DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: HRSA Competing Training Grant Application, Instructions and Relating Regulations (OMB No. 0915-0060)—Revision

The Health Resources and Services Administration uses the information in the application to determine the eligibility of applicants for awards, to calculate the amount of each award and to judge the relative merit of applications. The form is distributed electronically via the Internet. The budget is negotiated for all years of the project period based on this application and program-specific instructions that include greater standardization of content for the project summary and the detailed description of the project.

The Bureau of Health Professions is planning to remove from the Code of Federal Regulations the existing training grant regulations under 42 CFR parts 57 and 58. It is the intent of the Department to operate under new statute for compliance, implementation, and administration of the training grant programs under titles VII and VIII of the PHS Act. The existing regulations are fundamentally and extensively inconsistent with the new law which takes an interdisciplinary approach (and thus inhibits the achievement of the statute’s objectives). Program specific guidance and information for preparing applications are now provided in the grant application materials (which makes them now self-contained).

The burden estimate is as follows:

<table>
<thead>
<tr>
<th>Form</th>
<th>Number of respondents</th>
<th>Response per respondent</th>
<th>Total responses</th>
<th>Hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progress Report</td>
<td>1,250</td>
<td>1</td>
<td>1,250</td>
<td>56.25</td>
<td>70,313</td>
</tr>
</tbody>
</table>

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute (NCI) and the NIH Center for Information Technology (CIT): Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of Software Enhancement for Expanding the Medical Uses of the TELESYNERGY™ Medical Consultation WorkStation

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) and the Center for Information Technology (CIT) seek a Cooperative Research and Development Agreement (CRADA) Collaborator to provide programming and systems integration support to NCI for the further development and commercialization of the TELESYNERGY™ Medical Consultation WorkStation. Over the past six years, the Center for Information Technology at the National Institutes of Health has developed TELESYNERGY™, a multimedia medical imaging and personal interaction infrastructure within an electronic imaging environment, to facilitate professional collaboration and education concerning cancer research protocols and clinical cancer care. TELESYNERGY™ has been designed to provide for the simultaneous high-resolution display of images from numerous medical modalities, in both real-time and store-and-forward modes, as well as for the simultaneous interaction of medical experts and other research professionals. One example of implementation of TELESYNERGY™ is underway within the Radiation Oncology Branch (ROB) in the National Cancer Institute. ROB’s initial applications are in the areas of research participation in radiotherapy planning and treatment, and the related subsequent clinical and research interactions and collaborations as a result.

Potential areas of application for the TELESYNERGY™ platform include oncology, general medicine, family practice, and specialties such as OB/
GYN, cardiology, nuclear medicine, radiology, otolaryngology, ophthalmology, dermatology, urology, cytogenetics and pathology. Further development of this system will ultimately bring expanded participation in NCI clinical research and eventual improvement in clinical care to urban and rural health care systems both nationally and internationally.

DATES: Interested parties should notify Technology Development and Commercialization Branch of the NCI in writing of their interest in filing a formal proposal no later than thirty (30) days from the date of this announcement. Potential CRADA Collaborators will then have an additional thirty (30) days to submit a formal proposal. CRADA proposals submitted thereafter may be considered if a suitable CRADA Collaborator has not been selected.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Stephanie Amoroso, Ph.D., Technology Development Specialist (Tel. #301-496-0477, FAX #301-402-2117), Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into with NCI and the CIT pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995. The NCI and CIT are seeking a CRADA collaborator to further develop and integrate systems for the TELESYNERGY™ program. The proposed term of the CRADA can be up to five (5) years.

The TELESYNERGY™ system functions by transporting audio and video data streams continuously through a 155 Mbits/sec ATM and/or ISDN line link connecting the NCI and national and international sites. Microphones and speakers allow bi-directional voice communication, and video capability is provided with S-Video cameras and monitors. As stated above, if ATM capability is not available or is too expensive at a remote site, a 1.5 Mbits/sec ISDN PRI telephone circuit can utilized for connectivity, with only very minimal degradation in audio and video quality.

Two high-resolution monochrome image display systems each function as an Electronic View Box (EVB) for the display of 14 x 17 inch format digitized "electronic films." Utilizing the EVBs, discussion, diagnosis, or organ and lesion contouring can be performed via a shared-cursor technique in consultation mode, which allows the oncologists to collaborate in identifying features. These identified regions-of-interest are transmitted simultaneously and in real-time as is audio during the TELESYNERGY™ consultation session.

A remote-controlled microscope capability allows biopsy specimens to be discussed and manipulated by a number if sites concurrently. In addition, a patient exam camera allows high-resolution viewing of patient exams, including identification of dermatological lesions, skin coloration, and other physical characteristics during a patient examination.

TELESYNERGY™ also included a mechanism to allow remote consultations and education between geographically distributed medical specialists of all types Pairing the TELESYNERGY™ system with the NCI’s Net-Trials™ Clinical Trials Information System will allow Phase I and Phase II research trials to be conducted “beyond the NIH campus.” Patient protocol data may then be directly entered into the NCI’s Net-Trials™ research database from the offsite location.

NCI and the CIT are seeking a CRADA partner to collaborate with them in the further development, commercialization, education, installation and maintenance of the TELESYNERGY™ Medical Consultation WorkStation. The CRADA, with the intellectual assistance of NCI and CIT, would provide systems development and integration of TELESYNERGY™ for the applications mentioned above.

References:

Under the present proposal, the overall goal of the CRADA collaboration will involve the following:

1. To expand and enhance upon the current technology and its usage as developed by CIT and the NCI regarding the TELESYNERGY™ Medical Consultation WorkStation.
2. To provide programming support for the broad commercialization/dissemination and enhancement into other medical disciplines of the TELESYNERGY™ system.
3. To develop a distribution and service plan for the TELESYNERGY™ system.

Party Contributions

The role of the NCI/CIT in the CRADA may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
2. Providing the CRADA Collaborator with information and data relating to the current methods implemented for the applications of TELESYNERGY™.
3. Publishing research results.
4. Development additional potential clinical applications for the TELESYNERGY™ system.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise or experience to the research project.
2. Providing programming support for writing novel software, and technical support for writing system manuals.
3. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.
4. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not limited to:

1. A demonstrated record of success in the development and dissemination of medical software.
2. A demonstrated background and expertise in ATM-ISDN based technology.
3. The ability to collaborate with NCI/CIT on further research and development of this technology. This ability will be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
4. The demonstration of adequate resources to perform the research and development of this technology (e.g. facilities, personnel and expertise) and to accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator’s proposal.
5. The willingness to commit best effort and demonstrated resources to the research and development of this
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. 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.

ADDRESS: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting John Rembosek, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 270; fax: 301/402–0220; e-mail: jr312d@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods and Compositions for Correlating CCR5 Expression With Essential Hypertension

Dr. Thomas O’Brien (NCI)
DHHS Reference Number E–257–99/0
filed October 14, 1999

Hypertension is a disease which afflicts as many as 1 in 5 persons in the United States and is the most common cause of visits to physicians. Once diagnosed with hypertension, treatment of the disease is lifelong. There is mounting evidence that lifestyle changes can prevent the usual rise in blood pressure with age, but for patients whose hypertension cannot be adequately treated by lifestyle changes, drug therapy must be instigated which can be difficult to control and have adverse side effects.

The present invention mutation in the CC-chemokine receptor 5 (CCR5) gene and an increased risk of developing hypertension. This technology will allow for the screening of individuals for the presence of the CCR5–D32/D32 genotype which correlates with an increased risk of developing hypertension and possibly prevent its occurrence through adequate antihypertensive therapy.

This technology may lead to a method of treating or preventing hypertension through the administration of: (1) an effective amount of a CCR5 expression enhancing agent; (2) CCR5 activity enhancing agent; (3) an effective amount of CCR5; or (4) an effective amount of a nucleic acid encoding CCR5. Also, this technology can be employed as a method of identifying an agent that could be used to treat or prevent hypertension through the above identified processes.

Cloning of the Human Nuclear Receptor Co-Repressor Gene

Johnson M. Liu, Jianxiang Wang (NHLBI)
DHHS Reference No. E–088–99/0
filed August 3, 1999

Alteration in the expression of human genes is critical to the development and progression of many diseases. These include, among others, cancer, inflammation, cardiovascular disease, hypercholesterolemia, high blood pressure, and diabetes. The Human Nuclear Receptor Co-Repressor (Hun-Cor) gene represents a technology that may be used to alter the transcription of genes. It provides a general mechanism by which many genes may be modulated throughout the entire range of being turned on to being completely turned off. The Hun-Cor gene is a ubiquitously expressed gene that codes for a protein that silences other genes. It does this by recruiting an enzyme complex that causes local folding of chromatin, not allowing other transcription factors to work. Hun-Cor represents a powerful research tool that can be used to study gene expression and characterization for many different genes. It may also be useful as a target for the isolation of pharmaceutical compounds that enhance or inhibit expression of genes.

Dated: April 7, 2000.

Jack Spiegel,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 00–9430 Filed 4–14–00; 8:45 am]

BILLING CODE 4140–01–M