MEMORANDUM

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

From: Chair, IRB # 4
       Institutional Review Board

Date: 8/31/2015

Subject: Human Protocol: IRB00025539
Reducing Lung Cancer Survivors' Anxiety (RELAX)
Amendment 6 for IRB Study #IRB00025539

Study Documents:
Informed Consent Version: Am 6 RELAX Consent
Clean 08-11-15 (approved);
Investigator's Brochure: What is Resperate;
Advertisements:
Physician Letter, RELAX Flyer 08-11-15;
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 15A Device Instructions - Blue, Appendix 15B - Device Instructions Green,
Appendix 15C - Device Instructions - Yellow, 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 8/20/2015.
This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

1. Title Page: Added “WF” to protocol number; added grant numbers; added NCI approval, activation, and amendment dates; Amendment 4 added to footer.
2. Schema: Baseline Data Collection deleted “for subsample at the Wake Forest site”; for baseline and Week 12, removed “only” for WF blood draw to allow blood collection at any sites that open the study. For endpoints, added clarifying language for blood draw and cortisol collection.
3. Table of Contents: updated to reflect correct page numbers.
4. Section 3. Updated language to clarify language for blood draw and cortisol collection.
5. Section 6.1: Added “A finger type pulse oximeter…during the six minute walk” and “A measuring wheel will be provided . . .”
6. Section 6.2: Added “/pulse oximeter, and measuring wheel”
7. Section 6.4.1: Online Registration: Added “NCORP” and removed “Ping Tan” and “Biologics”
8. Section 7.1: Fifth paragraph. Updated language to clarify language for blood draw and cortisol collection.
9. Section 7.1: Seventh paragraph: Added “include questionnaires, PFT’s and a 6 minute walk….during the six minute walk.” Eighth paragraph: Added “These measures” to first sentence.
10. Section 7.2 (pre-screening testing). Added language to allow pre-screening for anxiety symptoms over the phone.
11. Section 7.2: Baseline: added “will be needed for registration” to CDS, Six Minute Walk added “Heart rate and O2 Sat pre and post walk.” Other minor edits were made for clarity and grammatical correctness.
12. Section 7.3: Minor edits were made for clarity and grammatical correctness.
13. Section 7.4: Week 12: Six Minute Walk added “Heart rate and O2 Sat pre and post walk.” Other minor edits were made for clarity and grammatical correctness. Changed “Weekly breathing assessment” to Weekly Check-In Call/Data Capture from Device. Deleted “diffusion capacity” (7.8 and 11.1).
14. Section 7.5. Added language about storage and shipping of blood samples. Added clarifying language re: cortisol collection. Deleted “The blood will be stored…sample to the laboratory.”
15. Section 7.8: Study Parameter Table: added “will be needed for registration” to CDS; Six Minute Walk added “Heart rate and O2 Sat pre and post walk. Pulse ox and measuring wheel provided.” Added “**” note. Added pre-screen column to allow for HADS to be administered over the telephone.
16. Section 10: First paragraph: added “or not related” to second sentence. Deleted Sections 10.1-10.3.
17. Section 11.1: Table completely updated.

CONSENT
1. In “What Are the Study Groups?” section, the name of the device “Resperate” was removed so that there is reference to “the device” or “breathing device.”
2. Revised footer to include “NCI Version Date; WF Amend #.
4. Added first paragraph “Treatments for anxiety…choices you may have.”
5. Added “What Are My Other Choices…” section
6. Rewrote “Why is this study being done?” section and incorporated how many people will take part.
7. In the “Blood Collection” and related “What Is Involved” sections, we removed the word “optional” reference to the blood draw. Some of the text describing the rationale for the blood draw was added for clarity.
8. What Happens if I am Injured Section: Added WF IRB language.
9. Revised footer to include “NCI Version Date; WF Amend #.
10. In “During the Study” Grammatical changes made.
11. “End of Study” Grammatical change made.
12. Page 1: Replaced “Decreasing” with “Reducing”.
13. Other administrative changes throughout consent.

APPENDICES
1. Appendix 1: clarified HADs timing, fax of PFTs, removed cortisol and 6 min walk from Week 6.; added Wake Forest
2. Appendix 2: Added CDS to page 3. Other minor edits made for clarity and grammatical correctness.
3. Appendix 3: HADs: removed asterisks from page 2 and 3
4. Appendix 4: CDS: added visit question to header and other minor formatting changes
5. Appendix 5: added visit question to header and other minor edits for clarity and grammatical correctness.
6. Appendix 7: Date added to Weekly breathing assessment. Changed the name of the form to be more accurate with what we are collecting. Other minor edits for clarity and grammatical correctness.
7. Appendix 8: added “complete at baseline” to header and other very minor edits.
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8. Appendix 9: visit question added to header.
10. Appendix 12: 6 minute walk directions updated.
11. Appendix 14: Added the words blue, green and yellow and color dots for clarity.
12. Appendix 15: Created three different versions so that each group has their own specific instructions. Removed the word Resperate and other edits for clarity and grammatical correctness.
13. Appendix 16: “Complete at 12 weeks” moved to header.
15. Appendix 19: directions to please use military time added
16. All the appendices had the footer changed to show Am 5.
17. Appendix 14: A header was added, 15a, 15b and 15c had the header changed for consistency. Formatting changes were also made.
Flyer and Recruitment letter were added.

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.