WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Edward Shaw, M.D.
Radiation Oncology

From: Chair, IRB # 7
Institutional Review Board

Date: 6/13/2013

Subject: Human Protocol: IRB00012856
A Phase II, Double-Blinded Feasability Study of Armodafinil for Brain Radiation-Induced Fatigue
Sponsor Title: Amendment 6

Study Documents:
Protocol Version: 97509 Am 6 Protocol; Informed Consent Version: 97509 Am 6 Consent (approved); Investigator's Brochure: 97509 FDA exemption letter, Armodafinil Labeling Information; Other Documents: Appendix 1 Data Submission Checklist, Appendix 10 End RT Booklet, Appendix 11 Week 4 Post RT Booklet, Appendix 12 Monoamine Oxidase Inhibiting Drugs, Appendix 13 Radiation Therapy Summary, Appendix 14 Quality of Life Forms, Appendix 15 Brief Fatigue Inventory, Appendix 16 Epworth Sleepiness Scale, Appendix 17 Telephone Contact Form, Appendix 2 , Appendix 3 Performance Status, Appendix 4 Patient Medication Diary, Appendix 5 MedWatch, Appendix 6 Flow Sheet, Appendix 7 , Appendix 8 Current Medications Form, Appendix 9 Baseline Assessment Booklet

The Institutional Review Board voted approval of the amendments listed below at its meeting of 5/22/2013. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

Protocol:
1. Title Page: Added Amendments 4-6 and dates
2. Table of Contents: Added Appendix 16 6 Month Post RT Test booklet
3. Section 1.2.4 added objective for WF patients only
4. Section 2.3 added 2 bullet points explaining the SRT testing for Wake Forest
5. Section 3.4 added last sentence concerning WF patients' final visit
6. Section 3.5 added last paragraph explaining > 6 month assessment
7. Section 4.4.1 added last sentence concerning WF patients' final visit
8. Section 7.1 added last paragraph concerning WF patients' final visit
9. Section 7.5.1 added section describing evaluations at > 6 month visit for WF patients
10. Section 7.7 added last column and SRT row of study parameter table for WF patients
11. Section 8.2 5)added WF assessment to cognitive function tests
12. Section 10.1.1 added clarification about AE collection for >6 month WF patients
13. Section 11.1 added last row for WF > 6 month patient assessment
14. Section 12.5 final paragraph added to read "Wake Forest patients.. quality of life measures."

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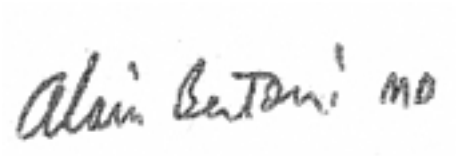
15. References: 48-52 added

Consent:

1. Version number changed from 4 to 5
2. Page 2, third bullet point: added last sentence to read “If you are being seen at Wake Forest…treatments have stopped.”
3. Page 3, second bullet point added to read “If you are being seen at Wake Forest…treatments have stopped.”
4. Page 3 study calendar: added last column for WF patients
5. Page 4: How Long Will I Be in the Study? Added sentence for WF patients about voluntary visit.
6. Disclosure Section: Added information about insurance coverage

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.



Alain Bertoni, M.D.