

Dated: September 4, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98-24506 Filed 9-10-98; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the National Institutes of Health (NIH), Office of the Director (OD), Office of Extramural Research (OER), Office of Policy for Extramural Research Administration (OPERA) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 5, 1998, pages 24813-24814 and allowed 60-days for public comments. No public comments were received. The purpose of this notice is to allow an additional 30-days for public comments. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought: 42 CFR Part 50 Subpart F and Responsible Prospective Contractors: 45 CFR Part 94. **Type of Information Collection Request:** Extension of a currently approved collection, OMB No. 0925-0417, expiration date 09/30/98. **Need and Use of Information Collection:** This is a request for OMB approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR Part 50 Subpart F and Responsible Prospective Contractors: 45 CFR Part 94. The purpose of the regulations is to promote objectivity in research by requiring institutions to establish standards which ensure that there is no reasonable expectation that the design, conduct, or reporting of research will be biased by a conflicting financial interest of an investigator.

Frequency of Response: On occasion. **Affected Public:** Individuals or households; Business or other for-profit; Not-for-profit institutions; and State, Local or Tribal Government. **Type of Respondents:** Any public or private entity or organization. The annual reporting burden is as follows: *Estimated Number of Respondents:* 57,235; *Estimated Number of Responses per Respondent:* 10; *Average Burden Hours Per Response:* 20; *Estimated Total Annual Burden Hours Requested:* 171,110. The annualized cost to respondents is estimated at: \$5,068,850. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points. (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Thomas F. McCormack, Assistant Grant's Policy Officer, Office of Extramural Research, Office of Policy for Extramural Research Administration, 6701 Rockledge Drive, Bethesda, MD 20892, or call non-toll-free number (301) 435-0935 or E-mail your request, including your address, to: TM102d@NIH.gov

Comments Due Date

Comments regarding this information collection are best assured of having

their full effect if received on or before October 13, 1998.

Dated: September 4, 1998.

Diana Jaeger,

Acting Director, Office of Policy for Extramural Research Administration.

[FR Doc. 98-24369 Filed 9-10-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health Clinical Center (NIHCC): Opportunity for Cooperative Research and Development Agreement (CRADA) in the Fields of Magnetic Resonance Imaging, Magnetic Resonance Spectroscopy, Molecular Imaging, Image Processing, and Surgery Under Image Guidance

AGENCY: Radiology Department, NIHCC, NIH, DHHS.

ACTION: Notice of CRADA Opportunity.

SUMMARY: The Radiology Department of the National Institutes of Health Clinical Center (NIHCC), seeks Cooperative Research and Development Agreements (CRADAs) with one or more medical equipment manufacturers to collaborate on research projects designed to develop improved technologies for radiological diagnosis and treatment. The term of the CRADA will be up to four (4) years.

DATES: Interested parties should submit a brief statement indicating: (i) area(s) of proposed research collaboration and (ii) interest in submitting a formal proposal. Statements of interest should be submitted to NIHCC in writing no later than December 10, 1998. Parties will then have an additional thirty (30) days in which to submit a formal proposal.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Steve Galen, Technology Development Coordinator, National Institutes of Health, Warren Grant Magnuson Clinical Center, 6011 Executive Boulevard, suite 559B, Rockville, MD 20852. Phone: (301) 594-4509, FAX (301) 402-2143.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NIHCC pursuant to the Federal Technology Transfer Act of 1986 as amended by the National Technology Transfer Act (Pub.L. 104-113 (Mar. 7, 1996)) and by Executive Order 12591 of April 10, 1987.

The CRADA objective is the rapid publication of research findings and the timely commercialization of improved diagnostic and treatment strategies in

the fields of Magnetic Resonance Imaging, Magnetic Resonance Spectroscopy, Molecular Imaging, Image Processing, and Surgery Under Image Guidance. Particular emphasis is placed on discoveries that enhance clinical research.

Under a CRADA, the NIHCC can offer selected collaborators access to facilities, staff, materials, and expertise. The collaborator may contribute facilities, staff, materials, expertise and funding to the collaboration. The NIHCC cannot contribute funding. The CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA and may qualify as a co-inventor of new technology developed under the CRADA.

CRADA proposals will be evaluated under the following criteria:

- Corporate research and development competencies.
- Demonstrated abilities to productively collaborate in research programs.
- The nature of resources to be contributed to the collaboration.
- Key staff expertise, qualifications and relevant experience.
- Willingness to assign technical staff to on-site collaborative efforts.
- Ability to effectively commercialize new discoveries.

Dated: August 26, 1998.

Kathleen Sybert,

Acting Director, Technology Development and Commercialization Branch, National Institutes of Health.

[FR Doc. 98-24370 Filed 9-10-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

LIF And Related Cytokines That Operate Through The gp130 Receptor Pathway As A Means To Enhancing Embryo Implantation In Mammals And As An Alternative To Using Estrogen

CL Stewart, T Shatzer, T Sullivan, JR Chen, L Hernandez (NCI)

DDHS Reference No. E-166-98/0 filed 06 Jul 98

Licensing Contact: Dennis Penn, 301/496-7056 ext. 211

The present invention is directed to the use of Leukemia Inhibitory Factor (LIF), or certain other cytokines as a means for enhancing successful embryo implantation. This discovery may lead to increased success rates in normal embryonic development in human and non-human embryos following in vitro fertilization. The present invention, tested in LIF deficient mice, confirms that single injections of LIF lead to implantation and the embryo's normal development to birth. LIF may be useful as a replacement for estrogen in inducing embryo implantation. The invention indicates that LIF can substitute for estrogen in animal models, in regulating the receptibility of the uterus to the implanting embryo, and results in a significant increase in successful implantation. This technology has both human and veterinary applications.

Protection Of Neural Cells From Catecholamine-Induced Apoptosis By Macrophage Migration Inhibitory Factor (MIF)

G Wistow (NEI)

DDHS Reference No. E-028-98/0 filed 28 Jul 98

Licensing Contact: Stephen Finley, 301/496-7735 ext. 215

Macrophage Migration Inhibitory Factor (MIF) was shown to have neuroprotective properties with important implications for conditions such as Parkinson's Disease (PD). MIF is widely distributed in mammalian tissues. However, in vivo studies show that while the levels of MIF expression significantly decrease with age in most tissues, including lens, liver and kidney,

it is maintained at high levels in neural tissues, brain and retina. This suggests the possibility of an important role for MIF in aging neural tissues. It was also shown that MIF has catalytic enzyme activity towards the toxic quinones dopaminechrome (DNC), epinephrinechrome (EC) and norepinephrine (NEC) which arises by oxidation of the catecholamine neurotransmitters dopamine, epinephrine and norepinephrine. These catecholamines induce cell death by apoptosis in cultured neural cells and other cell types. It was shown that in cell culture, MIF can block this catecholamine-induced cell death. Death of catecholaminergic neurons is an important feature of PD in human brain. This suggests a physiological and/or therapeutic role for MIF in protection of neural and other cells from apoptosis induced by toxic quinones. Decreased levels of MIF in the aging brain may be a risk factor for PD and similar neurodegenerative disorders. MIF may also be involved in the synthesis of neuromelanin, which is prominent in the aging human substantia nigra, since the quinones DNC, EC and NEC are known neuromelanin precursors.

A surprising additional property of MIF was also observed. Lens epithelial cell cultures differentiated into neuronlike cells, containing neuronal cell markers, axons, and processes, upon the constitutive expression of endogenous recombinant MIF. Thus, in addition to its neuroprotective properties, MIF has potential to contribute to culture methods for neural cells that may be useful in transplantation.

G-Protein Coupled Receptor Antagonists

N Tarasova, SJ Michejda (NCI)

Serial No. 60/076,105 filed 27 Feb 98

Licensing Contact: Carol Salata, 301/496-7735 ext. 232

This invention is a potentially broadly applicable method of disrupting the functioning of G-protein coupled receptors (GPCR). GPCRs are a large family of receptors involved in the regulation of physiological activities. GPCRs have seven transmembrane regions, i.e. they cross the cell membrane seven times. The inventors have found that if a peptide consisting of one of the transmembrane regions of a GPCR with an added charged amino acid on the extracellular side, is brought into contact with a cell having the same GPCR, the functioning of the GPCR is disrupted. It is thought that the added peptide interferes with the correct assembly of the GPCR. Cells containing