Form, Appendix 18 - Saliva Collection Instructions and Diary, Appendix 19 - RNA/DNA Lab Instructions, Appendix 2 - Eligibility Checklist, Appendix 20 - Early Withdrawal Form, Appendix 3 - HADS Anxiety/Depression Scale, Appendix 4 - Cancer Dyspnea Scale, Appendix 5 - Current Medication Form, Appendix 6 - Flow Sheet - Addendum, Appendix 7 - Weekly Breathing Assessment, Appendix 8 - Participant Expectations, Appendix 9 - Manchester Cough in Lung Scale

The Institutional Review Board voted approval of the amendments listed below at its meeting of 1/12/2015. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

1. Editorial and clarifying changes.
2. Two new objectives were added.
   a) To determine if changes in anxiety attributed to device-guided breathing are correlated with epigenetic (DNA methylation) and/or gene expression changes.
   b) To obtain preliminary data on changes in salivary cortisol in each intervention group and associations between salivary cortisol and anxiety.
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.

Scott Rushing