

# NIH GUIDE

# for GRANTS and CONTRACTS

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

No. 10, August 30, 1971

## COLLABORATIVE (CONTRACT) PROGRAMS OF THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The National Institute of Allergy and Infectious Diseases, through its Collaborative Research Programs, provides and evaluates a variety of essential research resources and develops associated research methodology and information. Activities include: the production and distribution of virus reagents and tissue typing materials; development and testing of vaccines, and antiviral substances; and support of research on methodology in selected areas of transplantation immunology. These are projects through which specific needs of medical research and delivery of health services can be met. Information on program developments and contractor progress are made available through the Clearinghouse for Scientific and Technical Information (U.S. Department of Commerce) and through publications in scientific journals.

Collaborative programs are designed, through use of contracts, to be flexible and responsive. When an activity reaches an appropriate stage of development, efforts are made for other Federal agencies or the private sectors to assume responsibility for delivery and utilization. New programs are initiated in response to demands of public health needs and related opportunities resulting from research breakthroughs.

Within Collaborative Research are three operating branches--Research Resources, Transplantation and Immunology, and Infectious Disease --each designed to carry out a facet of a broad mission of meeting vital health research needs.

The programs of the three branches are described below:

### Infectious Disease Branch

The Institute's Infectious Disease Branch functions in concert with intramural scientists of NIAID and the Division of Biologic Standards. It also benefits from the experience of advisory groups and the collaboration of university and drug industry scientists. Within this framework, the branch promotes target research leading to the development and evaluation of promising prophylactic and therapeutic agents for the control of selected infectious diseases. A vaccine development program was set up in 1962 to conduct collaborative vaccine studies,

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

particularly against acute respiratory infections. A rubella (German measles) vaccine program, undertaken in 1965, resulted in a licensed vaccine in 1969. Other current interests are concerned with pneumococcal polysaccharide vaccine; smallpox vaccine; and a program on antiviral substances which is currently stressing work on interferon, a naturally-occurring antiviral substance.

#### Research Resources Branch

The Research Resources Branch, formerly the Research Reference Reagents Branch, was established in 1962. This branch conducts a collaborative program for the support of microbiological research by stimulating the production, testing, and distribution to research scientists of a wide range of seed virus and corresponding anti-serum. These materials are used in accurate identification of viruses and in studies on virus characterization. With the help of advisory groups, the branch supports research on the development of techniques and materials for virus identification, isolation, and preservation, and disseminates information and technical advice on reagent production, testing, and use. Reagents for most of the important viruses and mycoplasma involved in infections of the respiratory and gastrointestinal tracts are available for distribution. Also available are reagents to selected arthropod-borne viruses and Australia antigen reagents associated with serum hepatitis. Antigen E from bulk ragweed pollen is presently being produced. This program also maintains a Molecular Anatomy Laboratory in Rockville, Maryland, which provides the application of engineering methodology toward development of separation systems, such as the zonal centrifuge, and serves both NIAID Intramural and Collaborative research needs. To date, the Molecular Anatomy Laboratory has played a key role in the preparation of reagents for Australia antigen and has done biophysical characterization work on respiratory syncytial virus, its temperature-sensitive mutants, and mycoplasma.

#### Transplantation and Immunology Branch

The program of the Transplantation and Immunology Branch was started in 1964 to encourage research and provide resources designed to solve the immunological problem of graft rejection in organ transplantation.

From the beginning, the Transplantation Immunology Committee, made up of experts in the field, has pinpointed objectives to be pursued through contracts with selected laboratories. The branch's program now includes developing and providing reagents useful in tissue typing; providing facilities and training for tissue matching; investigating biological immunosuppressives which help slow graft rejections; developing methods for recognition of early graft rejection; and investigating techniques for organ preservation.

SOURCES SOUGHT FOR CONDUCT OF RESEARCH  
ON DEVELOPMENT OF RESPIRATORY SYNCYTIAL  
VIRUS AND PARAINFLUENZA VACCINES

ANNOUNCEMENT

Qualified sources are sought which are interested in and have capabilities for conducting research on the development of live attenuated strains of respiratory syncytial virus and/or parainfluenza viruses. The respondent organizations must possess a comprehensive background and experience in research in this area and technical competence, personnel, and facilities for the development of virus strains acceptable for a vaccine against one or more of these agents. Investigators may indicate interest in one or more of these agents. In addition, investigators should indicate any interest and capability to clinically evaluate these vaccines in appropriate closed adult and/or pediatric populations.

This synopsis is not a request for proposal. Only those sources considered to be fully qualified for this project will be invited to submit proposals. Other respondents will not be notified of the results of evaluation. Ten copies of the resumes of experience and capabilities must be submitted to Mr. Merle Callahan, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 7A-17, Bethesda, Maryland 20014, to be received no later than close of business, 5:00 p.m. (local time of addressee), September 24, 1971. Telephone inquiries will not be honored, and all inquiries must be in writing and addressed to the office listed above.

All investigations must be conducted in accordance with the DHEW and NIH regulations relative to investigations involving use of human subjects. This announcement does not commit the Government to award a contract.

SOURCES SOUGHT FOR CONDUCT OF CLINICAL  
EVALUATION OF RESPIRATORY SYNCYTIAL,  
PARAINFLUENZA, AND OTHER RESPIRATORY VIRUS VACCINES

ANNOUNCEMENT

Qualified sources are sought which are interested in and have capabilities for conducting a clinical evaluation of various candidate respiratory virus vaccines in a pediatric population. Most of the vaccines will be live and all vaccines will be furnished by the Government. The respondent organizations must possess technical competence, personnel, and both clinical and laboratory facilities for conducting clinical studies to determine the antigenicity and safety of candidate vaccines. In addition, investigators should indicate any interest and capability to conduct field trials to demonstrate the protective efficacy of one or more of these vaccines. Investigators should also indicate the availability of appropriate adult populations for initial clinical screening of new vaccines and the feasibility of conducting challenge studies in these adult populations.

This synopsis is not a request for proposal. Only those sources considered to be fully qualified for this project will be invited to submit proposals. Other respondents will not be notified of the results of evaluation. Ten copies of the resumes of experience and capabilities must be submitted to Mr. Merle Callahan, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 7A-17, Bethesda, Maryland 20014, to be received no later than close of business, 5:00 p.m. (local time of addressee), September 24, 1971. Telephone inquiries will not be honored, and all inquiries must be in writing and addressed to the office listed above.

All investigations must be conducted in accordance with the DHEW and NIH regulations relative to investigations involving use of human subjects. This announcement does not commit the Government to award a contract.

SOURCES SOUGHT FOR CONDUCT OF CLINICAL  
EVALUATION OF MENINGOCOCCAL AND HEMOPHILUS  
INFLUENZAE TYPE B VACCINES IN YOUNG CHILDREN

ANNOUNCEMENT

Qualified sources are sought which are interested in and have capabilities for conducting, in young children and especially infants, a clinical evaluation of bacterial polysaccharide vaccines prepared from *Neisseria meningitidis*, *Hemophilus influenzae* type b, and *Streptococcus pneumoniae*. Vaccines will be furnished by the Government. The respondent organizations must possess technical competence, personnel, and both clinical and laboratory facilities for conducting clinical studies to determine the antigenicity and safety of candidate vaccines. In addition, investigators should indicate any interest and capability to conduct field trials to demonstrate the protective efficacy of one or more of these vaccines.

This synopsis is not a request for proposal. Only those sources considered to be fully qualified for this project will be invited to submit proposals. Other respondents will not be notified of the results of evaluation. Ten copies of the resumes of experience and capabilities must be submitted to Mr. Merle Callahan, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 7A-17, Bethesda, Maryland 20014, to be received no later than close of business, 5:00 p.m. (local time of addressee), September 24, 1971. Telephone inquiries will not be honored, and all inquiries must be in writing and addressed to the office listed above.

All investigations must be conducted in accordance with the DHEW and NIH regulations relative to investigations involving use of human subjects. This announcement does not commit the Government to award a contract.

SOURCES SOUGHT FOR CONTRACT  
STUDIES ON MYCOTOXINS

ANNOUNCEMENT

The National Institute of Environmental Health Sciences, National Institutes of Health, is interested in organizations having capabilities and facilities to carry out studies on mycotoxins. Specifically it is interested in organizations with constant access to, expertise in, and an ongoing animal testing program for evaluation of mycotoxins in a broad spectrum of high caloric foodstuffs, particularly grain and seed crops; organizations with demonstrated ability to identify toxigenic fungi, isolate and identify mycotoxins, evaluate environmental parameters conducive to mycotoxin production, and develop sensitive analytical methods for monitoring toxins in foodstuff and animal tissues; and organizations with facilities for biosynthesizing sufficient quantities of mycotoxins of interest for collaborative long-term toxicological and pharmacological testing at NIEHS. Exploration for new toxins among the well-known toxigenic genera such as *Fusarium*, *Aspergillus*, and *Penicillium* spp is of interest; however, strong emphasis should be placed also on toxigenic strains of *Cladosporium*, *Chaetomium*, *Epicoccum*, *Sclerotinium*, *Scopulariopsis*, and other genera which have been shown to be highly toxigenic but have been studied relatively little.

It is emphasized that expression of interest must relate to the specific project which falls within the scope of the area outlined above, and include a scientifically evaluable rationale for the project. Compilation of organizational reports, C.V.'s, and general expression of capabilities alone will not suffice.

This synopsis is not a request for proposal. Only those sources deemed, after review of the resumes, to be fully qualified for all aspects of the project will be invited to submit proposals. Other respondents will not be notified of the results of the evaluation.

Ten copies of the resume of experience and capabilities should be submitted to:

Executive Officer  
National Institute of Environmental Health Sciences  
P.O. Box 12233  
Research Triangle Park, N.C. 27709

before close of business on September 17, 1971.

Telephone calls will not be honored and all inquiries must be in writing and addressed to the office listed above. In order that all prospective contractors be treated on an equal basis, any questions raised by individual prospective contractors and the answers thereto will be made available upon request to all potential contractors.

DISPOSITION OF NIH GRANT-RELATED INCOME

Appendix D  
NIH 5601  
(To Guide No. 2,  
June 19, 1970)

NIH Policy on Disposition of Income Derived  
from the Sale of Communications  
Materials Produced by NIH Grant Funds

1. PURPOSE This issuance states the NIH policy concerning disposition of income derived from the sale of books, monographs, films, and other communications materials produced, in whole or in part, with funds from NIH grants. It is an amendment of a PHS policy which has been in effect since April 1, 1966.
2. APPLICABILITY This policy is applicable to all NIH grant programs.
3. BACKGROUND NIH policy on Disposition of Grant-Related Income, NIH 5601 (Guide No. 2, June 19, 1970), is concerned primarily with grant-related income resulting from direct grant activities and does not specifically identify the treatment of income from the sale of materials produced with support from grant funds. DHEW policy, as contained in DHEW Grants Administration Chapter 1-420 (released 3/31/69), states, in part, "Existing agency policies for treating income from such publication rights, including disposition of royalty payments, shall remain in effect until such time as the Department issues a policy on these subjects."
4. DEFINITIONS

Net Proceeds - The amount of funds remaining from the sale and rental of communications material after deduction of all applicable production costs and accrued losses, including prior years of the grant.

Production Costs - Production costs include the costs of printing (including the processes of composition, plate-making, press work, binding, and the end products produced by such processes), distribution, promotion, mailing, and general handling.
5. POLICY The NIH will provide support to grantee organizations engaged in research, research training, and related biomedical activities for the production of books, monographs, films, and other communications materials that are within the scope of the NIH's interest. It is the intent of NIH to recover funds which represent production costs of publications, films, and other communications materials to the extent they were supported by an NIH grant. The cost of a meeting, writing and editing, and other grant activities which lead to production of such materials are within the mission of NIH, and therefore are its contribution to scientific advances.
6. IMPLEMENTATION If there is to be a charge for communications materials for which support, in part or in whole, has been provided with NIH funds, two general conditions may obtain which will be treated as follows:
  - a. Where the grant-supported activity is a non-continuing function of the grantee organization (e.g., support of the publication of the proceedings of a symposium or other meeting), grantee must maintain an open account for five years from the date of completion of the production or until the grant account is fully reimbursed for production costs,

whichever comes first. Reimbursement of the grant account will be from the NIH share of the net proceeds of the sale of such communication material. The return of such funds to the U.S. Treasury will be made on a yearly basis, on the anniversary date of the production, unless otherwise directed by the NIH awarding unit. Checks should be made payable to the Department of Health, Education, and Welfare, National Institutes of Health, and forwarded to the Director, Office of Financial Management, NIH, Bethesda, Maryland 20014. Checks must identify the relevant grant account and the reason for the payment.

- b. Where the grant-supported activity (e.g., support of a scientific periodical) is a continuing function of the grantee organization, the grantee will utilize the net proceeds, as specified by the NIH awarding unit, in accordance with paragraph 4 of NIH Grants Policy Guide No. 2, June 19, 1970, Disposition of Grant-Related Income (NIH 5601).

7. COST SHARING Grant-related income, as described in this issuance, may not be used to meet cost sharing or matching requirements for any NIH supported program.

8. EFFECTIVE DATE September 1, 1971.

#### References

- (1) DHEW Grants Administration Staff Manual, Chapter 1-420, Disposition of Grant-Related Income.
- (2) NIH Grants Policy Guide No. 2, June 19, 1970, Disposition of Grant-Related Income, (NIH 5601).
- (3) DHEW Grants Administration Staff Manual, Chapter 1-450, Use of Grant Funds for Production of Motion Picture Films.
- (4) PHS Grants for Research Projects, Policy Statement, PHS Pub. No. 1301.
- (5) PHS Grants for Training Projects, Policy Statement, PHS Pub. No. 1302.



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