1. Call to Order/Announcements
   - Audio-recording of meeting
   - Introduction of Guests
   - Conflict of Interest
   - Expedited Actions Report

2. Review of Draft Minutes, December 18, 2017

3. Old Business

4. New Business

5. Submissions

6. NIH Problem Form 16C0128-F, "A Phase I/II Study of Mesothelin-Targeted Immuno-oncotox LMB-100 Alone or in Combination with Nab-Paclitaxel in Participants with Previously Treated Metastatic and/ or Locally Advanced Pancreatic Ductal Adenocarcinoma and Mesothelin Expressing Solid Tumors" - Christine Alewine, PI

7. NIH Problem Form 17C0007-B, "Phase I/II Study of PROSTVAC in Combination with Nivolumab and or Ipilimumab in Men with Prostate Cancer " - James L Gulley, MD PhD, PI

8. NIH Problem Form 10C0054-N, "Administration of Anti-CD19-Chimeric-Antigen-Receptor-Transduced T Cells from the Original Transplant Donor to Patients with Recurrent or Persistent B-Cell Malignancies After Allogeneic Stem Cell Transplantation" - Jim Kochenderfer, PI

9. NIH Problem Form 15C0075-D, "A Randomized, Placebo-Controlled Phase II Study of Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccination in Men with Stage D0 Prostate Cancer" - Hoyoung Maeng, M.D., PI

10. NIH Problem Form 17C0066-B, "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

11. NIH Problem Form 16C0107-C, "A Phase I/II Trial of CRLX101, a Nanoparticle Camptothecin with Olaparib in Patients with Relapsed/Refractory Small Cell Lung, Bladder and Prostate Cancers" - Anish Thomas, PI

12. NIH Problem Form 01C0030-R, "Short-Course EPOCH - Rituximab in Untreated CD-20+ HIV-Associated Lymphomas" - Wyndham Wilson, PI

13. NIH Problem Form 15C0087-C, "Care of the Urothelial Cancer Patient and Prospective Collection of Biospecimens from Healthy Volunteers and Urothelial Cancer Patients" - Piyush Agarwal, PI

14. NIH Problem Form 15C0087-C, "Care of the Urothelial Cancer Patient and Prospective Collection of Biospecimens from Healthy Volunteers and Urothelial Cancer Patients" - Piyush Agarwal, PI
15. NIH Problem Form 15C0179-F, "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, MD PhD, PI

16. NIH Problem Form 14C0037-F, "A Phase 2 Study of the MET Kinase Inhibitor INC280 in Papillary Renal Cell Cancer" - Ramaprasad Srinivasan, MD, PI

17. NIH Problem Form 10C0114-T, "A Phase II Study of Bevacizumab and Erlotinib in Subjects with Advanced Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC) or Sporadic Papillary Renal Cell Cancer" - Ramaprasad Srinivasan, MD, PI

18. NIH Problem Form 17C0086, "An Open-label Phase 2 Study to Evaluate PT2385 for the Treatment of Von Hippel-Lindau Disease-Associated Clear Cell Renal Cell Carcinoma" - Ramaprasad Srinivasan, MD, PI

19. Continuing Review 02C0210-T, ""Clinical, Laboratory, and Epidemiologic Characterization of Individuals and Families at High Risk of Blood and Lymph Node Malignancy"" - Neil E Caporaso, MD, PI


21. Continuing Review 10C0066-J, "Collection of Human Samples to Study Hairy Cell and Other Leukemias and to Develop Recombinant Immunotoxins for Cancer Treatment" - Robert Kreitman, PI


23. Continuing Review 13C0044-P, "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


25. Continuing Review 16C0086-D, "An Open Label Phase 1B/2 Trial of TRC 105 and Sorafenib in Patients with Hepatocellular Carcinoma (HCC)" - Tim Greten, PI

26. Continuing Review 04C0246-U, "An Open Label Pilot Study to Evaluate the Safety and Tolerability of PANVAC(TM)-V (Vaccinia) and PANVAC (TM)-F (Fowlpox) in Combination with Sargramostim in Adults with Metastatic Carcinoma" - James L Gulley, MD PhD, PI
27. Continuing Review 04C0257-R, "A Phase II Trial of Docetaxel, Thalidomide, Prednisone, and Bevacizumab in Patients with Androgen-Independent Prostate Cancer" - Ravi Madan, PI

28. Continuing Review 09C0005-R, "Randomized Trial of Cladribine (CdA) with Simultaneous or Delayed Rituximab to Eliminate Hairy Cell Leukemia Minimal Residual Disease" - Robert Kreitman, PI

29. Continuing Review 10C0174-R, "Related and Unrelated Donor Hematopoietic Stem Cell Transplant for DOCK8 Deficiency" - Nirali Shah, MD, PI

30. Continuing Review 12C0205-N, "A Phase II Study of Cabozantinib (XL184) in Patients With Advanced/Metastatic Urothelial Carcinoma" - Andrea Apolo, PI


32. Continuing Review 15C0118-F, "A Randomized, Double-Blind, Phase 2 Trial of GI-6301 (Yeast-Brachyury Vaccine) Versus Placebo in Combination with Standard of Care Definitive Radiotherapy in Locally Advanced, Unresectable, Chordoma." - Deric Park, PI

33. Continuing Review 16C0027-G, "A Prospective Randomized and Phase 2 Trial for Metastatic Melanoma using Cell Transfer Therapy with Tumor Infiltrating Lymphocytes Plus IL-2 either alone or following the Administration of Pembrolizumab" - Steve Rosenberg, PI

34. Continuing Review 16C0171-B, "Phase I/II Study of Lenalidomide Combined with Modified DA-EPOCH and Rituximab (EPOCH-R2) in Primary Effusion Lymphoma or KSHV-associated Large Cell Lymphoma" - Robert Yarchoan, PI

35. Continuing Review 17C0061-B, "Phase II Trial of Pembrolizumab in Recurrent or Metastatic Medullary Thyroid Cancer" - Ravi Madan, PI

36. Continuing Review 10C0054-N, "Administration of Anti-CD19-Chimeric-Antigen-Receptor-Transduced T Cells from the Original Transplant Donor to Patients with Recurrent or Persistent B-Cell Malignancies After Allogeneic Stem Cell Transplantation" - Jim Kochenderfer, PI

37. Continuing Review 14C0168-H, "A Phase I Clinical Trial of T-cells Targeting B-cell Maturation Antigen for Previously Treated Multiple Myeloma" - Jim Kochenderfer, PI
38. Continuing Review
10C0052-M, "Phase II Study of Dose-Adjusted EPOCH +/-Rituximab in Adults with Untreated Burkitt Lymphoma, c-MYC+ Diffuse Large B-Cell Lymphoma and Plasmablastic Lymphoma" - Mark Roschewski, PI

39. Continuing Review

40. Continuing Review
97C0147-II, "Collection of Serum and Tissue Samples from Patients with Biopsy-Proved or Suspected Malignant Diseases" - William Linehan MD, PI

41. Continuing Review
89C0086-GG, "Clinical Manifestations and Molecular Bases of Heritable Urologic Malignant Disorders" - William Linehan MD, PI

42. Response to Stips
P173248, "An open-label Phase 1 trial to evaluate the safety and tolerability of a Modified Vaccinia Ankara (MVA) priming followed by fowlpox booster vaccines modified to express brachyury and T-cell costimulatory molecules (MVA-BN-Brachyury/FPV-Brachyury)" - Marijo Bilusic, PI

43. Response to Stips
P152611, "A Phase II Study Using the Administration of Autologous T-cells Genetically Engineered to Express T-Cell Receptors Reactive Against Mutated Neoantigens in Patients with Metastatic Cancer" - Steve Rosenberg, PI

44. Response to Stips
P162997, "Phase 1 Dose Escalation Study of CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults with Recurrent or Refractory CD19/CD22-expressing B Cell Malignancies" - Nirali Shah, MD, PI

45. Amendment
99CC0168-R, "Collection and Distribution of Blood Components from Healthy Donors for In Vitro Research Use" - Cathy Conry Cantilena, MD, PI

46. Amendment
17C0037-A, "Phase 0 Trial of LB100, a Protein Phosphatase 2A Inhibitor, in Recurrent Glioblastoma" - Deric Park, PI

47. Amendment
17C0177, "A Phase II Trial to Evaluate the Ability of a Dendritic Cell Vaccine to Immunize Melanoma or Epithelial Cancer Patients Against Defined Mutated Neoantigens Expressed by the Autologous Cancer" - Steve Rosenberg, PI

48. Initial Review
P173351, "A Phase I/II study of immunotherapy combination BN-Brachyury vaccine, M7824, ALT-803 and Epacadostat (QuEST1) in men with mCRPC" - James L Gulley, MD PhD, PI

49. Initial Review
P173357, "Individual Patient Expanded Access Use of CV301 for the Treatment of Triple Positive Metastatic Breast Cancer " - Margaret Gatti-Mays, PI
50. Initial Review

P173166, "A Bioequivalence Study to Compare Capsule and Liquid Formulations of Enzalutamide After Single Dose Administration Under Fasting Conditions in Prostate Cancer" - William Figg, PI

51. Initial Review

P162889, "A Single Arm Pilot Study Combining CRLX101, a Nanoparticle Camptothecin, with Enzalutamide in Patients with Progressive Metastatic Castration Resistant Prostate Cancer Following Prior Enzalutamide Treatment" - Ravi Madan, PI

52. Initial Review

P173389, "A Phase 1 Study of Intraperitoneal MCY-M11 Therapy for Women with Platinum Resistant High Grade Serous Adenocarcinoma of the Ovary, Primary Peritoneum, or Fallopian Tube, or Subjects with Peritoneal Mesothelioma with Recurrence after Prior Chemotherapy" - Christina Annunziata, PI