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

2. **Review of Draft Minutes, March 12 and April 23, 2018**

3. **Old Business**

4. **New Business**

5. **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

6. **NIH Problem Form** 16C0003-I, "Pilot Trial of Allogeneic Blood or Marrow Transplantation for Primary Immunodeficiencies" - Jen Kanakry, PI


8. **Continuing Review** 12C0111-O, "Phase I/II Study of Metastatic Cancer Using Lymphodepleting Conditioning Followed by Infusion of Anti-mesothelin Gene Engineered Lymphocytes" - Steve Rosenberg, PI

9. **Continuing Review** 15C0191-D, "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, MD, PI


11. **Continuing Review** 17C0117-D, "A Phase 1/2a, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Anti-Tumor Activity of PEN-866 in Advanced Solid Malignancies" - Anish Thomas, PI

12. **Continuing Review** 14C0104-K, "A Phase II Study Using Autologous Young Tumor-Infiltrating Lymphocytes (TIL) Derived from Patients with Non-Small Cell Lung Cancer Following Non-Myeloablative Lymphocyte Depleting Preparative Regimen" - Jim Yang, PI

13. **Continuing Review** 18C0024, "A Single-Arm Phase II Study of Hepatic Artery Infusion Pump Chemotherapy with Floxuridine and Dexamethasone in Combination with
14. **Continuing Review**
17C0125-A, "Phase 2 Trial of Nivolumab in Epstein-Barr Virus (EBV)-Positive Lymphoproliferative Disorders and EBV-Positive Non-Hodgkin Lymphomas" - Mark Roschewski, PI

15. **Continuing Review**

16. **Continuing Review**
14C0036-E, "A Randomized, Prospective, Phase II Study to Determine the Efficacy of Bacillus Calmette-Guerin (BCG) given in combination with PANVAC versus BCG given alone in Adults with High Grade Non-Muscle Invasive Bladder Cancer (NMIBC) who failed at least 1 Induction Course of BCG" - Piyush Agarwal, PI

17. **Continuing Review**
10C0114-U, "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. **Continuing Review**
09C0161-K, "Follow up Protocol for Subjects Previously Enrolled in NCI Surgery Branch Studies" - Steve Rosenberg, PI

19. **Continuing Review**
11C0123-K, "Prospective Randomized Study of Cell Transfer Therapy for Metastatic Melanoma Using Short-Term Cultured Tumor Infiltrating Lymphocytes Plus IL-2 Following Either a Non-Myeloablative Lymphocyte Depleting Chemotherapy Regimen Alone or in Conjunction with 12Gy Total Body Irradiation (TBI)" - Steve Rosenberg, PI

20. **Continuing Review**
14C0015-H, "Pilot Trial of BMN 673, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Deleterious BRCA Mutations" - Alice Chen, PI

21. **Continuing Review**
12C0066-R, "Phase I Trial of Oral 5-Fluoro-2'-Deoxycytidine With Oral Tetrahydrouridine in Patients With Advanced Solid Tumors" - Jim Doroshow, PI

22. **Continuing Review**
15C0179-G, "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

23. **Response to Stips**
P173276, "A Phase IIB/II Single-arm Study of M7824 (MSB0011359C) in Combination with Gemcitabine in Adults with Previously Treated Advanced Adenocarcinoma of the Pancreas" - Udo Rudloff, PI

24. **Amendment**

25. **Amendment**
12C0107-K, "Carfilzomib, Lenalidomide, and Dexamethasone in High-Risk Smoldering Multiple Myeloma: a Clinical and Correlative Study" - Dickran Kazandjian, PI
26. Amendment 16C0062-D, "A Phase I Study of Subcutaneous Recombinant Human IL-15 (S.C. RhIL-15) and Alemtuzumab for Patients with Refractory or Relapsed Chronic and Acute Adult T-Cell Leukemia (ATL)" - Milos Miljkovic, PI

27. Amendment 16C0154-G, "A Phase I Trial of T Cell Receptor Gene Therapy Targeting HPV-16 E7 with or without PD-1 Blockade for HPV-Associated Cancers" - Christian Hinrichs, PI


29. Amendment 16CC0098-A, "Pilot Study of Ultrasound Guided Focal Thermal Ablation of Prostate Cancer" - Brad Wood, PI

30. Amendment 13C0016-L, "A Phase I Study of an Adenoviral Transduced Autologous Dendritic Cell Vaccine Expressing Human HER2/neu ECTM in Adults with Tumors with 1-3+ HER2/neu Expression" - Hoyoung Maeng, M.D., PI

31. Amendment 11C0255-N, "Clinical, Epidemiologic, and Genetic Studies of Li-Fraumeni Syndrome" - Payal Khincha, PI

32. Amendment* 15C0029-O, "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" - Shah Nirali, PI

33. Initial Review P183473, "A Phase 1/2 open-label, multi-center, safety and tolerability study of a single dose of 68Ga-PSMA-R2 in patients with biochemical relapse (BR) and metastatic prostate cancer (mPCa)." - Liza Lindenberg, PI

34. Initial Review P183488, "A Phase 2 Trial of The MEK Inhibitor Selumetinib (AZD6244 Hydrogen Sulfate) in Combination with the Dual mTOR Kinase Inhibitor Vistusertib (AZD2014) for Patients with Unresectable or Metastatic Malignant Peripheral Nerve Sheath Tumors" - Brigitte Widemann, PI