



Pediatric CIRB Meeting Agenda

August 8, 2024

I. Amendment Review

ANHL2121, Phase 2 Study of Tovorafenib (DAY101) in Relapsed and Refractory Langerhans Cell Histiocytosis (Version Date 05/21/24)

II. Amendment Review

ARET2121, Intravitreal Melphalan for Intraocular Retinoblastoma (Version Date 06/20/24)

III. Amendment Review

PBTC-N14, CSF Cell-free Tumor DNA (CSF cfDNA) Liquid Biopsies for Pediatric, Adolescent, and Young Adult Patients with Primary Brain Tumors (Version Date 06/21/24)

IV. Continuing Review

ACNS2021, A Phase 2 Trial of Chemotherapy followed by Response-Based Whole Ventricular & Spinal Canal Irradiation (WVSCI) for Patients with Localized Non-Germinomatous Central Nervous System Germ Cell Tumor (Version Date 03/29/24)

V. Continuing 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 (Version Date 04/03/24)

VI. Continuing Review

ANHL1931, A Randomized Phase 3 trial of Nivolumab(NSC# 748726 IND# 125462) in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma (Version Date 01/30/24)

VII. Continuing Review

AOST2031, A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma (Version Date 01/04/24)

VIII. Unanticipated Problem Review

PBTC-059, Phase 1 Trial of Autologous HER2-specific CAR T cells in Pediatric Patients with Refractory or Recurrent Ependymoma (Version Date 12/20/23)
