

Cancer Prevention and Control Central IRB

Meeting Agenda

Thursday, July 27, 2017 9:00 am –12:50 pm Eastern Time

Agenda

I. General Business

- Next Meeting: <u>Thursday, August 24, 2017</u>
- Board Member Education: Presentation on "Electronic Patient-Reported Outcomes (ePRO)" by Lori Minasian, MD from DCP
- Response from Dr. Eva Szabo Re: Tobacco and Alcohol Assessment

II. Reports for 06/01/17 - 06/30/17

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

III. Review/Approval of Minutes

• June 22, 2017

IV. Study Chair Response to Tabled Review

MAY2016-08-01, A Pilot Study of MUC1 Vaccine in Current and Former Smokers at High Risk for Lung Cancer (Protocol Version 06/27/17)

V. Continuing Review

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

VI. Amendment Review

UWI2015-05-01, Phase Ib 9cUAB30 in Early Stage Breast Cancer to Evaluate Biologic Effect (Protocol Version 06/30/17)

VII. Amendment Review

NRG-CC003, Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with Or without Hippocampal Avoidance for Small Cell Lung Cancer (Protocol Version 06/12/17)

VIII. Amendment Review

MDA2014-04-02, VADIS Trial: Phase II trial of Nelipepimut-S Peptide Vaccine in Women with DCIS of the Breast (Protocol Version 06/29/17)

IX. Initial Review

UAZ2016-08-02, A Phase I safety and dose-finding trial of alternate-weekly, self-administered, intravaginal application of 5-fluorouracil and imiquimod for treatment of high-grade cervical intraepithelial lesions (Protocol Version 05/22/17)

X. Initial Review

MAY2017-09-01, Phase I Double-Blind, Placebo-Controlled Trial of 0.3 mg Linaclotide Delayed-Release (DR1) to Demonstrate Colorectal Bioactivity in Healthy Volunteers (Protocol Version 06/02/17)