participate in biomedical research. Increase the exposure of K–12 students, their teachers and the public to the life sciences. Construct or renovate biomedical research facilities.

Biomedical research investigators supported by the NIH require a broad array of technologies, tools and materials for their research. The NCRR plays a key role in addressing trans-NIH research issues, such as access to state-of-the-art instrumentation and technologies; containment of the escalating costs of highly sophisticated research; development of appropriate, specialized research models; efforts to remedy the shortage of clinical and minority investigators; and efforts to improve the research infrastructure.

To ensure the continued relevance of its strategic plan, the NCRR seeks input to the following questions in terms of the issues described above:

(A) What are the most important research trends that will drive biomedical research?

(B) What research resources and technologies will be critical in addressing these trends and meeting biomedical investigators' needs?

(C) What strategies will eliminate barriers to progress and enhance access to research resources and technologies?

(D) Who would you recommend to serve as a panel member for NCRR's strategic planning process? Please list the name, degree, position title, department, institution name and address, phone and fax numbers, and specific area of expertise for each person recommended.

We have provided a user-friendly response form at NCRR's Strategic Planning Survey Web site: <http://www.ncrr.nih.gov/survey.htm>; or you may mail your response to the Office of Science Policy, NCRR/NIH, One Rockledge Center, 6705 Rockledge Drive MSC 7965, Suite 5046, Bethesda, MD 20892–7965; FAX 301–480–3654.

Dated: January 22, 1997.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 97–2482 Filed 1–30–97; 8:45 am]

BILLING CODE 4140–01–M

Recombinant DNA Research: Action Under the Guidelines

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of Action under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496, 59 FR 40170, 60 FR 20726, 61 FR 1482, 61 FR 10004).

SUMMARY: This notice sets forth an action taken by the Director, National Institutes of Health (NIH), under the NIH Guidelines for Research Involving Recombinant DNA Molecules.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Ms. Debra Knorr, Acting Director, Office of Recombinant DNA Activities (ORDA), Office of Science Policy, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, (301) 496–9838.

SUPPLEMENTARY INFORMATION: Today's action is being promulgated under the NIH Guidelines for Research Involving Recombinant DNA Molecules. The action was proposed and published for comment in the Federal Register of July 8, 1996 (61 FR 35774), then revised and proposed for comment in the Federal Register of November 22, 1996 (61 FR 59726), and reviewed and recommended for approval by the NIH Recombinant DNA Advisory Committee (RAC) at its meeting on December 9, 1996.

I. Background Information and Decision on Action Under the NIH Guidelines

A. Amendments to Section IV–C–2 of the NIH Guidelines Regarding the Recombinant DNA Advisory Committee

On July 8, 1996, the Director, NIH, published a 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 in the Federal Register (61 FR 35774). In the Notice of Intent, the NIH Director requested public comment on proposed mechanisms to enhance scientific, ethical, and societal oversight of human gene transfer research under the NIH Guidelines. Specifically, in part, the termination of the RAC and the establishment of the Office of Recombinant DNA Activities Advisory Committee (OAC) consisting of 6–10 members.

Comments in support of termination of the RAC reflected an interest in making substantive changes in the role of the RAC. Most of these comments supported the proposed restructuring of the functions of the RAC and did not specifically endorse termination of RAC. Opposing comments focused on the historical importance of retaining the RAC as an internationally recognized forum for public discussion of the science, safety, and ethics of human gene therapy research. These authors articulated the critical role that the RAC plays in maintaining public confidence in human gene therapy research.

The importance of the continuation of the RAC, *per se,* was underscored by comments which specifically addressed the establishment of the OAC. Of the 53 comments which addressed this issue, 12 expressed support and 41 expressed opposition. The majority of comments submitted in opposition to the OAC stated that the proposed functions of the OAC could be accomplished by the RAC, or by a restructured version of the RAC. Several authors emphasized that, absent the historic credibility of the RAC, the OAC might suffer from an inability to attract and motivate the type of expertise and judgement needed for this important public forum.

On November 22, 1996, the NIH Director published Notice of Proposed Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules in the Federal Register (61 FR 59726). In these Proposed Actions, in part, the NIH Director proposed retaining the RAC, while modifying its roles and responsibilities relevant to human gene therapy research and reducing the membership from 25 members to 15 members, and requested comments.

During the December 9, 1996, meeting, the RAC, which had reviewed the comments received, approved the overall concepts in the Proposed Actions. The RAC specifically approved reducing the membership of the RAC from 25 members to 15 members. The motion passed by a vote of 12 in favor, 0 opposed, and 2 abstentions.

The action is detailed in Section II—Summary of Action. I accept this recommendation to reduce the membership of the RAC from 25 members to 15 members, and the NIH Guidelines will be amended accordingly.

II. Summary of Action

A. Amendments to Section IV–C–2, Recombinant DNA Advisory Committee (RAC)

In Section IV–C–2, the first paragraph is amended to read:

''Section IV–C–2. Recombinant DNA Advisory Committee (RAC)

''The RAC is responsible for carrying out specified functions cited below as well as others assigned under its charter or by the DHHS Secretary and the NIH Director. The RAC consists of 15 members including the Chair, appointed by the DHHS Secretary or his/her designee, at least 8 of whom are selected from authorities knowledgeable in the fields of molecular genetics, molecular

biology, recombinant DNA research, or other scientific fields. At least 4 members of the RAC shall be persons knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields. Representatives from Federal agencies shall serve as non-voting members. Nominations for the RAC may be submitted to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, (301) 496–9838.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) 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 not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. 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.

Effective Date: January 23, 1997.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 97–2485 Filed 1–30–97; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

National Institute of Environmental Health Sciences; National Toxicology Program; Fiscal Year 1996 Annual Plan Now Available

The National Toxicology Program (NTP) announces the availability of National Toxicology Program; Fiscal Year 1996 Annual Plan, solicits comments on it, and urges all interested persons to propose chemicals for possible toxicological evaluation.

The eighteenth edition consists of two parts. First, the National Toxicology Program; Fiscal Year 1996 Annual Plan describes FY 1996 NTP plans in research, applied studies, methods development and validation efforts, as well as resources and FY 1995 program accomplishments. Second, the Review of Current DHHS, DOE, and EPA Research Related to Toxicology FY 1996 lists chemicals being studied by the various Department of Health and Human Services (DHHS) agencies, the Department of Energy (DOE), and the Environmental Protection Agency (EPA), and describes toxicology research and toxicology methods currently being developed by these agencies.

The format for the FY 1996 Annual Plan differs somewhat from previous years in that there are two versions. New is the Fiscal Year 1996 Annual Plan Summary which was prepared in response to a perceived need for a briefer and simpler version. The summary version is being sent to the larger mailing list and in response to general requests for information about the National Toxicology Program. The full version is similar to previous Annual Plans in length and detail and will be sent with the companion document, the Review of Current DHHS, DOE, and EPA Research Related to Toxicology FY 1996.

Background

The National Toxicology Program was established within the Public Health Service of the Department of Health and Human Services in November 1978. The continuing broad goals of the NTP are to coordinate and strengthen DHHS basic and applied toxicology research and methods development and validation, and to provide toxicological information for use by health research and regulatory agencies and others in protecting the public health. Overall objectives are to:

- broaden the spectrum of toxicological information obtained on selected chemicals;
- develop and validate more sensitive and specific test methods;
- develop improved strategies for generating scientific data that strengthen the scientific foundation for risk assessments; and
- communicate NTP plans and results to government agencies, the medical and scientific communities, and the public.

To achieve these objectives, a balanced program, which uses chronic bioassays, short-term tests, collection and application of mechanistic information, model development, alternative methods, and human studies, has been created.

The NTP coordinates selected toxicology activities of the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health; the National Center for Toxicological Research, Food and Drug Administration; and the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. The Director of the NTP is also the Director of the National Institute of Environmental Health Sciences.

Primary program oversight is provided by the NTP Executive Committee, which links DHHS health research institutes and centers with Federal health regulatory agencies to ensure that the basic and applied toxicology research and development activities are responsive to regulatory and public health needs. Agencies represented on the Executive Committee are:

- Agency for Toxic Substances and Disease Registry
- Consumer Product Safety Commission
- Environmental Protection Agency
- Food and Drug Administration
- National Cancer Institute
- National Institute for Occupational Safety and Health
- National Institute of Environmental Health Sciences
- National Institutes of Health
- Occupational Safety and Health Administration

The NTP Board of Scientific Counselors provides scientific oversight, advising the NTP Director and the NTP Executive Committee on scientific content and evaluating the scientific merit and overall quality of NTP science. The Board has two standing Subcommittees, the Biennial Report on Carcinogens Subcommittee and the Technical Reports Review Subcommittee. The members are appointed by the Secretary, DHHS.

Scientific activities are divided into several major program areas: Carcinogenesis; genetic toxicology; risk assessment research; alternative methods; and toxicology. The latter area covers activities in immunologic, neurobehavioral, and respiratory toxicologies, as well as reproductive and developmental toxicology. There are special projects on studying toxicities of AIDS therapeutics and toxicity of Superfund chemicals. Program and project leaders, along with addresses and telephone numbers, are identified in the Annual Plan.