Dated: November 26, 2003.

Julie Brown,

Acting, Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

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BILLING CODE 4120–03–P

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 to 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 Additonal Information and Questions: 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; email: *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 commerical 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/newpages/crada.pdf*).

Dated: November 26, 2003.

Carl Roth,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive