

## Reading Materials and Resources

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### *Clinical Trials on Dietary Supplements: Human Investigation*

What Constitutes Human Subject Research?

<http://hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

HIPPA Information

<http://www.cms.hhs.gov/hippa/>

<http://www.hhs.gov//ocr/hippa/>

<http://aspe.hhs.gov/admsimp/pl104191.htm>

<http://www.nemc.org/resadmin/HIPAA/default.htm>

NIH Protocol Review Standards

<http://ohsr.od.nih.gov/irb/protocol.html>

<http://www.irbforum.org/>

Informed Consent Checklist And Tips

<http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm>

<http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm>

FDA Frequently Asked Questions On IRBs As Well As Guidance For Clinical Investigators And Sponsors

<http://www.fda.gov/oc/ohrt/irbs/faqs.html#IRBOrg>

<http://www.fda.gov/oc/ohrt/irbs/default.htm> (IND/IDE links)

### ***Key Publications***

#### BETA CAROTENE

Omenn GS, Goodman GF, Thornquist MD. Effects of a Combination of Beta Carotene and Vitamin A on Lung Cancer and Cardiovascular Disease. 1996 N Engl J Med 1996;334: 1150-1155.

Hennekens CH, Buring JE, Manson JE et al. Lack of Effect of Long-Term Supplementation with Beta Carotene on the Incidence of Malignant Neoplasms and Cardiovascular Disease; N Engl J of Med 1996; 334: 1145-1149.

#### SELENIUM

Whanger PD. Selenocompounds in Plants and Animals and Their Biological Significance. Journal of the American College of Nutrition, vol 21, No3, 223-232 (2002).

Clark LC, Combs GF Jr, Trumbull BW, et al: Nutritional Prevention of Cancer Study Group. Effects of Selenium Supplementation for Cancer Prevention in Patients with Carcinoma of the Skin: A Randomized Controlled Trial. JAMA.1996; 276 (24):1957-1963.

Duffield-Lillici AJ, Dalkin BL, Reid ME, et al; Nutritional Prevention of Cancer Study Group. Selenium Supplementation, Baseline Plasma Selenium Status and Incidence of Prostate Cancer: An Analysis of the Complete Treatment Period of the Nutritional Prevention of Cancer Trial. BJU Int. 2003; 91(7): 608-612.

Lippman SM, Klein EA, Goodman PJ, et al. Effect of Selenium and Vitamin E on Risk of Prostate Cancer and Other Cancers: The Selenium and Vitamin E Cancer Prevention Trial. 2009; 301(1): 39-51.

El-Bayoumy K. The Negative Results of the SELECT Trial Do Not Necessarily Discredit the Selenium-Cancer Prevention Hypothesis. 2009; 61(3): 285-286.

#### VITAMIN E

Heinonen OP, Albanes D, Virtamo J, et al. Prostate Cancer and Supplementation with Alpha-Tocopherol and Beta-Carotene: Incidence and Mortality in a Controlled Trial. J Natl Cancer Inst.1998; 90 (6): 440-446.

The Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study Group. The Effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and Other Cancers in Male Smokers. N Engl J MED 1994; 330: 1029-35.

#### ECHINACEA

Turner RB, Bauer R, Woelkart K et al. An Evaluation of Echinacea angustifolia in Experimental Rhinovirus Infections. N Engl J Med 2005; 353: 341-348.

#### CHONDROITIN

Barnhill, FYe, Cl, Williams DW et al. Chondroitin Product Selection for the Glucosamine/Chondroitin Arthritis Intervention Trial. J Am Pharm Assoc. 2006; 46: 14-24.