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NIH/ADAMHA Proposed Guidelines for Policies on Conflict of Interest

The proposed guidelines, published in the "NIH GUIDE", Vol. 18, No. 32, September 15, 1989:

I. Would require the institution to:

- a. enact policy and establish procedures;
- b. furnish the policy to NIH/ADAMHA;

c. inform all investigators and relevant employees, etc. of policy and procedures;

- d. appoint a panel (three members, one non-institutional) to:
 - receive and review financial disclosures from PI's with each federal proposal (financial interests of spouse and dependents, too);
 - 2. consider and issue waivers and report these to NIH/ADAMHA;
 - 3. certify compliance to NIH/ADAMHA with each proposal and award;
 - 4. receive and review updated financial disclosures annually.
- e. report changes to NIH/ADAMHA;
- f. notify NIH/ADAMHA of any practice or situation involving conflict of interest;
- g. resolve any conflict of interest; and finally
- h. maintain records of disclosures, etc. for 3 years after project terminates.

II. Would require individuals with primary management, advisory, or supervisory responsibilities for NIH/ADAMHA-funded research to:

- a. comply with the institutional conflict of interest policy;
- b. avoid circumstances that would put them in conflict of interest situations;
- c. make full disclosure of all financial interests and outside professional activities of themselves, their spouses and dependents to the institutional review panel;
- d. update these disclosures annually; and
- e. report immediately any conflict of interest to the institutional review panel.

Ben G. Harris, Ph.D., Associate Dean for Research, has already submitted the institutional response to the proposed guidelines. Anyone wishing to submit an individual response is encouraged to do so. Comments should clearly identify the respondent's frame of reference and address the following question:

"If your institution adopts and implements policies based on the NIH/ADAMHA Proposed Guidelines for Policies on Conflict of Interest, what impact will those policies and procedures have on your research, on basic biomedicine in general, on clinical trials, on technology transfer, on product development, and on commercialization of research results".

Comments are due before December 15, 1989.

3500 Camp Bowie Boulevard

Fort Worth, TX 76107

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CHANGES IN NSF PROPOSAL FORMAT

6. 4.6

- The following proposal format changes will be effective for proposals submitted after October 1, 1989:
- 1. Education and Human Resources: a statement must be included specifying the potential of the proposed research to contribute to the education and the development of human resources in science and engineering at the postdoctoral, graduate and undergraduate levels. This statement may include, but is not limited to, the role of the research in student training, course preparation, and seminars, particularly for undergraduates. Special effectiveness or achievement in the area of producing professional scientists and engineers from groups presently under represented should be described.
- Biographical Sketches: in addition to data on educational background and career, must now include the following information:
 - A list of up to five (5) publications most relevant to the research proposed and up to five (5) other significant research publications. Patents, copyrights, or software systems developed may be substituted for publications. These publications may overlap the continuing requirement for a list of all publications resulting from and citing prior NSF Support. A complete list of publications for the past five years is *no longer required*. Only the list of ten will be used for merit review.
 - A list of the names of graduate students with whom the PI has had an association as thesis advisor and postdoctoral scholars sponsored by the PI over the past five years, with a summary of the total numbers of graduate students advised and postdoctoral scholars sponsored.
 - c. To avoid potential conflicts of interest in merit review, a list of scientists with

whom the investigator has had a longterm association and/or with whom he/she has collaborated on a project or book, article, report or paper within the past 48 months; and the investigator's own graduate and postdoctoral advisors.

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) was established in 1974 by the Research on Aging Act (PL 93-296), which authorized the NIA to support biomedical, behavioral, and social research and research training on the aging process and on the diseases and other special problems and needs of older people.

In response to this mandate, NIA has established programs in biomedical research and clinical medicine, the neuroscience and neuropsychology of aging, and behavioral and social research. These three programs comprise its extramural research activities. In addition, the intramural epidemiology, demography, and biometry program conducts certain aspects of its research activities through the award of extramural research contracts and cooperative agreements.

NIA support for research and research training is primarily provided through the award of grants. Research contract awards are generally reserved for the development and support of research resources, including animal, cellular, and data resources as well as community populations of older people. NIA encourages the submission of applications and proposals for such support by means of Program Announcements and Requests for Applications (for grants) and Requests for Proposals (for contracts) and through individual contact. Applicants are encouraged to discuss questions about the NIA mission or the procedure for submitting applications with institute staff.

GENERAL PROGRAMS

Biomedical Research and Clinical Medicine This program provides support through all award mechanisms to further the goals of understanding the aging process and improving the ability of the individual and health care practitioner to respond to the diseases and other clinical problems of older people. Included are studies of the mechanisms and expressions of aging, with research on immunology, genetics, molecular biology, cell biology, exercise physiology, nutrition, endocrinology, and geriatrics. The program is divided into two areas of research and an office for the administration of biological resources and resource development.

Molecular and Cellular Biology Branch (MCBB)

The Molecular and Cellular Biology Branch includes four programmatic areas: Cell Biology, Genetics, Immunology, and Molecular Biology. The overall objectives of these programs are to elucidate the biochemical, physiological, genetic, and molecular events that lead from gene action to phenotypic expression in relation to the aging of cells and animals, including humans. These objectives are all related to understanding normal DNA functions and the alterations in these functions that can be induced by interaction with the environment and disease processes as aging proceeds. They include investigations of the gradual or programmed alterations of structure and function that characterize normal aging, as well as investigations of the abnormal changes that are characterized by agerelated disease states .

Office of Biological Resources and Resource Development

The overall objectives of the Office of Biological Resources and Resource Development (ORD) are to provide aging animals to investigators for research at a reasonable cost, and to explore the development of new animal models for research on aging through grants funded by the Animal Models Program.

Geriatrics Branch

The Geriatrics Branch supports research on clinical problems that occur predominantly among older persons or that are associated with increased morbidity and mortality in older people; investigations of clinical problems associated with nursing homes and other sites of long-term care for frail older persons; and the development of scholarly leadership in geriatrics and other areas of research in aging through training and research support for both junior and established clinical investigators entering the field of aging. This branch administers: Cardiovascular/Pulmonary/Renal Program (CPR); Endocrinology Program (END); Geriatric Research and Training Program (GRT); Genitourinary Disorders Program (GUD); Infectious Diseases, Hematology, and Oncology Program (IHO); Musculoskeletal Program (MSK); and the Nutrition, Metabolism, and Gastroenterology Program (NMG).

Neuroscience and Neuropsychology of Aging

This program fosters and supports extramural and collaborative research and training to further the understanding of the aging process relevant to the neurosciences and associated areas of the psychological sciences. The activities of this program devoted to the aging nervous system can be distinguished by an interest in: aging as a process; age-related changes in the brain or nervous system in the context of other agerelated physiological or homeostatic regulatory changes (e.g., degenerative processes or pathological changes in the aging brain in the context of understanding normal age related changes); and the sensory, perceptual, and cognitive processes and changes that occur with aging, as related to their underlying biological mechanisms. An important component of this program is the support of basic, clinical, and epidemiological studies on Alzheimer's disease and related dementias of aging. This support includes such Congressionally mandated initiatives as the Alzheimer's Disease Research Centers, the Alzheimer Disease Patient Registry, and the further stimulation of research on the diagnosis and epidemiology of Alzheimer's disease.

Behavioral and Social Research

This program (BSR) supports basic behavioral and social research through all award mechanisms on the aging process and the problems and needs of older people. It focuses on understanding how psychological and social aging interact with biomedical aging processes; how older people relate to social institutions (e.g., the family, health care systems); and the antecedents and consequences of the dramatic changes in age composition of the population.

The goal of the program is to produce a scientific knowledge base which, by informing professional practice, public policy, and everyday life can maximize people's health, effective functioning, independence, and well-being in their middle and later years. In order to explain the wide diversity among older people, it encourages comparisons between males and females; persons with differing racial, ethnic, and socioeconomic background; and inhabitants of countries that vary in styles and standards of living.

Special attention is given to studies of the oldest old (those aged 85 and over), one of the fastest growing segments of the population. Two disease-oriented targets for attention are: (1) the care of Alzheimer's Disease patients and their families; and (2) the little-understood implications for older people of an AIDS epidemic, which involve all aspects of the BSR program. Emphasis is also placed on many kinds of interventions that can prevent, postpone, or reverse such decrements of old age as chronic ill health, sense of incompetence, memory loss, functional disability, or withdrawal from active participation in social and economic roles.

The program is divided into three areas of research. It also supports development of data sets, methodologies, and other research resources, and it works with other agencies to coordinate the preparation of statistical data on aging.

Adult Psychological Development

Adult Psychological Development (ADP) supports development research concerned with behavioral and social mechanisms and processes influencing cognitive and intellectual functioning, personality, attitudes, and interpersonal relationships over the adult life course. An emphasis is placed on research relevant to maintaining and improving well-being, independence, and effective functioning. Research is needed for seeking out the conditions under which agerelated changes occur or do not occur, and for supplying information to use in the design of roles and environments that can utilize the special strengths of middle-aged and older people and maintain and enhance their functioning.

Social Science Research on Aging

Social Science Research on Aging (SSR) aims to understand the social and environmental conditions influencing health, well-being, and functioning of people in middle and later years. Its two sections focus respectively on the dynamic processes linking health, behavior, and aging and on those linking social structures with behaviors, attitudes, health, and status of older people. Both sections are concerned with social and behavioral factors in health and functioning and with assessment and testing of planned interventions and natural environments for health promotion and disease prevention.

Special attention is given to research on aging and health care, especially such issues in long-term care as: family structures and relationships affecting provision of home care, and interventions to prevent the need for long term care (e.g., injury prevention and control). Particular emphasis is placed on studies of long-term care of Alzheimer's Disease patients and their families, in line with the NIA initiative. This program also encompasses social science research on two other institute-wide initiatives: gender, health, longevity, and minority health.

Demography and Population Epidemiology

Demography and Population Epidemiology (DPE) supports research and training on the dynamics and consequences of population aging and aims to describe and understand the changing older population in terms of its social, demographic, economic, health, and functional characteristics and the impact of these changes on society as a whole. Epidemiology, Demography, and Biometry The Epidemiology, Demography, and Biometry Program (EDBP) conducts and supports research and research training in the epidemiology of health and disease as well as the interaction of demographic, social, and economic factors as they affect the health of the elderly. This program only awards extramural research contracts and cooperative agreements.

SPECIAL PROJECTS, PROGRAMS OR AWARDS

• Geriatric Leadership Academic Award: This award is designed to support leadership Academic Award Activities in the development of research and research training programs in aging.

• Complementary Training Award for Research on Aging: This award enables established research training programs to increase their efforts to train investigators for careers in aging through the addition of a training program supported by the NIA.

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NIH DEVELOPS NEW TELEPHONE INFORMATION LINE

The Division of Research Grants, NIH, has available a telephone information line that provides biweekly messages pertaining to DRG or peer review at NIH and ADAMHA. Included are extramural program or policy changes, statistics on extramural programs or peer review, special events, new and revised publications, personnel changes and other items of interest to the biomedical research community.

To use the system, just dial (301) 496-3115. You will hear a recorded message at the end of which you will have the opportunity to make any comments or suggestions for future items.

PROGRAM ANNOUNCEMENTS AVAILABLE

NATIONAL EYE INSTITUTE: supplemental information for predoctoral and/or postdoctoral National Research Service Award institutional training grants is available. Emphasis is placed on (1) enhancing fundamental training in basic disciplinary areas at the predoctoral level, where an introduction to vision research opportunities would be expected; and (2) using more specialized training at the postdoctoral level to meet national research priorities in vision research. Predoctoral training should be focused on cell biology, immunology, molecular biology, molecular genetics, epidemiology, or biostatistics. Postdoctoral training programs may be proposed in any discipline relevant to vision research.

AMFAR PEDIATRIC RESEARCH GRANTS: Letters of intent are sought in three areas of pediatric AIDS research:

The Effect of HIV on Growth and Development HIV Infection and the Central Nervous System Opportunistic Infection in Pediatrics AIDS

Detailed descriptions of the targeted research areas are available from the Research Office.

EXTERNAL AWARDS 09/01/89 - 11/30/89

MICHAEL W. EMMETT-OGLESBY, PH.D. (Pharmacology) "Detection of anxiolytic efficacy and potency using the pentylenetetrazol drug-discrimination test" (10/26/89 - Open) \$4,003.

BEN G. HARRIS, PH.D. (Biochemistry) "Metabolic enzymes of parasitic nematodes" The Upjohn Company (10/01/89 - 09/30/90) \$750.

ROBERT L. KAMAN, PH.D. (PH/PM)

"Evaluation of AVSCOM employee health promotion program" DHHS (09/01/89 -08/19/90) \$24,755.

ANDRAS G. LACKO, PH.D. (Biochemistry) "International symposium on reverse cholesterol transport" Multi-donor \$20,050.

JOHN LANE, PH.D. (Pharmacology) "Stress, CD agents and cholinergic receptors" US Army (10/01/89 - 09/30/90) \$161,272

FRANK J, PAPA, D.O. (Medical Education) "The development of expertise in the diagnosis of chest pain" (10/15/89 - 10/14/90) \$5,000.

ROBERT M. PIRTLE, PH.D. and IRMA L. PIRTLE, PH.D. (Biochemistry) "Human rRNAs involved in viral replication and ribosomal frameshifting" NIH subcontract (09/01/89 - 08/31/90) \$5,397.30

THOMAS YORIO, PH.D. (Pharmacology) "Angiotensin II antagonist as an ocular hypotensive drug" E.I. Dupont De Nemours & Co. (11/01/89 - 04/30/90) *\$33,740*.

TOTAL FUNDING \$254.967.30

EXTERNAL APPLICATIONS SUBMITTED 10/01/89 - 11/30/89

Barbara A. Barron, Ph.D. (Physiology) "Myocardial opioid peptides" American Osteopathic Association \$22,980.

James L. Caffrey, Ph.D. (Physiology) "Endogenous opioids and the neural control of muscle blood flow" American Osteopathic Association \$23,027.

James L. Caffrey, Ph.D. (Physiology) "Opiate/autonomic interactions in the circulatory system" NIH - NHLBI \$713,533.

Patrick Cammarata, Ph.D. (Anatomy/Cell Biology) "Mechanism of sugar cataract formation in lens cells" NIH - NEI \$885,286. Paul F. Cook, Ph.D. (Microbiology/ Immunology) "Determination of kinetic and chemical mechanisms of enzymes" NIH -NIGMS \$1,437,935.

Henry DeLisle, D.O. (General & Family Practice) "First annual joint family practice residency research workshop" American Osteopathic Association \$2,500.

Henry DeLisie, D.O. (General & Family Practice) "First annual joint family practice residency workshop" American Academy of Family Practice \$2,500.

Patricia A. Gwirtz, Ph.D. (Physiology) "Adrenergic limitation of coronary flow during exercise" NIH - NHLBI \$944,571.

Patricia A. Gwirtz, Ph.D. (Physiology) "Ischemia-induced coronary constrictor tone during exercise" American Health Assistance Foundation \$25,000.

Carl E. Jones, Ph.D. (Physiology) "Visceral reflexes affecting the coronary circulation" NIH - NHLBI \$558,510.

Peter B. Raven, Ph.D. (Physiology) "Education of scientists in cardiovascular regulation" NIH - NHLBI \$52,040.

Peter B. Raven, Ph.D. (Physiology) "Determination of muscle strength, endurance and work efficiency during EVA type arm work" NASA \$60,000.

Research Office "Minority High School Student Research Apprentice Program" Pate Foundation \$2,600.

Richard J. Sinclair, Ph.D. (Admissions) "Health careers opportunities program project" DHHS - BHP \$460,763.

TOTAL REQUESTED \$5,191,245

TEXAS RESEARCH ENHANCEMENT AWARDS 1989-90

Rafael Alvarez-Gonzalez, Ph.D. (Microbiology/Immunology) "2'-deoxy NAD+ as an ADP-ribosylation Substrate for Pertussis Toxin" \$6,000.

Patrick Cammarata, Ph.D. (Anatomy/Cell Biology) "Phosphoinositide turnover in Cultured Lens Cells" \$2,000.

James Dzandu, Ph.D. (Anatomy/Cell Biology) "Cell Surface Reorganization in Red Cell Aging" \$2,000.

Edward E. Elko, Ph.D. and Ying Jin, M.D., Ph.D.(Pharmacology) "Cellular Mechanism(s) and Drug-Induced Ocular Hypotension" \$2,000.

Stephen R. Grant, Ph.D. (Biochemistry) "Molar Abundance of BCGF-R and IL-4 Receptor on Human B Cells" \$5,800.

Phyllis Kutsky, Ph.D. (Physiology) "Mechanism of Vasodilatory Action of Cachectin (TMFa)" \$2,500.

Andras G. Lacko, Ph.D. and B.J. Kudchodkar, Ph.D. (Biochemistry) "Cholesterol Metabolism in Aging" \$2,800.

Michael Martin, Ph.D. (Pharmacology) "Identification and characterization of P2Ypurinergic receptors in rat brain" \$6,000.

Edward L. Orr, Ph.D. (Anatomy/Cell Biology) "Induction of Mast Cell Release in EAU" \$5,000.

Raymond Pertusl, D.O. and Elaine L. Jacobson, Ph.D. (Medicine) "Poly(ADP-ribose) metabolism in SLE" \$4,853.

Tony Romeo, Ph.D. (Microbiology/ Immunology) "Molecular Biology of Bacterial Polysaccharide Biosynthesis" \$7,500.

Patrick Shaklee, Ph.D. (Biochemistry)

"The biochemistry of RNA virus replication" \$9,000.

Paula Sundstrom, Ph.D. (Microbiology/Immunology) "Role of actin in dimorphism of Candida albicans" \$9,000.

Gary Wise, Ph.D. and Victoria Rudick, Ph.D. (Anatomy/Cell Biology) "Immunocytochemical Localization of EGF Receptor" \$4,900.

Thomas Yorlo, Ph.D. (Pharmacology) "Regulation of Proton Excretion by Eicosanoids" \$4,983.

TOTAL AWARDS \$74,336

PUBLICATIONS AND PRESENTATIONS

Licciardone, J., R.D. Hagan, S. Welss, R.L. Kaman, S.C. Taylor, and R.M. Woodworth "Projected incidence of cardiovascular disease in male firefighters based on current risk factor prevalence" JAOA 89(10):1293-1302 (1989.)

Jerry L. Dickey, D.O. "Postoperative osteopathic manipulative management of median sternotomy patients" JAOA 89(10): 1309-1322 (1989.)

Licciardone, J., J.R. Wilkins, III, R.C. Brownson and J.C. Chang "Cigarette smoking and alcohol consumption in the aetiology of uterine cervical cancer" Int. J. Epidemiology 18(3) 533-537 (1989.)

Jacobson, E.C., M.D. Lockwood, V.C. Hoefner, J.L. Dickey, and W.L. Kuchera "Shoulder pain and repetition strain injury to the supraspinatus muscle: etiology and manipulative treatment" JAOA 89(8):1037-1045 (1989.)

Elizabeth F. Harris, Ph.D. (Microbiology) and two graduate students attended the meeting of the Texas Branch, American

Society for Microbiology in San Antonio, TX.

G/S Ernest Adams presented a poster session "Evaluation of a double stain method for detection of treponemal antibodies by fluorescence microscopy."

G/S Larry Kirschner presented a paper titled "Isolation and characterization of principal toluene degrading bacteria in a leachate stream." Mr. Kirschner's paper won a Certificate of Merit and a cash award for research in general microbiology.

Paul F. Cook, Ph.D. (Microbiology/ Immunology) and his lab group attended the Robert A. Welch Foundation Conference on Chemical Research in Houston, TX.

Drs. Harbans Lal, Michael Emmett-Oglesby, Michael Forster, Paul Prather, Ejem Ahanotu, Mehdi Rezazadeh and Grace Rowan (Pharmacology) attended the meeting of the Society for Neuroscience in Phoenix, AZ. The Following poster presentations were made:

Forster, M.J., Flores, M.J., and Lal, H. "Acute and long-term caloric restriction effect coordinated motor performance of three mouse genotypes."

Lal, H., Ahanotu, E.N., Apte, V. and Forster, M.J. "Gangliosides prevent recognition of brain antigens by serum antibodies from aged mice."

Apte, V., Ahanotu, E.N., Lal, H. and Forster, M.J. "Appearance of diverse brainreactive antibodies in sera of aging NZB/BINJ mice."

Harris, C.M. and Lal, H. "Tolerance to anxiety-life effect of nicotine (NIC) in rats."

The following members of the Department of Anatomy/Cell Biology presented at numerous meetings:

Patrick Cammarata, T. Jackson and Thomas Yorio (Pharmacology) presented a poster titled "Galactosemic-induced loss of gluthione does not elicit PGH synthase inactivation in cultured bovine lens epithelial cells" at the annual meeting of the American Society for Cell Biology, Houston, TX.

Robert Wordinger, S/D John Nile and S/D Glen Stevens presented a poster "In utero exposure to Diethylstilbestrole promotes neonatal ovarian angiogenesis and uterine gland formation."

James Dzandu made a presentation at the 5th annual Inherited Blood Disease Conference of the Oklahoma Chapter of National Association for Sickle Cell Disease in Tulsa, OK.

Edward Orr and Carol Lee attended the 19th annual meeting of the Society for Neuroscience in Phoenix, AZ and presented a poster "Changes in ocular histamine in rats with EAU."

Edward Orr, Fred Jackson and Nancy Stanley presented the poster "Experimental autoimmune encephalomyclitis: effect of intracisternal injection of compound 48/80."

TCOM Committees Affecting Research Applications

Following is a list of committees/offices that you **may** need to contact before submitting an application for a grant or contract:

ACUC Dr. Eugene Quist (735-2056) (Animal Care & Use Committee)

IRB Dr. Peter Raven (735-2561) (Human Subjects)

Radiation Safety Dr. James Sims (735-2697) (Radioactive material & waste)

Intellectual Property Dr. Tom Yorio (735-2056) (Patents & copyrights)

Recomb. DNA

Dr. Mike Jacobson (735-2045)