

National Cancer Institute  
Institutional Review Board

**AGENDA**  
**October 17, 2016**  
1:00 – 4:30 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, September 26, 2016 and September 29, 2016**

**3. Old Business**

- 14C0157, Kieron Dunleavy, PI: FDA Inspection 483

**4. New Business**

**5. Problem Report Forms**

**6. Continuing Reviews**

**7. Amendment** 14C0090-F, "A Phase 2 Open-Label Study to Evaluate the Efficacy and Safety of VT-464 in Patients with Metastatic Castration Resistant Prostate Cancer Who Have Previously Been Treated with Enzalutamide, Androgen Receptor Positive Triple-Negative Breast Cancer Patients, and Men with ER-positive Breast Cancer" - Ravi Madan, PI

**8. Amendment** 15C0101-F, "Phase I/II Study of Nivolumab (IND#124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab" - Brigitte Widemann, PI

**9. Initial Review** P131361, "A Pilot Study of Vincristine Sulfate Liposome Injection (Marqibo®) in Combination with UK ALL R3 Induction Chemotherapy for Children, Adolescents, and Young Adults with Relapse of Acute Lymphoblastic Leukemia" - Nirali Shah, PI

**10. Initial Review** P162723, "A Randomized Blinded Phase II Trial of Radiation Therapy plus Temozolomide and MK-3475 with and without HSPPC-96 in Newly Diagnosed Glioblastoma (GBM)" - Mark Gilbert, PI

**11. Initial Review** P152483, "A Pilot Study to Investigate the Safety and Clinical Activity of Avelumab (MSB0010718C) in Thymoma and Thymic Carcinoma after Progression on Platinum-Based Chemotherapy" - Arun Rajan, PI