

National Cancer Institute
Institutional Review Board

AGENDA

November 07, 2016

1:00 – 5:00 p.m.

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, October 17, 2016**

- 3 Old Business**
 - 14C0157, Patient/Family Script

- 4 New Business**

- 5 Problem Report Forms**

- 6 Continuing Reviews**

- 7 Response to Stips** 02C0052-GG, "Etiologic Investigation of Cancer Susceptibility in Inherited Bone Marrow Failure Syndromes: A Natural History Study" – Blanche Alter, PI

- 8 Response to Stips** P141998, "Clinical Sequencing of Cancer and Tissue Repository" – Javed Khan, PI

- 9 Amendment** 15-C-0191-C, "A Phase 1 Study of the Safety, Pharmacokinetics, and Pharmacodynamics of Escalating Oral Doses of the Glutaminase Inhibitor CB-839, as a Single Agent and in Combination with Standard Chemotherapy in Patients with Advanced and/or Treatment-Refractory Solid Tumors" – Ramaprasad Srinivasan, PI

- 10 Amendment** 11C0016-O, "Rapamycin-Resistant T Cell Therapy of Multiple Myeloma: Relapse Prevention and Relapse Therapy" – Daniel Fowler, PI

- 11 Amendment** 16C0013-E, "An Open-Label, Phase 1 Study of the Safety and Immunogenicity of JNJ-64041757, a Live Attenuated Listeria Monocytogenes Immunotherapy, in Subjects with Non-Small Cell Lung Cancer"—Raffit Hassan, PI

- 12 Amendment** 14C0156-G, "A Phase II Single Arm Pilot Study of the Chk1/2 Inhibitor (LY2606368) in BRCA1/2 Mutation Associated Breast or Ovarian Cancer, Triple Negative Breast Cancer, High Grade Serous Ovarian Cancer, and Metastatic Castrate-Resistant Prostate Cancer"—Jung-Min Lee, PI
- 13 Amendment** 15C0029-I, "Phase I Dose Escalation Study of Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults with Recurrent or Refractory CD22-expressing B Cell Malignancies" – Terry Fry, PI
- 14 Initial Review** P162675 "A Phase I Study of Indenoisoquinoline LMP744 in Adults with Relapsed Solid Tumors and Lymphomas" – Alice Chen, PI
- 15 Initial Review** P162641 "Phase II Trial of Pembrolizumab in Recurrent or Metastatic Medullary Thyroid Cancer" – Ravi Madan, PI
- 16 Initial Review** P162629 "Phase I/II Study Administering Peripheral Blood Lymphocytes Transduced with a Murine T-Cell Receptor Recognizing the G12V Variant of Mutated RAS in HLA-A*1101 Patients" – James Yang, PI
- 17 Initial Review** P162895 "Long-Term Follow up of Patients Undergoing Hematopoietic Stem Cell Transplantation" – Steven Pavletic, PI