DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) Announces the Opportunity for Clinical Trial Agreements (CTA) in Conjunction with a Major Multicenter Clinical Trial Aimed at Developing Practical, Safe and Effective Means of Preventing the Progression of Liver Disease in Patients With Chronic Hepatitis C Virus (HCV) Infection

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

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) seeks capability statements from parties interested in entering into a potential Clinical Trial Agreement (CTA) to provide agent for treating subjects in the Hepatitis C Clinical Trial (HCCT). Collaborator applicants developing capability statements must also include plans for packaging, labeling, and distributing agent and placebo. The primary criterion for selecting a potential Collaborator is the scientific merit of proposals for use of preventing the progression of liver disease in patients with chronic hepatitis C virus infection.

The control of the HCCT shall reside entirely with the Institute and the scientific participants of the trial. In the event that any adverse effects are encountered which, for legal or ethical reasons, may require communication with the FDA, the relevant collaborating institutions will be notified. Neither the conduct of the trial nor the results should be represented as a NIDDK endorsement of the drug under study.

DATES: Only written Capability Statements received by the NIDDK on or before August 1, 1999 will be considered during the initial design phase. 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 opportunity during the design of the trial if circumstances change or if the trial design alters substantially.

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: The HCCT will be conducted as collaborative contracts among nine (9) Clinical Centers (CCs) a central data coordinating (DCC) with biostatistical expertise and with input from a hepatologist, and a central virological testing laboratory (VL). The HCCT will be designed to evaluate whether continuous long-term antiviral therapy can slow the progression of liver disease, preventing cirrhosis or preventing worsening of cirrhosis, decompensation, development of hepatocellular carcinoma (HCC) and death from liver disease. The Trial will also evaluate the natural history of hepatitis C and the factors that predict or correlate with disease progression. The major focus will be to evaluate whether antiviral therapy, despite not leading to eradication of HCV, can suppress hepatocellular injury, necrosis and fibrosis.

HCCT is expected to recruit approximately 800 patients with chronic hepatitis C who have failed to respond to therapy with alpha interferon (with or without ribavirin) and who have significant fibrosis on liver biopsy. The carefully designed cohort of patients will be enrolled in a study of the efficacy and safety of a continuous long-term antiviral therapy (for as long as four years)

Capability Statements

The design concept described above is not final. The final design will be developed over the course of the first year of the trial by the HCCT Steering Committee (which will include the Principal Investigators of the Clinical Centers, the Data Coordinating Center, the Virology Laboratory and the NIDDK Project Officer). It is possible that the final design for HCCT may include more than one agent.

A Selection Committee will utilize the information provided in the ''Collaborator Capability Statements'' received in response to this announcement to help in its deliberations. The Selection Committee will interact with the Steering Committee to develop the most appropriate design, based on a thorough understanding of the efficacy and side effects associated with all agents proposed.

It is the intention of the NIDDK that qualified Collaborators have the opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 8 pages and should address the following selection criteria:

(1) The statement should provide specific details regarding the safety and efficacy of the proposed agent for long-term use in hepatitis C patients.

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

(3) The statement should outline plans for packaging, labeling, and distributing the agent along with placebo. The statement should describe the commitment of other resources such as scientific research, personnel, services, facilities, or equipment that would be used to support conduct of the trial.

(4) The statement must address willingness to promptly publish research results and ability to be bound by PHS policies.

Dated: June 4, 1999.

L. Earl Laurence,

Deputy Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4445–N–16]

Proposed Information Collection: Comment Request; Application for Fee Personnel Designation—VA, Fee or Roster Designation—HUD–92563

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Coments due date: August 10, 1999.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, Room 4176, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Vance Morris, Director, Home Mortgage