

5. Staffing and Management System (10 Points)

a. Extent to which key personnel have the qualifications, skills, and experience in epidemiologic and laboratory methods, data management, and analysis to develop and implement analytic studies of reproductive and developmental outcomes.

b. Extent to which the applicant has the ability to manage and coordinate the project.

c. Extent to which there is appropriate dedicated staff time to develop and implement the project.

d. Extent to which the applicant provides an appropriate time line and includes activities and personnel responsibilities.

e. Extent to which the applicant demonstrates an organizational structure (include an organizational chart) and facilities/space/equipment that are adequate to carry out the activities of the program.

6. Human Subjects Review (Not Scored).

The extent to which the applicant complies with 45 CFR Part 46 for the protection of human subjects.

7. Budget (Not Scored).

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of—

1. Annual progress reports (English language only);
2. Financial status report, no more than 90 days after the end of the budget period (in US Dollars); and
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement in the application kit.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 307 of the Public Health Service Act, [42 U.S.C. section 2421], as amended. The Catalog of Federal Domestic Assistance number is 93.184.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

To obtain business management technical assistance, contact: Nancy Pillar, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 02006, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: 770-488-2716, Email: nfp6@cdc.gov.

For program technical assistance, contact: Diana Schendel, Ph.D., Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, Mail Stop F-15, Atlanta, Georgia 30341, Telephone number: 770-488-7359, Email: dcs6@cdc.gov.

Dated: November 5, 2001.

Rebecca O'Kelley,

Acting Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Cooperative Research and Development Agreement (CRADA)

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking a CRADA partner(s) for collaboration to utilize the newly acquired knowledge that the CX3C chemokine region in the respiratory syncytial virus (RSV) G glycoprotein binds to the chemokine receptor CX3CR1 and this binding facilitates RSV infection of cells and induces chemokine-like responses to

develop ways to treat or prevent RSV disease. The CRADA partner could be involved in all or part of studies examining (1) alteration of the CX3C region in the G glycoprotein of live viruses in such a way as prevent CX3C interaction with the CX3C receptor (CX3CR1) on cells and improve the safety and/or efficacy of a live virus vaccine; (2) alteration of the G glycoprotein to enhance induction of antibodies that block G glycoprotein binding to the CX3C chemokine receptor, CX3CR1, and treat or prevent RSV disease; (3) development of reagents (drugs, antibodies, peptides, polypeptides, etc.) that block interaction of the CX3C region in G glycoprotein with CX3CR1 on cells to treat or prevent RSV disease; (4) development of assays to detect blocking of G glycoprotein binding to the CX3C receptor, CX3CR1, or detect blocking of the biological activity initiated by G glycoprotein binding to CX3CR1 to identify reagents (drugs, antibodies, peptides, polypeptides, etc.) or evaluate candidate vaccines that might be used as prophylactic or therapeutic treatments for preventing RSV disease.

Because CRADAs are designed to facilitate the development of scientific and technological knowledge into useful, marketable products, a great deal of freedom is given to Federal agencies in implementing collaborative research. The CDC may accept staff, facilities, equipment, supplies, and money from the other participants in a CRADA; CDC may provide staff, facilities, equipment, and supplies to the project. There is a single restriction in this exchange: CDC MAY NOT PROVIDE FUNDS to the other participants in a CRADA.

DATES: This opportunity is available until December 10, 2001. Respondents may be provided a longer period of time to furnish additional information if CDC finds this necessary.

ADDRESSES: The responses must be made to: Lisa Blake-DiSpigna, Technology Development Coordinator, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd. NE., Mailstop C-19, Atlanta, GA 30333.

FOR FURTHER INFORMATION CONTACT:

Technical: Ralph A. Tripp, Ph.D., Respiratory and Enteric Viruses, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd. NE., Mailstop G-09, Atlanta, GA 30333, telephone (404) 639-3427.

Business: Lisa Blake-DiSpigna, Technology Development

Coordinator, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd. NE., Mailstop C-19, Atlanta, GA 30333, telephone (404) 639-3227 or by E-Mail at LCB3@CDC.GOV.

SUPPLEMENTARY INFORMATION: The goal of this CRADA is to seek a partner(s) for collaboration to develop studies examining (1) live RSV vaccines produced by modifying the RSV G glycoprotein CX3C region to render it nonfunctional for viral attachment to host cells, (2) producing live or non-live RSV vaccines, or improving existing live or non-live RSV vaccines by modifying the CX3C region or proximal regions thereof so that when administered, higher titers of antibodies are produced that block the biological activity of the CX3C region on the G glycoprotein of subsequently infecting RSV viruses, (3) treatment provided by administration to an RSV infected individual an effective amount of a drug, antibody, peptide, polypeptide, or other molecule that block interaction of the CX3C region in G glycoprotein with CX3CR1 on host cells or the biological activity of the CX3C region in the G glycoprotein, and (4) development of assays to detect blocking of G glycoprotein binding to the CX3C receptor, CX3CR1, or detect blocking of the biological activity initiated by G glycoprotein binding to CX3CR1 to identify reagents (drugs, antibodies, peptides, polypeptides, etc.) that might be used as prophylactic or therapeutic treatments for preventing RSV disease.

Respondents should provide evidence of expertise in all or one of the following areas including the development and evaluation of RSV vaccines and vaccine agents, evidence of experience in animal models systems including non-human primate models, commercialization of vaccines and vaccine agents, and supporting data (e.g., publications, proficiency testing, certifications, resumes, etc.) of qualifications for the principle investigator who would be involved in the CRADA. The respondent will develop the final research plan in collaboration with CDC.

Applicant submissions will be judged according to the following criteria:

- (1) Expertise in development and evaluation of RSV vaccines;
- (2) Expertise in evaluation of RSV vaccines in animal model systems including non-human primates;
- (3) Evidence of scientific credibility;
- (4) Evidence of commitment and ability to produce RSV vaccines; and

(5) Evidence of an existing infrastructure to commercialize successful technologies.

With respect to Government IP rights to any invention not made solely by a CRADA partner's employees for which a patent or other IP application is filed, CDC has the authority to grant to the CRADA partner an exclusive option to elect an exclusive or nonexclusive commercialization license. This option does not apply to inventions conceived prior to the effective date of a CRADA that are reduced to practice under the CRADA, if prior to that reduction to practice, CDC has filed a patent application on the invention and has licensed it or offered to license it to a third party. This CRADA is proposed and implemented under the 1986 Federal Technology Transfer Act: Public Law 99-502, as amended.

Dated: November 5, 2001.

Karen Groux,

Deputy Associate Director for Management and Operations, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Study Team for the Los Alamos Historical Document Retrieval and Assessment Project

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the following meeting.

Name: Public Meeting of the Study Team for the Los Alamos Historical Document Retrieval and Assessment Project.

Time and Date: 5 p.m.-7 p.m., November 27, 2001.

Place: Radisson Santa Fe Hotel (Board Room), 750 North Street Francis Drive, Santa Fe, New Mexico 87501, telephone 505-992-5800.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with Department of Energy (DOE) and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) is given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy

production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 between the ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This Study Team is charged with locating, evaluating, cataloguing, and copying documents that contain information about historical, chemical, or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purpose of this meeting is to review the goals, methods, and schedule of the project, discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns and provide advice to CDC.

Matters to be Discussed: Agenda items include an update from the National Center for Environmental Health (NCEH) and its contractor regarding the information-gathering project that is underway. This will include discussion of the extent to which access to classified documents has been restored, limitations still in place, and the second draft of the project's historical operations and releases report, which will be issued in September. There will be time for public input, questions, and comments. All agenda items are subject to change as priorities dictate.

CONTACT PERSONS FOR ADDITIONAL

INFORMATION: Robert C. Whitcomb, Ph.D., Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, Building 6, Room T006, Executive Park Drive (E-39), Atlanta, GA 30329, telephone 404-498-1800, fax 404-498-1811.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: November 6, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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