

**NATIONAL INSTITUTES OF HEALTH
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)**

112th Meeting

**NIH Campus
Building 31, Sixth Floor, C Wing, Room 6**

**March 11-12, 2008
Draft Agenda***

Tuesday, March 11, 2008

8:00 AM **Call to Order and Opening Remarks**

David Williams, M.D., Acting Chair, NIH RAC
Eric Kodish, M.D., Acting Chair, NIH RAC

Tab 2489 For Your Information
Notice of Meeting
Conflict of Interest Guidance

8:05 AM **Minutes of the December 3-5, 2007, RAC Meeting**

RAC Reviewers: Hung Fan, Ph.D.
Ellen Grant, Ph.D., LCSW-R

Tab 2490 Minutes of the December 3-5, 2007, RAC Meeting
Minutes of the January 14, 2008, RAC Meeting

8:10 AM **Discussion of Human Gene Transfer Protocol #0801-896: *A Phase I, Open-Label, Nonrandomized, Dose-Escalation, Multicenter Study to Assess the Safety and Cardiovascular Effects of the Implantation of Autologous Skeletal Myoblasts Modified to Express the SDF-1 Protein (MyoCell™ SDF-1) via Multielectrode Percutaneous Transendocardial Catheter (MyoStar™) with Cardiac Navigation Guidance (NOGA™) in Congestive Heart Failure Patients with Postmyocardial Infarction(s) with Prior Placement of an Implantable Cardioverter Defibrillator (ICD)***

PI: Carl J. Pepine, M.D., University of Florida, Gainesville, FL
[Slide Presentation](#)

Sponsor: Bioheart, Inc., Sunrise, FL

RAC Reviewers: Hildegund Ertl, M.D.
Prediman Shah, M.D.
Robyn Shapiro, J.D.

Tab 2491 Protocol

Tuesday, March 11, 2008 (continued)

Tab 2492 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Ertl and Shah and Ms. Shapiro

9:40 AM **Public Comment**

9:50 AM **BREAK**

10:00 AM **Discussion of Insertional Mutagenesis in X-SCID Gene Transfer: New
Developments and Implications for Future Trials**

RAC Moderators: Eric Kodish, M.D.
Nikunj Somia, Ph.D. – [Slide Presentation](#)

Speakers: Adrian J. Thrasher, Ph.D., M.D., Institute of Child
Health, University College London, London, United
Kingdom (*via teleconference*)

Brian P. Sorrentino, M.D., St. Jude Children’s
Research Hospital, Memphis, TN -- [Slide Presentation](#)

Fabio Candotti, M.D., National Human Genome
Research Institute, National Institutes of Health,
Bethesda, MD -- [Slide Presentation](#)

Harry L. Malech, M.D., National Institute of Allergy
and Infectious Diseases, National Institutes of Health,
Bethesda, MD -- [Slide Presentation](#)

Tab 2493 Background Materials

12:30 PM **LUNCH**

1:15 PM **Discussion of Human Gene Transfer Protocol # 0801-895: A Phase I
Study of Gene Transfer for Patients with Fanconi Anemia Complementation
Group A (FANCA)**

PI: Pamela S. Becker, M.D., Ph.D., University of Washington,
Seattle, WA
[Slide Presentation A](#) [Slide Presentation B](#)

RAC Reviewers: Eric Kodish, M.D.
David Williams, M.D.

Ad hoc Reviewer: Naomi Rosenberg, Ph.D., Tufts University, Boston,
MA

Tuesday, March 11, 2008 (continued)

Tab 2494 Protocol
Tab 2495 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Kodish, Williams, and Rosenberg

2:40 PM **Public Comment**

2:50 PM **BREAK**

3:00 PM **Proposed Changes to the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* to Address the Biosafety Considerations for Synthetic Biology**

RAC Presenter: Naomi Rosenberg, Ph.D.
[Slide Presentation](#)

4:30 PM **ADJOURNMENT**

Wednesday, March 12, 2008

8:15 AM **Call to Order and Opening Remarks**

John Zaia, M.D., Acting Chair, NIH RAC
Scott Strome, M.D., Acting Chair, NIH RAC

8:20 AM **Gene Transfer Safety Assessment Board Report**

Tab 2496 Responses to M-I-C-1
Protocol List
Protocols Not Selected for In-Depth Review and
Public RAC Discussion

RAC Reviewers: Steven Albelda, M.D.
Howard Federoff, M.D., Ph.D.
Scott Strome, M.D.

8:35 AM **Discussion of Human Gene Transfer Protocol #0801-890: *A Phase I, Single-Center, Open-Label, Dose-Escalation Study to Evaluate the Safety and Tolerability of GHRH DNA Plasmid (VGX-3200) + Electroporation in Adults with Cancer Cachexia***

PI: Rammurti T. Kamble, M.D., Baylor College of Medicine, Houston,
TX
[Slide Presentation](#)

Sponsor: VGX Pharmaceuticals, Inc., Blue Bell, PA

Wednesday, March 12, 2008 (continued)

RAC Reviewers: Jeffrey Bartlett, Ph.D.
Jeffrey Kahn, Ph.D., M.P.H.
Scott Strome, M.D.

Tab 2497 Protocol

Tab 2498 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Bartlett, Kahn, and Strome

10:00 AM **Public Comment**

10:10 AM **BREAK**

10:20 AM **Discussion of Human Gene Transfer Protocol #0801-897: A Phase I/II Multicenter, Open-Label, Dose-Escalation Study to Evaluate the Safety and Tolerability of DVC1-0101 Administered Intramuscularly in Subjects with Stable Peripheral Artery Disease**

PI: Brian H. Annex, M.D., Duke University, Durham, NC
[Slide Presentation](#)

Sponsor: DNAVEC Corporation, Ibaraki, Japan

RAC Reviewers: Hung Fan, Ph.D.
David Weber, M.D., M.P.H.
John Zaia, M.D.

Ad hoc Reviewer: Brian Murphy, M.D., National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD

Tab 2499 Protocol

Tab 2500 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Fan, Weber, Zaia, and Murphy

12:05 PM **Public Comment**

12:15 PM **LUNCH**

12:45 PM **Appendix M-VI-A of the NIH Guidelines (the “Vaccine Exemption”): Discussion of Immunotherapy for Human Papillomavirus**
[Slide Presentation](#)

Wednesday, March 12, 2008 (continued)

1:45 PM **Public Comment**

2:00 PM **ADJOURNMENT**

*Meeting agenda as of 2/25/08. Please check the OBA Web site for updates. Times are approximate and subject to change.