National Cancer Institute
Institutional Review Board

AGENDA
July 10, 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, June 26, 2017

3. Old Business

4. New Business

5. NIH Problem Form 15C0029-L, "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

6. NIH Problem Form 14C0142-C, "An Open Label Phase I Study to Evaluate the Safety and Tolerability of a Modified Vaccinia Ankara (MVA) Based Vaccine Modified to Express Brachyury and T-cell Costimulatory Molecules (MVA-Brachyury-TRICOM)" - James Gulley, PI

7. NIH Problem Form 15C0145-L, "Phase I/II Study of the Anti-programmed Death Ligand-1 Antibody MEDI4736 in Combination with Olaparib or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Cancers" - Jung-Min Lee, PI

8. NIH Problem Form 15C0145-L, "Phase I/II Study of the Anti-programmed Death Ligand-1 Antibody MEDI4736 in Combination with Olaparib or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Cancers" - Jung-Min Lee, PI

9. NIH Problem Form 15C0145-L, "Phase I/II Study of the Anti-programmed Death Ligand-1 Antibody MEDI4736 in Combination with Olaparib or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Cancers" - Jung-Min Lee, PI

10. NIH Problem Form 16C0048-E, "Docetaxel and PROSTVAC for Metastatic Castration Sensitive Prostate Cancer" - Ravi Madan, PI

11. Continuing Review 01C0070-U, "Evaluation of the Natural History of Patients with Tumors of the Central Nervous System" - Mark Gilbert, PI


13. Continuing Review 05C0252-R, "Phase III Randomized Study of R-CHOP v. Dose-Adjusted EPOCH-R with Molecular Profiling in Untreated de Novo Diffuse Large B-Cell Lymphomas" - Wyndham Wilson, PI
14. Continuing Review
   06C0014-O, "Prospective Evaluation of Genetic and Epigenetic Alterations in Patients with Thoracic Malignancies" - David Schrump, PI

15. Continuing Review
   14C0037-F, "A Phase 2 Study of the MET Kinase Inhibitor INC280 in Papillary Renal Cell Cancer" - Ramaprasad Srinivasan, PI

16. Continuing Review
   15C0205-D, "Phase II Randomized, Placebo-Controlled Trial of PROSTVAC (PSA-TRICOM) in Patients with Clinically Localized Prostate Cancer Undergoing Active Surveillance" - Peter Pinto, PI

17. Continuing Review
   16C0010-F, "Care of the Prostate Cancer Patient and Prospective Procurement of Prostate Cancer Tissue" - Peter Pinto, PI

18. Continuing Review
   11C0191-Q, "A Phase I and Phase II and Retreatment Study of AZD6244 for Recurrent or Refractory Pediatric Low Grade Glioma" - Kathy Warren, PI

19. Continuing Review
   13C0042-I, "A Phase I Study of XL184 (Cabozantinib, IND# 116059) in Children and Adolescents with Recurrent or Refractory Solid Tumors, Including CNS Tumors" - Brigitte Widemann, PI

20. Continuing Review
   11C0161-M, "A Phase I/II Study of the Mitogen Activated Protein Kinase Kinase (MEK) 1 Inhibitor Selumetinib (AZD6244; Hydrogen Sulfate in Children with Neurofibromatosis Type 1 (NF1) and Inoperable Plexiform Neurofibromas (PN))" - Brigitte Widemann, PI

21. Continuing Review
   09C0214-T, "A Multi-Histology Phase II Study of 5-Fluoro-2-Deoxycytidine with Tetrahydrodouridine (FdCyd + THU)" - Jim Doroshow, PI

22. Continuing Review
   11C0149-C, "Evaluation of Diagnostic and Prognostic Molecular Markers in Adrenal Neoplasm" - Electron Kebebew, PI

23. Continuing Review
   03C0304-F, "Phase 2 Trial of Alemtuzumab and Dose-Adjusted EPOCH In Chemotherapy Naive Aggressive T and NK-Cell Lymphomas" - Wyndham Wilson, PI

24. Continuing Review
   04C0055-KK, "Allogeneic HSCT Without Preparative Chemotherapy or With Low-Intensity Preparative Chemotherapy Using Sirolimus and Sirolimus Generated Donor Th2 Cells for Therapy of Refractory Leukemia, Lymphoma, Myeloma, or Myelodysplastic Syndrome" - Daniel Fowler, PI

25. Continuing Review
   11C0140-Q, "A Phase I Study of Gemcitabine, Carboplatin and Lenalidomide (GCL) for Treatment of Patients with Advanced/Metastatic Urothelial Carcinoma (UC) and Other Solid Tumors" - Andrea Apolo, PI

26. Continuing Review
   13C0071-J, "A Phase 2 Study of Anakinra in Inflammatory Pustular Dermatoses: Evaluation of Therapeutic Efficacy and Validation of Pathogenic Mechanisms" - Edward Cowen, PI
27. **Continuing Review** 15C0021-B, "A Pilot Study of AMP-224, a PD-1 Inhibitor, in Combination with Stereotactic Body Radiation Therapy (SBRT) in Patients with Metastatic Colorectal Cancer" - Tim Greten, PI

28. **Continuing Review** 12C0081-H, "Phase I/II Study of Cediranib and Olaparib in Combination for Treatment of Recurrent Papillary-Serous Ovarian, Fallopian Tube, or Peritoneal Cancer or for Treatment of Recurrent Triple-Negative Breast Cancer" - Jung-Min Lee, PI
   *(REVIEWER: Hamilton)*

29. **Response to Stips** P162643, "A Phase II Trial of Niclosamide in Patients with Metastatic and Locally Advanced Adrenocortical Carcinoma" - Electron Kebebew, PI

30. **Response to Stips** P173022, "Exploring Outcomes and Risk in Patients with Ependymoma" - Terri Armstrong, PI


32. **Amendment** 04C0165-M, "Care of the Adult Oncology Patient, CCR, NCI" - James Gulley, PI

33. **Initial Review** P173201, "Phase 2 Trial of Pembrolizumab in Relapsed and Refractory Gray-Zone Lymphoma (GZL), Primary Central Nervous System Lymphoma (PCNSL), and other Extra-Nodal Diffuse Large B-cell Lymphomas" - Mark Roschewski, PI

34. **Initial Review** P173221, "Longitudinal Sample Collection and Tracking for the Developmental Therapeutics Clinic, National Cancer Institute" - Alice Chen, PI

35. **Initial Review** P173172, "Phase I Trial of 5-aza-4′-thio-2′-deoxycytidine (Aza-TdC) in Patients with Advanced Solid Tumors" - Jim Doroshow, PI