



Pediatric Central IRB Meeting Agenda
Thursday, June 8, 2017
11:00am – 3:00 pm Eastern Time
Agenda

I. General Business

- **Next Meeting Date:** Thursday, July 13, 2017
- Introduction to Online CIRB Membership Application Process

II. Reports for 05/01/17 – 05/31/17

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

III. Review/Approval of Minutes

- April 21, 2017

IV. Continuing Review

ADV1414, A Phase 1 Study of Selinexor (KPT-330), A Selective XPO1 Inhibitor in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors (Protocol Version Date 01/17/17)

V. Continuing Review

ADV1412, A Phase 1/2 Study of Nivolumab in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab (Protocol Version Date 02/24/17)

VI. Continuing 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 (Protocol Version Date 02/10/10)

VII. Study Chair Response to 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 (Protocol Version Date 05/09/17)

VIII. Continuing Review

ANHL12P1, A Randomized Phase II Trial of Brentuximab Vedotin (SGN35, NSC# 749710) or Crizotinib (NSC#749005, commercially labeled) in Combination with Chemotherapy for Newly Diagnosed Patients with Anaplastic Large Cell Lymphoma (ALCL) IND # 117117 (Protocol Version Date 09/20/16)

IX. Amendment Review

ANHL12P1, A Randomized Phase II Trial of Brentuximab Vedotin (SGN35, NSC# 749710) or Crizotinib (NSC#749005, commercially labeled) in Combination with Chemotherapy for Newly Diagnosed Patients with Anaplastic Large Cell Lymphoma (ALCL) IND # 117117 (Protocol Version Date 04/26/17)

X. Continuing Review

AALL0932, Treatment of Patients with Newly Diagnosed Standard Risk B-Lymphoblastic Leukemia (B-ALL) or Localized B-lineage Lymphoblastic Lymphoma (B-LLy): A Groupwide Phase III Study (Protocol Version Date 04/11/16)

XI. Continuing Review

ACNS1022, A Phase II Randomized Trial of Lenalidomide (NSC # 703813, IND # 70116) in Pediatric Patients with Recurrent, Refractory or Progressive Juvenile Pilocytic Astrocytomas and Optic Pathway Gliomas (Protocol Version Date 05/08/17)

XII. Amendment Review

AALL1231, A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T- Lymphoblastic Leukemia (T-ALL) and T- Lymphoblastic Lymphoma (T-LLy): A Groupwide Phase III Study (Protocol Version Date 04/24/17)

XIII. Amendment Review

ARST1321, Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613) (Protocol Version Date 04/24/17)

XIV. Amendment Review

AAML1031, A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib (IND#114480; NSC# 681239, NSC# 724772) for Patients with High Allelic Ratio FLT3/ITD (Protocol Version Date 04/24/17)

XV. Study Chair Response to Amendment Review

APEC14B1, The Project: Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Protocol Version Date 05/05/17)

XVI. Initial Review

ADVL1521, A Phase 2 Study of the MEK Inhibitor Trametinib (IND #119346, NSC# 763093) in Children with Relapsed or Refractory Juvenile Myelomonocytic Leukemia (Protocol Version Date 04/06/17)

XVII. Initial Review

ALTE1631, A Randomized Web-based Physical Activity Intervention among Children and Adolescents with Acute Lymphoblastic Leukemia (Protocol Version Date 04/11/17)
