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]

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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]

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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.

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