

Department of Veterans Affairs

Office of Research & Development

Neurobiological Mechanisms of Reduced AD Neuropathology by Treatment of Diabetes Statement of Work (SOW)

A. GENERAL INFORMATION

1. **Title of Project:** Project is entitled “**Neurobiological Mechanisms of Reduced AD Neuropathology by Treatment of Diabetes.**” This project is funded by VA Merit award to Dr. Vahram Haroutunian, PhD; Research Scientist, for the VHA.
2. **Background:** QuantiGenePlex Assay (QGP) Kits are used to measure levels of various RNA transcripts in a given sample. In support of VA Merit project entitled: Neurobiological Mechanisms of Reduced AD Neuropathology by Treatment of Diabetes
3. **Scope of Work:** Produce QGP Assay Kits
4. **Period of Performance:** 11/01/2015-09/30/2016
5. **Type of Contract:** Cost Per Item
6. **Place of Performance:** At the Vendor’s Factory.

B. GENERAL REQUIREMENTS

1. The Vendor shall have a facility capable of producing QGP Assay kits of the quantity and quality required.
2. The Vendor shall have the capability to ship the product to an overseas laboratory.

C. SPECIFIC MANDATORY TASKS AND ASSOCIATED DELIVERABLES

1. Produce QGP Assay kits
2. Ship QGP Assay kits to JJP VAMC

Deliverable: QGP Assay kits pieces as identified

D. Quality Assurance

Vendor’s own QA will review product prior to shipment. Our Scientists will review as used.

Task: Submit a Confidentiality Plan and Data Security Procedures: NA

E. SCHEDULE OF DELIVERABLES: As soon as possible, ideally within 30 days of receipt of purchase order.

F. INSPECTION AND ACCEPTANCE CRITERIA : Sealed packages received at collaborating laboratory will be inspected prior to use. Packages arriving in broken packages or containers will be rejected and returned to the vendor for replacement.

This section will be a part of the Quality Assurance Surveillance Plan (QASP). Note that the table below is directly related to the tasks and deliverables in Section C, Specific Mandatory Tasks & Deliverables above, and Attachment A, Schedule of Deliverables.

TASKS	DELIVERABLE	STANDARD	AQL	METHOD(S) OF SURVEILLANCE
Task: Produce QGP Assay Kits	Deliverable: Specified QGP Assay kits and pieces as required	Received within 45 days	<45 days	Physical Receipt of kits
Task: Ship kits to JJP VAMC	Deliverable: Ship kits as required	Received within 45 days	<45 days	Physical Receipt of kits

The Government will monitor performance and review deliverables utilizing solicited and unsolicited feedback from all applicable resources as follows:

Months 1-6: Telephone conferences between the VA PI and the Vendor POC estimated once a month.

Month A/R: Inspection of the output files (fastq files) by the VA PI.

F. CHANGES TO STATEMENT OF WORK

Any changes to this SOW shall be authorized and approved only through written correspondence from the Contractor POC. A copy of each change will be kept in a project folder along with all other products of the project. Costs incurred by the Contractor through the actions of parties other than the Contractor shall be borne by the Contractor.

G. GOVERNMENT RESPONSIBILITIES

Receive and inspect shipped product.

H. KEY PERSONNEL

The Vendor shall be responsible for managing and overseeing the activities of all Vendor personnel, as well as subcontractor efforts used in performance of this effort. The Vendor's management responsibilities shall include all activities necessary to ensure the accomplishment of timely and effective support, performed in accordance with the requirements contained in the statement of work.

The Contracting Officer may notify the Vendor and request immediate removal of any personnel assigned to the task order by the Vendor that are deemed to have a conflict of interest with the government or if the performance is deemed to be unsatisfactory. The reason for removal will be

documented and replacement personnel shall be identified within three business days of the notification. Employment and staffing difficulties shall not be justification for failure to meet established schedules.

1. Key Personnel: A point of contact may be designated by the vendor.

Name

Title

2. Substitution of Key Personnel: All Vendor requests for approval of substitutions hereunder shall be submitted in writing to the COR and the Contracting Officer at least thirty (30) calendar days in advance of the effective date, whenever possible, and shall provide a detailed explanation of the circumstances necessitating the proposed substitution, a complete resume for the proposed substitute, and any other information requested by the Contracting Officer necessary to approve or disapprove the proposed substitution. New personnel shall not commence work until all necessary security requirements, as defined in Section J, have been fulfilled and resumes provided and accepted. The COR and the Contracting Officer will evaluate such requests and promptly notify the Contractor of approval or disapproval in writing.

I. PERSONNEL QUALIFICATIONS:

Those skillsets and provided as determined by the Vendor.

J. SECURITY

This information should come directly from the most current Handbook 6500: Information Security Program, as directed by the Information Security & Privacy Officers.

Information System Security

The contractor shall ensure adequate LAN/Internet, data, information, and system security in accordance with VA standard operating procedures and standard contract language, conditions laws, and regulations. The contractor's firewall and web server shall meet or exceed the government minimum requirements for security. All government data shall be protected behind an approved firewall. Any security violations or attempted violations shall be reported to the VA project manager and the VHA Headquarters Information Security Officer as soon as possible. The contractor shall follow all applicable VA policies and procedures governing information security, especially those that pertain to certification accreditation.

Security Training

NA

Contractor Personnel Security

NA

All contractor employees who require access to the Department of Veterans Affairs' computer systems shall be the subject of a background investigation and must receive a favorable adjudication from the VA Security and Investigations Center (07C). The level of background security investigation will be in accordance with VA Directive 0710 dated September 10, 2004 and is available at: <http://www.va.gov/pubs/asp/edsdirec.asp> (VA Handbook 0710, Appendix A, Tables 1-3). Appropriate Background Investigation (BI) forms will be provided upon contract (or task order) award, and are to be

completed and returned to the VA Security and Investigations Center (07C) within 30 days for processing. Contractors will be notified by 07C when the BI has been completed and adjudicated. These requirements are applicable to all subcontractor personnel requiring the same access. If the security clearance investigation is not completed prior to the start date of the contract, the employee may work on the contract while the security clearance is being processed, but the contractor will be responsible for the actions of those individuals they provide to perform work for the VA. In the event that damage arises from work performed by contractor personnel, under the auspices of the contract, the contractor will be responsible for resources necessary to remedy the incident.

The investigative history for contractor personnel working under this contract must be maintained in the databases of either the Office of Personnel Management (OPM) or the Defense Industrial Security Clearance Organization (DISCO). Should the contractor use a vendor other than OPM or Defense Security Service (DSS) to conduct investigations, the investigative company must be certified by OPM/DSS to conduct contractor investigations.

M. SECTION 508

The contractor shall comply with Section 508 of the Rehabilitation Act (29 U.S.C. § 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998.

In December 2000, the Architectural and Transportation Barriers Compliance Board (Access Board), pursuant to Section 508(2) (A) of the Rehabilitation Act Amendments of 1998, established Information Technology accessibility standards for the Federal Government. Section 508(a)(1) requires that when Federal departments or agencies develop, procure, maintain, or use Electronic and Information Technology (EIT), they shall ensure that the EIT allows Federal employees with disabilities to have access to and use of information and data that is comparable to the access to and use of information and data by other Federal employees. The Section 508 requirement also applies to members of the public seeking information or services from a Federal department or agency. Section 508 text is available at:

<http://www.opm.gov/HTML/508-textOfLaw.htm>
<http://www.section508.gov/index.cfm?FuseAction=Content&ID=14>

N. CONFIDENTIALITY AND NONDISCLOSURE

It is agreed that:

1. The preliminary and final deliverables and all associated working papers, application source code, and other materials deemed relevant by the VA which have been generated by the contractor in the performance of this task order are the exclusive property of the U.S. Government and shall be submitted to the CO at the conclusion of the task order.
2. The CO will be the sole authorized official to release verbally or in writing, any data, the draft deliverables, the final deliverables, or any other written or printed materials pertaining to this task order. No information shall be released by the contractor. Any request for information relating to this task order presented to the contractor shall be submitted in writing to the CO for response.

3. Press releases, marketing material or any other printed or electronic documentation related to this project, shall not be publicized without the written approval of the CO.

4. The Contractor will sign a National Business Associate Agreement with the VA, in accordance with the mandated guidelines.

O. RIGHTS IN DATA

Performance of this effort may require the contractor to access and use data and information proprietary to a Government agency or Government contractor which is of such a nature that its dissemination or use, other than in performance of this effort, would be adverse to the interests of the Government and/or others.

Contractor and/or contractor personnel shall not divulge or release data or information developed or obtained in performance of this effort, until made public by the Government, except to authorize Government personnel or upon written approval of the Contracting Officer (CO). The contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as required in the performance of this effort. Nothing herein shall preclude the use of any data independently acquired by the contractor without such limitations or prohibit an agreement at no cost to the Government between the contractor and the data owner which provides for greater rights to the contractor.

The Department of Veterans Affairs shall have unlimited rights to and ownership of all deliverables provided under this effort, including reports, recommendations, briefings, work plans and all other deliverables. This includes the deliverables provided under the basic award as well as and any optional task deliverables that are exercised by the Contracting Officer. The definition of “unlimited rights” is contained in Federal Acquisition Regulation (FAR) 27.401, Definitions.

P. TASK ORDER TERMINATION

VA has the right to terminate (in whole or in part) this task order at any time in accordance with the termination clauses of the governing GSA Schedule Contract. The Contractor will be paid only for the services rendered up to the point of receiving the termination notice, and then only to the extent that those services meet the requirements of this SOW.

Q. CONTRACT ADMINISTRATION:

Notwithstanding the Contractor's responsibility for total management during the performance of this contract, the administration of the contract will require maximum coordination between the Government and the Contractor. The following individuals will be the Government's points of contact during the performance of this contract:

1. Contracting Officer: TBD
Contract Specialist: TBD

2. Contracting Officer's Technical Representative (COR): To be designated at time of contract award.

The COR shall be designated on the authority of the Contracting Officer at the time of contract award to monitor all technical aspects of the contract. In no event is the COR empowered to change any of the terms and conditions of the contract. Changes in any section of this contract shall be made only by the Contracting Officer pursuant to a properly executed modification. The types of actions within the purview of the COR's authority are to ensure that the Contractor performs the technical requirements of the contract, and to notify both the Contractor and the Contracting Officer of any deficiencies observed. A memorandum of designation shall be issued to the COR and a copy shall be sent to the Contractor at the time of contract award setting forth in full the responsibilities and limitations of the COR

Attachment A

Note that the Deliverable Table is directly related to the tasks and deliverables in Section C above.

Schedule of Deliverables

DELIVERABLE NUMBER	ITEM	QUANTITY	DELIVERY DATE
1	Task: Produce QGP Assay kits	Deliverable: Specified QGP Assay kits and pieces as required	Received within 45 days
2	Task: Ship kits to JJP VAMC	Deliverable: Specified QGP Assay kits and pieces as required	Received within 45 days