National Cancer Institute  
Institutional Review Board  
AGENDA  
January 9, 2017  
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 19, 2016**

3. **Old Business**

4. **New Business**  
   - Letter from Patient, 13C0119, Deb Citrin, PI

5. **NIH Problem Form** 15C0046-F, “Phase 2 Study of MK-3475 in Patients with Microsatellite Unstable (MSI) Tumors” - Tim Greten, PI

6. **NIH Problem Form** 11C0267-D, “A Phase 2, Randomized, Multicenter, Open-Label Study of the Efficacy and Immune Response of the Sequential Administration of GVAX Pancreas Vaccine (with Cyclophosphamide) Alone or Followed by CRS-207 in Adults with Metastatic Pancreatic Adenocarcinoma” - Tim Greten, PI

7. **NIH Problem Form** 11C0262-F, “A Randomized, Double-blind, Phase 3 Efficacy Trial of PROSTVAC-V/F ± GM-CSF in Men with Asymptomatic or Minimally Symptomatic Metastatic, Castrate-Resistant Prostate Cancer” - James L Gulley, PI

8. **NIH Problem Form** 15C0179-C, “A Phase I, Open-Label, Multiple-Ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0011359C in Subjects with Metastatic or Locally Advanced Solid Tumors with Expansion to Selected Indications” - James L Gulley, PI

9. **NIH Problem Form** 16C0091-A, “Long-term Follow-up of Subjects Treated with bb2121” - Jim Kochenderfer, PI

10. **NIH Problem Form** 89C0086-FF, “Clinical Manifestations and Molecular Bases of Heritable Urologic Malignant Disorders” - William Linehan, PI

11. **NIH Problem Form** 14I0009-F, “Characterization and Management of Patients With HIV-1 Infection Who Experience Virologic Failure Despite Combination Antiretroviral Therapy” - Alice Pau, PI

12. **NIH Problem Form** 14C0037-E, “A Phase 2 Study of the MET Kinase Inhibitor INC280 in Papillary Renal Cell Cancer” - Ramaprasad Srinivasan, PI

13. **NIH Problem Form** 15C0028-A, “Follow-Up Evaluation for Gene-Therapy Related Delayed Adverse Events after Participation in Pediatric Oncology Branch Clinical Trials” - Terry Fry, PI

14. **NIH Problem Form** 15C0116-E, “Phase I Trial of 4’t-thio-2’dexoxycytidine (TdCyd) in Patients With Advanced Solid Tumors” - Jim Doroshow, PI
15. NIH Problem Form 13C0044-I, "A Phase 2 Study of Cabozantinib (XL184), a Dual Inhibitor of MET and VEGFR, in Patients With Metastatic Refractory Soft Tissue Sarcoma" - Alice Chen, PI

16. NIH Problem Form 15C0086-D, "Phase I Trial of the Combination of Nilotinib and Paclitaxel in Adults with Refractory Solid Tumors" - Alice Chen, PI

17. NIH Problem Form 10C0166-V, "A Phase II Study Using Short-Term Cultured, Autologous Tumor-Infiltrating Lymphocytes Following a Lymphocyte Depleting Regimen in Metastatic Cancers Plus the Administration of Pembrolizumab" - Steve Rosenberg, PI

18. NIH Problem Form 09C0082-BB, "Assessment of the Safety and Feasibility of Administering T cells Expressing an anti-CD19 Chimeric Antigen Receptor to Patients with B-cell Lymphoma" - Steve Rosenberg, PI

19. NIH Problem Form 11C0200-P, "A Phase II Trial in Which Patients With Metastatic Alveolar Soft Part Sarcoma Are Randomized to Either Sunitinib or Cediranib Monotherapy, With Cross-Over at Disease Progression" - Alice Chen, PI

20. NIH Problem Form 13C0176-D, "Tumor, Normal Tissue and Specimens from Patients Undergoing Evaluation or Surgical Resection of Solid Tumors" - Jeremy Davis, PI

21. NIH Problem Form 16C0135-A, "A Pilot Study of Combined Immune Checkpoint Inhibition in Combination with Ablative Therapies in Subjects with Hepatocellular Carcinoma (HCC) or Biliary Tract Carcinomas (BTC)" - Tim Greten, PI

22. NIH Problem Form 10C0052-L, "Phase II Study of Dose-Adjusted EPOCH +/-Rituximab in Adults with Untreated Burkitt Lymphoma, c-MYC+ Diffuse Large B-Cell Lymphoma and Plasmablastic Lymphoma" - James L Gulley, PI

23. NIH Problem Form 14C0157-F, "Phase 1 Study of Ibrutinib and Immuno-chemotherapy using Dose-Adjusted-Temozolomide, Etoposide, Doxil, Dexamethasone, Ibrutinib, Rituximab (DA-TEDDI-R) in Primary CNS Lymphoma" - James L Gulley, PI

24. NIH Problem Form 14C0157-F, "Phase 1 Study of Ibrutinib and Immuno-chemotherapy using Dose-Adjusted-Temozolomide, Etoposide, Doxil, Dexamethasone, Ibrutinib, Rituximab (DA-TEDDI-R) in Primary CNS Lymphoma" - James L Gulley, PI

25. NIH Problem Form 12C0170-K, "A Phase 1B Study to Evaluate the Safety and Induction of Immune Response of CRS 207 in Combination with Pemetrexed and Cisplatin as Front-line Therapy in Adults with Malignant Pleural Mesothelioma" - Raffit Hassan, PI

26. NIH Problem Form 14C0168-D, "A Phase I Clinical Trial of T-cells Targeting B-cell Maturation Antigen for Previously Treated Multiple Myeloma" - Jim Kochenderfer, PI

27. NIH Problem Form 12C0068-G, "A Randomized Double-Blind Pilot Study of Topical Clobetasol 0.05% Oral rinse for Oral Chronic Graft-Versus-Host Disease" - Steven Pavletic, PI
28. **NIH Problem Form** 16C0094-A, "A Phase 1/2 Study of Baricitinib, a JAK1/2 Inhibitor, in Chronic Graft-versus-Host Disease (cGVHD) after Allogeneic Hematopoietic Stem Cell Transplantation (SCT)" - Steven Pavletic, PI

29. **Continuing Review** 01C0038-P, "Collection of Blood, Bone Marrow, Tumor, or Tissue Samples from Patients with HIV Infection, KSHV Infection, Viral-related Pre-malignant Lesions, and/or Cancer" - Robert Yarchoan, PI

30. **Continuing Review** 12C0193-E, "Lymphoid Malignancies and Precursors: Tissue Acquisition Protocol" - Wyndham Wilson, PI


33. **Continuing Review** 15C0095-C, "Expanded Access (Compassionate Use) Treatment Protocol with Rindopepimut (CDX-110)" - Mark Gilbert, PI

34. **Continuing Review** 97C0143-R, "Collection of Blood, Bone Marrow and Tissue samples for the Investigation of the Human Immune Response, Lymphoma Biology and HTLV-1 Infection" - Thomas Waldmann, PI

35. **Continuing Review** 11C0034-H, "Dicer1-Related Pleuropulmonary Blastoma Cancer Predisposition Syndrome: A Natural History Study" - Douglas Stewart, PI

36. **Continuing Review** 11C0060-S, "Phase I Pharmacokinetic Study of Belinostat for Solid Tumors and Lymphomas in Patients with Varying Degrees of Hepatic Dysfunction" - Alice Chen, PI

37. **Continuing Review** 16C0087-E, "Phase I Study of Veliparib (ABT-888), an Oral PARP Inhibitor, and VX-970, an ATR Inhibitor in Combination with Cisplatin in Patients with Refractory Solid Tumors" - Alice Chen, PI

38. **Continuing Review** 09C0053-H, "Autologous and Related Allogeneic Hematopoietic Stem Cell Transplant and Cellular Therapies Data Submission to the Center for International Blood and Marrow Transplant Research (CIBMTR) and the National Marrow Donor Program (NMDP)" - Ronald Gress, PI

39. **Continuing Review** 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

40. **Continuing Review** 08C0079-H, "Natural History Study and Longitudinal Assessment of Children, Adolescents, and Adults with Neurofibromatosis Type 1" - Brigitte Widemann, PI
41. Continuing Review 12C0178-C, "Longitudinal Assessment and Natural History Study of Children and Young Adults with MEN2A or MEN2B with or without Medullary Thyroid Carcinoma" - John Glod, PI

42. Continuing Review 14C0059-F, "A Phase I Trial of T Cells Expressing an anti-GD2 Chimeric Antigen Receptor in Children and Young Adults with GD2+ Solid Tumors" - Rosandra Kaplan, PI

43. Continuing Review 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

44. Continuing Review 15C0105-C, "Randomized Controlled Trial of Total Thyroidectomy with and without Prophylactic Central Neck Lymph Node Dissection in Patients with Low-risk Papillary Thyroid Cancer" - Naris Nilubol, PI

45. Continuing Review 10C0138-P, "Allogeneic Tumor Cell Vaccine with Metronomic Oral Cyclophosphamide and Celecoxib as Adjuvant Therapy for Lung and Esophageal Cancers, Thymic Neoplasms, Thoracic Sarcomas, and Malignant Pleural Mesotheliomas" - David Schrump, PI


48. Continuing Review 14C0105-A, "Tissue Procurement and Natural History Study of Patients with Non-Small Cell Lung Cancer, Small Cell Lung Cancer, Extrapulmonary Small Cell Cancer, Pulmonary Neuroendocrine Tumors, and Thymic Epithelial Tumors" - Udayan Guha, PI

49. Response to Stips 02C0052-FF, "Etiologic Investigation of Cancer Susceptibility in Inherited Bone Marrow Failure Syndromes: A Natural History Study" - Blanche Alter, PI

50. Response to Stips 16C0025-B, "A Phase 1 Study of bb2121 in BCMA-expressing Multiple Myeloma" - Jim Kochenderfer, PI

51. Response to Stips P152529, "T Cells Expressing a Fully-human Anti-CD30 Chimeric Antigen Receptor for Treating CD30-expressing Lymphomas" - Jim Kochenderfer, PI
52. **Response to Stips**  
P152525, "A Randomized Phase II trial of Standard of Care Alone or in Combination with Ad-CEA vaccine and Avelumab in Patients with Previously Untreated Metastatic Colorectal Cancer" - Austin Duffy, PI

53. **Amendment**  
16C0035-C, "Prostvac in Patients with Biochemically Recurrent Prostate Cancer" - Ravi Madan, PI

54. **Amendment**  
02C0077-O, "Characterization of High Risk Breast Duct Epithelium by Cytology, Breast Duct Endoscopy, and cDNA Gene Expression Profile" - David Danforth, PI

55. **Amendment**  
13C0132-H, "Allogeneic Hematopoietic Stem Cell Transplant for Patients with Mutations in GATA2 or the MonoMAC syndrome" - Dennis Hickstein, PI

56. **Amendment**  
15C0086-D, "Phase I Trial of the Combination of Nilotinib and Paclitaxel in Adults with Refractory Solid Tumors" - Alice Chen, PI

57. **Amendment**  
15IN071-G, "Partnership for Research on Ebola Vaccines in Liberia (PREVAIL)"—Cliff Lane, PI

58. **Initial Review**  
P162870, "Lu-177-DOTATATE (Lutathera) in Therapy of Inoperable Pheochromocytoma/Paraganglioma" - Frank I. Lin, PI

59. **Initial Review**  
P152489, "A Phase II Trial of the Mitogen Activated Protein Kinase Kinase (MEK1/2) inhibitor Selumetinib (AZD6244 hydrogen sulfate) in Patients with Neurofibromatosis Type 1 (NF1) related Gastrointestinal Stomal Tumors (GIST)" - Brigitte Widemann, PI

60. **Initial Review**  
P162809, "Evaluation of 18F-DCFPyL PSMA- versus 18F-NaF-PET imaging for Detection of Metastatic Prostate Cancer" - Peter Choyke, PI