STATEMENT OF WORK

Title: Collection, Storage, Advertisement and Distribution of Biological Reagents

I. Introduction

The National Cancer Institute (NCI) is an institute within the National Institutes of Health (NIH), one of eight agencies that compose the Public Health Service (PHS), Department of Health and Human Services (DHHS). The mission of the NCI is to plan, conduct, and coordinate the National Cancer Program and involves (a) research on the causes, detection, diagnosis, prevention, treatment, and palliative care of cancers and on rehabilitation of the cancer patient and (b) demonstration of the effectiveness of cancer control methods and techniques.

II. Background

Since 1988 the Biological Resources Branch (BRB) has operated a Preclinical Repository that obtains, stores, aliquots and distributes bulk cytokines, monoclonal antibodies, cytokine standards, imaging and molecular biology reagents and other useful research reagents. Recently the repository has been instrumental in preserving and distributing an array of reagents developed at NCI by NCI investigators or contractors. The goal of the repository has been expanded to provide high quality research reagents to the research community via cooperative efforts with DCTD such as the DTP and CTEP supported Immunotherapy Workshop Initiative.

III. Scope

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, material, equipment and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work set forth below.

The Contracting Officer's Technical Representative (COTR) as identified under Section G. of this contract shall monitor and oversee all technical and programmatic aspects of this Statement of Work.

IV. Specific Tasks

1. Provide a suitable air-conditioned facility containing sufficient floor space (approximately 350 – 400 sq feet) for the installation and storage of equipment and all items necessary for the operation of a biologics repository and for the distribution of reagents contained therein. The facilities shall be suitable for performance of the following primary contract activities: storing reagents at appropriate temperatures; packaging reagents for shipment; processing requests for reagents; receiving, aliquoting and labeling new products; and maintaining a computerized inventory and tracking system.

2. Maintain and operate Government provided equipment for the storage of bulk and packaged biological material at -130^{0}C to -196^{0}C, -70^{0}C, -20^{0}C and at +4^{0}C, and to maintain and operate all other supplies and equipment necessary for repository and distribution operation. The Contractor shall maintain the biological material at temperatures designated by the Contracting Officer's Technical Representative (COTR) and shall provide a backup electrical power supply to accommodate the specified refrigeration units in the event of a loss of electrical power. In addition, the Contractor shall house the refrigeration units in an air-conditioned facility with the capacity to maintain a room temperature of 72^{0}C +/- 4^{0}F when all equipment is operational. Freezers used for storage of NCI Repository reagents shall be dedicated solely for that purpose.

3. Supply electrical power to accommodate the refrigerator/freezer units. Supply liquid nitrogen for the nitrogen freezers.

4. Maintain security of all storage facilities and the integrity of reagents stored therein. All refrigerators and freezers shall be connected to a central alarm system, which is continuously monitored 24 hours a day. A system shall be employed to notify designated responsible personnel in the event of freezer malfunction. The Contractor shall immediately respond to emergency freezer malfunctions, and take appropriate action (i.e., transfer reagents to standby freezer if necessary). The Contractor shall notify the COTR in writing of any electrical failure or freezer malfunction within 2 business days.

5. Maintain storage units and arrange for the repair of malfuncting equipment as specified in the Quality Assurance Plan. The temperature distribution in each piece of equipment shall be "mapped" and calibrated on an annual basis to assure proper temperature control throughout the entire unit. If necessary, provide storage units that meet the federal regulatory requirements for storage of biologicals produced under Good Manufacturing Practices (GMP). Since GMP requirements may change, prior written approval from the NCI COTR is required on validation plans (mapping and calibrating) before they are undertaken.

6 Maintain and operate a standby facility for use in the event of a loss of refrigeration capacity of any repository area, including the maintenance of standby refrigerators and freezers, and the maintenance and operation of a standby electrical power supply (e.g. diesel generator).

7. Maintain space for the aseptic processing (aliquoting and labeling) of bulk reagents or specimen preparations for storage at the repository using appropriate biosafety measures. The determination of which agents to aliquot, into which size and number of aliquots, and labeling requirements will be made by the NCI COTR.

8. Distribute reagents to qualified investigators and process orders submitted by appropriate Program Officers. Review investigators' submitted forms for accuracy and completeness and request additional information if necessary. Inform non-domestic and commercial requestors that all costs associated with pulling samples, handling, packaging supplies (to include, but not limited to dry ice, liquid nitrogen, insulated shipping containers, refrigerant packs, etc.) and shipping charges for the reagents shall be the responsibility of the requestor. Provide to the requestor a price estimate for these charges and receive proper payment of these charges via credit card, check, wire or ACH transfer prior to shipping the reagents. Processing of checks may take up to twenty (20) business days. These charges will not be reimbursed under this contract. Arrange the collect express shipment of reagents and instructional materials according to the conditions outlined by the COTR using standard commercial delivery carrier or one specified by the requestor. Forms may be viewed at http://web.ncifcrf.gov/research/brb/PreClinRepo-Home.asp. Shipments shall be made within ten (10) business days after receipt of completed documents and/or receipt and processing of payment from the requestor, whichever is later. Each package shall include documentation regarding the contents of the package. (Note: The NCI BRB will flag those investigators who are considered non-domestic (outside the USA) and/or commercial requestors.) It is estimated that approximately 4,500 samples will be shipped annually.

9. Provide a mechanism to invoice investigators for reagent handling fees, packaging supplies and shipping charges. The Contractor shall be responsible for collecting, monitoring and tracking all shipments to approved investigators. As part of ARTICLE C.2., REPORTING REQUIREMENTS, include a list of reagents provided along with the

requestor's name, institution, type (i.e. government/industrial), and geographic location of institution, type of material shipped, number of each type, mode of shipment(wet/dry ice, ambient) and payment received.

10. Upon receipt and processing of payment from non-domestic and/or commercial requestors, notify, by facsimile or other rapid communication system, all foreign investigators receiving frozen or refrigerated shipments, informing them of the carrier, waybill number and estimated time of arrival. Verify that such communications have been received by foreign investigators.

11. Acquire and use shipping containers that comply with all domestic and international postal regulations and pertinent ICC regulations for providing a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specified products in transit. The size and type of packaging used may vary depending on the mode of transportation used. The Contractor shall also develop a protocol and periodically perform quality control assessments of shipping procedures.

12. Keep current with all regulations concerning the transportation of biological reagents. The Contractor shall be responsible for assuring that all proper packaging and shipping procedures are followed, including obtaining any necessary export/import permits and attaching any required labels.

13. Make arrangements to pick up incoming shipments of biological reagents from the airport or other specified sites. It is essential that personnel be available to receive incoming shipments at any given time and to arrange for their immediate and appropriate storage in order to avoid the loss of important biological material. It is expected that there will be no more than 10 incoming shipments in any year. Storage and inventory shall be performed on incoming shipments per the instructions of the COTR.

14. Maintain current inventory of repository reagents, utilizing a computerized inventory system as follows:

    a. Maintain current records on all agents, including; name of agent, unique identification number, source of material, amount/vial, number of vials, and expiration date.

    b. Add new reagents to the inventory, edit existing reagent information, and debit orders from inventory. Identify reagents by biological type as designated by the COTR. On a quarterly basis, flag reagents which have expired or reached a critical inventory level (as defined by the COTR).

    c. Enter records of requests and shipments that shall include: requestor name, institution, type (i.e. government/industrial), and geographic location of institution, type of material shipped, number of each type, mode of shipment (wet/dry ice, ambient).

    d. Provide quarterly and annual reports that include data generated from the inventory data base, e.g.: summary of reagent distribution by type, mode of shipment (set/dry ice/ambient), geographic regions, shipments received, agents which have expired or are at a critical inventory level.

    e. Provide annual inventory of reagents by freezer and agent number.

    f. Maintain a back-up database inventory file that is updated at least weekly.

g. At end of contract period, provide an updated computer file of the reagent inventory to the Government.

15. Advertise, in appropriate journals, the availability of reagents available from this repository as per instructions of the COTR.

16. Provide direct telephone line service to the repository and personnel to answer the telephone Monday-Friday 8:30 a.m. through 5:00 p.m. except for Federal Government-designated holidays.

17. Consult as necessary with the COTR to discuss in detail the acquisition, receipt, storage, testing and distribution of all repository materials. Such consultations may normally be by telephone, but may occasionally require meeting with the COTR to discuss progress on the contract.

18. Provide a quality assurance plan that describes procedures for establishing and maintaining a program to monitor all laboratory and repository processes including a) standard operating procedures for activities related to handling biological materials, b) approaches and methods to document and correct problems and deficiencies and c) plans for training contractor staff on all SOPs and measures used to assure quality.

19. All materials provided to the contractor under this project are the property of the U.S. Government and may not be used for any other purpose without the written consent of the Contracting Officer's Technical Representative (COTR). All such materials and by-products shall be returned to the National Cancer Institute at the completion of this contract.

20. **Phase In Transition Plan:** In collaboration with the current Contractor, transfer within fourteen (14) calendar days of award of this contract: 1) the entire inventory of repository reagents; 2) all Government furnished property (Attachment 21); and 3) the entire database for the repository from the incumbent contractor to the new site of the repository. Develop protocols and procedures that describe in detail the transfer of reagents, equipment, and database will be provided to the incoming/new contractor. These procedures and protocols shall be approved by the NCI COTR before implementation. Establish a fully operational repository at the new repository site within twenty-one (21) calendar days of award of this contract. The systems to process requests, deliver reagents, process incoming biological reagents, and track inventory shall be fully operational within this 21-day period of time.

21. **Phase Out Transition Plan:** The contractor shall transfer within fourteen (14) calendar days prior to the expiration of this contract: 1) the entire inventory of repository reagents; 2) all Government furnished property (Attachment 21) and 3) the entire database for the repository under this contract to the new site of the repository. Developed protocols and procedures that describe in detail the transfer of reagents, equipment, and database shall be provided to the incoming/new contractor within fourteen (14) calendar days of award of the contract. Procedures and protocols shall be approved by the NCI COTR before implementation.

V. Personnel

Principal Investigator/Project Director (PI/PD)

The PI/PD shall be responsible for the overall implementation of this project and shall have at least ten (10) years of extensive experience in the management of a repository operation on

the magnitude of this requirement. In addition, the PI/PD shall have a PhD in biology, chemistry or related field.