

Meeting Agenda

**Thursday, January 25, 2018
9:00am –12:00pm Eastern Time**

I. Initial Review

S1600, A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes (Protocol Version Date 11/21/17)

II. Initial Review

NWU2017-09-01, Phase I Trial of Endoxifen Gel versus Placebo Gel in Women Undergoing Breast Surgery (Protocol Version Date 09/28/17)

III. Continuing Review

UAZ2015-05-01, A prospective, single-arm, open-label, non-randomized, phase IIA trial of a nonavalent prophylactic HPV vaccine to assess immunogenicity of a prime and deferred-booster dosing schedule among 9-11 year-old girls and boys (Protocol Version Date 11/09/16)

IV. Continuing Review

UWI2014-03-01, A Phase I Trial of the Safety and Immunogenicity of a DNA Plasmid Based Vaccine (WOKVAC) Encoding Epitopes Derived from Three Breast Cancer Antigens (IGFBP-2, HER2, AND IGF-1R) in Patients with Breast Cancer (Protocol Version Date 10/9/17)

V. Patient Recruitment Materials

NWU2015-06-04, Phase IIB trial of neoadjuvant oral tamoxifen versus transdermal 4-hydroxytamoxifen in women with DCIS of the breast (Protocol Version Date 09/14/17)
