

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 fluoroscopic 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]

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: 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, Gaithersburg, 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]

BILLING CODE 4140-01-M