

**CCCWFU CCOP RESEARCH BASE
PROTOCOL AMENDMENT CHANGE FORM**

Study Title: Randomized Study of Soy Protein and Effexor on Vasomotor Symptoms of Men with Prostate Cancer

IRB Number: BG05-529 WFU 97405

Date of IRB Approval: 08/19/09

Principal Investigator: Mara Vitolins, Dr.P.H.

Protocol Amendment # 8

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

1. Header: Added "Amendment/Update # 8" Deleted amendment 7 date. NCI protocol corrected to read WFU 06-02-06
2. Page ii: Added Amendment 7 date and "Amendment 8"; Added new NCI version date: 08-03-09
3. Page viii: Deleted "Any CTSU Participating Member" per CTSU
4. Page x: Table of Contents; Appendix B: amended to read 'through week 13'

Consent Form Changes

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

none

Appendices Changes

Brief description of each change in the appendices.

1. Appendix N: Updated CTSU Logistics to include correct protocol number and deleted specimen shipping information