

SAMPLE TASK ORDER 1 STATEMENT OF WORK

Please note: This Sample Task is for Technical Evaluation Purposes Only. No work will be awarded.

“Evaluate a Novel Class of Immunomodulators for Basic Biological Function, Mechanism of Action and Potential as an Antitumor Therapy in Murine Models”

Scope

The purpose of this Task Order is to evaluate a novel class of naturally occurring biological immunomodulators that has been identified. A member of this class of immunomodulators was originally discovered and patented by a Pharmaceutical Company. It has been found in multiple mammalian species and has activity across species including mice and humans. Because the Company is not focused on basic research or pre-clinical studies, the Company is providing it to researchers for basic research/pre-clinical evaluation provided that results are shared with them. The Company produces the immunomodulator using non-cGMP procedures. Moreover, there are other research groups that have reported the identification of other molecules that may be other members of this class of immunomodulators. Because of the expertise of the National Cancer Institute and the resources of the Frederick National Laboratory for Cancer Research, the NCI has decided to have the FNLCR perform studies on this new class of immunomodulators, including the one originally identified by the Pharmaceutical Company and others that have been more recently identified. Appropriate in vitro and vivo assays need to be selected/developed based upon the biological activity that has already been described. These assays are to be used to perform studies to elucidate the biological activity of this class of molecules, understand mechanism of action and to evaluate potential as an antitumor therapy.

Period of Performance: 12-month Base, plus 4 one-year option periods

The Contractor shall perform the following tasks:

A. Project Management

1. Manage staff and resources to effectively provide services to perform this work.
2. Coordinate and integrate all of the Task Order activities including staffing decisions, development and implementation of Standard Operating Procedures (SOPs), prioritizing support for projects, preparing required reports, deliverables and other official documentation. The Contractor shall ensure quality assurance/quality control of the

work performed, fostering internal/external communications, tracking projects, and monitoring the budget.

3. Analyze the task requirements and employ appropriate innovative and standardized approaches in the performance of tasks.
4. Provide services in task-centric manner ensuring that similar tasks are performed in a similar standardized manner as directed by the Contracting Officer's Representative (COR).
5. Propose the research design for the project including, but not limited to animal models, experimental approach, and experimental design and provide it to the Government Contracting Officer's Representative for review and approval.
6. Meet for one-hour on a monthly basis with the COR to review progress and priorities and discuss strategies and plans. The Contractor shall meet with the COR and noted technical designees in face-to-face and/or teleconference meetings quarterly to review task order performance and discuss project management issues.
7. Ensure that any new hire or departure of staff on tasks shall be performed with minimal impact on delivery of work.

B. Establishment of BSL-2 testing laboratory in existing temporary space

1. Establish and validate initially available assays (including dose and time response) for measuring *in vitro* biological and antitumor activity of this novel class of compounds.
2. Evaluate the *in vitro* biological and antitumor activity of initially available materials from the Pharmaceutical Company and employing the Pharmaceutical Company's previously developed relevant assays (including dose and time response).
3. Repeat experiments in sufficient number to meet statistical and peer-review expectations.

C. Establishment of animal testing services in existing animal facilities

1. The Contractor shall establish and validate initially available animal models (including dose and time response) for measuring *in vivo* biological and antitumor activity.

2. The Contractor shall evaluate the *in vivo* biological and antitumor activity of initially available materials employing initially available animal models (including dose and time response).
3. Repeat experiments in sufficient number to meet statistical and peer-review expectations.

D. Implement strategy for thorough evaluation of activity and testing of additional molecules

1. The Contractor shall establish and validate additional assays (including dose and time response) to elucidate the biological function, mechanism of action and potential as an antitumor agent for this novel class of compounds using *in vitro* assays and/or *in vivo* animal models. These additional assays and animal models may come from: NIH/NCI investigators, other government agencies, industry, or academic investigators.
2. The Contractor shall acquire additional molecules that may be members of this new class of immunomodulators and employ relevant assays (including dose and time response) to evaluate the *in vitro/in vivo* biological function, mechanism of action and potential as an anti-tumor agent. These additional molecules may come from: NIH/NCI investigators, other government agencies, industry, or academic investigators.
3. Repeat experiments in sufficient number to meet statistical and peer-review expectations.

E. Coordinate studies with additional sites

1. Distribute molecules from this new class of immunomodulators to other laboratories that have unique assays that can be applied to further evaluate these molecules. The other laboratories may be located at the NIH/NCI, other government agencies, industry or academia.
2. Establish agreements for distribution which may be in the form of collaborations or other appropriate mechanisms.

F. Travel

1. Scientist level research staff shall attend one national/international scientific meeting per year. This staff person shall present research data at the meeting.
2. Scientist level research staff shall travel to visit with one collaborator per year.

G. Equipment

1. Obtain necessary specialty laboratory equipment for use in performance of the project.
2. Be provided by the Government with standard laboratory equipment such as chemical fume hoods, biosafety cabinets, refrigerators, freezers, incubators, computers and centrifuges.
3. Be provided by the Government with standard office furniture including desks, file cabinets, copiers, and computers.

H. Materials and Supplies

1. Obtain, in sufficient quantity, the appropriate materials and supplies for the performance of these studies. These materials and supplies include but are not limited to: common laboratory supplies (such as pipets, test tubes, flasks, pipet tips, tissue culture plates/flasks, etc.), non-capital equipment (such as pipettors, gel box apparatus, small centrifuges, water bathes, etc.) and research reagents (such as antibodies, tissue culture medium, restriction enzymes, cell lines, radioisotopes, etc.)
2. Obtain, in sufficient quantity, the appropriate types of mice to perform the research studies.

I. Other Considerations

1. For all aspects of this Statement of Work, identify elements of risk and describe alternative approaches to mitigate risk.
2. Identify applicable regulations, certifications, accreditations and/or guidelines.
3. Establish go, no-go milestones for all aspects of this Statement of Work.
4. Publish results as appropriate, in peer-reviewed scientific journals.
5. Communicate all findings to the Pharmaceutical Company as described in agreements.
6. Apply for patents as appropriate.

7. Identify all technology transfer issues and assure that all are addressed to meet regulations, policies and guidance.
8. Identify effective bioassay for use in cGMP production and documentation containing information needed to transition to clinical trials.
9. Assume suitable and sufficient laboratory, office and animal facility space is available to perform these studies. Sufficient animal husbandry will be provided.