CCCWFU CCOP RESEARCH BASE
PROTOCOL AMENDMENT CHANGE FORM

Study Title: A Randomized Phase II Dose Finding Study of ArginMax for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy

Protocol #: 98110 **Date of Submission to IRB: 7/11/11**
IRB Number: IRB00012793 **IRB Approval Date: 7/25/11**

Principal Investigator: **Protocol Amendment # 3**

Brief description of each change in the study protocol and rational. (Additional pages may be used as needed):

1. Footer: added Amendment 3: 7/25/11
2. Title page: Added 'Amendment 3: 7/25/2011, email addressed updated from @wfubmc.edu to @wakehealth.edu
3. Table of Contents: Added 'Appendix 16 FACT-P'
4. Section 1.2 Number 3, first bullet: added 'and the Functional Assessment of Cancer Therapy (FACT-P (Appendix 16))'
5. Section 2.3: added paragraph "The Functional Assessment of Cancer therapy….to detect change over time."
6. Section 4.1: added bullet "Hormonal therapy injection may be given once prior to seed implants to "down-size" the patient's prostate. (A testosterone level is not required prior to registration)"
7. Section 6.8.1: Updated online registration webpage
8. Section 7.2.2: Added 'and the FACT-P (Appendix 16) at baseline.
9. Section 7.5: Added FACT-P to Study Parameters Table
10. Section 11.1:Data Management Schedule, added FACT-P to Baseline, Week 4 and Week 8, Combined Week 4 and 8 forms into one row

Consent Form Changes

Brief description of each change in the consent form and rational.

1. Footer: Changed version number to 4
2. 'What Is Involved In The Study?' Baseline: Number of questionnaires changed from 2 to 3; 4 Weeks and 8 Weeks: Number of questionnaires changed from 4 to 5
3. 'Confidentiality' Section: added 'A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.' And deleted "Data collected in this study….National Library of Medicine."

Appendices Changes

Brief description of each change in the appendices.

1. Appendix 1: Added Data Submission Checklist to mirror Section 11.1
2. Appendix 2: Eligibility Checklist questions 3 and 14 updated to include hormonal therapy
3. Appendix 6 TAS: CTC updated to reflect version 4.0
4. Appendix 7: Study parameters table updated to include FACT-P
5. Appendix 16: FACT-P: added form

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