

Meeting Agenda

Thursday, March 23, 2017 9:00 am -11:05 am Eastern Time

Agenda

I. General Business

Next Meeting: <u>Thursday, April 27, 2017</u>

II. Reports for 02/01/17 – 02/28/17

- CPC CIRB Local Context Subcommittee Report
- Expedited Reviews and Study Acknowledgements
- Study Activation Acknowledgements
- Amendment Activation Acknowledgements

III. Review/Approval of Minutes

• February 23, 2016

IV. 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)

V. 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 04/29/16)

VI. Amendment Review

NWU2014-04-01, Statin Therapy to Reduce the Risk of Recurrent Pancreatitis (Protocol Version Date 02/08/17)

VII. Study Chair Response to Tabled Initial Review

A221505, Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction (Protocol Version 03/02/17)

VIII. Study Chair Response to Tabled Initial Review

UWI2015-05-01, Phase Ib 9cUAB30 in Early Stage Breast Cancer to Evaluate Biologic Effect (Version 5, Protocol Version Date 03/09/17)