



RECOMBINANT DNA ADVISORY COMMITTEE MEETING

Office of Biotechnology Activities - Office of Science Policy
National Institutes of Health
Porter Neuroscience Research Center (Building 35)
NIH Campus, Bethesda, MD
144th RAC Meeting



DRAFT AGENDA – DECEMBER 4, 2015

8:30 AM

Call to Order and Opening Remarks

Hans-Peter Kiem, MD, PhD – RAC Chair

Tab 2849: For Your Information
Notice of Meeting
Conflict of Interest Guidance

8:35 AM

June 9, 2015 Meeting Minutes

RAC Reviewers: William Curry, MD
Dawn Wooley, PhD

June 10, 2015 Meeting Minutes

RAC Reviewers: Michael Atkins, MD
Howard Kaufman, MD

Tab 2850: Minutes of the June 9-10, 2015 RAC Meeting

September 9, 2015 Meeting Minutes

RAC Reviewers: Kevin Donahue, MD
Patrick Hearing, PhD

Tab 2851: Minutes of the September 9, 2015 RAC Meeting

8:40 AM

Discussion on Human Gene Transfer Protocol #1510-1468 titled: *A Phase I, Multicenter, Open-label, Single-dose, Dose Ranging Study to Assess the Safety and Tolerability of SB-318, a rAAV2/6-based Gene Therapy in Subjects with Mucopolysaccharidosis I (MPS I)*

Presenters: Chester Whitley, MD, PhD
Thomas Wechsler, PhD
R. Scott McIvor, PhD

Sponsor: Sangamo

RAC Reviewers: Saswati Chatterjee, PhD
Marie-Louise Hammarskjöld, MD, PhD
Lainie Ross, MD, PhD

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Tab 2852: Protocol

Tab 2853: NIH Summary
NIH Letter to PI on In-depth RAC Review and Public Discussion
Reviews from Drs. Chatterjee, Hammarskjöld, and Ross
PI's Response

9:50 AM Public Comments

10:00 AM BREAK

10:10 AM Discussion on Human Gene Transfer Protocol #1508-1455 titled: *The Effect of Vorinostat and AGS-004 on Persistent HIV-1 Infection (The VOR VAX Study)*

Presenters: David Margolis, MD
Cynthia Gay MD, MPH

RAC Reviewers: Marie-Louise Hammarskjöld, MD, PhD
Angelica Hardison, MBA
Dawn Wooley, PhD

Tab 2854: Protocol

Tab 2855: NIH Summary
NIH Letter to PI on In-depth RAC Review and Public Discussion
Reviews from Drs. Hammarskjöld, Wooley, and Ms.
Hardison
PI's Response

11:20 AM Public Comments

11:30 AM LUNCH

12:15 PM Discussion on Human Gene Transfer Protocol #1510-1469 titled: *A Phase I/2 Study of Autologous T Lymphocytes with Antibody-Dependent Cellular Cytotoxicity in Subjects with Relapsed or Refractory Cd20-Positive B Cell Lymphoma*

Presenters: Seth Ettenberg, PhD
Michael Vasconcelles, MD
Philip Cross, MS
Limei Michelle Poon, MD (by teleconference)

Sponsor: Unum Therapeutics

RAC Reviewers: Hans-Peter Kiem, MD, PhD
Joseph Pilewski, MD
Laurie Zoloth, PhD

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Tab 2856: Protocol

Tab 2857: NIH Summary
NIH Letter to PI on In-depth RAC Review and Public Discussion
Reviews from Drs. Kiem, Pilewski, and Zoloth
PI's Response

1:30 PM Public Comments

1:40 PM BREAK

1:50 PM Discussion Regarding the Deliberate Transfer of Chloramphenicol Resistance to *Rickettsia felis*, *R. rickettsii*, and *R. typhi*

Co-Chairs: Richard Whitley, MD
Dawn Wooley, PhD

Presentation by Olaf Schneewind, MD, PhD, University of Chicago

Presentation by Dawn Wooley, PhD

Tab 2858: Background Materials

2:50 PM Public Comments

3:05 PM Containment Discussion for delta VP30 Ebola

Chair: Paula Cannon, PhD

Presentation by Yoshihiro Kawaoka, DVM, PhD, University of Wisconsin

Presentation by Paula Cannon, PhD

Tab 2859: Background Materials

4:05 PM Public Comments

4:15 PM Gene Transfer Safety Assessment Board Update

Chair: Hans-Peter Kiem, MD, PhD

Tab 2860: Responses to M-I-C-1
Protocol List
Protocols Not Selected for In-Depth Review and Public
Discussion

4:45 PM ADJOURN