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, 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, hayes@mail.nih.gov.


David Clary,
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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”).

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...