Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 2, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–32514 Filed 12–7–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Licensing Opportunity and/or Cooperative Research and Development Agreement (CRADA) Opportunity to Develop a Hepatitis C virus (HCV) Vaccine Based Upon the Synthesis and Purification of Non-infectious HCV-like Particles Containing HCV Structural Proteins

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 licensees and/or capability statements from parties interested in entering into a Cooperative Research and Development Agreement (CRADA) to develop a hepatitis C virus (HCV) vaccine based on in the synthesis, large scale production and purification of non-infectious HCV-like particles containing HCV structural proteins (Baumert, TF et al. 1998, J. Virol. 72:3827–3836).

The invention claimed in DHHS Reference No. E–009–97/0, ''Synthesis and Purification of Hepatitis C Virus-Like Particles In Vitro'' (TJ Liang, TF Baumert), field 08 Nov 96, is available for licensing (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) and/or further development under one or more CRADAs in the clinically important applications described below in the **SUPPLEMENTARY INFORMATION** section.

DATES: Only written CRADA capability statements received by the NIDDK on or before March 1, 1999 will be considered. There is no deadline by which license applications must be received.

ADDRESSES: Capability statements should be submitted to Dr. Michael W. Edwards, Office or Technology Development, National Institute 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; Electronic mail: mels@nih.gov.

Questions about the licensing opportunity, copies of the patent application, or requests for license applications should be addressed to Carol Salata, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852–3804; Tel: 301/496–7057 ext. 232; Fax: 301/402–0220; Electronic mail: cs253n@nih.gov.

SUPPLEMENTARY INFORMATION: HCV is a major causative agent of post-transfusion and community-acquired non-A, non-B hepatitis world-wide. About 4 million people in the U.S. and probably more than 100 million worldwide are infected with HCV. The majority of HCV infected individuals become persistently infected and many develop chronic hepatitis which progresses eventually to liver cirrhosis and hepatocellular carcinoma.

HCV is a member of the flavivirus family. The HCV viron contains a positive-strand RNA genome of 9.5 kilobases including a highly conserved 5′ non-coding region followed by a long open reading frame of 9030 to 9099 nucleotides that is translated into a single polyprotein about 3,010 to 3030 amino acids long. Although the viral genomic organization has been characterized in detail, morphologic analysis of hepatitis C virus has been hampered by low levels of HCV particles in infected patients and the inability to propagate efficiently the virus in cultured cells. The levels of the viral particles present in infected patient plasma and/or liver tissues are very low, making it difficult to visualize the virus. Studies of HCV infection in chimpanzees, a reliable animal model for hepatitis C, have provided evidence that HCV is inactivated by chloroform, indicating that it contains lipids and therefore is probably enveloped. Filtration studies have estimated the viron particle size to be about 30–60 nm in diameter.

Under the CRADA the synthesis, large scale production, and purification of HCV virus-like particles will be optimized and the agent evaluated in a series of preclinical studies in animals as well as initial safety testing in humans. Positive outcomes of these studies will indicate continued clinical development aimed at supporting regulatory approval of a product to be labeled for use in humans.

NIDDK's principal investigator has extensive experience with recombinant technology as applied to the synthesis, purification and testing of HCV-like particles. The Collaborator in this endeavor is expected to assist NIDDK in evaluating its current system for producing HCV vaccine formulation and to develop and optimize adjuvants, if necessary, to manufacture sufficient quantities of the product for preclimical testing in animals and initial safety studies in humans. The Collaborator must have experience in the manufacture of vaccine formulations according to applicable FDA guidelines and Points to Consider documents to include Good Manufacturing Procedures (GMP). In addition, it is expected that the Collaborator would provide funds to supplement the NIDDK PI's research budget for the project and to support the preclinical and initial human testing.

The capability statement should include detailed descriptions of: (1) Collaborator's expertise in vaccine formulation and development, (2) Collaborator's ability to manufacture sufficient quantities of the product according to FDA guidelines and Points to Consider documents, (3) the technical expertise of the Collaborator's principal investigator and laboratory group in preclinical safety testing (e.g., expertise in in vitro and in vivo toxicity, efficacy and pharmacology studies) and initial human safety studies, and (4) Collaborator's ability to provide adequate funding to support preclinical and initial human safety studies required for marketing approval.

The Public Health Service (PHS) has filed patent applications both in the U.S. and internationally related to this technology. Notice of the availability of the patent applications for licensing was first published in the **Federal Register** on January 28, 1998 (63 FR 4274). Information about the patent applications and pertinent information not yet publicly described may 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.

Dated: December 1, 1998.

Jack Spiegel,

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

[FR Doc. 98–32491 Filed 12–7–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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: National Center for Research Resources Special Emphasis Panel Biomedical Research Technology

Date: February 11–12, 1999

Time: February 11, 1999, 8:00 AM to Adjournment

Agenda: To review and evaluate grant applications

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814

Contact Person: John L. Meyer, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, 301–435–0822

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306, 93.333, Clinical Research, 93.333, 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: December 1, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32493 Filed 12–7–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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: National Human Genome Research Institute Special Emphasis Panel

Date: December 11, 1998

Time: 3:00 PM to 5:00 PM

Agenda: To review and evaluate grant applications

Place: National Human Genome Research Institute, National Institutes of Health, Building 38A, Room 609, Bethesda, MD 20892, (Telephone Conference Call)

Contact Person: Ken D. Nakamura, PHD, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, (301) 402–0838

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS).

Dated: December 1, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32494 Filed 12–7–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice if 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: National Institute of Mental Health Special Emphasis Panel

Date: December 15, 1998

Time: 2:00 PM to 4:00 PM

Agenda: To review and evaluate grant applications

Place: Parklawn Building—Room 9–101, 5600 Fishers Lane, Rockville, MD 20857, (Telephone Conference Call)

Contact Person: Russell E. Martenson, PHD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Parklawn Building, 5600 Fishers Lane, Room 9–101, Rockville, MD 20857, 301–443–3936

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: December 1, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32492 Filed 12–7–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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.