

**Wake Forest University School of Medicine Institutional Review Board
Protocol Amendment Request Form**

Study Title: 97405 Randomized Study of Soy Protein and Effexor on Vasomotor Symptoms of Men with Prostate Cancer*** (Form never submitted to IRB, created for website use only.)***

IRB Number: BG BG-05-529 **Date of submission to IRB:** 4-18-07

Principal Investigator: Mara Vitloins

Name

SIGNATURE: _____



Protocol Amendment - Amendment # 4
Information Office

CC: Gina Enevold, Sarah C. Hahne, Protocol

Give a brief description of each change in the study protocol and rationale (Additional pages may be used as needed):

1. Cover Page: Added activation date of "2-15-07" for WFU and site; Columbus CCOP, Bay Area Tumor Institute and LSU PI information deleted; added information for Beaumont, Minnesota, Michigan, Indiana, Our Lady of Mercy, Hilton Head and Miami; corrected Robin Rosdhal's fax number to read "713-6476"; deleted "Jim Palermo" under Hugh Chatham and added "Greg Fiets"
2. Page vii: Table of Contents: numbered sub-sections in sections 1 and 2; deleted "N/A" in section 4.5; deleted subsection in 5, 8, and 9 sections; added "N/A" to sections 6, 7 and 10; added Appendices and Consent form to table of contents; Table of contents page numbers updated to reflect body of protocol; added appendix L "Telephone Contact Sheet";
3. Page xi: deleted "Week 2 clinic visit" and added "Week 2 contact (telephone)" and "request" to blood pressure; Under 12 week clinic visit: deleted "Effexor XR, other" and added "study pills"; bottom of page: deleted "*Severe symptoms: Having reported 4 or more days of severe symptoms during the run-in period." and corresponding asterisk
4. Page 4: Eligibility Criteria: 3.1.3 rewritten to read "Prior or current androgen deprivation... and/or pelvis"; 3.1.4 added "(Average of 28 per week)"; 3.1.5: deleted "Participant report of 4 or more days of " and "must be"; Section 3.1.8 added "SNRI's"; Section 3.1.9 deleted "preexisting" and added "uncontrolled" hypertension "(160/90)"; Section 3.1.12 changed Bilirubin < 2.0 to less than or equal to 2.0; added 3.1.16 "Patients should maintain... throughout entire study."
5. Page 4: Exclusion Criteria: Deleted 3.2.1 and renumbered remaining criteria; 3.2.1 deleted "currently receiving" and added " and added "example: discontinuation of current"; added "3.2.6 Current use of medication to relieve hot flashes."; "Drug Information" added as title to Section 4.1
6. Page 5: Section 4.1: deleted last sentence reading "The lowest manufactured dose of extended release Effexor XRTM is 37.5 mg."; Section 4.1.3: added "Participants will be given a 1 week taper of the Effexor/Placebo."
7. Page 6: Section 4.2.3 second paragraph: added "Participants will be given a 1 week taper of the Effexor/Placebo."
8. Page 7: Section 4.3.2 moved to Section 14
9. Page 8: Section 4.4: first paragraph: switched arms 1 and 2; changed numbers to letters for 4 study arms; third paragraph: deleted first 2 sentences and added "At week 2, the participant will be contacted by telephone... research personnel. Study coordinators will"; fourth and fifth paragraphs: "in same envelope" deleted
10. Page 9: removed underline from Section 4.4.1
11. Page 9: "Two week clinic visit" changed to "Two week telephone contact"; "assess" deleted and "record" added; added "as reported per participant"
12. Page 11: Study Parameters: Added "Physical exam and lab tests required within 3 months of registration."; first row: "clinic" contact changed to "telephone" contact during week 2; second row: added "Physical Exam"

**Wake Forest University School of Medicine Institutional Review Board
Protocol Amendment Request Form**

and "X(A)" added to second column; superscript B added to third row second column; Bilirubin and SGOT "X" moved from baseline to 'pre-study' and superscript A added; Superscript C added to last row fourth column; deleted "X" in weight row 2 week column; Notes A-C added to read "(A) Must be completed within the last 3... results reported to research personnel."; Study Measures columns: added appropriate appendices title ie "Appendix H" and deleted "flowsheet" in last 5 rows; Section 12: deleted "Online Registration" and added "Registration Procedures" as section title; first sentence: added "or IRB letter of approval" and fax number 13. Page 12: Section 13: added "Lab reports < 1 week from registration" row, added "2 weeks" to Phone Contact row

14. Page 12: Section 14: second full paragraph: deleted "See Section 13.0...schedule."

15. Page 13: Section 14.3: deleted "Adverse Event reports are discontinued 30 days after the discontinuation of the study drug." and added "Adverse Events occurring within 30 days of study completion must be reported via FDA form 3500 (Medwatch)."; added "3. Any medical event requiring hospitalization or prolongation of existing hospitalization must be reported regardless of attribution or whether the adverse event is expected or unexpected." and renumbered points;

16. Page 14: Section 14.4: deleted "Not Supplied by NCI" and added "Commercially available"; deleted "and/or Treatment Study" and "If the study drug is not supplied by NCI"; deleted 'method is' and added 'for all commercially available drugs should be reported'; deleted "A" in 3500A Medwatch

17. Page 15: Table A: deleted "that occur within 30 days... Investigator or Sponsor holds IND"; deleted "not required" in Grade 3 unexpected and expected without hospitalization columns and added "10 Calendar Days"

18. Page 17: Section 15.1: deleted "as shown in Appendix A"; and "as shown in Appendix B"

19. Page 20: Section 15.6: last paragraph: deleted "7" and added "28" when referring to the number of hot flushes per week; changed hot "flushes" to "flashes"

Consent Form Changes

Give a brief description of each changes in the consent form and rational. Provide one copy of the consent form with the changes red lined and two clean copies of the revised consent form for IRB approval stamp.

1. Header: deleted "date"
2. Page 1: last paragraph: added "Twenty men...Forest University."
3. Page 2: first paragraph under "What is involved in the study?" deleted sentence "In order to evaluate...severity of your hot flashes."; second group: added "and"; last paragraph: added "by mouth"; deleted group name and numbers; added "OR" between each study arm
4. Page 3: Second paragraph deleted; third paragraph: added "2, 4 and 8", and "with the study pills and powders." to first sentence. Second sentence added to read "During the 2 week... blood pressure."; last sentence: updated to reflect multiple phone calls; fourth paragraph: deleted "had" and last sentence reading "Also if you were in the Effexor...stopping the medication."; deleted last paragraph in "What is involved in the study?" section reading "Do you request that we send important... in this research study."
5. Page 3: "How long will I be in the study?" section: "deemed" removed from second paragraph; third paragraph: deleted "of course" and added "Wake Forest University Baptist Medical Center."; fourth paragraph: last sentence deleted "consequences" and added "concerns."; fifth paragraph: added "During the last week of the study, you will be given a one week supply of a lower dose of study drugs regardless of your assigned study group."
6. Page 4: Risks section: added "may or may not" and "potential risks"; side effects changed to bullet format; "The dose of Effexor" changed to "pills you will take" and "gradually" added; deleted "to reduce the potential for drug withdrawal side effects."

**Wake Forest University School of Medicine Institutional Review Board
Protocol Amendment Request Form**

- | |
|---|
| <p>7. Page 5: added "National Cancer Institute (NCI)" to first full paragraph</p> <p>8. Page 6: added creditials to Mara Vitolins name; In "Benefits" section: deleted "are not expected to" and added "may or may not"; added last sentence "The benefits of...in hot flashes."; deleted second paragraph in costs section</p> |
| <p>9. Page 8: "What happens if you experience an injury... section" second paragraph: deleted second phone number for Mara Vitolins; "Whom do I call if... section" deleted second phone number for Mara Vitolins;</p> <p>10.</p> |

Amendment requests for approved protocols and consent forms may be submitted at any time. If only minor changes are requested, expedited review may be possible. Other amendments will be considered at a convened meeting of the full IRB.
