Base Notice: Support for Epidemiological Studies of Cancer Among Atomic Bomb Survivors - HHS-NIH-NCI-RDSS-14-003

Notice Type:
Sources Sought

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Classification Code:
A -- Research & Development

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541 -- Professional, Scientific, and Technical Services/541712 -- Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)

NOTICE INFORMATION
Agency/Office:
National Institutes of Health

Location:
National Cancer Institute, Office of Acquisitions

Title:
Support for Epidemiological Studies of Cancer Among Atomic Bomb Survivors

Description(s):

Type of Notice:
This is a Research and Development (R & D) Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding the availability and capability of all qualified sources to perform a potential R & D requirement.

Background:
The mission of the Radiation Epidemiology Branch (REB), Epidemiology and Biostatistics Program (EBP), Division of Cancer Epidemiology and Genetics (DCEG), National Cancer Institute (NCI) is to plan and conduct studies on cancer risk associated with exposure to radiation. This work is relevant to understanding the role of radiation exposure as a cancer cause and, more generally, to understanding principles and mechanisms of carcinogenesis through epidemiological and multi-disciplinary investigations of the action of a particular carcinogen and its modification by other factors. Ionizing radiation is the best understood, and best quantified, of common human carcinogens, and this knowledge base is an enormous advantage for investigating why certain individuals, under certain circumstances or with certain characteristics, have a higher risk of developing radiation-related cancers than others.

In support of this mission, Radiation Effects Research Foundation (RERF) has collected data on cancer risk in the long-term follow up of cohorts of Japanese atomic-bomb survivors and their children (mainly in Hiroshima and Nagasaki but also in other places in Japan to which they may have migrated). Cancer cases have been identified by RERF primarily through its mortality surveillance program that covers all of Japan and its tumor registry that covers the general populations in Hiroshima and Nagasaki prefectures. Ancillary information on tumor characteristics and/or access to tissue specimens have been obtained from tissue registries in Hiroshima and Nagasaki and other sources including RERF data files and records, its autopsy series and hospital and clinic records at other institutions in Hiroshima and Nagasaki. Well-characterized individual radiation dose estimates from the dosimetry system, "DS02", have been made available for RERF cohort subjects, together
with information on lifestyle and other cancer risk factors obtained from a series of previously conducted mail
and interview surveys in the cohort population. Information desired for epidemiological studies have been
obtained by conducting specially designed case-control studies, and through pathology reviews and biomedical
and molecular assays of stored or fresh biological specimens.

**Purpose and Objectives:**
The purpose of this acquisition is to conduct epidemiological and multi-disciplinary studies of cancer among
atomic bomb survivors. The Contractor shall collaborate with REB in their investigations of cancer risk,
radiation dose, and other factors among members of the Life Span Study (LSS) and other RERF study cohort
in Hiroshima and Nagasaki.

**Project Requirements:**
Major tasks of the Contractor include the following:

**Continuation of Existing Studies**

1. As specified by the appropriately approved protocol: (a) Ascertain cancer cases and if required by the
   protocol, ascertain cases with benign or pre-cancer lesions among members of the LSS cohort and other
   cohort samples to collect information on demographics, tumor diagnosis and treatment to be entered into
databases. (b) Provide confirmation of tumor diagnosis and histological characterization of tumors. (c) Establish
   and maintain computer databases linking tumor information with previously conducted mail survey and other
data on risk factors relevant in evaluating tumor risks. With input from the COR, design the database and
   provide computer programming support to implement these databases.

2. Perform statistical analyses and prepare scientific reports to be published in peer-reviewed journals.

**Pilot Studies**

1. Write protocols for the conduct of pilot studies of genomic characterization of thyroid tumors (malignant and
   benign) and molecular genetic characterization of central nervous system (CNS) tumors (malignant and
   benign) both related to radiation exposure in the LSS cohort. If found feasible, the Contractor shall collaborate
   with NCI in the development of protocols for the full studies.

2. Collect small amounts of archival and/or fresh frozen tumor, non-tumor tissue samples and other samples of
   persons from RERF repositories or by negotiation with other institutions such as universities, hospitals, or
   pathology laboratories in Hiroshima and Nagasaki. Perform diagnostic confirmation of the cases from which the
   archived tumor tissue was obtained.

3. Prepare scientific reports based on the pilot study results for publication in peer-reviewed journals.

**Full Studies**

1. Obtain tissue samples for use in the full-scale studies of genomic characterization of thyroid tumors
   (malignant and benign) and molecular genetic characterization of central nervous system (CNS) tumors
   (malignant and benign) related to radiation exposure in the LSS cohort. These samples will be collected from
   RERF repositories or by negotiation with by negotiation with other institutions such as universities, hospitals, or
   pathology laboratories in Hiroshima and Nagasaki.

2. Collaborate with the COR in establishing diagnosis and performing laboratory assays and tests.

3. Prepare scientific reports based on the full study results for publication in peer-reviewed journals.

**Anticipated Period of Performance:**
The anticipated period of performance for this requirement is one year, with four one-year options and four
options for additional quantities.

**Other Important Considerations:**
The studies to be conducted related to the cohort require data that is only available to RERF. The cohort
populations, radiation dosimetry, cancer follow-up data, risk factor information and other cohort data to which
NCI seeks to access are not accessible outside RERF. Furthermore, the multidisciplinary epidemiological
studies to be conducted under this contract cannot be undertaken outside the RERF cohorts. There is no reasonable alternative to contracting directly with RERF.

**Capability Statement/Information Sought:**
We encourage all responsible sources, particularly small businesses, to submit a capability statement which will be considered by the agency. Organizations that submit capability statements in response to this notice will be evaluated against the following criteria:

1. Documented access to this unique cohort population consisting of survivors of the atomic bombings of Hiroshima and Nagasaki. This includes having ownership and a controlling interest in all existing information on atomic bomb survivors in Japan.

2. Documented ability to obtain the necessary IRB approvals for the studies related to the RERF cohort.

3. Documented infrastructure and training to ascertain cancer cases among members of the RERF cohort.

4. Documented ability and experience in conducting nation-wide mortality follow-up through the Japanese family registry system, linkage to the Hiroshima and Nagasaki tumor registries, and clinical follow-up by biennial health examinations.

Interested qualified organizations should submit a tailored capability statement for this requirement, not to exceed 20 single-sided pages (including all attachments, resumes, charts, etc.) presented in single-space using a 12-point font size minimum, that clearly details the ability to perform the aspects of the notice described above. Statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement, as well as the eligible small business concern's name, point of contact, address and DUNS number.

All capability statements sent in response to this SOURCES SOUGHT notice must be submitted electronically (via email) to Jame Chang, Contract Specialist, at jame.chang@nih.gov in MS Word or Adobe Portable Document Format (PDF), by January 2, 2014, 4:30PM, EST. All responses must be received by the specified due date and time in order to be considered. No collect calls or facsimile transmissions will be accepted.

**Disclaimer and Important Notes:**
This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

**Confidentiality:**
No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation.

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**Contracting Office Address:**
9609 Medical Center Drive, Room 1E128  
Rockville, Maryland 20852
United States

Place of Contract Performance: Hiroshima, Japan

Allow Vendors To Add/Remove From Interested Vendors: Yes

Allow Vendors To View Interested Vendors List: No