Description: Wisconsin proposes to limit the amount of exempt funds that may be set aside as burial and related expenses for SSI-related Medicaid beneficiaries.

Date Received: March 9, 1994.

State Contact: Jean Sheil, Division of Economic Support, Wisconsin Department of Health and Social Services, 1 West Wilson Street, Room 650, P.O. Box 7850, Madison, WI 53707, (608) 266–0613.

Federal Project Officer: J. Donald Sherwood, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–16–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

3. Approved Conceptual Proposals (Award of Waivers Pending)

No conceptual proposals were awarded during the months of August and September.

4. Approved Proposals

No proposals were approved during the months of August and September.

5. Disapproved Proposals

No proposals were disapproved during the months of August and September.

6. Withdrawn Proposals

No proposals were withdrawn during the months of August and September.

IV. Requests for Copies of a Proposal

Requests for copies of a specific Medicaid proposal should be made to the State contact listed for the specific proposal. If further help or information is needed, inquiries should be directed to HCFA at the address above.

(Catalog of Federal Domestic Assistance Program, No. 93.779; Health Financing Research, Demonstrations, and Experiments)

Dated: November 30, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–30066 Filed 12–8–95; 8:45 am]

BILLING CODE 4120–01–P

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Licensing Opportunity and/or Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of Influenza A PB2 Gene Technology

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

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking licensees and/or CRADA Collaborators for the joint research, development, evaluation, and commercialization of its influenza A polymerase basic 2 (PB2) patent portfolio. The inventions claimed in U.S. Patent Application Serial No. 08/123,933 (''Method for Generating Influenza A Viruses Bearing Attenuating Mutations in Internal Protein Genes,'' filed September 20, 1993), and its related patent applications, are available for either co-exclusive or non-exclusive licensing (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) and/or further development under one or more CRADAs for important clinical and research applications described below in the Supplementary Information section.

DATES: License applications must be received on or before March 11, 1996. CRADA proposals should be received on or before April 11, 1996 *for priority consideration*. However, CRADA proposals submitted thereafter will be considered until a suitable CRADA Collaborator is selected.

ADDRESSES: CRADA proposals and questions about this opportunity should be addressed to: Claire T. Driscoll, Technology Transfer Manager, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 3B62, 9000 Rockville Pike, Bethesda, MD 20892; Telephone: 301/496–2644; Fax: 301/402–7123; E-mail: cd68y@nih.gov.

Licensing proposals and questions about this opportunity should be addressed to: Cindy K. Fuchs, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301/496–7735 ext. 232; Fax: 301/402–0220; E-mail: Cindy__Fuchs@nih.gov.

Information on the patent applications and pertinent information not yet publicly disclosed can be obtained under a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondees interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA agreement.

SUPPLEMENTARY INFORMATION: This invention involves the use of modern molecular virologic techniques to introduce temperature sensitive (ts) attentuating mutations into a complementary DNA (cDNA) copy of the influenza A polymerase basic 2 (PB2) protein gene and to recover viruses bearing the mutant PB2 gene. Viral RNA (vRNA) transcribed in vitro from the PB2 DNA is transfected into avian kidney cells in the presence of an influenza A helper virus. The PB2 gene of the helper virus, which restricts its replication in mammalian cells, is substituted by the transfected mutant PB2 gene, which is known to function efficiently in mammalian cells. Using this system it has been possible to introduce three attenuating temperature sensitive mutations into the PB2 gene and to recover an infectious virus bearing this triple mutant gene. The virus bearing this mutant gene was highly attenuated in animals, was stable genetically even after prolonged replication in immunosuppressed rodents, and induced resistance to challenge with wild type influenza A virus. This gene can now be transferred from a donor virus to new epidemic or pandemic variants of influenza A virus as they appear in nature. The end result is a live attenuated reassortant influenza A virus vaccine that not only contains an attenuating PB2 gene from the attenuated donor but also the protective antigens, i.e., the hemagglutinin and neuraminidase glycoproteins, from the newly emerged wild type virus. Such a reassortant virus can serve as a protective vaccine, when administered into the respiratory tract of a vaccine, against disease caused by the epidemic influenza A viruses.

To speed the research, development, and commercialization of these agents, the NIH is seeking one or more license agreements and/or CRADAs with pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed agents. Proposals relating to any biomedical area will be considered.

The CRADA aims will include the rapid publication of research results consistent with protection of proprietary information and patentable inventions as well as the timely exploitation of commercial opportunities. The CRADA Collaborator will enjoy the benefits of first negotiation for licensing Government rights to any inventions arising under the agreement and will advance funds payable upon signing the CRADA to help defray Government expenses for patenting such inventions and other CRADA-related costs.

The role of the National Institute of Allergy and Infectious Diseases will be as follows:

1. Provide the PB2 technology to the CRADA Collaborator.

2. Jointly develop a series of donor viruses containing the mutant PB2 gene with or without a second non-hemaglutinin (HA), non-neuraminidase (NA) attenuating gene.

3. Jointly produce a series of reassortants bearing current H1 or H3 hemagglutinins (HAs) for evaluation in clinical trials in humans.

4. Jointly produce experimental vaccines and evaluate them in clinical trials.

The role of the Collaborator(s) will be to:

1. Participate in joint activities 2–4 above.

2. Evaluate a variety of mammalian cell lines for production of live attenuated virus vaccines in lieu of production in the allantoic cavity of eggs.

Selection criteria for choosing the CRADA Collaborator(s) will include but are not limited to the following:

1. The ability to collaborate with the NIAID on further research and development of this technology. This ability can be demonstrated through experience and expertise in this and related areas of technology.

2. The demonstration of adequate resources to perform the research, development, and commercialization of this technology (e.g., personnel, expertise, and facilities) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. The ability to perform clinical testing or trials, and obtain IND, ELA/PLA and FDA approval for a new vaccine or other products based on this technology.

4. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this technology.

5. The level of financial support to CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the NIAID in the timely publication of research results consistent with the protection of proprietary information and patentable inventions that may arise during the period of the CRADA.

7. Agreement to be bound by DHHS rules and regulations involving human subjects, patent rights, ethical treatment of animals, and randomized clinical trails.

8. The willingness to accept the language and legal provisions of the NIH model CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to any inventions developed under the CRADA. Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with (1) The grant of an irrevocable, non-exclusive, royalty-free license for research purposes to the Government when the CRADA Collaborator's employee(s) is/are the sole inventor(s), or (2) the grant of an option to negotiate an exclusive or non-exclusive license to the CRADA Collaborator when a Government employee(s) is/are the sole inventor(s).

Dated: November 30, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95–30004 Filed 12–8–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of the rescheduling of the meeting of the Ad Hoc Clearinghouse Subcommittee of the National Deafness and Other Communication Disorders Advisory Council, the notice of which was published in the Federal Register 60 FR 55849 on November 3, 1995. This meeting could not be convened on November 16 due to the partial shutdown of the Federal Government. It is rescheduled for December 18 from 11:00 a.m. to 1:00 p.m., as a telephone conference call originating in room 3C05, Building 31, 9000 Rockville Pike, Bethesda, Maryland. The meeting will be open to the public, limited to space available.

Dated: December 4, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–30001 Filed 12–8–95; 8:45 am]

BILLING CODE 4140–01–M

Consensus Development Conference on Physical Activity and Cardiovascular Health

Notice is hereby given of the NIH Consensus Development Conference on ''Physical Activity and Cardiovascular Health,'' which will be held December 18–20, 1995, in the Natcher Conference Center of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:30 a.m. on December 18, at 8 a.m. on December 19, and at 9 a.m. on December 20.

Over the past 25 years, the United States has experienced steady declines in the death toll from cardiovascular disease (CVD), primarily in coronary heart disease and stroke. Despite these declines, heart disease remains the number one and stroke the third leading cause of death. Lifestyle improvements by the American public and better control of the risk factors for heart disease and stroke have been a major factor in this decline.

Cardiovascular disease is of multifactorial etiology. Modifiable risk factors include high blood pressure, high blood cholesterol, obesity, smoking, diabetes, and physical inactivity. In contrast to the positive trends observed with the reduction of high blood pressure and high blood cholesterol, overweight and physical inactivity have been on the increase. In light of this, the accumulating evidence of the risk of cardiovascular disease associated with a sedentary lifestyle and the role of physical activity in the prevention and treatment of CVD and other CVD risk factors needs to be examined.

In 1991, 58 percent of adults reported that they exercised sporadically or not at all. Data from the 1990 Youth Risk Behavior Survey suggests that adolescents are less active than they were a decade ago. Only 37 percent of teenagers in grades 9 through 12 reported performing at least 20 minutes of vigorous exercise at least three or more times per week. About 50 percent of students reported they did not participate in physical education (PE) classes. Of those who reported participating in PE classes, 25 percent said they do not do any physical activity.

Physical activity not only independently protects against the development of cardiovascular disease but also has effects through the CVD risk factors of high blood pressure, high blood cholesterol, diabetes mellitus/insulin resistance, and overweight. The type, frequency, and intensity of the physical activity, however, remains controversial. Some experts suggest that moderate forms of physical activity can help prevent cardiovascular disease, while others suggest it must be vigorous and sustained.

Physical activity is also important in the treatment and management of patients with CVD or its risk factors, including patients who have stable angina, have suffered a myocardial infarction, or have heart failure. Physical activity is an important component of cardiac rehabilitation but questions remain regarding the type, frequency, and intensity needed for patients.

In addition, to potential benefits, questions remain regarding risks