NCI-CAR Contract Statement of Work

A. Background and Objectives

The Drug Synthesis and Chemistry Branch (DSCB) of the Developmental Therapeutics Program (DTP) of the Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) is seeking support services to operate and maintain the National Cancer Institute's Chemotherapeutic Agents Repository (NCI-CAR). The principal goal of this contract is to support the DTP anticancer pre-clinical drug evaluation program which seeks to identify new small molecule therapeutic agents. The primary tasks of the contract are the receipt, registration, storage, analysis, arraying and distribution of small molecules and purified natural products that will be evaluated in DTP anti-cancer screens, and also distributed to extramural researchers. In addition, a small number of compounds from other NIH (e.g. NIAID, CBC) programs may be handled through this contract.

This contract is also responsible for providing an informational interface with NCI and external investigators that are submitting or requesting research compounds; for updating of the chemical database which includes chemical, inventory, receiving and shipping information; systematic file and record keeping of both current and archival information related to Repository activities; and reacquisition of samples for continued chemical and biological studies.

The program is highly flexible and the Contractor shall have the flexibility to respond to changing Program priorities.

B. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below.

Specific Tasks

1. Acquisition/Documentation

a. Execute registration policies and procedures developed by DTP for the submission of structures, associated chemical data and compound samples using the DTP website: http://dtp.nci.nih.gov/. These procedures may be revised and updated over time. This includes the assignment of NSC registration numbers to chemical structures and other entities (e.g. biologics, creams, investigational, ethical and OTC drug products) using polices and procedures developed by DSCB.

b. Maintain and execute procedures for the non web-based manual submission and registration of structures, associated chemical data and the compounds.

c. Act as primary point-of-contact between DSCB and compound submitters.

d. Assist investigators on structure and sample submission, and website registration procedures.

e. Input chemical structures and chemical data into the NCI chemical database. The majority of structures are submitted by investigators requesting anti-cancer testing.

f. Check the chemical accuracy of structures and chemical data entered into the database.

g. Maintain permanent files of all supplier correspondence related to submission of structures, chemical data and physical compound samples. This includes a file of legal confidentiality agreements between NCI and investigators.

h. Reacquire compounds from submitters as requested by the COR. Generally, this material will be used for additional in vitro/in vivo evaluation.

i. Acquire, through purchase order process, additional quantities of commercial compounds as requested by the COR.

j. Distribute copies of requested documentation to NCI staff and external investigators as directed by the COR. These may be as hard copies or in electronic form.

k. Maintain relevant, accurate, and current records such as identity, inventory and shipping history, for all registered compounds.

2. Receipt and Storage

a. Store chemicals, purified natural products and bulk compounds. This includes approximately 500,000-600,000 individual samples in current long-term storage. The majority of compounds are in amounts ranging from 5 mg to 20 g, with a few samples of bulk drug up to 50 kg.

b. Receive weekday chemical sample shipments and related documentation and, safely store until registered and moved to permanent storage or shipped to researchers.

c. Store chemicals, drugs and plated sets under their recommended storage conditions. This includes capabilities for temperature storage at controlled ambient, 0-5 deg C., -15 to -20 deg C., and -70- to -80 deg C; under nitrogen or argon atmosphere; protected from light; under controlled humidity conditions.

d. Provide sufficient monitoring of storage conditions to guarantee continuous proper storage including, for a limited number of bulk API samples, adequate monitoring and documentation to meet cGMP guidelines.

e. Notify COR immediately when physical changes in chemical samples are noticed.

f. Provide safe storage and security measures to conform to all pertinent drug/chemical regulations. This includes an adequate waterless fire suppression system to protect staff, the chemical inventory and storage infrastructure.

g. Prepare Material Safety Data Sheets for specific compounds as directed by COR.

h. Maintain the current computerized inventory of compounds of interest and bulk drugs in the repository. In addition, infrequently requested drugs shall be inventoried for accuracy at the time an order request is filled.

i. Provide for the safe and proper disposal of items to be eliminated from the inventory stock as the result of decomposition or for other reason at the request of the COR. No samples should be disposed without authorization of the COR.

j. Receive returned chemicals and drugs and return to inventory or dispose.

k. All work shall be performed utilizing good laboratory techniques in accordance with accepted industry standards.

3. Shipping and Distribution

a. Weigh, package and ship chemicals and drugs as approved by the COR to NCI screening laboratories and external research investigators. These may be located domestically or internationally (e.g. Europe, Asia, Australia).

b. Provide special handling and packaging for heat and/or light sensitive and labile chemicals and drugs. The shipments shall conform to all laws and regulations, both domestic and international, governing the shipping of hazardous substances and other regulated substances.

c. Furnish shipping cartons, cushioning materials, labels, containers, insulating material, dry ice and any other supplies to insure the safe, intact arrival of the contents of each package shipped.

d. Update inventory transactions, document the shipment of compounds, and associated data to the NCI chemical database.

e. Provide for regular (3-4/week) overnight shipments of samples to the NCI testing and screening laboratories in Frederick, MD. Include provisions for 1-day turnaround for a limited number of expedited shipments.

4. Plating Operations

a. Array selected compounds in 96-well plates. Plates will generally be generated using DMSO solvent. Employ appropriate methods to preclude absorption of water both while generating and storing plates (e.g. inert atmosphere conditions). Maintain government provided plating apparatus in good working condition.

b. Create mother plates and replicate copies (up to 50) of plated compound sets for distribution to investigators as needed. These sets include a Diversity Set of ~1600 samples representative of the total structural database, a Mechanistic Diversity Set of ~880 compounds, and an Approved Oncology Drug Set of ~97 compounds. The generation of additional diverse and focused plated sets may be requested by the COR as determined by Program needs.

c. Store plated sets (-20 to -25 deg C.) until distribution is requested.

d. Receive, document and store, prior to distribution, plated libraries from outside investigators and institutions.

e. Appropriately package and ship DMSO plated compounds to investigators. Packaging and shipping methods should be selected to maintain integrity of plates and their contents. In general, this requires insulated shipping containers containing dry-ice or cool packs.

f. Maintain the capability to ship packages to all countries worldwide.

5. Analytical Testing

a. The Contractor should have the capability to provide analytical data on a limited number of samples. This should include standard analytical methods to determine chemical structure and purity (e.g. elemental analysis, IR, 1H NMR, 13C NMR, MS and LC/MS). The specific test required will be directed by the COR.

b. The turnaround time for analyses should not exceed 5 working days.

6. Security and Safety

a. The Contractor shall not divulge any information concerning the suppliers, chemicals and drugs received, stored, or shipped except to authorized personnel as indicated by the COR. All other inquires should be directed to the COR (See Article H).

b. The Contractor shall comply with all pertinent security and safety requirements required by applicable Federal, State and local government regulations.

c. Personnel assigned to the project shall be bonded.

d. The chemical storage areas shall be protected from fire damage by systems other than water sprinklers.

e. The Contractor shall be the authorized waste disposal agent for work performed under this contract and comply with all local, State and Federal regulations.

f. The Contractor shall provide appropriate and adequate safeguards to insure for the safety and security of all Government-owned property including but not limited to, chemical inventory, laboratory equipment, computers and hard copy, film and electronic information. The Contractor shall also maintain all Government-owned equipment in good working order.

g. The Contractor shall provide appropriate and adequate safeguards to insure for the safety and security of all Government-owned property which is removed by the Contractor's employees from the Contractor' facility (e.g. hard copy documents, laptops, compact discs, flash memory devices).

h. The Contractor shall conform to all applicable NIH policies in regards to Internet and computer security and training (e.g. firewalls, virus protection, password protection, encryption, etc.).