DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement for the National Emerging Infectious Diseases Laboratories Facility in Boston, MA

AGENCY: National Institutes of Health, (NIH), DHHS.

ACTION: Notice of intent to prepare an environmental impact statement for the National Emerging Infectious Diseases Laboratories facility in Boston, MA.

SUMMARY: The Department of Health and Human Services (DHHS), National Institutes of Health (NIH), announces its intent to prepare an environmental impact statement (EIS) to evaluate a proposed new National Emerging Infectious Diseases Laboratories facility in Boston, MA. This EIS is being prepared and considered in accordance with the requirements for the National Environmental Policy Act (NEPA) of 1969, regulations of the President's Council on Environmental Quality (40 CFR parts 1500–1508), and NEPA Compliance Procedures of the DHHS General Administration Manual, Part 30 (Environmental Protection) 25 February 2000.

Cooperating Agencies: There are no cooperating agencies for this project.

SUPPLEMENTARY INFORMATION: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the NIH, conducts and supports research of infectious diseases and the human immune system. Its resources and expertise have been applied to studying emerging infectious diseases such as SARS, West Nile virus and Lyme disease and organisms that might be used as agents of bioterrorism such as anthrax and tularemia. Knowledge of how these organisms cause disease and the response of the immune system to those organisms is desperately needed. This knowledge will be used to develop new and improved diagnostic tests, vaccines, and therapies to protect civilians.

Since fall 2001, NIAID has greatly accelerated its biodefense research program. Achievement of the research goals requires the construction and certification of biological containment laboratories with facilities and procedures for handling potentially lethal agents. Equally important is the need to minimize potential threats from infectious agents to laboratory and clinical personnel working within these facilities and to adjacent communities. The Federal Government has awarded a grant in the amount of $128 million to partially fund the National Emerging Infectious Diseases Laboratories facility in Boston, MA as a crucial element of this NIH initiative.

This proposed action is the funding of the construction of the National Emerging Infectious Diseases Laboratories in Boston, MA, a new building comprised of laboratories designed and constructed to Biosafety Levels –2, –3, and –4 standards that will allow translational and clinical research on emerging infectious diseases including agents of bioterror. The proposed new facility will have imaging capabilities and will include administrative support offices. It will occupy approximately 3 acres on the BioSquare Medical Research campus at 600–620 Albany Street, Boston, MA and will be located on the Boston University Medical Center campus.

Significant issues to analyzed in the EIS will include safety of laboratory operations; public health and safety; handling, collection, treatment, and disposal of biomedical research waste related to the proposal; and analysis of other risks, as well as concerns for pollution prevention and impacts of the proposed action on air quality, biological resources, cultural resources, water resources, land use, and socioeconomic resources. The No Action alternative under which the new facility would not be built will also be considered. Additional alternatives may be identified during the Scoping Process.

Publication Participation: The DHHS will invite full public participation to promote open communication and better decision-making. All interested persons and organizations, including minority, low income, disadvantaged, and Native American groups, are urged to participate in this NEPA environmental analysis process. Assistance will be provided upon request to anyone having difficulty with learning how to participate.

To ensure that the full range of issues related to the proposed action and the scope of this EIS are addressed, oral and written comments are invited from all interested parties, including appropriate Federal, state, and local agencies and private organizations and citizens. Pursuant to this, a Public Scoping meeting will be held on Monday, January 26, 2004 from 7 to 9 p.m. in the auditorium at the Thomas P. O'Neil, Jr. Federal Building, 10 Causeway Street, Boston, MA.

Comments on the scope of the EIS for the proposed project should be received no later than January 28, 2004. Comments and questions should be directed to the address listed below. Public comments are welcomed anytime throughout the NEPA process and should be directed to the address listed below. Additional formal opportunities for public participation after the Public Scoping are tentatively scheduled as follows:

Review and comment on Draft EIS (including a public meeting): Spring, 2004.

Review of Final EIS: Summer, 2004.

Notices of availability for the Draft EIS, Final EIS and Record of Decision will be provided through direct mail, the **Federal Register**, and other media. Notification also will be sent to Federal, State, and local agencies and persons organizations that submit comments or questions. Precise schedules and locations for public meetings will be announced in the local news media. Interested individuals and organizations may request to be included on the mailing list for public distribution of meeting announcements and associated documents.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief, Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities, National Institutes of Health, DHHS, B13/2W64, Bethesda, MD 20892; by telephone 301–496–7775; fax 301–480–8056; or e-mail *nottingv@ors.od.nih.gov*.

Dated: January 5, 2004.

Stephen A. Ficca,

Associate Director for Research Services, National Institutes of Health.

[FR Doc. 04–452 Filed 1–8–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute (NHLBI): Opportunity for Cooperative Research and Development Agreements (CRADAs) to Develop Novel Mechanical and Biological Treatments in Interventional Cardiovascular Medicine Using X-ray Fluoroscopy and/or Real-Time Magnetic Resonance Imaging

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) announces the opportunity for Cooperative Research and Development Agreements (CRADAs) to develop novel mechanical and biological treatments in

interventional cardiovascular medicine using x-ray fluoroscopy and real-time magnetic resonance imaging. The NHLBI seeks potential collaborators wishing to provide expertise in (1) novel biological treatments for cardiovascular disease, including agents to facilitate mobilization of bone-marrow-derived stem and progenitor cells, (2) novel agents for therapeutic angiogenesis for myocardial or peripheral artery applications, (3) novel immune-modulating agents to treat or prevent manifestations of atherosclerosis, coronary artery occlusion, or myocardial ischemia/infarction, (4) novel mechanisms of drug, gene, or cell delivery to the myocardium or skeletal muscle to treat manifestations of coronary or peripheral artery atherosclerosis, and (5) intravascular devices for real-time magnetic resonance imaging-guided treatments including but not limited to angioplasty balloons, recanalization systems, percutaneous cardiac valves, stents, endografts, and bypass grafts.

The NHLBI seeks capability statements from parties interested in entering into a potential CRADA to manufacture, prototype, and test the above-specified agents or devices leading to early clinical testing and development. The availability of private sector support may increase the feasibility of particular aspects of the final design, but the primary criterion for selecting potential collaborators is the scientific merit of proposals for developing a plan to identify novel putative therapeutic agents and devices.

The NHLBI can provide extensive preclinical and clinical support in the development of collaborator deliverables, including animal experiments, advanced x-ray fluorscopic and magnetic resonance imaging laboratories, and investigations conducted in the Warren G. Magnuson Clinical Center at the Bethesda campus of the National Institutes of Health.

The control of clinical trials 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 U.S. Food and Drug Administration, the relevant collaborating institutions will be notified. Neither the conduct of the trial nor the results should be represented as an NHLBI endorsement of the agent, drug, or device under study.

DATES: Only written CRADA capability statements received by the NHLBI within 21 days of publication of this notice will be considered during the initial design phase. Confidential information must be clearly labeled. Potential collaborators may be invited to meet with the Selection Committee at the Collaborators' expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity during the design phase if circumstances change or if the design alters substantially.

FOR FURTHER INFORMATION CONTACT: Capability statements should be submitted to Ms. Peg Koelble, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892–7992; Tel: 301–594–4095; Fax: 301–594–3080; e-mail: *koelblep@nhlbi.nih.gov.*

Capability Statements: A selection committee will use 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 NHLBI 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 used in the development of novel candidate biological treatments, delivery systems, or real-time MRI-guided mechanical treatments for cardiovascular disease.

2. The statement should include a detailed plan demonstrating the ability to provide sufficient capacity in drug, gene, or stem cell development and manufacturing or in mechanical device prototyping, testing, development, and manufacturing.

3. The statement may include outline measures of interest to the collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to: expertise in the proposed field, specific personnel allocation to the proposed collaboration, specific internal or external funding commitment to support the advancement of scientific research, services, facilities, equipment, or other resources that would contribute to the conduct of the commercial development.

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

Dated: January 2, 2004.

Carl Roth,

Associate Director for Scientific Program Operation, National Heart, Lung, and Blood Institute.

[FR Doc. 04–451 Filed 1–8–04; 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: National Heart, Lung, and Blood Institute Special Emphasis Panel, SCCOR in Cardiac Dysfunction and Disease Review.

Date: February 23–25, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaitherburg, MD 20878.

Contact Person: William J Johnson, PhD, Review Branch, Division of Extramural Affairs, National Heart, Lung and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7184, MSC 7924, Bethesda, MD 20892, 301/435–0275.

(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: January 2, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–446 Filed 1–8–04; 8:45 am]

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