DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health Clinical Center: Cooperative Research and Development Agreement (CRADA) Opportunity for the Development of Medical Magnetic Imaging Methods for Diagnostic or Therapeutic Purposes

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

ACTION: Notice.

SUMMARY: The National Institutes of Health Clinical Center (NIHCC), Laboratory of Diagnostic Radiology Research, has developed technology in the area of Magnetic Resonance Imaging (MRI) and *in vivo* cell tracking and wishes to further develop the technology through a collaboration with a company or institution having expertise in the areas of medical imaging and/or medical diagnostics. Companies with expertise in transplantation of cells, including neural cells, stem cells, transgenic cells, or other cell types, and companies with expertise in therapeutic cell research, including the possible therapeutic use of stem cells, are encouraged to apply. The NIHCC's Laboratory of Diagnostic Radiology Research (LDRR) has developed a compound and technique for magnetically tagging cells—without the use of radioisotopes—and imaging those cells using MRI. The NIHCC system of magnetic tagging transfers nanoparticles of iron oxide into a cell via a monoclonal antibody to the cell's transferrin receptor. The cells internalize the iron particles in the endosomes. In early neurological disease studies related to repair of demyelination, LDRR researchers tagged oligodendrocyte precursor cells *in vitro* and introduced the tagged cells into myelin-deficient rats. The researchers followed the migration and integration of these cells in the spinal cord by non-invasive techniques and found that the distribution of the tagged precursor cells correlated with the extent of myelination. Thus, this non-invasive tracking method may be useful in human transplantation studies and for diagnostic procedures. In the proposed project, other cell types, including tumor or other transplantable cells could be labeled and tracked. Additionally, direct *in vivo* labeling methods using this tagging system could be developed. Clinical applications using imaging of the tagged cells could be investigated. Also, new methods which use the magnetic tag applied to a variety of therapeutic compounds or other clinically relevant molecules could be developed. Research data suggests that the iron tag does not impair the viability, migration or other cellular functions of the labeled cells.

The NIH has filed a patent application on the technology and is currently preparing to file a second related application that involves a new method for magnetic tagging of cells. Any successful CRADA collaborator may need to negotiate a license on the patent applications in order to commercialize developments under this CRADA. Contact information to obtain information on the patent applications is listed below.

The proposed duration of the collaboration is two (2) years.

ADDRESSES: Proposals and questions about this opportunity may be addressed to Steven Galen, Technology Development Coordinator, NIHCC, tel: (301) 594–4509, fax: (301) 402–2143 or David A. Steffes, Technology Development and Commercialization Branch, National Cancer Institute, Tel: (301) 496–0477, Fax: (301) 402–2117.

DATES: Interested parties should submit a one page statement of interest that outlines the proposed research project and addresses the collaborator's ability to fulfill its collaborative responsibilities. The statement of interest should be submitted in writing no later than August 14, 2000. CRADA proposals submitted thereafter may be considered if a suitable CRADA collaborator has not been found.

SUPPLEMENTARY INFORMATION: A ''Cooperative Research and Development Agreement'' or ''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 October 10, 1987.

Under a CRADA, the NIHCC can contribute facilities, staff, materials, and expertise to the effort. The NIHCC Cannot Contribute Funding. The CRADA collaborator receives an exclusive option to negotiate an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA in a pre-determined field of use and may qualify as a co-inventor of new technology developed under the CRADA.

Background information, including reprints of this announcement and issued patents pertaining to the technology, is available from the above-referenced address. Patent applications and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement.

The CRADA objective is the development and timely commercialization of imaging techniques and clinical diagnostic and therapeutic methods based on the magnetic tagging procedures developed by the NIHCC.

CRADA proposals will be evaluated under the following criteria:

- Corporate research and development competencies.
- Demonstrated ability to collaborate productively in research programs.
- The nature of resources to be contributed to the collaboration.
- Key staff expertise, qualifications and relevant experience.
- Willingness to assign technical staff to on-site collaborative efforts.
- Ability to commercialize new discoveries effectively.
- For collaborations involving stem cells, whether the proposed study complies with current federal regulations and NIH policy concerning stem cell research.

The roles of the NIHCC for the proposed CRADA may include the following responsibilities. Additional responsibilities may be added if the parties agree to other relevant and scientifically appropriate collaborative research projects.

1. Participate in identification of various cell types to label with the magnetic tagging system.
2. Participate in imaging studies for detection and tracking of various labeled cell types.
3. Participate in development of methods for *in vivo* labeling of cells.
4. Participate in development of methods to magnetically tag clinically relevant molecules.
5. Participate in development of diagnostic and therapeutic magnetic imaging methods using magnetically tagged compounds or cells.
6. Jointly publish research results.

The roles of the Collaborator for the proposed CRADA may include the following responsibilities. Additional responsibilities may be added if the parties agree to other relevant and scientifically appropriate collaborative research projects.

1. Development of methods to label various cell types with the magnetic tagging system.
2. Participate in imaging studies for detection and tracking of various labeled cell types.
3. Participate in development of methods for *in vivo* labeling of cells.

4. Participate in development of methods to magnetically tag clinically relevant molecules.

5. Participate in development of diagnostic and therapeutic magnetic imaging methods using magnetically tagged compounds or cells.

6. Jointly publish research results.

Dated: July 6, 2000.

Kathleen Sybert,

Chief, Technology Development and Commercialization Branch, NCI.

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BILLING CODE 4140–18–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4566–N–08]

Notice of Proposed Information Collection; Comment Request; Community Development Block Grant Entitlement Program

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of proposed information collection for public comments.

SUMMARY: The proposed information collection requirement for the Community Development Block Grant (CDBG) entitlement program described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 12, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Shelia Jones, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street, SW, Room 7232, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Sue Miller, Acting Director, Entitlement Communities Division, (202) 708–1577 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Community Development Block Grant Entitlement Program.

OMB Control Number, if applicable: 2506.0077.

Description of the need for the information and proposed use:

Agency form numbers, if applicable: Community Development Block Grant (CDBG) Entitlement grantees are required by 24 CFR 570.506 to retain records necessary to document compliance with statutes, regulations, Executive Orders, and OMB Circulars applicable to the CDBG Entitlement Program. Also, Description of the need for the information and Entitlement grantees are required by Section 104(e) of Title I of the Housing and Community Development Act to annually submit a performance report, which is necessary for the Secretary to perform an annual review of performance required by that section of the law, as well as providing the documentation necessary to prepare the Annual Report to Congress on the CDBG program.

Entitlement grantees report on their CDBG activities in the Consolidated Annual Performance and Evaluation Report (CAPER) (which also includes performance report information for the HOME Investment Partnership, Emergency Shelter Grants [ESG], and Housing Opportunities for Persons with AIDS [HOPWA] programs as well, should the CDBG grantee also be a recipient of any funds under these programs).

The automated Integrated Disbursement and Information System (IDIS) is a key component in the production of the CAPER report. Grantees input information about their CDBG program activities into IDIS on a on-going basis throughout their program year, reducing duplication of information and inconsistent reporting. There are no standard forms required to be used in the CAPER; therefore, grantees have much flexibility with respect to its design and format.

The proposed information collection requirement includes a revision of the currently approved recordkeeping and reporting requirements for entitlement grantees in the CDBG program based on an increase in the number of eligible grantees over the past three years. The exiting approval granted under OMB Number 2506–0077 is due to expire September 30, 2000.

Although the IDIS and the CAPER can contain information on a grantee's CDBG, HOME, ESG, and HOPWA programs, this information collection requirement submitted to OMB requests approval for CDBG Entitlement Program recordkeeping and reporting requirements only.

The Department has converted all of its CDBG entitlement grantees into the IDIS and each new grantee begins using IDIS at the time it first elects to take its status as an entitlement. Also, since this Information Collection was last approved, the required Financial Summary report has been integrated into IDIS, although IDIS does not yet collect/generate all information necessary to meet all reporting requirements for the Entitlement CDBG program. As a result, the estimation shown below does not reflect a decrease in the number of reporting hours used annually, on average, by each grantee. Grantees have to review the financial data and identify any adjustments that need to be input prior to generating the Financial Summary, and some supplementary documents may have to be submitted with the CAPER to meet the CDBG reporting requirements.

Members of affected public: Entitlement grantees (metropolitan cities and urban counties) of the Community Development Block Grant program.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The Department estimates that each of its 1,013 grantees will annually use, on average, 125 hours to keep records (non-IDIS recordkeeping) on their CDBG activities, and 305 hours to prepare reports on activities (both IDIS-generated and non-IDIS reports).

570.506 (recordkeeping) (on-going): $1,013 \times 125$ hours = 126,625 hours.

570.507 (reporting) $1,103 \times 305$ hours = 308,965 hours

Total burden hours = 435,590.

(Quarterly and annual reports from IDIS, annual total) $1,013 \times 284$ = 287,692 hours.