RESPONDENT AND BURDEN ESTIMATE INFORMATION

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
IRB chairs	400	1	0.5	200
Total	400			200

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dave Wendler, Ph.D., Head, Unit on Vulnerable Populations, Department of Clinical Bioethics, NIH, Building 10, Room 1C118, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435–8726 or fax or e-mail your request, including your address, to: Facsimile number (301) 496–0760 and email address *DWendler@cc.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before April 11, 2001.

Dated: March 2, 2001.

David K. Henderson,

Deputy Director, Warren G. Magnuson Clinical Center, National Institutes of Health.

[FR Doc. 01–6010 Filed 3–9–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute (NCI) Collaborative Development of Methods for Selective T Cell Depletion To Improve Bone Marrow Transplantation Procedures

Opportunities for Collaborative Research and Development Agreements are available for collaboration with the Biological Resources Branch (BRB), Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) to develop methods that could be applicable, in the setting of clinical bone marrow transplants, to deplete selected populations of T cells prior to the infusion of donor cells into the recipient. Selective T cell population depletion has been suggested as a possible approach to the goal of reducing the incidence of Graft versus Host Disease (GVHD) associated with bone marrow transplants, with the goal of also retaining clinical antitumor efficacy.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for cooperative research and development agreements (CRADAs).

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710a; and Executive Order 12591 of April 10, 1987) as amended, the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks one or more Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or medical device companies to discover and develop potential new methods of *ex vivo* depletion of selected populations of donor T cells with the goal of reducing Graft versus Host Disease (GVHD) in the transplant recipient, while still retaining antitumor efficacy. Each CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, and methods of treatment or prevention that may result from research. The CRADA collaborator will have an option to negotiate an exclusive or non-exclusive license to subject inventions arising under the CRADA and which are a subject of the CRADA Research Plan.

Proposals and questions about this CRADA opportunity may be addressed to Donna L. Bialozor, Technology Development Specialist, Technology Development & Commercialization Branch, National Cancer Institute-Frederick, 1003 West Seventh Street, Fairview Center, Room 502, Frederick, MD 21701 (Phone 301–846–5465; Fax: 301–846–6820; E-mail: *bialozod@mail.nih.gov*).

Scientific inquiries should be submitted to Dr. Stephen Creekmore, Chief, Biological Resources Branch (BRB), Developmental Therapeutics Program (DTP), National Cancer Institute-Frederick Research & Development Center, Building 1052, Room 251, NCI-Frederick, P.O. Box B, Frederick, MD 21702–1201 (Phone: 301–846–1100; Fax: 301–846–5429; E-mail: *creekmor@mail.ncifcrf.gov*).

Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential, preliminary CRADA proposals, preferably five pages or less, must be submitted to the NCI within 90 days from the date of this publication. Guidelines for preparing final CRADA proposals will be submitted shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA proposals submitted at a later date may be considered if a suitable CRADA collaborator has not been selected.

Technology Available

The Biological Resources Branch (BRB) of the Developmental Therapeutics Program (DTP) is an NCI extramural research activity with a mission to evaluate and support development of innovative

biopharmaceutical approaches to cancer therapy. To this end, the BRB has established contracts to manufacture biopharmaceuticals to be used in late preclinical and early clinical studies. The goal of these efforts is to provide scientific and technical expertise and key resources for the development of selected concepts through phase I/II and proof-of-concept clinical trials. Through its contract resources, the BRB possesses scientific and technical expertise in process development, manufacture, purification, vial filling, documentation, testing, and release of a wide range of monoclonal antibody, recombinant protein, natural product, peptide, oligonucleotide, viral, and bacterial-based clinical agents, devices, and vaccines. DTP also possesses expertise in toxicological and pharmaceutical support for these efforts. Depending on the circumstances and subject to future review and approval, the NCI may elect to provide resources for regulatory affairs support and IND filing through the Regulatory Affairs Branch of the Cancer Therapy Evaluation Program (CTEP), or through the offices of the outside collaborators. NCI may also elect to provide resources for design and execution of clinical trials at collaborating extramural sites, or intramural NCI clinics, or through the efforts of CTEP. Background and contact information for BRB and DTP resources are available at the following web sites: *http://www.ncifcrf.gov/brb/* and *http://www.dtp.nci.nih.gov*.

Technology Sought

BRB now seeks potential collaborators having expertise in one or more of the component approaches, molecules, or devices for development in the clinical setting of bone marrow transplantation:

(1) Monoclonal antibodies directed at normal T cell populations;

(2) Other targeting molecules appropriate for *ex vivo* selection of appropriate populations of donor T-cells;

(3) Devices that employ these targeting molecules to deplete appropriate populations of donor T-cells;

(4) Alternative approaches to the problem of *ex vivo* depletion of selected populations of donor T-cells.

Primary consideration will be given to collaborators having significant and relevant preclinical and/or clinical experience in the development of these or similar approaches, molecules, or devices.

Collaborators Sought

Accordingly, DHHS now seeks collaborative agreements for the joint BRB and Collaborator discovery, research and development of novel, clinically useful approaches for the selective *ex vivo* depletion of donor T-cell populations, for use in the setting of bone marrow transplantation. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide for equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid publication of research results as well as timely exploitation of commercial opportunities.

At a minimum, the successful Collaborator should either possess broad experience in, or possess highly specialized experience or unique expertise in one or more of the areas particularly pertinent to drug or device lead-discovery and development within the scope of this project.

NCI will provide no funding to the Collaborator inasmuch as financial contributions by the U.S. Government to non-Federal parties under a CRADA are not authorized under the Federal Technology Transfer Act (15 U.S.C. 3710a(d)(1)).

NCI and Collaborator Responsibilities

The role of the National Cancer Institute in this CRADA may include, but not be limited to:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project.

(2) Providing facilities for process development and production of monoclonal antibodies or relevant targeting molecules, to support preclinical development of these approaches.

(3) Providing the Collaborator(s) with process development, production and QC test data for evaluation.

(4) Provision of Quality Assurance and Quality Control of targeting molecules with or without devices used in T cell depletion, to support preclinical development of these approaches.

(5) Planning preclinical (*in vivo* and *in vitro* testing) research studies and interpreting research results.

(6) Publishing research results.

(7) Depending on the results of these preclinical investigations, NCI may elect to provide additional support for clinical-grade (cGMP) production of the targeted monoclonal antibodies or molecules derived from the CRADA. Commitment of substantial resources would require specific review and approval by the NCI's Division of Cancer Treatment and Diagnosis.

The role of the CRADA Collaborator may include but not be limited to:

(1) Providing significant intellectual, scientific, and technical expertise or experience to the research project.

(2) Providing monoclonal antibody clones or other production expression systems and test data to the research project.

(3) Providing other targeting molecules and test data to the research project.

(4) Providing devices that can employ targeting molecules, along with test data to the research project.

(5) Planning research studies and interpreting research results.

(6) Publishing research results.

Selective criteria for choosing the CRADA collaborator may include, but not be limited to:

(1) The ability to collaborate with the NCI on research and development of this technology involving discovery, optimization, production, testing, and biological evaluation. This ability can be demonstrated through experience, expertise, and the ability to contribute intellectually in this or related areas of drug discovery, research, and development.

(2) The demonstration of adequate resources to perform the research, development and commercialization of this discovery, optimization and biological evaluation technology (e.g., facilities, personnel, and expertise) and to accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

(3) The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology as defined above.

(4) The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

(5) The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

(6) The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor; or (2) the grant of an option to elect an exclusive or non-exclusive license to the CRADA

Collaborator when the Government employee is the sole inventor.

Dated: February 22, 2001.

Kathleen Sybert,

Chief, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 01–6039 Filed 3–9–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Child Health and Human Development (NICHD); Opportunity for Cooperative Research and Development Agreement

SUMMARY: The National Institute of Child Health and Human Development (NICHD) is seeking research statements from parties interested in entering into a Cooperative Research and Development Agreement (CRADA). The purpose of the CRADA is to develop new strategies for the identification of MATER (Maternal Effect Gene) specific to the remodeling of chromosomal architecture, and the transcription and translation that support healthy mammalian oocytes and early embryonic development. The project is part of the ongoing activities of the Developmental Endocrinology Branch (DEB), Division of Intramural Research, NICHD. The term of the CRADA will be up to five (5) years.

DATES: Interested parties should notify this office in writing of their intent to file a formal proposal no later than April 11, 2001. Formal proposals must be submitted to this office no later than May 11, 2001.

ADDRESSES: Research Statements should be submitted to Kate Sinclair Dunn, Technology Development Specialist, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health, Executive Plaza South, Room 450, 6120 Executive Blvd., MSC 7182, Bethesda, MD 20892–7182, Phone: 301–496–0477, Fax: 301–402–2117, e-mail *sinclaik@otd.nci.nih.gov.* Scientific questions should be addressed to Lawrence M. Nelson, M.D., Head, Gynecological Endocrinology Unit Developmental Endocrinology Branch, NICHD, NIH, Building 10, Room 10N262, Bethesda, MD 20892–1862; Phone (direct): 301–402–6608, Office: 301–496–4686; Fax: 301–402–0574, e-mail: *Lawrence_Nelson@nih.gov.* Inquiries directed to obtaining patent license(s) related to participation in the CRADA opportunity should be addressed to Dennis Penn, Pharm.D., MPH, Senior Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852–3804, Phone: 301–496–7735, Fax: 301–402–0220, e-mail: pennd@od.nih.gov.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NICHD and a collaborator pursuant to the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710 a), as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. The NICHD is prohibited from transferring funds to a CRADA Collaborator. Under a CRADA, the NICHD can offer the selected collaborator access to facilities, staff, materials, and expertise. The collaborator may contribute facilities, staff, materials, expertise, and funding to the collaboration. A 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. As between two or more sufficient, overlapping research proposals (where the overlap cannot be cured), the NICHD, as specified in 15 U.S.C. 3710a(c)(4), will give special consideration to small businesses, and will give preference to business units located in the U.S. that agree to manufacture CRADA products in the U.S.

The CRADA will employ a MATER null mouse line to examine the role of MATER in effecting the embryonic program switch from the maternal genome to the zygotic genome. The project's goal is to define MATER's role in embryonic transcription, transition from control by the maternal to the zygotic genome, signal transduction, cell cycle control, and to identify proteins that interact with MATER. A strategy should be developed to extract RNA from oocytes and early stage mouse embryos to create cDNA libraries to identify the genes that are critical to oocyte function and early embryonic development. Furthermore, a strategy will be implemented for development of a chip technology for oocyte and embryonic gene activation. Preimplantation mouse embryos may also be used for protein analysis and profiling. Specific gene loci or gene sequences that are identified will be analyzed and may be employed in the molecular manipulation of animal oocytes or early embryos.

The described methods are the subject of a U.S. provisional patent application filed October 18, 2000 by the Public Health Service on behalf of the Federal Government. Furthermore, the initial report and characterization of the invention is described in: Tong *et al., Mamm. Genome* 11:281–287, 2000. Commercialization of new CRADA technology may require obtaining an appropriate PHS license.

The collaborator in this endeavor is expected to commit scientific personnel commensurate with the level of research activities defined by the CRADA Research Plan. It is anticipated that PHS laboratories and/or those of the collaborator will be utilized, as appropriate, for the research activities as defined by the Research Plan. NICHD anticipates, in addition, that the Collaborator, as appropriate, will provide funding for the project.

Party Contributions

The NICHD anticipates that its role may include, but not be limited to, the following:

(1) Plan research studies, interpret research results, and, as appropriate, jointly publish the conclusions with the collaborator;

(2) Provide collaborator with access to existing NICHD research data (both already collected and yet to be collected);

(3) Provide staff, expertise, and materials for the development and testing of promising products;

(4) Provide work space and equipment for testing of any prototype compositions developed.

The NICHD anticipates that the role of the successful collaborator will include the following:

(1) Provide significant intellectual, scientific, and technical expertise in the development and manufacture of relevant products;

(2) Plan research studies, interpret research results, and, as appropriate, jointly publish the conclusions; and

(3) Provide NICHD a supply of necessary materials, access to necessary proprietary technology and/or data, and as necessary for the project, staff and funding in support of the research goals.

Other contributions may be necessary for particular proposals.

Selection Criteria

Proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following: