



Pediatric Central IRB Meeting Agenda
Thursday, March 9, 2017
11:00am – 1:15pm Eastern Time
Agenda

I. General Business

- **Next Meeting:** Thursday, April 13, 2017
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II. Reports for 02/01/17 – 02/28/17

- 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

- February 9, 2017
 - February 24, 2017
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IV. Initial Review

AALL1631, International Phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones (Protocol Version Date 02/16/17).

V. Continuing Review

ADVL1522, A Phase II Study of IMG901 (Lorvotuzumab Mertansine; IND #126953, NSC, 783609) in Children with Relapsed or Refractory Wilms Tumor, Rhabdomyosarcoma, Neuroblastoma, Pleuropulmonary Blastoma, Malignant Peripheral Nerve Sheath Tumor (MPNST) and Synovial Sarcoma (Protocol Version Date 07/08/16)

VI. Continuing Review

ARET12P1, Multi-institutional Feasibility Study of Intra-Arterial Chemotherapy Given in the Ophthalmic Artery of Children with Retinoblastoma (Protocol Version Date 03/30/16)

VII. Continuing Review

AOST1321, Phase II Study of Denosumab (IND #127430, NSC# 744010), a RANK Ligand Antibody, for Recurrent or Refractory Osteosarcoma (Protocol Version Date 01/04/16)

VIII. Continuing Review

ADVL1416, A Phase I Study of Ramucirumab, A Human Monoclonal Antibody Against the Vascular Endothelial Growth Factor-2 (VEGFR-2) Receptor in Children with Refractory Solid Tumors, Including CNS Tumors (Protocol Version Date 09/03/15)

IX. 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 (Amendment #1D, Protocol Version Date 01/04/17)
