

National Cancer Institute
Institutional Review Board

AGENDA

November 21, 2016

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, November 7, 2016 and October 17, 2016

3. Old Business

- 14C0157 FDA 483 Response

4. New Business

- 02CN042 GDS Institutional Certification

5. Problem Report Forms

6. Continuing Reviews

7. Response to Stips 16C0025C, "A Phase 1 Study of bb2121 in BCMA-expressing Multiple Myeloma" - Jim Kochenderfer, PI

8. Response to Stips P162883, "Prospective Evaluation and Molecular Profiling in Patients with Gastric Tumors" - Jeremy Davis, PI

9. Initial Review P162898, "A Phase Ib Open Label, Dose Finding Trial to Evaluate the Safety, Tolerability, and Pharmacokinetics of Avelumab in Combination with M9241 (NHS-IL12) in Subjects with Locally Advanced, Unresectable, or Metastatic Solid Tumors" - James Gulley, PI

10. Initial Review P162877, "Phase IIB Study of Cediranib and Olaparib Combination in Women with Recurrent Platinum Resistant Epithelial Ovarian Cancer, Fallopian Tubal and/or Primary Peritoneal Cancer without Germline BRCA Mutation, Who Had Prior Bevacizumab" - Jung-Min Lee, PI

11. Initial Review P162915, "Hereditary Gastric Cancer Syndromes: An Integrated Genomic and Clinicopathologic Study of the Predisposition to Gastric Cancer" - Jeremy Davis, PI