

# Pediatric Central IRB Meeting Agenda

## Thursday, February 8, 2018 11:00am – 1:20pm Eastern Time

I Initial Review

AHEP1531, Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT) (Protocol Version Date 01/10/18)

#### II Amendment Review

**AALL1621**, A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND#133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL) (Protocol Version Date 06/20/17)

## III Continuing Review

**ACNS1422,** A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients (Protocol Version Date 07/17/17)

## IV Continuing Review

**ACNS0332**, Efficacy of Carboplatin Administered Concomitantly With Radiation and Isotretinoin as a Pro-Apoptotic Agent in Other Than Average Risk Medulloblastoma/PNET Patients: A Groupwide Phase III Study (Protocol Version Date 06/30/17)

#### V Continuing 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 11/09/17)

#### VI Continuing Review

AALL08B1, Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) (Protocol Version Date 06/30/17)

## VII Continuing Review

**AOST1421,** A Phase II Study of Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 (Dinutuximab, NSC# 764038, IND# 4308) in Combination with Sargramostim (GM-CSF) in Patients with Recurrent Osteosarcoma (Protocol Version Date 05/17/17)