NIH GUIDE for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, Division of Research Grants, NIH, Room 219, Westwood Building, Bethesda, Maryland 20014, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

The GUIDE is published at irregular intervals to provide policy and administrative information to individuals and organizations who need to be kept informed of requirements and changes in grants and contracts activities administered by the National Institutes of Health.

Supplements, printed on yellow paper, are published by the respective awarding units concerning new projects, solicitations of sources, and requests for proposals.

IN THIS ISSUE: (continued)

DISPOSITION OF GRANT-RELATED INCOME

NOTICE

During the course of many NIH-supported research projects, property of value may be produced in excess of the needs of the project itself. Examples of such property, although not all-inclusive, are fabricated equipment, animals, enzymes and other blood and tissue products, cell cultures, and chemical synthetics. When such property is disposed of through a sales process, the proceeds of such a sale are grant-related income.

All grant-related income earned during the period of NIH grant support except royalties* and proceeds from the sale of real property shall be retained by the grantee and unless the terms and conditions of the award specify which option is to be used, the income shall be treated in accordance with one or a combination of the following options:

A. Used by the grantee for any purposes that further the objectives of the legislation under which the grant was made.

B. Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

*See *Public Health Service Grants Policy Statement* for special treatment of royalties received as copyright- or patent-earned income.

NATIONAL PRIMATE PLAN AVAILABLE

NOTICE

A draft of the National Primate Plan is available for comment by interested individuals. This plan was developed by the Interagency Primate Steering Committee as an overall strategy for nonhuman primate supply for U.S. bioscientific activities. The plan sets forth the need for primates, estimates future supplies, and proposes actions to provide an adequate supply of primates. Comments on the draft plan are being solicited from all interested parties by April 4, 1978, and will be considered before issuance of the final version. Copies of the draft plan may be obtained from Dr. B. D. Blood, Executive Director, Interagency Primate Steering Committee, Room 102, Building 14G, National Institutes of Health, Bethesda, Maryland 20014.

INDIA ANNOUNCES BAN ON PRIMATE EXPORTS

NOTICE

The Government of India recently announced that it would make no new commitments for the export of nonhuman primates. All current export commitments for the United States are due to expire on March 31, 1978. No official reason was given for the ban but it coincided with reports in the Indian press about allegedly cruel experiments involving rhesus monkeys exported from India. The newspaper accounts told of the use of rhesus monkeys in neutron irradiation tests and alleged that this was in violation of the U.S.-India agreement on use of primates exported from India. This agreement provides that the animals will be used only for medical research and vaccine production. Specifically prohibited uses are atomic blast experiments and space research.

Steps are being taken to try to get the Indian Government to rescind or modify its ban on primate exports. It is not realistic to predict at this time whether or not this effort will be successful.

India is the principal source country for rhesus monkeys. Domestic breeding programs started in recent years are making satisfactory progress but in 1978 will be able to supply only about 10% of the 13,000 rhesus monkeys used annually in the U.S. Bangladesh is also a supplier of rhesus monkeys and an estimated 2,000 to 5,000 animals can be obtained from this source annually. Re-use of animals already in this country and use of other species are tactics that individual investigators might find helpful if the ban is not rescinded.

TRAINING GRANT CONTINUATION APPLICATION

NOTICE

A number of training grant continuation application forms (PHS 2499-2 formerly NIH 2003-2) have been received by NIH with the Terms and Conditions block (item 16) on the face page modified in a way which is inconsistent with the instructions for completion of the application. The instructions for item 16 ask the applicant to insert ("and policies") after the word "regulations" in the first line of item 16 on page 1 of the application and strike the remainder of that first sentence which appears on the second line because it refers to a superseded policy brochure. Some applicants have erroneously struck the second and third sentences as well which deal with Civil Rights and conflict of interest. Although a corrected face page will not be required, we are calling to your attention that the Terms and Conditions in sentences one (as modified) and sentences two and three (as printed) are fully applicable to any award made as a result of the application.

ACKNOWLEDGMENT ON PUBLICATIONS OF PHS SUPPORT

NOTICE

Scientific publications resulting from work supported to any extent by PHS grant or contract funds must contain a credit line or footnote acknowledging the source of support. This requirement for acknowledgment of support became critical with the implementation on January 1, 1978, of the new copyright law. Any failure to adhere to the acknowledgment requirement is a disservice to the scientific public since this is often the only means by which investigators can identify articles of which they are permitted to make a single copy for their own use without regard to the copyright of the journal. Investigators on PHS-supported grants or contracts are therefore urged to pay particular attention to appropriate acknowledgment. (See PHS copyright policy in the *NIH Guide for Grants and Contracts*, Vol. 6, No. 21, p. 15, December 1, 1977.)

APPLICATION RECEIPT DATES

DEADLINES

NOTICE

It is occasionally brought to our attention that there is some confusion regarding receipt dates for grant applications submitted to the National Institutes of Health. It seems that many investigators and institutional staff are under the impression that the application must be *postmarked* on the day indicated as a receipt date for the application. This information is incorrect. The application for any given receipt date *must be received* at the National Institutes of Health *in its entirety* by the stated date. Any application received after the stated date will be considered as *not* meeting that particular receipt date.

Requests for waiver will be considered on an individual basis by contacting Dr. Luis Angelone, Chief, Referral Branch, Division of Research Grants, NIH. It should be pointed out, however, that in these days of extraordinarily heavy workloads, *very few* waivers are granted. All investigators are urged to plan the preparation of their applications in sufficient time to meet the announced schedule of receipt dates *and to allow for possible delays in the mail.*

NOTICE

DNA RECOMBINANT RESEARCH

Revisions are in italics.

This supersedes the article entitled "DNA Recombinant Research" in the *October 17, 1977,* issue of the *NIH Guide for Grants and Contracts* and the "Important Notice" concerning recombinant DNA in the Public Health Service research grant and training application kits. Described herein are (1) requirements for notations on research and training grant applications, (2) a restatement of the requirements for the Institutional Biohazards Committee, (3) refinements to the MUA, (4) new notations that will appear on the NIH Notice of Grant Award forms for grants involving recombinant DNA, (5) procedures for requesting prior approval in funded recombinant DNA projects, and (6) specifications for shipping and transfer requirements for recombinant DNA materials.

I. NOTATION ON RESEARCH AND TRAINING GRANT APPLICATIONS

Application forms are under revision to include a check block indicating whether or not recombinant DNA research is involved. Until such time as these forms are available, applicants should specify in capital letters at the bottom of the first page of the application "THIS APPLICATION DOES/ DOES NOT INVOLVE RECOMBINANT DNA." Labelling the face page of the application will assist in expediting the processing of the application.

II. INSTITUTIONAL BIOHAZARDS COMMITTEE (IBC)

Each institution where research involving recombinant DNA technology is being or shall be conducted must establish a standing biohazards committee. Suggestions for the composition of such a committee are discussed under Section IV of the Guidelines, which also discusses the roles and responsibilities of principal investigators and institutions. A roster of the members of the Institutional Biohazards Committee must be submitted to the NIH.

The minimum information must include the names, addresses, occupations, and qualifications of the chairman and members of the committee. This information must be submitted to:

Office of Recombinant DNA Activities
National Institute of General Medical Sciences
National Institutes of Health
Room 4A52, Building 31
Bethesda, Maryland 20014

The composition of Institutional Biohazards Committees is subject to review by the Office of Recombinant DNA Activities for compliance with recommendations stated in the Guidelines. It is the responsibility of each grantee institution to update this information at least annually. As stipulated in the Guidelines, the Office of Recombinant DNA Activities shall assist in the formation of an Area Biohazards Committee (ABC) when this is appropriate. Such an Area Committee shall be necessary when additional expertise from outside a given institution is necessary for the Biohazards Committee to fulfill its functions.

III. CONTENTS OF MEMORANDUM OF UNDERSTANDING AND AGREEMENT (MUA)

Applications for the National Institutes of Health involving recombinant DNA research, as defined by the Guidelines, must be accompanied by a proposed MUA with the statements shown in the attached illustration. Because the information provided is captured by a data management system, for NIH use, applicants are urged to follow the sequence and format of the illustration as closely as possible.

Incomplete MUAs render the application incomplete. An application without a proposed MUA is incomplete and will not be reviewed until a properly executed MUA is provided. *Once an MUA has been submitted for the proposed project, changes desired to that project must be made by submitting a revised MUA. The revised MUA should contain either a copy of the original MUA, showing the desired changes, or a statement explaining how the original MUA should be modified.*

The proposed MUA must contain:

A. A description of each proposed *series of* experiments that involves recombinant DNA molecules and the individual investigator responsible for each experiment, if other than the principal investigator. *Do not submit a separate MUA for each experiment.*

   Descriptions should *include a summary of the research project and should* indicate the sources of DNA, *nature of inserted nucleic acid sequences,* hosts, and vectors. Descriptions *must* be of sufficient detail to provide information about the experiments without need for reference to the application. Descriptions should provide for each recombinant DNA experiment an indication of the approximate time of initiation after the start date of the project period (e.g., first year, second year, third year). The time of availability of the required facilities should also be provided in the description. Ordinarily no more than two pages of description for each experiment are acceptable.

B. An assessment of the level(s) of physical and biological containment for each experiment *as* required by the current NIH Guidelines for these experiments.

C. A *description* of the facilities and specific procedures that shall be used to provide the required levels of containment. Each performance site must be identified with the name of the organization, city, and state.

D. A specific brief statement by the principal investigator agreeing to abide by the provisions of the current NIH Guidelines and the requirements contained in this Notice concerning shipment and transfer of recombinant DNA materials (see Section VI).

The principal investigator must also attest to the accuracy of the information in A through D of this document.

E. Information concerning Institutional Biohazards Committee review:

1. When facilities are in existence, a certification is required indicating that the Institutional Biohazards Committee has reviewed the proposed project for recombinant DNA experiments and found adequate and in compliance with the NIH Guidelines, this Notice, and other specific NIH instructions pertaining to the proposed project, the (a) procedures, (b) project and facilities personnel in place at the time of review, and (c) facilities. The date of the review must be specified.

2. When facilities are proposed or are under construction or renovation at the time of the application, an assurance in lieu of a certification must be provided. The assurance is signed by the appropriate institutional official(s) to indicate that the Institutional Biohazards Committee has reviewed the proposed project for recombinant DNA experiments and found adequate and in compliance with NIH Guidelines, this Notice, and other specific NIH instructions pertaining to the proposed project, the (a) procedures, (b) project and facilities personnel in place at the time of review, and (c) plans for facilities proposed or under construction or renovation. The assurance includes a statement that recombinant DNA experimentation shall not occur until the completed facility has been reviewed by the Institutional Biohazards Committee and a *revised* MUA, with certification, has been approved by NIH and research is authorized by issuance of a revised award with a Footnote 2 (see Section IV).

NOTE: Some MUAs will incorporate provisions of both a certification and an assurance if there are several experiments at different stages.

F. A statement by the appropriate institutional official that the Institutional Biohazards Committee shall monitor, throughout the duration of the project, the facilities, procedures, and training and expertise of the personnel who are working on the project and for the facilities.

G. The signature of both the institutional official(s) and the principal investigator.

H. The date of signature by the institutional official of the applicant institution. This shall become the date of the proposed MUA for future reference.

Multiple Sites: When recombinant DNA research is proposed at multiple sites, the proposed MUA must specify items A through C above by each site. When recombinant DNA research is proposed at sites governed by other than the applicant institution, signatures of the appropriate officials at the applicant institution and the institution(s) where the recombinant DNA *research is to* be conducted are required. The signatures shall indicate that the Institutional Biohazards Committees of the institutions where the research is to be performed have given the

certification and/or assurance required in item E of the MUA, and that the other information is complete and accurate concerning the research to be performed at the site under the jurisdiction of the signer's institution.

MUAs with Noncompeting Applications: All noncompeting continuation applications involving recombinant DNA research projects must be accompanied by a proposed, updated MUA that incorporates a statement that the facilities, procedures, and project and facilities personnel in place at the time of review have been reviewed by the Institutional Biohazards Committee prior to the submission of the application, and that the project continues to be in compliance with NIH Guidelines.

Fellowship Applicants, Research Career Development Award Candidates (RCDA), Research Career Awardees (RCA), and Program Directors for Institutional Research Training Grants:

1. Fellowship applicants, RCDA candidates, RCAs, or Program Directors for Institutional Research Training Grants may attach to the application a copy of the MUA(s) approved by the Office of Recombinant DNA Activities when the proposed research or training is part of a funded NIH project involving recombinant DNA.

   The fellowship applicant, RCDA candidate, RCAs, or Program Director (if other than the principal investigator) must sign the MUA copy under the signature of the principal investigator, indicating that he/she has become familiar with and agrees to abide by the provisions of the current NIH Guidelines, this Notice, and other specific NIH instructions pertaining to the proposed project. The principal investigator and the appropriate institutional official must also initial and date the approved MUA copy to indicate that the copy is current and accurate and that the research or training proposed for the fellowship applicant, RCDA candidate, RCAs, or Program Director is consistent with the approved recombinant DNA project.

2. If any recombinant DNA work is proposed other than that indicated in the approved MUA(s), a separate proposed MUA must be submitted to NIH.

IV. APPROVAL OF MUAs AND AWARD PROCEDURES

This section applies only to grants awarded by NIH. NO PROJECT INVOLVING RECOMBINANT DNA RESEARCH CAN BE FUNDED WITHOUT AN MUA APPROVED *BY THE NIH*. NOTE THE CONCEPTS OF A PROPOSED MUA VERSUS AN MUA APPROVED BY THE OFFICE OF RECOMBINANT DNA ACTIVITIES, AND AN ASSURANCE VERSUS A CERTIFICATION ON AN MUA. AUTHORIZATION FOR USE OF FUNDS TO CONDUCT RECOMBINANT DNA EXPERIMENTS CAN ONLY BE EFFECTED BY THE ISSUANCE OR REVISION OF A NOTICE OF GRANT AWARD. All NIH awards made for approved applications which propose *recombinant* DNA experimentation shall carry one of the following footnotes:

A. Footnote 1: "Funds from this award may not be used to conduct recombinant DNA experiments."

B. Footnote 2: "Recombinant DNA experiments must be conducted in compliance with NIH Guidelines and approved MUA dated --/--/--."

C. Footnote 3: "No funds from this or future awards may be used for recombinant DNA experiments until a revised MUA is approved by NIH and authorized on an award document."

Footnote 1 shall be used in those instances where recombinant DNA research was originally proposed by the applicant but, for whatever reason, an MUA has not been approved by the NIH at time of award.

Footnote 2 shall be used in those instances where recombinant DNA experiments shall begin during the awarded budget period and an approved MUA, with proper certification, is on file with the NIH at time of award.

Footnote 3 shall be used in those instances where, at time of award, an approved MUA is on file with the NIH containing: (1) an assurance that adequate facilities shall be available at some time in the future, or (2) certification that adequate facilities exist for experiments to take place during a future budget period. It should be noted that noncompeting applications must include a proposed MUA recertifying existing facilities, procedures, and personnel.

V. PRIOR APPROVAL REQUIREMENT FOR CHANGES IN CURRENTLY FUNDED PROJECTS

Grantees engaged in active projects supported by NIH who wish to modify their existing projects with respect to recombinant DNA research must obtain prior approval from the NIH in the following instances: (1) initiation of recombinant DNA experimentation not previously approved by NIH; (2) acceleration of the schedule for recombinant DNA experimentation to the current budget period; (3) change of experiments to different physical or biological levels; (4) changes of host, vector, or source DNA; (5) cloning other than originally approved DNA segments; (6) change of physical location of the experiments; and (7) change in principal investigator.

The institution and the principal investigator must apply to the awarding Bureau, Institute, or Division for permission before proceeding with the proposed changes. The request to conduct such experiments must be accompanied by a new MUA; a revised MUA; or in the case of minor modifications to approved recombinant DNA experiments, a letter, signed by the principal investigator and the appropriate institutional official, requesting an amendment to the current MUA. *A revised MUA should contain a copy of the current MUA, showing the desired changes, or a statement explaining how the current MUA should be modified.* The signature of the institutional official shall signify that the change has been cleared with the Institutional Biohazards Committee.

For approved changes requested via a new or revised MUA, the Bureau, Institute, or Division shall issue a revised award citing the date of the approved MUA, For approved changes requested via a letter, the Bureau, Institute, or Division shall issue a revised award citing the approved MUA date and specifying the approved changes. The Office of Recombinant DNA Activities may authorize the Bureau, Institute, or Division to inform by letter, the appropriate institutional official of the approval of minor changes in lieu of issuing a revised award.

NOTE: *No changes in recombinant DNA experiments in currently funded projects may be initiated prior to obtaining written approval from the NIH.*

VI. SHIPPING REQUIREMENTS

All MUAs submitted with competing and noncompeting applications involving recombinant DNA research must indicate that the principal investigator (program director, fellow, or candidate) agrees to comply with the NIH Guidelines, this Notice, and other specific NIH instructions pertaining to the proposed project. Included in the provisions are the following pertaining to shipment or transfer of recombinant DNA materials:

A. Prior to shipment or transfer of recombinant DNA materials to other Federally funded investigators within the United States, the sending laboratory shall obtain a letter from the requesting laboratory stating that:

1. Research involving recombinant DNA molecules shall be conducted in compliance with the NIH Guidelines, this Notice, and other NIH instructions, and that the requesting laboratory shall not transfer the recombinant DNA materials to other laboratories;

2. The requesting laboratory has been reviewed by its Institutional Biohazards Committee which has certified that facilities, procedures, and the training and expertise of the personnel involved are adequate;

3. An approved MUA with a certification is on file with the funding agency of the requesting laboratory;

4. A copy of this letter is on file with the requesting laboratory's Institutional Biohazards Committee.

B. Prior to shipment or transfer of recombinant DNA materials to non-Federally funded investigators or institutions within the United States, the sending laboratory shall obtain a letter from the requesting laboratory stating items 1, 2, and 4 under A above.

C. Prior to international shipment of recombinant DNA materials, the sending laboratory shall obtain a statement from the requesting laboratory stating that research involving recombinant DNA molecules shall be conducted in accordance with the containment levels specified by the NIH Guidelines, or applicable national guidelines if such have been adopted by the country in which the research is to be conducted,

and that the requesting laboratory shall not transfer the recombinant DNA material to *other* laboratories.

D. The sending laboratory shall maintain a record of all shipments of recombinant DNA materials and shall provide NIH with a complete list of such shipments in the annual progress report for NIH grants and contracts.

VII. FOREIGN GRANT APPLICATIONS

Applicants for NIH awards in foreign countries first should contact the Office of Recombinant DNA Activities for information on NIH policies and procedures for recombinant DNA research projects to be conducted outside of the United States.

MEMORANDUM OF UNDERSTANDING AND AGREEMENT

Description

(To be supplied)

Levels of Physical and Biological Containment

(To be supplied)

Facilities and Procedures for Containment

(To be supplied)

The information above is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines, the Notice contained in the *NIH Guide for Grants and Contracts* of *February 15, 1978*, and other specific NIH instructions pertaining to the proposed project. I agree to comply with the requirements specified by the *Guide* pertaining to shipment and transfer of recombinant DNA materials.

Principal Investigator Date

I certify that the Institutional Biohazards Committee (IBC) has reviewed on (date) the proposed project for recombinant DNA experiments, and found adequate and in compliance with NIH Guidelines, the Notice contained in the *NIH Guide for Grants and Contracts* of *February 15, 1978*, and other specific NIH instructions pertaining to the proposed project, the (a) procedures; (b) project and facilities personnel in place at the time of review; and (c) facilities. I agree to comply with the requirements specified in the *Guide* pertaining to the shipment and transfer of recombinant DNA materials.

AND/OR

I assure that the IBC has reviewed on (date) the proposed project for recombinant DNA experiments, and found adequate and in compliance with NIH Guidelines, the Notice contained in the *NIH Guide for Grants and Contracts* of *February 15, 1978*, and other specific NIH instructions pertaining to the proposed project, the (a) procedures; (b) project and facilities personnel in place at the time of review; and (c) plans for facilities proposed or under construction or renovation. Recombinant DNA experimentation shall not occur until the completed facilities have been reviewed by the IBC and an MUA with certification has been approved by NIH and research authorized by issuance of a revised award citing the date of the approved MUA.

I agree that the IBC shall monitor throughout the duration of the project the facilities, procedures, and training and expertise of the personnel who are working on the project and for the facilities.

Applicant Institutional Official Date

Institutional Official Date
(Additional Performance Sites, if applicable)

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