

National Cancer Institute  
Institutional Review Board

**AGENDA**

**December 19, 2016**

1:00 – 5:00 pm

10 CRC/3-1608

**1. Call to Order/Announcements**

- Audio-recording of meeting
- Introduction of Guests
- Conflict of Interest
- Expedited Actions Report

**2. Review of Draft Minutes, December 12, 2016**

**3. Old Business**

- 14C0157, FDA 483 and Response to 483

**4. New Business**

**5. Problem Report Forms**

**6. Continuing Reviews**

- 7. Amendment** 09C0019-T, "A Phase I Study of Dasatinib in Combination with Bevacizumab in Advanced Solid Tumors" - Christina Annunziata, PI
- 8. Amendment** 13C0063-M, "A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of Avelumab (MSB0010718C), a Monoclonal Anti-PD-L1 Antibody, in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications" - James Gulley, PI
- 9. Amendment** 15C0093-F, "Phase I/II Trial of PLX3397 in Children and Young Adults with Refractory Leukemias and Refractory Solid Tumors Including Neurofibromatosis Type 1 (NF1) Associated Plexiform Neurofibromas (PN)" - Rosandra Kaplan, PI
- 10. Amendment** "15C0116-E, "Phase I Trial of 4'-thio-2'-deoxycytidine (TdCyd) in Patients with Advanced Solid Tumors" – James Doroshow, PI
- 11. Initial Review** P162730, "Heated Intraperitoneal Chemotherapy for Gastric Cancer with Positive Peritoneal Cytology" - Jeremy Davis, PI
- 12. Initial Review** P162894, "Administration of Most Closely HLA-matched Multivirus Specific Cytotoxic T-Lymphocytes for the Treatment of EBV, CMV, Adenovirus Infections Post Allogeneic Stem Cell Transplant (CHAPS)" - Jen Kanakry, PI
- 13. Initial Review** P162892, "Administration of LMP-Specific Cytotoxic T-Lymphocytes to Patients with Relapsed EBV-Positive Lymphoma" - Jen Kanakry, PI
- 14. Initial Review** P152337, "Phase II Evaluation of Nivolumab, an Immune Checkpoint Inhibitor, Alone or in Combination with Oral Decitabine/Tetrahydrouridine as Second Line Therapy for Non-Small Cell Lung Cancer" - David Schrupp, PI
- 15. Initial Review** P152349, "A Phase II Trial of the DNA Methyl Transferase Inhibitor, SGI-110, in Children and Adults with Wild Type GIST, Pheochromocytoma and Paraganglioma Associated with Succinate Dehydrogenase Deficiency and HLRCC-associated Kidney Cancer " - John Glod, PI