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P.T. 34; K.W. 1014006, 1016004

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

The following comments provide a brief review of current regulations affecting inventions made with support from the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) research grants or related awards (G, H, K, M, P, R, S, and U awards); research and development contracts (N01 awards); and grants and contracts (N43, N44, R43, and R44 awards) made under the Small Business Innovation Research Program. Inventions made solely by trainees or fellows (assisted only by a T or F award) are not subject to these guidelines.

Congress has long encouraged the use of the patent system by universities, non-profit organizations, and small business firms. The principal concern is to protect the public interest in inventions developed with the aid of Federal funds, while giving due recognition to the legitimate interests of those who have contributed to the invention. The key provisions of patent law as they apply to inventions made with NIH and ADAMHA support are contained in several references cited at the end of this notice under "Citations." The following guidelines, based on those sources, describe procedures for the reporting and subsequent disposition of such inventions.

DISCLOSURE: Federal law requires that any invention arising from experimental, developmental, or research activities assisted by public funds from Government grants and contracts be promptly and fully reported (disclosed) by the inventor to his or her employer, i.e., the contractor or grantee organization (non-profit or for-profit, public or private). In turn, the organization must fully disclose the invention to the NIH or ADAMHA at the address shown immediately below. This disclosure must be submitted within a reasonable time (60 days) of the inventor's initial report to the organization and it shall be sufficiently complete in technical detail to convey a clear understanding of the invention. The disclosure will also identify the inventor, the grant or contract under which the invention was made, and any publication or manuscript submitted for publication that describes the invention. NOTE: Many organizations disclose inventions by providing a single copy of any report form the inventor submits for the organization's internal use. However, reporting an invention to the NIH or ADAMHA by merely submitting its title or summary description is NOT an acceptable disclosure. Since these disclosure reports contain proprietary information they are not released to the public without the organization's specific permission.

MAILING ADDRESS: The following office is the designated receipt point for any of the documents described in this Notice, as well as for any invention-related inquiries:

Extramural Inventions Office
National Institutes of Health
ATTN: Dr. Howard Jenerick
Building 31, Room 5B-41
Bethesda, MD 20892
Telephone: (301) 402-0850

INVENTION RIGHTS: Most Government grant and contract awards for the performance of experimental, developmental, or research work incorporate standard patent rights clauses which state that, subject to certain limitations, the ownership of rights to any invention is usually left with the contractor or grantee organization. However, the organization must elect in writing whether or not to retain title to the invention during the next one or two years (see below) after the required disclosure to the Extramural Inventions Office. Any organization electing to retain the title agrees to file an initial patent application within a reasonable period of time, i.e., one year or prior to any statutory bar date. If the organization elects not to take title and file for a patent, it must so inform the NIH or ADAMHA which then have the right to take title. (The title does not flow to the inventor by default.) Agency staff will promptly evaluate the invention and will file a patent application from it if this seems in the public interest and it is practical to do so. If the Government obtains a patent, the organization may retain a nonexclusive, royalty-free license and the inventor may receive royalty payments according to a standard formula. If the agency elects not to exercise the Government's rights in the invention, the...
organization may request these rights be granted back to the inventor who may then file for a patent.

PATENT APPLICATION and ACKNOWLEDGEMENT: At the time the organization or the inventor submits the formal application to the U.S. Patent and Trademark Office, a copy should also be sent to the Extramural Inventions Office along with the obligatory license (see below). The patent application must include the following statement:

"This invention was made with Government support under (identify the grant/contract) awarded by the (cite the awarding agency, e.g., National Institutes of Health or Alcohol, Drug Abuse, and Mental Health Administration). The Government has certain rights in the invention."

TIMELINESS for ELECTION OF RIGHTS and FILING of PATENT APPLICATIONS: Timing is critical in patent law because of statutory deadlines which must be met to avoid loss of valuable patent rights. The laws distinguish between inventions that are "disclosed" by confidential reporting to the Government and inventions that are "disclosed" to the public through speeches or publications. NOTE: Abstracts and posters presented at scientific meetings are considered as publications, and if the published abstracts for society meetings are mailed out early, the POST MARK DATE is considered the publication date.

If the invention has NOT been disclosed to the public, i.e., it has only been reported to the Government on a confidential basis, there is the two-year open period for taking title and then another year for filing a patent application.

Timing for United States Patent Applications after Public Disclosure: Under U.S. patent law a valid patent application may be filed only within a one-year open period after the publication date of a printed article that discloses the invention.

Timing for Foreign Patent Applications after Public Disclosure: Other countries usually do not allow a one-year open period after publication, unless a U.S. patent application has been filed prior to the publication date. Note: Despite a possible lack of interest in foreign filing, organizations should be aware that inattention to the proper timing between publication and filing a U.S. patent application will cause the loss of the Government's rights to foreign patents.

NOTE: If no application is filed during these open periods, the invention is considered to have been dedicated to the public and can no longer be patented. Since the Government and the inventor have certain rights to the invention as outlined above, the limited open periods for seeking patent protection makes it important for the organization to proceed promptly in its evaluation of the invention and inform the Extramural Inventions Office of its decision in timely fashion.

LICENSE: Every patent applicant (individual or institutional) is required to provide the Government with a nonexclusive, irrevocable, paid-up license in the invention. (A sample license is provided at the end of this Notice.) A single copy of this license should be sent to the Extramural Inventions Office at the time the patent application is filed.

PATENT: The successful applicant will furnish a copy of the issued patent to the Extramural Inventions Office.

PREFERENCE FOR UNITED STATES INDUSTRY: The patent holder or its assignee will not license or grant any person the exclusive right to use or sell the invention in the United States unless the products are manufactured substantially in the United States.

INVENTION UTILIZATION REPORTS: Periodic utilization reports for each invention must be filed with the Extramural Inventions Office. Such reports shall be submitted every two years and shall include information regarding the status of development, date of first sale or use, and gross royalties received by the organization. These utilization reports are not releasable to persons outside the Government without permission of the grantee or contractor, or within the Government except on a need-to-know basis.

SPECIAL NOTE: Chemical compounds having potential medicinal or other utilities are often synthesized or identified during research financed by Federal funds. Such a compound is not patentable until a use can be described. Although the compound need not be tested, the patent application must "teach" the reader how to use the substance. It is NIH and ADAMHA policy that such compounds should be adequately screened so that all possible uses may be ascertained and any promising compounds be developed for widest
possible use. The screening services of the National Cancer Institute and the Walter Reed Army Institute of Research should be utilized for this purpose, whenever appropriate.

LEGAL CONTACT: It is important that institutions rely primarily on their own legal counsel for advice and interpretation of relevant Governmental laws and regulations. However, if a technical question arises that requires an answer from a Government patent attorney please contact:

Patent Branch
DHHS Office of the general Counsel
Public Health Division
National Institutes of Health
Building 31, Room 2B-62
Bethesda, MD 20892
Telephone: (301) 496-7056

INVENTION REPORTS in GRANT APPLICATIONS and FINAL REPORTS: Please note that inventions arising from NIH and ADAMHA supported projects must be reported to the awarding component in competing and non-competing applications for continuation awards. To insure confidentiality, inventions reported through this channel should be described by title or summary paragraph only. It may be wise to discuss these descriptions with the organization's patent counsel before submission.

At the expiration or termination of each project, the Final Invention Statement and Certification (Form HHS 568) is sent to the Grants Management Officer of the awarding component. In the case of terminated contracts any inventions are identified in the contract close-out letter. (NOTE: Grantees are reminded that the Statement is required within 90 days following the expiration or termination of support for the project.) Because of brevity, these latter reports do not meet the requirements for full disclosure.

CITATIONS: Important changes in public laws in recent years have led to substantial revisions of the Agency regulations affecting inventions made with Federal support. The requirements of Public Laws 96-517 and 98-620 are embodied in Title 35 United States Code (USC) Sections 200-212, and have been implemented in the regulations published in Title 37 Code of Federal Regulations (CFR) Part 401. (The corresponding Department of Health and Human Services regulations, 45 CFR Part 6 and 8, are currently under revision.) The standard patent rights clauses which are incorporated into all NIH and ADAMHA grants and research contracts appear in 37 CFR Section 401.14.

SAMPLE License form for use by Institutional Official or individual inventor:

LICENSE TO THE UNITED STATES GOVERNMENT

This instrument confers to the United States Government, as represented by the Department of Health and Human Services, a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on its behalf throughout the world the following subject invention. This license will extend to all divisions or continuations of the patent application and all patents or reissues which may be granted thereon:

Invention Title:
Inventor(s):
Patent Application
Serial No.:
Filing Date:
Title:
Country, if other than
United States:

This subject invention was conceived or first actually reduced to practice in performance of a government-funded project, (National Institutes of Health or Alcohol, Drug Abuse, and Mental Health Administration grant/contract) No. Principal rights to this subject invention have been left with the Licensor, subject to the provisions of 37 CFR 401 and 45 CFR 8.

Signed:
Typed Name:
Title:
UPDATE ON THE NIH POLICY REGARDING PROGRAM PROJECT, AND OTHER COMPLEX MULTIFACETED, UNSOLICITED GRANT APPLICATIONS

P.T. 34; K.W. 0710030, 1014006

National Institutes of Health

The Institutes, Centers, and Divisions (ICDs) of the National Institutes of Health (NIH) accept a variety of large unsolicited grant applications, such as those for program projects and other large, complex coordinated research grants. However, guidelines and policies governing preparation, review, and funding of these applications are not uniform across the NIH and may differ because of a variety of factors such as legislative mandates, fiscal constraints and programmatic management.

In order to serve the extramural community better, the National Institutes of Health advise that prior to submission of any application for an unsolicited, multifaceted grant, applicants communicate with appropriate ICD staff. This action will allow the applicant to be apprised of the guidelines and policies that govern the preparation, review and funding of such applications for a particular ICD. Of special concern is the fact that the different ICDs have different dollar limits for such multifaceted applications, and applications that exceed these limits will be returned without review.

The assignment of an application to a potential funding source within the NIH is based on scientific guidelines developed for each ICD in conjunction with the Division of Research Grants (DRG) and is the responsibility of the DRG, not of the individual ICDs. Thus, when the potential applicant discusses plans for a complex program grant application with the initial ICD contact, he/she is strongly advised to inquire whether other ICDs may also have relevant scientific interests so that additional staff contacts can be made if appropriate.

The following individuals may be contacted for specific questions related to such applications:

National Institute on Aging
9000 Rockville Pike
Bldg. 31, Room 5C06
Bethesda, MD 20892
Att.: Dr. Miriam Kelty
Telephone: (301) 496-9322

National Institute of Allergy and Infectious Diseases
5333 Westbard Avenue
Westwood Bldg., Room 703
Bethesda, MD 20892
Att.: Dr. John Diggs
Telephone: (301) 496-7291

National Institute of Arthritis and Musculoskeletal and Skin Diseases
9000 Rockville Pike
Bldg. 31, Room 4G32
Bethesda, MD 20892
Att.: Dr. Michael Lockshin
Telephone: (301) 496-0802

National Cancer Institute
9000 Rockville Pike
Bldg. 31, Room 10A03
Bethesda, MD 20892
Att.: Ms. Barbara Bynum
Telephone: (301) 496-5147

National Institute of Child Health and Human Development
9000 Rockville Pike
Bldg. 31, Room 2A03
Bethesda, MD 20892
Att.: Ms. Hildegard Topper
Telephone: (301) 496-0104

National Institute of Deafness and Other Communication Disorders
7550 Wisconsin Avenue
Federal Bldg., Room 1C11
Bethesda, MD 20892
Att.: Dr. Ralph Naunton
Telephone: (301) 496-1804
NOTICES OF AVAILABILITY (RFPs AND RFAs)

VISIBLE HUMAN PROJECT

RFP AVAILABLE: NLM-90-114/SLC

P.T. 34; K.W. 1004004, 1004005, 0705000, 0706030

National Library of Medicine

The National Library of Medicine (NLM) is undertaking a project to build a digital image library of volumetric data representing a complete normal adult human male and female. This "Visible Human Project" will include digital images derived from photographic images from cryosectioning, computerized tomography, and magnetic resonance imaging of cadavers. This project is viewed as a cornerstone for a future set of related image libraries and a test platform for developing methods and standards.

Technologies underlying computer-based representation and display of complex three-dimensional biological structure are sufficiently mature that the NLM can proceed with building prototype digital image libraries. The NLM's Long Range Planning effort of 1985-86 foresaw a coming era where the NLM's bibliographic and factual database services would be complemented by libraries of digital images, distributed over high-speed computer networks and by high-capacity physical media. The NLM Planning Panel on Electronic Imaging was convened to recommend when and how the NLM might proceed in the development of such digital image libraries. Much of our understanding of complicated processes of health and disease lies in images, pictures of body systems, organs, and molecules which cannot effectively be described in words.

This project will be implemented in three phases:

Phase 1 Acquisition of cadavers, CT and MRI data sets, and selection of a "typical" male and female cadaver for Stages 2 and 3

Phase 2 Acquisition of anatomy data set from either male or female cadaver

Phase 3 Acquisition of anatomy data set from remaining female or male cadaver

The major technical risks associated with this project will be the selection of the two cadavers which will prove to be appropriate for use in Phase 2 and Phase 3; and the techniques of tissue sectioning and image capture sufficient to obtain the required results. The Ad Hoc Technical Evaluation Committee will provide oversight at the transition points between phases 1 and 2 and between phases 2 and 3.

The contractor will be evaluated by the Ad Hoc Technical Evaluation Committee after the completion of Phase 1. Such evaluation may be on the basis of the contractor's Phase 1 report, by presentation to the committee or by site visit to the contractor's site by committee members.

RFP NLM-90-114/SLC will be available in late June 1990, and proposals will be due 30 days thereafter. Copies of the Request for Proposals may be obtained by written request only to:

National Library of Medicine
Office of Acquisitions Management
8600 Rockville Pike
Building 38A, Room B1N17
Bethesda, MD 20894
Attention: Sharon Cummings
Telephone: (301) 496-6546
ONGOING PROGRAM ANNOUNCEMENTS

ADDENDUM: RESEARCH GRANTS ON NARCOLEPSY

PA: PA-90-03

P.T. 34; K.W. 0715138, 0715187, 0765035, 1002058, 0745020, 0745070

National Institute of Neurological Disorders and Stroke
National Institute of Mental Health

The program announcement was originally published in the NIH Guide, Volume 19, No. 15, April 13, 1990. The following changes have been made to reflect the addition of The National Institute of Mental Health (NIMH) as a co-sponsor on this program announcement that originally was issued by the National Institute of Neurological Disorders and Stroke (NINDS).

APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on Form PHS-398 (Revised 10/88) according to instructions contained in the application kit. Application kits are available from most institutional business offices or may be obtained from the Division of Research Grants. Check "Yes" in Item 2 on the face sheet of the application and type "NINDS-NIMH grant related to Narcolepsy, PA-90-03," in the space provided.

Applications must be responsive to the Program Announcement and the goals of the NINDS or NIMH. Primary assignment of the grant to the sponsoring institutes will be according to existing referral guidelines of the Division of the Research Grants. Applications will be judged on scientific merit and program relevance in accordance with NIH or ADAMHA policy and procedures involving peer review. An initial review will be by an appropriate study section. A second level of review will be by an appropriate National Advisory Council.

For further information, applicants may contact:

Charlotte B. McCutchen, M.D.
NIH, NINDS, DCDND, EB
Federal Building, Room 114
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1917

or

Susan Blumenthal, M.D., M.P.A.
Chief, Behavioral Medicine Program
NIMH
5600 Fishers Lane, Room 11-C-06
Rockville, MD 20857
Telephone: (301) 443-4337

MULTIDISCIPLINARY RESEARCH ON SOLID TUMORS

PA: PA-90-17

P.T. 34; K.W. 0715035, 0785140, 0710030

National Cancer Institute

Application Receipt Date: February 1, June 1, October 1

The National Cancer Institute (NCI) through the Organ Systems Coordinating Branch seeks grant applications to conduct multidisciplinary research on human solid tumors. This program announcement encompasses a full range of studies from basic through clinical, including technology research. Applications may focus on one or several solid tumors. The intent of the announcement is to encourage research on human solid tumors that contribute substantially to cancer incidence, morbidity and mortality. The NCI is especially interested in novel ideas and approaches to solid tumor.

I. BACKGROUND

In past years, significant progress has been reported for leukemia and lymphoma research, but advances in solid tumor research have not been
The establishment of the Cooperative Human Tissue Network, supported through the NCI Division of Cancer Biology, Diagnosis, and Centers, now makes human tissues more readily available for research purposes. Thus, an increased emphasis on human solid tumor research becomes feasible. The NCI now seeks to stimulate novel research in the solid tumors, particularly those tumors that account for significant cancer incidence, morbidity and mortality, e.g., lung, colon-rectum, breast, upper aerodigestive, prostate, bladder, pancreas, melanoma, stomach, kidney, ovary, brain. A major portion of NCI support for research on these tumors has been in applied research, e.g., clinical trials; basic research has received lesser attention.

In the past, NCI has supported solid tumor research through clinical cooperative trials which have addressed a variety of solid tumors, as well as through the Organ Systems Program (OSP) which sought to stimulate multidisciplinary research in selected solid tumor sites (i.e., bladder, breast, central nervous system, large bowel, pancreas, prostate, and upper aerodigestive tract). A recent reorganization of the OSP has broadened its responsibility to include research encompassing all solid tumors, with emphasis on those that contribute substantially to cancer incidence, mortality and morbidity and/or have particular significance to minorities and the aged.

II. RESEARCH GOALS AND SCOPE

This announcement seeks to encourage multidisciplinary research on human solid tumors. Research grant applications utilizing the traditional grant mechanisms, including the R01 investigator initiated or the P01 program project grant, are encouraged. Small P01 program project applications with three to four subprojects, addressing one or more tumor sites, would be particularly relevant. A P01 application could be multi-institutional, thereby providing multidisciplinary linkages not otherwise available. A full range of research activities including basic, clinical and technology development is within the scope of this announcement.

Examples of research areas include but are not limited to those being explored under the previous organization of the OSP, which utilized standing working groups of expert scientists to identify multidisciplinary research opportunities. For example, the Bladder Cancer Working Group concluded a workshop on "The Biology of Bladder Cancer and the Potential Implications" in which opportunities were identified relating to stromal epithelial interactions and oncogene activation, new potential markers in tumorigenesis, tumor growth influence on immunobiology, development of laboratory techniques for predicting chemotherapy and radiation responses, and opportunities for prevention trials. The Breast Cancer Working Group has addressed interactions between hormonal and cytotoxic adjuvant therapies and the effects of tamoxifen, estrogens, and progestins on high-risk breast lesions. The CNS Oncology Working Group was developing ideas for research on targets and mechanisms of CNS radiation damage in order to understand molecular lesions responsible for radiosensitivity and cellular elements and vasculature of the central nervous system. The Large Bowel Cancer Working Group was developing ideas focused on the transformation and progression of normal colonic epithelium to adenocarcinoma, as well as protocols for conservative treatment of rectal cancer thereby avoiding permanent colostomy. The Prostate Cancer Working Group was addressing genetic instability and tumor heterogeneity, the biology of latent cancer and its clinical progression, and a re-examination of prostate epidemiology. The Upper Aerodigestive Cancer Working Group convened a workshop on chemoprevention of upper aerodigestive tract cancers and was developing concepts for related research initiatives. In addition, ideas were being discussed relative to genetic susceptibility to carcinogenesis in the upper aerodigestive tract, magnetic resonance imaging of subclinical disease in the head and neck, and a possible viral etiology in the epidemiology of upper aerodigestive tract cancers. For further information on any of these working group activities, please call the Organ Systems Coordinating Branch (see below). These examples focus on single tumor sites and are not all inclusive. Other tumor sites and other areas are encouraged as well as approaches which study tumors across organ sites.

The NCI is especially interested in novel ideas and approaches. Applicants are encouraged to use multidisciplinary approaches for investigating common as well as unique properties and behavior of solid tumors. Human tissues for research purposes are available through the Cooperative Human Tissue Network (for details call Dr. Roger Aamodt, 301/496-7147). Prospective applicants could benefit by calling the Organ Systems Coordinating Branch (see below) to establish relevant contacts within the NCI. If a program project application is considered, preliminary contact should be made to assure adherence to guidelines for program project applications. Grant applications submitted in
response to this announcement will be assigned to the relevant divisional programs.

III. MECHANISM OF SUPPORT

This program will be supported through all traditional research grant mechanisms including the R01 investigator initiated and P01 program project grant mechanisms. Awards will be administered in accordance with Public Health Service Policy as described in the PHS Grant Policy Statement, DHHS Publication No. (OASH) 82-50,000 revised January 1, 1987.

IV. APPLICATION AND REVIEW PROCEDURES

Grant applications in response to this announcement will be reviewed in accordance with the usual Public Health Service peer review (Study Section) procedures. Review criteria include the significance and originality of research goals and approaches; feasibility of research and adequacy of experimental design; adequacy of available facilities and appropriateness of the requested budget relative to the work proposed. Following Study Section review, further evaluation will be provided by an appropriate National Advisory Board/Council. Funding decisions will be based on the above evaluations and on the availability of funds.

Applications should be submitted on Form PHS-398, revised 10/88, available in the business or grants office at most academic or research institutions, or from the Division of Research Grants, National Institutes of Health. Applications will be accepted in accordance with the dates for receipt of new applications on an indefinite basis:

February 1       June 1       October 1

The phrase "Multidisciplinary Research on Solid Tumors PA-90-17" should be typed on line 2 of the face page of the application. The original and six copies should be sent to:

Grant Applications Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

For further information, please call:

Dr. Andrew Chiarodo
Organ Systems Coordinating Branch
Centers, Training, and Resources Program
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executiva Plaza North, Suite 316
Bethesda, MD 20892
Telephone: (301) 496-8528

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Prevention Program. Awards will be made under authorization of the Public Health Service Act, Title III, Section 301(c) and Section 402 (Public Law 78-410, as amended: 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, Maryland 20816

*U.S.GOVERNMENT PRINTING OFFICE:1990-261-138:20003

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