

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-hemagglutinin (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 trials.

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