

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Research: Actions Under the Guidelines

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

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

SUMMARY: This notice sets forth actions to be taken by the Director, National Institutes of Health (NIH), under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496, amended 59 FR 40170, 60 FR 20726, 61 FR 1482, 61 FR 10004, 62 FR 4782).

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, Phone 301-496-9838, FAX 301-496-9839. The ORDA web site is located at <http://www.nih.gov/od/orda/> for further information about the office.

SUPPLEMENTARY INFORMATION: Today's actions are being promulgated under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). The proposed actions were published for comment in the **Federal Register** of August 20, 1997 (62 FR 44387), and reviewed by the NIH Recombinant DNA Advisory Committee (RAC) at its meeting on September 12, 1997.

I. Background Information and Decisions on Actions Under the NIH Guidelines

Amendment to the Submission Requirements—Human Gene Transfer Experiments Under Appendix M of the NIH Guidelines

During the June 12-13, 1997, RAC meeting, the following motions were approved by the RAC: (1) A motion was made to eliminate the point-by-point responses to Appendix M-II through M-V, Description of the Proposal, Informed Consent, Privacy and Confidentiality, and Special Issues; however, the questions raised in Appendix M-II through M-V must be addressed in the clinical protocol. The motion passed by a vote of 8 in favor, 0 opposed, and 1 abstention. (2) A motion was made to amend the Appendix M-I, Submission Requirements—Human Gene Transfer

Proposals of the NIH Guidelines with regard to: (i) The clinical protocol (including discussion of issues in Appendix M-II through M-V), and (ii) deletion of the requirement of three 3½ inch diskettes with the complete vector nucleotide sequence in ASCII format. The motion passed by a vote of 7 in favor, 0 opposed, and 1 abstention.

The RAC recommendations were published as proposed actions in the **Federal Register** of August 20, 1997, for public comment. A letter dated September 8, 1997, was received in response to the **Federal Register** notice from Alexander E. Kuta, Ph.D., Director, Regulatory Affairs, Genzyme Corporation, Framingham, Massachusetts. Genzyme disagreed with the motion to incorporate the responses to Appendix M-II through M-V into the clinical protocol stating that "this action would compromise the integrity of the clinical protocol without sufficiently addressing industry's concerns regarding Appendix M. * * * The clinical protocol * * * should be 'directed primarily at providing an outline of the investigation.'" At the September 12, 1997, RAC meeting, the RAC considered the comment from Genzyme and agreed to give the investigators or the sponsors the option to provide the discussion of all pertinent issues raised in Appendix M-II through M-V either in the clinical protocol or as an appendix to the clinical protocol.

A motion was made to eliminate the point-by-point responses to Appendix M-II through M-V, and discussion of all pertinent issues raised in Appendix M-II through M-V must be provided either in the clinical protocol or as an appendix to the clinical protocol. The motion passed by a vote of 10 in favor, 2 opposed, and 0 abstention.

No comments were received from the public in response to the proposed actions in the **Federal Register** of August 20, 1997, with regard to the RAC recommendation to delete the requirement of three 3½ inch diskettes with the complete vector nucleotide sequence in ASCII format from Appendix M-I, Submission Requirements—Human Gene Transfer Proposals of the NIH Guidelines.

The actions are detailed in Section II—Summary of Actions. I accept the RAC recommendations, and the NIH Guidelines will be amended accordingly.

II. Summary of Actions

Appendix M-I, Submission Requirements—Human Gene Transfer Proposals of the *NIH Guidelines*, is amended to read:

“Appendix M-I. Submission Requirements—Human Gene Transfer Proposals

Investigators must submit the following material to the Office of Recombinant DNA Activities, National Institutes of Health/MSB 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838 (see exemption in Appendix M-IX-A, Footnotes of Appendix M). Proposals will be submitted in the following order: (1) Scientific abstract—1 page; (2) non-technical abstract—1 page; (3) Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) approvals and their deliberations pertaining to your protocol (the IBC and IRB may, at their discretion, condition their approval on further specific deliberation by the RAC); (4) Responses to Appendix M-II through M-V, Description of the Proposal, Informed Consent, Privacy and Confidentiality, and Special Issues (the pertinent responses can be provided in the protocol or as an appendix to the protocol); (5) protocol (as approved by the local IBC and IRB)—20 pages; (6) Informed Consent document—approved by IRB (see Appendix M-III, Informed Consent); (7) appendices (including tables, figures, and manuscripts); and (8) curricula vitae—2 pages for each key professional person in biographical sketch format.”

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 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: October 20, 1997.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 97-28624 Filed 10-28-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 62 FR 51474 and 51479, dated October 1, 1997) is amended to reflect organizational changes within the National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete the functional statement for the *Scientific Resources Program (CRL)* and insert the following:

(1) Provides animals, animal blood products, glassware, mammalian tissue cultures, microbiological media, special reagents, and other laboratory materials in support of research and service activities to NCID laboratories and other CDC organizations; (2) installs, fabricates, modifies, services, and maintains laboratory equipment used in the research and service activities of CDC; (3) develops and implements applied research programs to expand and enhance the use of animal models necessary to support research and diagnostic programs and to improve breeding and husbandry procedures; (4) conducts both basic and applied research in cell biology and in the expansion of tissue culture technology as a research and diagnostic tool for infectious disease activities; (5) provides services for NCID investigators in protein and DNA synthesis and sequencing; (6) maintains a bank of serum specimens of epidemiological and special significance to CDC's research and diagnostic activities; (7) obtains and distributes experimental vaccines and drugs, antisera and

antitoxins, and immune globulins; (8) for reagents prepared at CDC, maintains a computerized inventory; provides dispensing, lyophilization, capping, and labeling; and retrieves from storage and ships to requesters; (9) provides support for liquid nitrogen freezers; (10) maintains an international hemoglobinometry reference laboratory; (11) produces, maintains, and distributes national and international hemoglobin reference standard preparations; (12) administratively and technically supports the CDC Animal Policy Board and the Atlanta Area Animal Care and Use Committee; (13) provides computer support services for the Program's activities.

Delete the title and functional statement for the *Molecular Pathology and Ultrastructure Activity (CRUE)* and insert the following:

Infectious Disease Pathology Activity (CRUE)

(1) Serves as a scientific and technical resource to NCID by providing expertise in molecular pathology, histopathology, and ultrastructural analysis for detecting infectious disease agents and studying the interactions between microbial agents and host cells; (2) develops, improves, evaluates, and applies special ultrastructural, immunohistologic, and/or nucleic acid probe technologies for detecting microbial agents and/or expressed gene products in tissue specimens or tissue culture; (3) conducts basic and applied research into the pathogenesis of infectious diseases; (4) provides intramural and extramural technical and professional expertise for assistance in training in infectious disease pathology and molecular approaches to the identification of specific nucleic acid sequences and specific antigens in tissue specimens; (5) provides for tracking, distribution, and testing of reference /diagnostic pathology specimens submitted through the data and special handling system; (6) provides molecular pathology, histopathology, and ultrastructure reference/diagnostic support and epidemic aid to state and local health departments, other federal agencies, and national and international health organizations.

Dated: October 16, 1997.

David Satcher,

Director.

[FR Doc. 97-28598 Filed 10-28-97; 8:45 am]

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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 for opportunity for public comment on proposed data collection projects, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the SAMHSA Reports Clearance Officer on (301) 443-8005.

Comments are invited on: (a) Whether the proposed collection of information is 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: Obligated Service for Mental Health.

Traineeships: Regulations and Forms—Extension—SAMHSA's Center for Mental Health Services (CMHS) awards grants to institutions for training instruction and traineeships in mental health and related disciplines. Graduate student recipients of these clinical traineeships must perform service, as determined by the Secretary to be appropriate in terms of the individual's training and experience, for a length of time equal to the period of support. The clinical trainees are required to submit the SMA 111, which ensures agency receipt of a termination notice prior to the end of support, and the SMA 111-2, which is an annual report on employment status and any changes in name and/or address, to SAMHSA.

The annual burden estimates are as follows: