Date: July 23–24, 1996.
Time: 8:30 a.m.
Place: National Institute of Environmental Health Sciences, South Campus, Building 101, Conference Center 101–C, Research Triangle Park, NC.
Contact Person: Dr. Carol Shreffler, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1445.
Purpose/Agenda: To review and evaluate grant applications.
The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.
This notice is being published less than fifteen days prior to this meeting due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.
(Catalog of Federal Domestic Assistance Programs Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health.)
Dated: July 1, 1996.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 96–17211 Filed 7–5–96; 8:45 am]
BILLING CODE 4140–01–M

Division of Research Grants; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.
Name of SEP: Clinical Sciences.
Date: July 17, 1996.
Time: 10:00 a.m.
Place: NIH, Rockledge 2, Room 4214, Telephone Conference.
Contact Person: Dr. Dan McDonald, Scientific Review Administrator, 6701 Rockledge Drive, Room 4214, Bethesda, Maryland 20892, (301) 435–1215.
This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.
Name of SEP: Biological and Physiological Sciences.
Date: July 22, 1996.
Time: 8:30 a.m.
Place: NIH, Rockledge 2, Room 5142, Telephone Conference.
Contact Person: Dr. Camilla Day, Scientific Review Administrator, 6701 Rockledge Drive, Room 5142, Bethesda, Maryland 20892, (301) 435–1024.
Name of SEP: Biological and Physiological Sciences.
Date: July 22, 1996.
Time: 1:00 p.m.
Place: NIH, Rockledge 2, Room 5196.
Contact Person: Ms. Carol Campbell, Scientific Review Administrator, 6701 Rockledge Drive, Room 5196, Bethesda, Maryland 20892, (301 453–1257.
Name of SEP: Multidisciplinary Sciences.
Date: July 29–29, 1996.
Time: 7:00 p.m.
Place: Holiday Inn, Chevy Chase, MD.
Contact Person: Dr. Lee Rosen, Scientific Review Administrator, 6701 Rockledge Drive, Room 5116, Bethesda, Maryland 20892, (301) 435–1171.
The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.
(Catalog of Federal Domestic Assistance Program Nos. 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: June 28, 1996.
Margery G. Grubb,
Senior Committee Management Specialist, NIH.
[FR Doc. 96–17212 Filed 7–5–96; 8:45 am]
BILLING CODE 4140–01–M

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.
Name of SEP: Clinical Sciences.
Date: July 23, 1996.
Time: 1:00 p.m.
Place: NIH, Rockledge 2, Room 4112, Telephone Conference.
Contact Person: Dr. Gopal Sharma, Scientific Review Administrator, 6701 Rockledge Drive, Room 4112, Bethesda, Maryland 20892, (301) 435–1783.
Name of SEP: Chemistry and Related Sciences.
Date: July 24, 1996.
Time: 10:00 a.m.
Place: NIH, Rockledge 2, Room 4156, Telephone Conference.
Contact Person: Dr. Ron Dubois, Scientific Review Administrator, 6701 Rockledge Drive, Room 4156, Bethesda, Maryland 20892, (301) 435–1722.
Name of SEP: Multidisciplinary Sciences.
Date: August 4–5, 1996.
Time: 7:30 p.m.
Place: Nittany Lion Inn, State College, PA.
Contact Person: Dr. Houston Baker, Scientific Review Administrator, 6701 Rockledge Drive, Room 5208, Bethesda, Maryland 20892, (301) 435–1175.
Name of SEP: Microbiological and Immunological Sciences.
Date: August 12, 1996.
Time: 8:00 a.m.
Place: Holiday Inn, Chevy Chase, MD.
Contact Person: Dr. Simi Mayyasi, Scientific Review Administrator, 6701 Rockledge Drive, Room 4194, Bethesda, Maryland 20892, (301) 435–1216.
Name of SEP: Microbiological and Immunological Sciences.
Date: August 13, 1996.
Time: 8:00 a.m.
Place: Holiday Inn, Chevy Chase, MD.
Contact Person: Dr. Simi Mayyasi, Scientific Review Administrator, 6701 Rockledge Drive, Room 4194, Bethesda, Maryland 20892, (301) 435–1216.
Name of SEP: Biological and Physiological Sciences.
Date: August 16, 1996.
Time: 10:00 a.m.
Place: Holiday Inn-National Airport, Arlington, VA.
Contact Person: Dr. Everett Sinnett, Scientific Review Administrator, 6701 Rockledge Drive, Room 5124, Bethesda, Maryland 20892, (301) 435–1016.
Purpose/Agenda: To review Small Business Innovation Research.
Name of SEP: Clinical Sciences.
Date: July 22, 1996.
Time: 8:00 a.m.
Place: Holiday Inn, Chevy Chase, MD.
Contact Person: Dr. Gopal Sharma, Scientific Review Administrator, 6701 Rockledge Drive, Room 4112, Bethesda, Maryland 20892, (301) 435–1783.
Name of SEP: Behavioral and Neurosciences.
Date: August 8, 1996.
Time: 8:30 a.m.
Place: Holiday Inn, Chevy Chase, MD.
Contact Person: Dr. Jane Hu, Scientific Review Administrator, 6701 Rockledge Drive, Room 5158, Bethesda, Maryland 20892, (301) 435–1245.
Name of SEP: Behavioral and Neurosciences.
Date: August 9, 1996.
Time: 8:30 a.m.
Place: Holiday Inn, Chevy Chase, MD.
Contact Person: Dr. Jane Hu, Scientific Review Administrator, 6701 Rockledge Drive, Room 5158, Bethesda, Maryland 20892, (301) 435–1245.
The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure

of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 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: July 1, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–17213 Filed 7–5–96; 8:45 am]

BILLING CODE 4140–01–M

Recombinant DNA Research: Notice of Intent To Propose Amendments to the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) Regarding Enhanced Mechanisms for NIH Oversight of Recombinant DNA Activities

AGENCY: National Institutes of Health (NIH), HHS.

ACTION: Notice of Intent to Propose Amendments.

SUMMARY: The NIH Director intends to propose amendments to the *NIH Guidelines* (59 FR 34496, amended 59 FR 40170, amended 60 FR 20726, amended 61 FR 1482, amended 61 FR 10004) to enhance NIH mechanisms for scientific and ethical oversight of recombinant DNA activities. To accomplish this objective, the NIH Recombinant DNA Advisory Committee (RAC) will be discontinued and all *approval* responsibilities for recombinant DNA experiments involving human gene transfer will be relinquished to the Food and Drug Administration (FDA) which retains statutory authority for such approval. Enhancement of NIH oversight of human gene therapy will be accomplished through three distinct mechanisms: (1) Establishment of the Office of Recombinant DNA Activities (ORDA) Advisory Committee (OAC) to ensure public accountability for recombinant DNA research and relevant data, (2) implementation of Gene Therapy Policy Conferences (GTPC) to augment the quality and efficiency of public discussion of the scientific merit and the ethical issues relevant to gene therapy clinical trials, and (3) continuation of the publicly available, comprehensive NIH database of human gene transfer clinical trials, including adverse event reporting.

Specifically, the NIH Director proposes to realign and extend the current roles and responsibilities of NIH oversight of human gene transfer by establishing OAC. This chartered committee will be comprised of a standing membership of 6 to 10 individuals representing the scientific, legal, ethical, and public advocacy communities. The OAC will meet regularly to: (1) advise ORDA regarding relevant gene therapy issues, (2) identify and prioritize proposed conference topics and participants, and (3) periodically review and analyze data submitted to the NIH gene therapy database. Through ORDA, the OAC will administer, propose modifications, and promulgate amendments to the *NIH Guidelines.* These *NIH Guidelines,* which set forth accepted principles, practices, and procedures under which investigators and institutions may safely conduct recombinant DNA research under a variety of settings, will continue to be the responsibility of the NIH Director. Investigator compliance with the relevant physical and biological containment standards in the *NIH Guidelines* ensures acceptable protection for human health and the environment.

The NIH Director proposes to convene the Gene Therapy Policy Conferences at regular intervals (3–4 times per year). These conferences will offer the unique advantage of assembling numerous participants who possess significant scientific, ethical, and legal expertise and/or interest that is directly applicable to a specific recombinant DNA research issue. In order to enhance the depth and value of scientific and ethical/social discussion, each GTPC will be devoted to a single issue relevant to scientific merit and/or safety as it relates to human gene therapy clinical trials. These may include topics such as basic research on the use of novel gene delivery vehicles and applications to human gene therapy, novel applications of gene transfer, or relevant ethical/societal implications of a particular application of gene transfer technology. Although NIH will no longer be responsible for the approval of gene therapy protocols, these modifications *do not* preclude the use of a novel protocol as a focus for a conference discussion, i.e., a novel protocol captured by the NIH database could be added by OAC, in consultation with ORDA, to a list of potential policy conference topics.

The findings and recommendations of the GTPC will be submitted to the NIH Director and will be made available to multiple Department of Health and Human Services (DHHS) components, including the FDA and the Office for Protection from Research Risks (OPRR). The NIH Director anticipates that this expanded public policy forum will serve as a model for interagency communication and collaboration, concentrated expert discussion of novel scientific issues and their potential societal implications, and enhanced opportunity for public discussion of specific issues and the potential impact of such applications on human health and the environment.

Finally, the NIH Director proposes to maintain the administration of gene therapy clinical trial data management functions through ORDA and in consultation with the OAC. Using current definitions, NIH will continue to capture incoming protocol information, ongoing data (including adverse and significant clinical events), and long-term follow-up data. In compliance with the *NIH Guidelines,* investigators will continue to be required to register human gene transfer experiments with ORDA to ensure continued public access to the comprehensive human gene transfer clinical trial database.

DATES: Written comments must be received by August 7, 1996.

ADDRESSES: Written comments should be submitted to the Office of Recombinant DNA Activities, Office of Science Policy, National Institutes of Health, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland, 20892–7010. Fax transmissions may be sent to (301) 496–9839.

FOR FURTHER INFORMATION CONTACT: Debra Knorr, Office of Recombinant DNA Activities, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland, 20892–7010, (301) 496–9838.

SUPPLEMENTARY INFORMATION:

I. Background

In 1974, the National Academy of Sciences (NAS) established a Committee on Recombinant DNA Molecules which was charged with examining the risks associated with recombinant DNA research and recommending specific actions or guidelines. The NAS Committee report requested: (1) that certain experiments be voluntarily deferred; (2) that plans to construct recombinants with animal DNA should be carefully weighed; (3) that the NIH Director establish a committee to oversee a program to evaluate hypothetical risks, to develop procedures to minimize the spread of recombinant DNA molecules, and to recommend guidelines to be followed by investigators; and (4) that an international meeting be convened to review progress and discuss ways to deal with potential hazards.

In that same year, the Department of Health, Education, and Welfare (currently the Department of Health and Human Services (DHHS)) chartered a committee (later identified as the RAC) in response to the NAS report. In 1975,