

Cancer Prevention and Control Central IRB

Meeting Agenda

Thursday, October 26, 2017 9:00 am -1:00 pm Eastern Time

Agenda

I. General Business

Next Meeting: <u>Thursday, November 30, 2017</u>

II. Reports for 09/01/17 - 09/31/17

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

III. Review/Approval of Minutes

- August 25, 2017
- September 28, 2017

IV. Initial Review

A221602, Olanzapine with or without fosaprepitant for the prevention of chemotherapy induced nausea and vomiting (CINV) in patients receiving highly emetogenic chemotherapy (HEC): A Phase III Randomized, Double Blind, Placebo-Controlled Trial (Protocol Version 08/31/17)

V. Initial Review

MDA2016-08-02, A Phase I Dose Escalation Study of Topical Bexarotene in Women at High Risk for Breast Cancer (Protocol Version 10/04/17)

VI. Amendment 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 10/09/17)

VII. Continuing Review

NHLBI-MDS, The National Myelodysplastic Syndromes (MDS) Study (Protocol Version 06/12/17)

VIII. Continuing Review

A221405, A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy (Protocol Version 06/09/17)

IX. Continuing Review

NRG-CC001, A Randomized Phase III Trial Of Memantine And Whole-Brain Radiotherapy With Or Without Hippocampal Avoidance In Patients With Brain Metastases (Protocol Version 08/24/17)

X. Initial Review

WF-30917CD, A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors (Protocol Version Date 008/25/17)