



Cancer Prevention and Control Central IRB

Meeting Agenda

**Thursday, August 24, 2017
9:00 am –12:00 pm Eastern Time**

Agenda

I. General Business

- Next Meeting: Thursday, September 28, 2017
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II. Reports for 07/01/17 – 07/31/17

- CPC CIRB Local Context Subcommittee Report
 - Expedited Reviews and Study Acknowledgements
 - Study Activation Acknowledgements
 - Amendment Activation Acknowledgements
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III. Review/Approval of Minutes

- July 27, 2017
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IV. Initial Review

UAZ2017-09-02, Clinical Study of Avmacol® for Detoxification of Tobacco Carcinogens in Heavy Smokers (Protocol Version 07/06/17)

V. Initial Review

NWU2016-08-02, A phase I single-arm, multicenter pilot study aimed at validating γ -OHPdG as a biomarker and testing the effects of Polyphenon E® on its levels in patients with cirrhosis (Protocol Version 08/14/17)

VI. Amendment Review

NWU2015-06-04, Phase IIB trial of neoadjuvant oral tamoxifen versus transdermal 4-hydroxytamoxifen in women with DCIS of the breast (Protocol Version Date 08/07/17)

VII. Study Chair Response to Tabled 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 08/18/17)

VIII. Continuing Review

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

IX. Continuing Review

NWU2015-06-02, Immunogenicity of Nonavalent HPV Vaccine Administered Prior To Living Donor Renal Transplantation in Adult Women: A Prospective, Single-Arm, Multi-Center Clinical Trial (Protocol Version Date 01/12/17)
