

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Mara Vitolins, Dr.P.H.
PHS - Epidemiology

From: Vice Chair, Institutional Review Board

Date: 8/19/2009

Subject: Human Protocol: BG05-529
Randomized Study of Soy Protein and Effexor on Vasomotor Symptoms of Men with
Prostate Cancer
Sponsor Title: Amendment 8

Study Documents:

Protocol Version: BG-05-529 Am 8 protocol without tracking; Informed Consent Version: BG-05-529
97405 Amendment 7 Consent (approved); Advertisements: 97405 Soy Flyer 12-16-08, Amend 5 -
Recruitment Letter 10-24-07, Appendix G - Flyer

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Protocol revision to include administrative and editorial changes.

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.



Andrea Fernandez, M.D.