MEMORANDUM

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

From: Chair, IRB # 8
   Institutional Review Board

Date: 8/14/2015

Subject: Human Protocol: IRB00031366
A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer
Amendment 2 for IRB Study #IRB00031366

Study Documents:

The Institutional Review Board voted approval of the amendments listed below at its meeting of 8/13/2015. 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 amendment 2, added amendment 2 to footer
2. Collaborators: Peiying Yang, PhD. added
3. Statistician: Doug Case email address added
4. Appendices Title added
5. Appendix Numbered
6. Section 2.2: Editorial/Clarification changes
7. Section 3.2.2: "Must be able to read, write, and understand English" added
8. Section 3.2.4: RTOG scale added with clarification
9. Section 3.2.7: "A focused (head/neck) history and exam conducted by a physician or dentist within the past year is required" added
10. Section 3.2.9: "A focused (head/neck) history and exam conducted by a physician or dentist within the past year is required" deleted
11. Renumbered criteria
12. Section 3.3 Renumbered
13. Section 3.3.3 Rewritten to read, "Currently receiving or planning to use drugs...questionnaire data collection"
14. Section 3.4 Section renumbered
15. Section 4.2: Editorial/Clarification Changes
16. Section 5.4: Editorial Clarification Changes
17. Section 6.1: Clarification Changes added fourth paragraph: "If a patient is using...an individual basis"
18. Section 6.3: Deleted paragraph and revised: "All patients will have study visits...conducted to assess response"
19. Section 6.3: Deleted Response Assessment
20. Section 6.3: Deleted "obtained"; added "will be completed"
21. Section 6.3: Deleted "TAT" and "SAT"; added "Acupuncture Treatment Form"
22. Section 6.5: Editorial Changes
23. Section 6.6: Deleted paragraph "Patients who miss...outlined in 6.4"; added paragraph "Patients who miss...secondary 'per protocol' analyses"
24. Section 7.5: Study Calendar of Events added
25. Section 7.6: Calendar deleted
26. Section 9.1: "SAT/TAT" deleted; added "Acupuncture treatment"
27. Section 11.0: Editorial changes

Appendices Changes:
1. Appendices renumbered: Integrative Medicine Safety Guidelines for Acupuncture, Study Calendar of Events, Symptom Inventory do longer listed
2. WF NCORP header added to each appendix
3. WF NCORP Data Submission information footer added to Acupuncture Treatment Form SAT
4. WF NCORP Data Submission information footer added to Acupuncture Treatment Form TAT

Consent Changes:
1. "dry mouth" added for clarification throughout the consent
2. During the Study: "This will end your participation in this study" added
3. If you are randomized group 1: "If your symptoms improved...no additional acupuncture" paragraph added for clarification
4. If you are randomized group 1: "Regardless of how you respond" deleted/"At" added
5. If you are randomized group 2: "If your symptoms improved...no additional acupuncture" paragraph added for clarification
6. If you are randomized group 2: "Regardless of how you respond" deleted/"At" added
7. If you are randomized group 2: "This will end your participation in this study" added for clarification
8. If you are randomized group 2: "If you were randomized...approach at no cost." paragraph added for clarification
9. Will my medical information be kept private?: Site specific privacy information added
10. What happens if I am injured: Section deleted
11. Who can answer my questions.....: PI information added
12. Who can answer my questions.....: IRB information added
Office of Research

INSTITUTIONAL REVIEW BOARD

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.