

MSC 7806, Bethesda, MD 20892, (301) 435-2037, [mackj2@csr.nih.gov](mailto:mackj2@csr.nih.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences, Integrated Review Group, Molecular and Cellular Endocrinology Study Section.

*Date:* October 9, 2012.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* John Bleasdale, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170 MSC 7892, Bethesda, MD 20892, 301-435-4514, [bleasdaleje@csr.nih.gov](mailto:bleasdaleje@csr.nih.gov).

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Auditory System Study Section.

*Date:* October 9, 2012.

*Time:* 8 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

*Contact Person:* Lynn E Luethke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806-3323, [luethkel@csr.nih.gov](mailto:luethkel@csr.nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group, Pathobiology of Kidney Disease Study Section.

*Date:* October 9–10, 2012.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301-435-1198, [sahaia@csr.nih.gov](mailto:sahaia@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Cell Biology.

*Date:* October 9, 2012.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Wallace Ip, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301-435-1191, [ipws@mail.nih.gov](mailto:ipws@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 29, 2012.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, ZEB1 OSR-D(J2) P Tissue Engineering Resource Center (P41).

*Date:* November 7–9, 2012.

*Time:* 6 p.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Best Western Hotel III Tria, 220 Alewife Brook Parkway, Cambridge, MA 02138.

*Contact Person:* John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Room 959, Bethesda, MD 20892, 301-451-3398, [hayesj@mail.nih.gov](mailto:hayesj@mail.nih.gov).

Dated: August 29, 2012.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Final Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

**SUMMARY:** On March 4, 2009, the National Institutes of Health (NIH)

Office of Biotechnology Activities, Office of Science Policy (NIH/OBA) published a proposal in the **Federal Register** (74 FR 9411) to revise the *NIH Guidelines* in two regards. The first was to address biosafety considerations for research with synthetic nucleic acids. The proposal modified the scope of the *NIH Guidelines* specifically to cover certain basic and clinical research with nucleic acid molecules created solely by synthetic means. The second proposed revision was to modify the criteria for determining whether an experiment to introduce drug resistance into a microorganism must be reviewed by the Recombinant DNA Advisory Committee (RAC) and approved by the NIH Director (as a Major Action under Section III-A-1-a of the *NIH Guidelines*). Comments submitted were discussed at the “NIH Public Consultation on Proposed Changes to the *NIH Guidelines* for Synthetic Nucleic Acids” on June 23, 2009 ([http://oba.od.nih.gov/rdna\\_rac/rac\\_pub\\_con.html](http://oba.od.nih.gov/rdna_rac/rac_pub_con.html)).

This notice sets forth final changes to the *NIH Guidelines* regarding those two proposals. The scope of the *NIH Guidelines* is being modified to cover certain classes of basic and clinical research with synthetic nucleic acids while exempting others. As discussed herein, the majority of research with synthetic nucleic acids that are not designed to replicate does not raise significant biosafety concerns that warrant oversight under the *NIH Guidelines*. Because of the modification of the scope of the *NIH Guidelines*, the title of the *NIH Guidelines* will be revised from *NIH Guidelines for Research Involving Recombinant DNA Molecules to NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules*.

These changes also clarify the criteria for determining whether an experiment to introduce drug resistance into a microorganism raises sufficient public health issues to warrant the experiment being reviewed by the RAC and approved by the NIH Director under Section III-A-1-a of the *NIH Guidelines*. While the current criteria for determining whether an experiment requires review under Section III-A-1-a are being retained, additional language is being added regarding the assessment of whether a drug is therapeutically useful. In addition, NIH/OBA has clarified that Institutional Biosafety Committees (IBCs) can consult with NIH/OBA regarding a specific experiment that does not meet the criteria for review under Section III-A-1-a but nonetheless raises important public health issues. Finally, a section is added to give NIH/OBA the authority