

Written comments will be available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and FTC regulations, 16 CFR 4.9, Monday through Friday between the hours of 8:30 a.m. and 5 p.m. at the Public Reference Room, Room 130-H, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580. This notice and, to the extent possible, all comments will also be posted on the FTC Web site, <http://www.ftc.gov>.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

AGENCY: National Heart, Lung, and Blood Institute.

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 adult-derived stem cell and cardiovascular progenitor cells, (2) novel agents for therapeutic angiogenesis for myocardial or peripheral artery applications, (3) novel mechanisms of drug, gene, or cell delivery to the myocardium or skeletal muscle to treat manifestations of coronary or peripheral artery atherosclerosis, and (4) 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. Collaborator applicants developing capability statements may also include proposals to provide funding for possible commercial uses of interest to the Collaborator. 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, 31 Center Drive, Room 1B30, Bethesda, MD 20892-2490; 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/newpages/crada.pdf>).

Dated: December 6, 2002.

Carl Roth,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

The National Toxicology Program (NTP) Announces the Availability of the Report on Carcinogens, Tenth Edition

The Report on Carcinogens, Tenth Edition was submitted to the Congress by the Secretary HHS and also released publicly on December 11, 2002. It is available on the Internet and can be accessed from the Environmental Health Perspectives web site at: <http://www.ehponline.org> or from the NTP