request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on (a) whether the agency needs to collect the proposed information to properly perform its functions and whether the information has any practical utility; (b) whether the agency's estimate of the burden of the proposed collection of information is accurate; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information for respondents (*e.g.,* by using automated collection techniques or other forms of information technology).

Proposed Project: Ryan White CARE Act Dental Reimbursement Program (OMB No. 0915–0151)—Revision

The Dental Reimbursement Program (DRP) under Part F of the Ryan White CARE Act offers grants to accredited dental schools and programs that provide non-reimbursed oral health care to patients with HIV disease. The Ryan White CARE Act Amendments of 2000 expanded eligibility of this program to accredited schools of dental hygiene, in addition to previously funded schools of dentistry and post-doctoral dental education programs.

HRSA requests a revision to the DRP Application that schools and programs use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV. Awards are authorized under section 776(b) of the Public Health Service Act (42 U.S.C. 294n). The 2001 DRP Application is intended to collect data in three different areas: program information, patient demographics and services, and reimbursement and funding. It also requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

The primary purpose of collecting this information annually, as part of the DRP Application, is to verify eligibility and determine the reimbursement amount each applicant should receive. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive CARE Act-supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) how applicants intend to use DRP funds once they are received. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected in the DRP Application is critical for HRSA, State and local grantees, and individual providers, to help assess the status of existing HIV-related health service delivery systems.

The reporting burden for reviewing the DRP Application Instructions and completing the Application Form is estimated as:

Collection	Number of responsents	Hours per application	Total burden hours
Reimbursement Request	125	20	2500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 30, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–11236 Filed 5–3–01; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): Opportunity for Cooperative Research and Development Agreements (CRADAs) To Perform Intervention Studies To Preserve Pancreatic Beta Cell Function and Prevent Type 1 Diabetes

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

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) is seeking proposals in the form of capability statements from potential collaborators for a Cooperative Research and Development Agreement (CRADA) to perform intervention studies to preserve pancreatic beta cell function and prevent type 1 diabetes. The clinical research will execute pilot and expanded studies of new agents to prevent or ameliorate type 1 diabetes in populations screened for or enrolled in these studies.

Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company to perform intervention studies to preserve pancreatic beta cell function and prevent type 1 diabetes.

The potential Collaborator(s) capability statement should provide proof of expertise in the design and implementation of new intervention studies of Type 1 Diabetes and should include the scientific rationale for the study proposed, the population to be studied, eligibility and exclusion criteria for the study, possible strategies for patient recruitment and data collection methods, primary and secondary endpoints to be determined, and a discussion of the sample size required given associated assumptions. The scientific rationale should include a discussion of what is the current ''state-of-the-art'', future opportunities, and obstacles in the prevention of type 1 diabetes, and discuss how the field may best be moved forward.

DATES: Only written CRADA capability statements received by the NIDDK on or before July 1, 2001 will be considered; confidential information must be clearly labeled. Potential Collaborators may be invited to meet with the Selection Committee at the Collaborator's expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity. This notice is directed toward companies with resources to support collaborations.

FOR ADDITIONAL INFORMATION AND QUESTIONS: Capability statements should be submitted to Dr. Michael W. Edwards, Office of Technology Development, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, BSA Building, Suite 350 MSC 2690, 9190 Rockville Pike, Bethesda, MD 20814–3800; Tel: 301/496–7778, Fax: 301/402–0535; Email: mels@nih.gov.

SUPPLEMENTARY INFORMATION: A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. The NIDDK is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NIDDK can contribute facilities, staff, materials, and expertise to the effort. The collaborator typically contributes facilities, staff, materials, expertise, and funding to the collaboration. The CRADA collaborator receives an exclusive option to negotiate an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA in a pre-determined field of use and may qualify as a co-inventor of new technology developed under the CRADA.

Study Organization: The Type 1 Diabetes TrialNet, or TrialNet, will be a national network of cooperative clinical research groups, consisting of a consortia of clinical centers and core support facilities, whose aim is to recruit patients and to support studies that may eventually result in an improved understanding of type 1 diabetes and the prevention of the disease.

Applicants must include a description of investigators and staff with experience and expertise to collaborate in multicenter clinical trials and Phase II and Phase III studies to assess interventions for preventing or ameliorating type 1 diabetes. Applicants should describe their ability to lead clinical trials that could be performed using Type 1 Diabetes TrialNet resources. Applicants must give evidence of their ability and experience to conduct multicenter clinical trials, with prediabetic or diabetic subjects. If applicants have particular expertise and accomplishments in recruiting individuals from minority groups, these should be described.

Applicants should provide a detailed description of the design of the proposed study, including what eligibility, baseline, and follow-up tests are to be done, what surrogate markers and endpoints will be examined, and the duration of follow-up. Examples of data forms and questionnaires proposed should be given. The process for biologic sample collection, storage and handling needs must be included. A description of the laboratory tests that are needed with appropriate methods for performing them should be provided, as well as other core facilities and interactions with core facilities that are needed. Also included should be the methods that would be used to assure privacy and maintain confidentiality of data. Sample size needs and the criteria and calculations used to estimate sample sizes should be detailed.

Capability Statements: A Selection Committee will utilize the information provided in the ''Collaborator Capability Statements'' received in response to this announcement to help in its deliberations. It is the intention of the NIDDK that all qualified Collaborators have the opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

(1) The statement should provide specific details of the method to be utilized in the investigation of promising new approaches to prevent or ameliorate type 1 diabetes.

(2) The statement should include a detailed plan demonstrating the ability to provide sufficient quantities of the agent in a timely manner for the duration of the study.

(3) The statement may include outcome measures of interest to the Collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to the following: Promising new approaches to prevent or ameliorate type 1 diabetes, specific funding commitment to support the advancement of scientific research, Personnel, services, facilities, equipment, or other resources that would contribute to the conduct of the commercial development.

(4) The statement must address willingness to promptly publish research results and ability to be bound by PHS intellectual property policies (see CRADA: http://ott.od.nih.gov/newpages/crada.pdf).

Dated: April 26, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01–11189 Filed 5–3–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Clinical Trials Review Committee.

Date: June 17–19, 2001.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Joyce A. Hunter, Ph.D, Review Branch, Room 7192, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892–7924, 301/435–0277.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 27, 2001.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–11182 Filed 5–3–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,