the random numbers used must be shown in the sampling plans. The OIG strongly recommends the use of its Office of Audit Services' Statistical Sampling Software, also known as ''RAT-STATS,'' which is currently available free of charge through the ''internet'' at ''www.hhs.gov/progorg/oas/ratstat.html''.

5. *Sample Design*—Unless the disclosing provider demonstrates the need to use a different sample design, the self-assessment should use simple random sampling. If necessitated, the provider may use stratified or multistage sampling. Details about the strata, stages and clusters should be included in the description of the audit plan.

6. *Estimate of Review Time per Sample Item*—The plan should estimate the time expended to locate the sample items and the staff hours expended to review a sample item.

7. *Characteristics Measure by the Sample*—The sampling plan should identify the characteristics used for testing each sample item. For example, in a sample drawn to estimate the value of overpayments due to duplicate payments, the characteristics under consideration are the conditions that must exist for a sample item to be a duplicate. The amount of the duplicate payment is the measurement of the overpayment. The sampling plan must also contain the decision rules for determining whether a sample item entirely meets the criterion for having characteristics or only partially meets the criterion.

8. *Missing Sample Items*—The sampling plan must include a discussion of how missing sample items were handled and the rationale.

9. *Other Evidence*—Although sample results should stand on their own in terms of validity, sample results may be combined with other evidence in arriving at specific conclusions. If appropriate, indicate what other substantiating or corroborating evidence was developed.

10. *Estimation Methodology*—Because the general purpose of the review is to estimate the monetary losses to the Federal health care programs, the methodology to be used must be variables sampling using the difference estimator. To estimate the amount implicated in the disclosed matter, the provider must use the mean point estimate. The statistical estimates must be reported using a ninety (90) percent confidence level. The use of RAT-STATS to calculate the estimates is strongly recommended.

11. *Reporting Results*—The sampling plan should indicate how the results will be reported at the conclusion of the review. In preparing the report, enough details must be provided to clearly indicate what estimates are reported.

D. Certification

Upon completion of the self-assessment, the disclosing health care provider, or in the case of an entity its authorized representative, must submit to the OIG a certification stating that, to the best of the individual's knowledge, the report contains truthful information and is based on a good faith effort to assist OIG in its inquiry and verification of the disclosed matter.

VI. OIG's Verification

Upon receipt of a health care provider's disclosure submission, the OIG will begin its verification of the disclosure information. The extent of the OIG's verification effort will depend, in large part, upon the quality and thoroughness of the internal investigative and self-assessment reports. Matters uncovered during the verification process, which are outside of the scope of the matter disclosed to the OIG, may be treated as new matters outside the Provider Self-Disclosure Protocol.

To facilitate the OIG's verification and validation processes, the OIG must have access to all audit work papers and other supporting documents without the assertion of privileges or limitations on the information produced. In the normal course of verification, the OIG will not request production of written communications subject to the attorney-client privilege. There may be documents or other materials, however, that may be covered by the work product doctrine, but which the OIG believes are critical to resolving the disclosure. The OIG is prepared to discuss with provider's counsel ways to gain access to the underlying information without the need to waive the protections provided by an appropriately asserted claim of privilege.

VII. Payments

Because of the need to verify the information provided by a disclosing health provider, the OIG will not accept payments of presumed overpayments determined by the health care provider prior to the completion of the OIG's inquiry. However, the provider is encouraged to place the overpayment amount in an interest-bearing escrow account to minimize further losses. While the matter is under OIG inquiry, the disclosing provider must refrain from making payment relating to the disclosed matter to the Federal health care programs or their contractors without the OIG's prior consent. If the OIG consents, the disclosing provider will be required to agree in writing that the acceptance of the payment does not constitute the Government's agreement as to the amount of losses suffered by the programs as a result of the disclosed matter, and does not affect in any manner the Government's ability to pursue criminal, civil or administrative remedies or to obtain additional fines, damages or penalties for the matters disclosed.

VIII. Cooperation and Removal from the Provider Self-Disclosure Protocol

The disclosing entity's diligent and good faith cooperation throughout the entire process is essential. Accordingly, the OIG expects to receive documents and information from the entity that relate to the disclosed matter without the need to resort to compulsory methods. If a provider fails to work in good faith with the OIG to resolve the disclosed matter, that lack of cooperation will be considered an aggravating factor when the OIG assesses the appropriate resolution of the matter. Similarly, the intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions, as well as exclusion from participation in the Federal health care programs.

Dated: October 21, 1998.

June Gibbs Brown,

Inspector General.

[FR Doc. 98–29064 Filed 10–29–98; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the Joint Evaluation and Development of Methods to Generate and Expand In-Vitro Modified Dendritic Cell Populations in Order to Elicit Phenotype Specific Immune Responses

The NCI is looking for CRADA Collaborators to jointly develop this dendritic cell immunology technology.

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

ACTION: Notice for CRADA opportunities.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), 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 Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies to evaluate and develop methods to generate, expand and modify dendritic cells to act in an immunologically specific manner. The Collaboration will focus on the development and evaluation of conditions for specific immunomodulatory maneuvers focused on induction of Th1 and Tc1 biased immune responses by dendritic cells. Additionally, the collaboration will include the characterization of human dendritic cell phenotypic subsets including the generation of subset specific reagents. These research efforts would be directed by our evolving understanding of dendritic cell biology which includes both the characterization of cytokine expression by dendritic cells (production and regulation of production) and the characterization of dendritic cell responses to both known and as yet uncharacterized cytokines.

Any CRADA for the biomedical use of this technology will be considered. The CRADAs would have an expected duration of one (1) to five (5) years. The goals of the CRADAs include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADAs which are the subject of the CRADA Research Plan.

ADDRESSES: Statements of interest, proposals and questions about this CRADA opportunity may be addressed to Gary Cuchural, Technology Development & Commercialization Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465, fax: 301–846–6820). Scientific inquiries may be addressed to Dr. Edward Nelson, Immunotherapy Laboratory, NCI Clinical Services Program, National Cancer Institute-Frederick Cancer Research & Development Center, phone: 301–846–1491; FAX: 301–846–6022.

EFFECTIVE DATE: Confidential CRADA statements of interest describing the proposed research, preferably one page or less, must be submitted to NCI on or before December 29, 1998. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents who have been selected on the basis of mutual scientific interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The Immunotherapy Laboratory of the NCI Clinical Services Program at the Frederick Center Research and Development Center has expertise in the following technological areas:

- Experience generating frequent, large dendritic cell (DC) preparations.
- Experience generating in excess of 80 DC preparations, from both normal donors and cancer patients.
- Well established, extensive systems for functional and phenotypic evaluation of dendritic cell preparations and their responses to various immune mediators.
- Access to Good Manufacturing Practice (GMP) monoclonal antibody production facility.
- Established human tumor antigen systems for final functional evaluations of immune response.

NCI's Dendritic Cell Patents and Patent Applications:

1. A Method and Compositions for Making Dentritic Cells from Expanded Populations of Monocytes and for Activating T Cells, filed in the United States Patent and Trademark Office May 21, 1997.

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

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the Collaborator with data from in-vitro and in-vivo studies.
3. Planning research studies and interpreting research results.
4. Publishing research results.

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. Planning research studies and interpreting research results.
3. Providing technical expertise and/or financial support for (e.g. facilities, personnel and expertise) CRADA related Government activities.
4. Accomplishing objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
5. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.
6. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.
7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
8. 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.
9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the licensing of patent rights to CRADA inventions.

Dated October 21, 1998.

Kathleen Sybert,

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

[FR Doc. 98–29074 Filed 10–29–98; 8:45 am]

BILLING CODE 4140–01–M

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 agencies 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 Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.