



Cancer Prevention and Control Central IRB

Meeting Agenda

**Thursday, September 28, 2017
9:00 am –12:05 pm Eastern Time**

Agenda

I. General Business

- Next Meeting: Thursday, October 26, 2017
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II. Reports for 08/01/17 – 08/31/17

- 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

- August 25, 2017
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IV. Initial Review

A171601, A Phase II Trial Assessing the tolerability of Palbociclib in combination with letrozole or fulvestrant in patients aged 70 and older with estrogen receptor positive, HER-2 negative metastatic breast cancer (Protocol Version 07/28/17)

V. Study Chair Response to Tabled 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 Date 09/13/17)

VI. Amendment Review

MAY2015-05-01, Randomized, double-blind, placebo-controlled trial of Meriva® (curcuminoids) as a candidate chemoprevention agent for gastric carcinogenesis" (Amendment 4, Protocol Version Date 08/28/17)

VII. Amendment Review

MDA2014-04-01, Alternative Dosing of Exemestane in Postmenopausal Women with Stage 0-II ER-Positive Breast Cancer: a Randomized Presurgical Trial (Protocol Version Date 08/09/17)

VIII. Recruitment Material Review

MAY2016-07-01, Phase II Trial of Weekly Erlotinib Dosing to Reduce Duodenal Polyp Burden Associated with Familial Adenomatous Polyposis (Protocol Version Date 08/25/17)

IX. Recruitment Material Review

MAY2016-08-01, A Pilot Study of MUC1 Vaccine in Current and Former Smokers at High Risk for Lung Cancer (Protocol Version Date 08/25/17)

X. Continuing Review

A221208, Randomized Phase II Study: Corticosteroids and Bevacizumab vs. Corticosteroids and Placebo (BeSt) for Radionecrosis after Radiosurgery for Brain Metastases (Protocol Version Date 01/10/17)

XI. Amendment Review

A221208, Randomized Phase II Study: Corticosteroids + Bevacizumab vs. Corticosteroids + Placebo (BeSt) for Radionecrosis after Radiosurgery for Brain Metastases (Protocol Version Date 08/23/17)

XII. Continuing Review

WF-97415, Understanding and Predicting Breast Cancer Events after Treatment (UPBEAT) (Protocol Version Date 11/15/16)

XIII. Determination of Reconsent Requirement

EA1141, Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women with Dense Breasts (Protocol Version Date 05/18/17)
