Federal Register

Monday
May 11, 1998

Part IV

Department of Health and Human Services

National Institutes of Health

Recombinant DNA Research: Actions Under the Guidelines; Notice

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, 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, 62 FR 53335, 62 FR 56196, 62 FR 59032, and 63 FR 8052).

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** on February 11, 1998 (63 FR 7054), and reviewed by the NIH Recombinant DNA Advisory Committee (RAC) at its meeting on March 10, 1998.

I. Amendment to Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, Under the NIH Guidelines Regarding Electronic Submission of Protocols

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

Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, of the NIH Guidelines, stipulates requirements for submission of documents to ORDA. In January 1998, Dr. C. Estuardo Aguilar-Cordova, a member of the RAC, participated in a pilot test with ORDA staff regarding electronic submission of documents to ORDA. In this test, the documents submitted electronically included a human gene transfer protocol; responses to Appendices M–II through M–V, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Subjects (Points to Consider); and the ORDA registration document. The 82-page electronic submission, including tables, satisfactorily proved the efficiency and effectiveness of using this method for submission of protocols.

ORDA recognizes that electronic submission of documents is an accepted standard of practice within the scientific community; therefore, this practice is not novel. The practice of using this medium to submit formal protocols to ORDA, however, is novel and requires amendments to the NIH Guidelines. As a result, ORDA proposed to amend Appendix M–I of the NIH Guidelines to provide guidance to investigators regarding optional electronic submission procedures.

Electronic submission of human gene transfer protocols to ORDA offers several distinct advantages over the current practice of submitting protocols by printed matter, including: (1) ORDA can review protocols more expeditiously because they are received immediately; (2) electronic submission allows ORDA to search protocols electronically for keywords or phrases; (3) registration tasks performed at ORDA will be reduced substantially because the investigator has already completed most of the registration document as part of the electronic submission; and (4) ORDA can facilitate RAC review of the protocol by forwarding the complete protocol to RAC members electronically.

Appendix M–I is proposed to read:

''Appendix M–I. Submission Requirements—Human Gene Transfer Experiments

''Investigators must submit the following material (see exemption in Appendix M–VIII–A, Footnotes of Appendix M) to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone 301–496–9838, FAX 301–496–9839. Investigators may submit this material electronically and can obtain specific instructions from the ORDA home page (http://www.nih.gov/od/orda) regarding electronic submission requirements. For all submissions, whether printed or electronic, ORDA will confirm receipt within three working days after receiving the submission. Investigators should contact ORDA if they do not receive this confirmation.

''Proposals in printed form and/or in an electronic version shall be submitted to NIH/ORDA in the following order: (1) Scientific abstract; (2) non-technical abstract; (3) Responses to Appendix M–II through M–V, Description of the Proposed, Informed Consent, Privacy and Confidentiality, and Special Issues (the pertinent responses can be provided in the protocol or as an appendix to the protocol); (4) clinical protocol as approved by the local Institutional Biosafety Committee and Institutional Review Board; (5) Informed Consent document as approved by the Institutional Review Board (see Appendix M–III, Informed Consent); (6) appendices (including tables, figures, and manuscripts); and (7) curricula vitae—no more than two pages for each key professional person in biographical sketch format.

''All submissions must include Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) approvals and their deliberations pertaining to your protocol. IBC approval must be obtained from each institution at which recombinant DNA material will be administered to human subjects (as opposed to each institution involved in the production of vectors for human application and each institution at which there is *ex vivo* transduction of recombinant DNA material into target cells for human application). Because these written IBC and IRB approvals require appropriate signatures, investigators cannot submit them electronically. Investigators should submit these signed approvals either by mail or by facsimile trnasmission.

''Investigational New Drug (IND) applications shall be submitted to the FDA in the format described in 21 CFR, Chapter I, Subchapter D, Part 312, Subpart B, Section 23, IND Content and Format. Submissions to the FDA should be sent to the Division of Congressional and Public Affairs, Document Control Center, HFM–99, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, Maryland 20852–1448.

''Note: NIH/ORDA will accept submission material at any time. However, if a protocol is submitted less than eight weeks before a scheduled RAC meeting and subsequently is recommended for public discussion by the full RAC, the public discussion of that protocol will be deferred until the next scheduled RAC meeting. This eight-week period is needed to ensure adequate time for review by the committee members.''

During the March 10, 1998, RAC meeting, a motion was made that the RAC accept the proposed action published in the **Federal Register** of February 11, 1998 (63 FR 7054) to permit submission of human gene transfer protocols to ORDA for registration in an optional electronic format, as opposed to the printed materials. The motion passed by a vote of 9 in favor, 0 opposed, and 1 abstention.

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

I–B. Summary of Actions

I–B–1. Amendments to Appendix M–I. Submission Requirements—Human Gene Transfer Experiments

Appendix M–I is to be amended to read:

''Section M–I. Submission Requirements—Human Gene Transfer Experiments

''Investigators must submit the following material (see exemption in Appendix M–VIII–A, Footnotes of Appendix M) to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone 301–496–9838, FAX 301–496–9839. Investigators may submit this material electronically and can obtain specific instructions from the ORDA home page (http://www.nih.gov/od/or/orda) regarding electronic submission requirements. For all submissions, whether printed or electronic, ORDA will confirm receipt within three working days after receiving the submission. Investigators should contact ORDA if they do not receive this confirmation.

''Proposals in printed form and/or in an electronic version shall be submitted to NIH/ORDA in the following order: (1) Scientific abstract; (2) non-technical abstract; (3) 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); (4) clinical protocol as approved by the local Institutional Biosafety Committee and Institutional Review Board; (5) Informed Consent document as approved by the Institutional Review Board (see Appendix M–III, Informed Consent); (6) appendices (including tables, figures, and manuscripts); and (7) curricula vitae—no more than two pages for each key professional person in biographical sketch format.

''All submissions must include Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) approvals and their deliberations pertaining to your protocol. IBC approval must be obtained from each institution at which recombinant DNA material will be administered to human subjects (as opposed to each institution involved in the production of vectors for human application and each institution at which there is *ex vivo* transduction of recombinant DNA material into target cells for human application). Because these written IBC and IRB approvals require appropriate signatures, investigators cannot submit them electronically. Investigators should submit these signed approvals either by mail or by facsimile transmission.

''Investigational New Drug (IND) applications shall be submitted to the FDA in the format described in 21 CFR, Chapter I, Subchapter D, Part 312, Subpart B, Section 23, IND Content and Format. Submissions to the FDA should be sent to the Division of Congressional and Public Affairs, Document Control Center, HFM–99, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, Maryland 20852–1448.

''**Note:** NIH/ORDA will accept submission material at any time. However, if a protocoal is submitted less than eight weeks before a scheduled RAC meeting and subsequently is recommended for public discussion by the full RAC, the public discussion of that protocol will be deferred until the next scheduled RAC meeting. This eight-week period is needed to ensure adequate time for review by the committee members.''

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 Guideline. 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: April 30, 1998.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 98–12327 Filed 5–8–98; 8:45 am]

BILLING CODE 4140–01–M