(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 22, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–336 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

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 meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: Microbiology and Infectious Diseases Research Committee.

Date: February 7–9, 2001.

Open: February 7, 2001, 9 a.m. to 10 a.m..

Agenda: Reports from various Institute staff.

Place: Holiday Inn Georgetown, Mirage II, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Closed: February 7, 2001, 10 a.m. to adjournment on February 9, 2001.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, Mirage II, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Gary S. Madonna, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2217, 6700–B Rockledge Drive, MSC 7610, Bethesda, MD 20892–7610, 301–496–2550.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 22, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–335 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Medicine; Notice of Meeting

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 meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 journals as potential titles to be indexed by the National Library of Medicine and the discussions could disclose confidential trade secrets of commercial property such as patentable material, and personal information concerning individuals associated with the journals as potential titles to be indexed by the National Library of Medicine, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Literature Selection Technical Review Committee.

Date: February 8–9, 2001.

Open: February 8, 2001, 9am to 11am.

Agenda: Administrative Reports and Program Developments.

Place: National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 8, 2001, 11 am to 5 pm.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

*Place:*National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 9, 2001, 8:30 am to 2 pm.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Sheldon Kotzin, BA, Chief, Bibliographic Services Division, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Bldg 38A/Room 4N419, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 27, 2000.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–333 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: This notice amends the NIH Guidelines to set forth NIH's policy on in utero gene transfer clinical research. At the present time, there is insufficient basic and preclinical data to justify the conduct of in utero gene transfer clinical research. Before any in utero gene transfer clinical trial could proceed, significant additional preclinical and relevant clinical studies addressing biodistribution, toxicity, and efficiency of vector transduction would be required, as would further deliberations of the ethical issues associated with this research. As new knowledge evolves from basic, preclinical, and relevant clinical research and as the ethical issues are addressed, the NIH would consider in utero gene transfer clinical protocols for review by the Recombinant DNA Advisory Committee (RAC).

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Biotechnology Activities (OBA), National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone 301–496–9838, FAX 301–496–9839. The OBA Web site is located at http://www.nih.gov/od/oba/.

Background Information

In September 1998, the NIH RAC discussed two preliminary proposals for human in utero gene transfer and

recommended a comprehensive public review of the scientific and ethical issues raised by such studies. In response, NIH convened a national Gene Therapy Policy Conference on Prenatal Gene Transfer: Scientific, Medical, and Ethical Issues (January 7–8, 1999) to further explore these issues.

The findings and conclusions of the Conference indicated that, at present, there is insufficient preclinical data to support the initiation of clinical trials involving in utero gene transfer clinical research. A substantial number of critical scientific, safety, ethical, legal, and social issues must be addressed before clinical trials proceed in this arena including: (1) Efficiency of gene transfer to target cells; (2) specificity of delivery to target cells; (3) level, duration, and regulation of gene expression; (4) appropriate disease candidates; (5) fetal immune response to transgene products and/or vectors; (6) emergence of fetal immune tolerance; (7) effects of gene transfer on pre- and post-natal development; (8) possibility of generation and activation of transmissible vector or virus; (9) possibility of initiating oncogenic or degenerative processes; (10) limitations related to the accuracy of disease diagnosis; (11) implications of diagnostic limitations on the design and conduct of clinical trials; (12) elements of optimal clinical trial design and analysis; (13) potential risk to the fetus and acceptable level of risk to the fetus in human experimentation; (14) potential risk to the pregnant woman; (15) detection and assessment of inadvertent germ-line transmission; (16) ethical issues specific to the fetus; (17) ethical issues specific to the pregnant woman; (18) patient recruitment/enrollment processes; (19) informed consent issues; (20) societal issues; and (21) legal issues. (See http://www4.od.nih.gov/oba/gtpcreport.pdf for further information.)

In March 1999, RAC discussed the findings and conclusions of the conference and developed the following consensus statement: ''The RAC continues to explore the issues raised by the potential of in utero gene transfer research. However, at present, the members unanimously agree that it is premature to undertake any human in utero gene transfer experiment.'' After providing an opportunity for public comments (64 FR 43884), the RAC unanimously recommended that this consensus statement be adopted as policy and incorporated into the NIH Guidelines (Appendix M). The NIH is implementing this recommendation through this notice of action.

Action Amending the NIH Guidelines

Appendix M. Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Research Participants (Points to Consider)

Appendix M is amended by adding the following paragraph after the third paragraph:

''The RAC continues to explore the issues raised by the potential of in utero gene transfer clinical research. However, the RAC concludes that, at present, it is premature to undertake any in utero gene transfer clinical trial. Significant additional preclinical and clinical studies addressing vector transduction efficacy, biodistribution, and toxicity are required before a human in utero gene transfer protocol can proceed. In addition, a more thorough understanding of the development of human organ systems, such as the immune and nervous systems, is needed to better define the potential efficacy and risks of human in utero gene transfer. Prerequisites for considering any specific human in utero gene transfer procedure include an understanding of the pathophysiology of the candidate disease and a demonstrable advantage to the in utero approach. Once the above criteria are met, the RAC would be willing to consider well rationalized human in utero gene transfer clinical trials.''

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which recombinant DNA techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: December 28, 2000.

Ruth L. Kirschstein,

Acting Director, National Institutes of Health.

[FR Doc. 01–337 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Pilot Testing of Outcome Measures in Programs Providing Services to Persons Who are Homeless and Have Serious Mental Illnesses—New—SAMHSA's Center for Mental Health Services (CMHS) provides funds to states and territories to provide services to individuals who are homeless and have serious mental illnesses. These services enable persons who are homeless and have serious mental illnesses to be placed in appropriate housing situations and linked to mental health services. To comply with requests for client outcome data, State and local providers have sought measures which could help them more effectively monitor and manage their programs as well as demonstrate program effectiveness.

Interest in performance measurement and evaluation of policies, programs and individual services has increased