

34. Evangelina Guzman-DeMello on behalf of Jeremy Xavier DeMello, St. Paul, Minnesota, Court of Federal Claims Number 00-0133

35. Nikki Embree on behalf of Mackenzie Embree, Independence, Missouri, Court of Federal Claims Number 00-0142

36. Norma Jean Allen, Indianapolis, Indiana, Court of Federal Claims Number 00-0145

37. George C. Lewis, Beeville, Texas, Court of Federal Claims Number 00-0146

38. Patricia A. Nash on behalf of James Todd Nash, Markham, Illinois, Court of Federal Claims Number 00-0149

39. Cindy Cairns on behalf of Mitchell Cairns, San Jose, California, Court of Federal Claims Number 00-0158

40. Margaret Althen, Boston, Massachusetts, Court of Federal Claims Number 00-0170

Claude Earl Fox,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health Clinical Center, Diagnostic Radiology Department, Division of Special Procedures (NIHCC): Opportunity for Cooperative Research and Development Agreement (CRADA) in the Field of Percutaneous Soft Tissue Ablation

AGENCY: NIHCC, NIH, PHS, DHHS.

ACTION: Notice of a Cooperative Research and Development Agreement (CRADA) opportunity.

SUMMARY: The Special Procedures division of the Diagnostic Radiology Department of the National Institutes of Health Clinical Center (NIHCC) are developing a research initiative in the area of percutaneous thermal ablation technologies, including radio-frequency, microwave, ultrasound, laser, and cryotherapy. Consequently, the NIHCC is seeking one or more partners for (a) Cooperative Research and Development Agreement(s) (CRADA) to further develop applications and to study clinical applications and the engineering basis of minimally-invasive percutaneous methods of soft tissue ablation.

Currently, the NIHCC is conducting studies to develop new clinical applications for thermal ablation, including kidney tumors, adrenal tumors, and painful soft tissue tumors for palliation. The NIHCC also plans to implement studies to combine radiofrequency ablation with other

treatment modalities and therapies, as well as to develop guidance and treatment planning systems for thermal ablations. Please see www.cc.nih.gov/drdr/fra for more information regarding the NIHCC ablation program.

Consequently, the NIHCC would like to further its research by establishing a collaborative, bench-to-bedside, basic-science initiative for investigating the potential applications of thermal ablation techniques, while refining existing ablative technologies. The collaborative effort will involve clinical refinements in ablation technology, development of novel imaging-guided techniques, and attempts to solve basic recurrent problems relating to local oncological ablative therapies. The collaboration, in part, will investigate the potential of combining new technology with existing surgical, medical, immunological, genetic, and radiation therapies.

The anticipated term of the CRADA is four(4) years.

Successful respondent(s) will be selected based upon their ability to collaborate with the NIHCC in the development of soft tissue ablation technologies.

DATES: Interested parties should submit a one-paragraph statement of interest addressing the collaborator's ability to perform the collaboration responsibilities. The statement of interest should be submitted to the NIHCC in writing no later than August 14, 2000.

ADDRESSES: Inquiries and statements of interest regarding this opportunity should be addressed to Steve Galen, Technology Development Coordinator, National Institutes of Health Clinical Center. Phone: (301) 594-4509, FAX (301) 402-2143, 6011 Executive Boulevard, Suite 511, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by the NIHCC pursuant to the Federal Technology Transfer Act of 1986 as amended by the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113 (Mar. 7, 1996)) and by Executive Order 12591 of April 10, 1987.

Under a CRADA, the NIHCC can offer selected collaborators access to facilities, staff, materials, and expertise. The collaborator may contribute facilities, staff, materials, expertise and funding to the collaboration. THE NIHCC CANNOT CONTRIBUTE FUNDING. The CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual property rights arising

under the CRADA and may qualify as a co-inventor of new technology developed under the CRADA.

The objective of the CRADA is the rapid publication of research findings and the timely commercialization of improved diagnostic and treatment strategies in the field of soft tissue ablation.

CRADA proposals will be evaluated under the following criteria:

- Corporate research and development competencies;
- Demonstrated abilities to collaborate productively in research programs;
- Expertise in performing clinical trials and regulatory affairs;
- The nature of resources to be contributed to the collaboration;
- Key staff expertise, qualifications, and relevant experience;
- Willingness to assign technical staff to participate in on-site collaborative efforts; and
- Ability to commercialize new discoveries effectively.

It is anticipated that the role of the NIHCC under the CRADA will include the following:

- Provide expertise in thermal ablation;
- Provide expertise in ablation engineering;
- Provide input on probe, generator, and treatment algorithm design;
- Evaluate technological considerations for patient safety;
- Provide an ongoing evaluation of the technologic advances and designs of the probes;
- Develop study designs to scientifically evaluate thermal ablation concepts; and
- Provide an existing protocol or create a new protocol for the phase 1 clinical study of the resulting device, if appropriate for clinical use.

It is anticipate that the role of the CRADA Collaborator will include the following:

- Provide expertise in thermal ablation;
- Provide advice and support in ablation engineering;
- Assist in the production of a probe prototype for clinical testing; and
- Provide equipment necessary to study the probe.

Dated: June 6, 2000.

Kathleen Sybert,

Chief, Technology Development and Commercialization Branch, NCI.

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