

NATIONAL INSTITUTES OF HEALTH (NIH)  
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)  
130<sup>th</sup> MEETING  
ROCKVILLE HILTON & EXECUTIVE MEETING CENTER  
SEPTEMBER 12, 2012

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*Wednesday, September 12, 2012*

2:00 PM            **Call to Order and Opening Remarks**

                         Yuman Fong, M.D., RAC Chair

                         Tab 2711            For Your Information  
                                                    Notice of Meeting  
                                                    Conflict of Interest Guidance

2:05 PM            **Minutes of RAC Meeting June 19, 2012**

                         RAC Reviewers:        Saswati Chatterjee, Ph.D.  
                                                    Rebecca Dresser, J.D.

2:10 PM            **Discussion of Human Gene Transfer Protocol #1206-1169:** *Phase I/II Study of Adoptive Immunotherapy after Allogeneic HCT with Virus Specific CD8+ T Cells that have been Transduced to Express a WT1-specific T Cell Receptor for Patients with High Risk or Relapsed AML, MDS, or CML*

**PIs:**                    Merav Bar, M.D., University of Washington/Fred Hutchinson Cancer Research Center, Seattle, WA  
                                                    and  
                                                    Aude Chapuis, M.D., University of Washington/  
                                                    Fred Hutchinson Cancer Research Center  
                                                    **Slide Presentation**

                         RAC Reviewers:        Marie-Louise Hammarskjöld, M.D., Ph.D.  
                                                    Donald Kohn, M.D.  
                                                    Marshall Strome, M.D., M.S.

                         Tab 2712            Protocol

                         Tab 2713            OBA Summary  
                                                    OBA Letters to PI on In-Depth RAC Review and  
                                                    Public Discussion  
                                                    Reviews from Drs. Kohn, Hammarskjöld, and  
                                                    Strome  
                                                    PI's Response

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(continued) Wednesday, September 12, 2012

3:20 PM            **Public Comment**

3:30 PM            **BREAK**

3:45 PM            **Gene Transfer Safety Assessment Board Report**

RAC Reviewers:     Andrew Badley, M.D.  
                         E. Antonio Chiocca, M.D., Ph.D.  
                         Yuman Fong, M.D.  
                         Hans-Peter Kiem, Ph.D., M.D.  
                         Donald Kohn, M.D.  
                         Marshall Strome, M.D., M.S.

**Slide Presentation**

Tab 2714            Responses to M-I-C-1  
                         Protocol List  
                         Protocols Not Selected for In-Depth Review and  
                         Public Discussion

4:00 PM            **Updates to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules***

Presenters:            Jacqueline Corrigan-Curay, M.D., J.D.  
                         Office of Biotechnology Activities, National  
                         Institutes of Health, Bethesda, MD

**Slide Presentation**

and

Joseph Kanabrocki, Ph.D., University of Chicago,  
Chicago, IL (via Teleconference)

**Slide Presentation**

Tab 2715            Background Material

4:40 PM            **Public Comment**

4:45 PM            **Adjourn**