



Pediatric Central IRB Meeting Agenda
Thursday, February 9, 2017
11:00 am – 2:25 pm Eastern Time

Agenda

I. General Business

- **Next Meetings:** Friday, February 24, 2017 and Thursday, March 9, 2017
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II. Reports for 01/01/17 – 01/31/17

- Pediatric 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

- January 12, 2017
 - January 20, 2017
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IV. Initial Review

AGCT1531, A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors (Protocol Version Date TBD)

V. Initial Review

ALTE15N2, LEAHRN (Late Effects After High-Risk Neuroblastoma) Study (Protocol Version Date 01/11/17)

VI. Amendment Review

ACNS0831, Phase III Randomized Trial of Post-Radiation Chemotherapy in Patients with Newly Diagnosed Ependymoma Ages 1 to 21 Years: A Groupwide Phase III Study (Amendment #1D, Protocol Version Date 01/04/17)

VII. Continuing Review

ACCL0933, A Randomized Open-Label Trial of Caspofungin versus Fluconazole to Prevent Invasive Fungal Infections in Children Undergoing Chemotherapy for Acute Myeloid Leukemia (AML): A Groupwide Phase III Study (Protocol Version Date 04/22/14)

VIII. Continuing Review

AHEP0731, Treatment of Children with All Stages of Hepatoblastoma with Temsirolimus (IND#122782, NSC#683864) Added to High Risk Stratum Treatment: A Groupwide Phase III Study (Protocol Version Date 09/25/15)

IX. Continuing Review

AALL1131, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Testing Clofarabine (IND# 73789, NSC# 606869) in the Very High Risk Stratum: A Groupwide Phase III Study (Protocol Version Date 06/02/16)

X. Continuing Review

AAML1531, Risk-stratified Therapy for Acute Myeloid Leukemia in Down Syndrome: A COG Groupwide Phase III Study (Protocol Version Date 09/29/16)

XI. Continuing Review

AHOD1331, A Randomized Phase III Study of Brentuximab Vedotin (SGN-35, IND #117117) for Newly Diagnosed High-Risk Classical Hodgkin Lymphoma (cHL) in Children and Adolescents: A Groupwide Phase III Study (Protocol Version Date 11/16/15)
