

**DEPARTMENT OF VETERANS AFFAIRS
VISN 1 NETWORK CONTRACTING ACTIVITY
JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION**

1. Agency and Contracting Activity Identification: The Department of Veterans Affairs VISN 1 Network Contracting Activity on behalf of the VA Connecticut Healthcare System as described in transaction number 689-11-3-373-0072.

2. Nature of Acquisition Being Approved: A new basic ordering agreement with Yale University Positron Emission Tomography (PET) Center. An agreement of three years duration is requested.

3. Description of Supplies or Services to Meet Agency Needs:
The Government expects that the contract will enable collection of PET research data at Yale University. The Government expects that each PET data collected is provided as high quality and usable for research purposes, not clinical purposes, to support scientific data analysis.

4. Statutory Authority Permitting Other Than Full and Open Competition: Contracting without providing for full and open competition is authorized by 41 U.S.C. 253(c)(5) as implemented by FAR 6.302-5 and VAAR 806-302-5(a)(2) Authorized or Required by Statute. Yale University is an affiliate of the Department of Veterans Affairs. (38 USC 8153)

5. Demonstration of the Proposed Contractor's Unique Qualifications or the Nature of the Acquisition Requires Use of the Authority Cited:

The Yale University Positron Emission Tomography (PET) Center is the only PET center in the New England and surrounding states that can provide the required state-of-the-art molecular imaging facilities required by our research protocols. Resources include a GE PETtrace cyclotron, with targetry for producing positron-emitting isotopes such as C-11, F-18, N-13 and O-15; a radiochemistry laboratory with 8 hotcells and modules for the production of a wide variety of radiotracers; a CTI HR+ whole body scanner; a Siemens HRRT scanner for imaging the brain and small animals; and a Focus220 small animal scanner. The Center also has a fully equipped laboratory for blood and metabolite analyses and an image analysis laboratory for investigators, with several workstations running image analysis software applications.

Specific and unique facilities provided by the PET center are as follows. The Radiotracer Laboratory Complex at the PET Center, Yale University School of Medicine, is fully equipped for radiotracer synthesis with 4 mini hot cells, 4 full size hot cells, and automated or remote synthesis devices for preparation of radiotracers labeled with C-11, F-18, N-13 and O-15. There is a water target (H216O) for the production of N-13 ammonia and a water target (H218O) for the production of [18F] fluoride, as well as nitrogen gas targets for the production of carbon-11 and oxygen-15, and an automated system for the production of [11C]cyanide. The lab is also equipped with several automated synthesis modules from GE Medical Systems, including Microlab for the production of [11C]methyl iodide, two FXc-Pro methylation boxes for synthesis of various C-11 tracers, an FDG synthesis machine and two F-18 synthesis modules

(nucleophilic substitution box and electrophilic substitution box). Another automated synthesis module for C-11 labeling is the Bioscan Autoloop. A semi-automated module for carrying out multi-step synthesis has also been set up. The Radiotracer Laboratory has TLC scanners, HPLCs with UV, radioactivity detectors, LC/MS, and counting equipment (ion chambers, pin diode detectors and well counters). There are also facilities for the preparation of sterile radiopharmaceuticals, including pyrogen burning ovens and laminar flow hoods, and for LAL testing of pyrogens, which is performed in-house. Cold chemistry laboratories in the LMP building are equipped for the purpose of developing new synthetic strategies for C-11 and F-18 labeled radiotracers and to synthesize the unlabeled precursors required for radiotracer development and production. The PET Center has a new GE PETtrace cyclotron for radioisotope production, with 19 MeV protons and 10 MeV deuterons for production of [11C]cyanide and [11C]methyl iodide (GE Medical Systems unit). This cyclotron has a total of six targets. In addition to the two C-11 targets, it also has a target to produce O-15, a water target (H216O) for the production of N-13 ammonia, a water target (H218O) for the production of [18F]fluoride, and a gas target for the production of [18F]F2. The PET Imaging suites have one whole body PET scanner (Siemens HR+ with 32 rings and 63 planes with a resolution of ~ 5 x 5 x 5 mm at center of field of view), one dedicated brain scanner (Siemens HRRT, 104 rings, 207 slices with resolution of better than 3 x 3 x 3 mm) and one small animal PET scanner (Focus 220, 48 rings, 95 slices with a resolution of ~ 1.4 x 1.4 x 1.4 mm at center field of view). Adjacent to each scanner room are patient prep and post-scan rooms. The HR+ has a SUN workstation dedicated to image acquisition, reconstruction, and archiving. The HRRT acquires its list-mode data on a high-end PC with 1 TB of disk. The list-mode data files are transferred over the local Gigabit network (behind a hardware firewall) to a dedicated Linux cluster with 58 nodes and 136 processors (3.0-3.2 MHz) and ~ 17.5 TB of disk storage. Images are reconstructed with the MOLAR algorithm (Motion-compensation OSEM List-mode Algorithm for Resolution-recovery Reconstruction). Subject motion information is collected with a Vicra (NDI, Canada), which records head motion at a rate of up to 20 Hz. These are stored in a time-synced file and used by MOLAR to correct head motion. The Focus 220 also acquires its list-mode data on a high-end PC, which is also used to reconstruct images using the manufacturer's software. Continuous bed motion and dual-gated acquisitions are features of the Focus 220. For both the HR+ and HRRT, final images are converted to DICOM format and saved on the 17.5 TB disk farm. The disk farm is backed up to tape nightly. Image processing is performed on one of 4 Linux (Redhat WS4) workstations housed in a data processing room connected to the network with NFS mounts to the 17.5 TB disk array. These systems may be used at their consoles or over the network via X windows. Image data are accessed via the HAVEN image database using scripts and programs employing the commercial programs IDL and MEDx. All data are identified with a code created at the time of the subject's first PET scan. Patient identification can only be obtained from password restricted access to the HAVEN database. Programs and scripts developed for image processing include PET-MR image registration, region-of-interest placement (on PET or MR), time-activity curve creation, input function creation (see Metabolite lab, below), mathematical modeling routines to create parametric images of flow, metabolism, binding potential, etc. and partial volume correction. An analytical laboratory is adjacent to the PET Imaging suites, with pass-through doors to allow direct passing of samples. This lab includes two Perkin Elmer Wizard gamma counters, scales, centrifuges, blood glucose analyzer and HPLC equipment to analyze plasma samples for unchanged radiotracer, enabling generation of input functions required for kinetic analysis and image quantization. As appropriate, all devices are connected to

the network (some via a terminal server) to allow direct reading of the data by IDL programs on the Linux machines. Adjacent to the scanner suites is a hot lab for dose preparation and assay. The Capintec CRC-15PET is connected to a terminal server to allow web-based reading of activity in the syringe. These measurements are automatically stored in the HAVEN database and can be displayed in real time via web browsers throughout the facility, with the current activity calculated using the appropriate decay constant.

The Yale PET Center also provides certified scanner technicians to assist with the contract request as part of the hourly price rate. The PET Center provides expertise and service for the state-of-the-art scans collected by the NCPTSD, making Yale one of the few places in the world capable of providing all the necessary resources to achieve our scientific aims. No other PET supplier is capable or will satisfy the requested contract as it relates the specific scientific aims/objectives. A scientific review of local sites was conducted to determine if Yale PET Center is truly a sole source. The results of this search including literature reviews, reviews of electronically available materials, and reviews of available PET hardware at local sites indicated that Yale PET Center is a sole source for the contract. The physical location of the Yale PET Center allows is relevant to the sole source justification as it is near in proximity to the VA Connecticut Healthcare System and a convenient location for research volunteers.

6. A Description of Efforts Made to Ensure That Offers Are Solicited From as Many Potential Sources as is Practicable and Whether a Notice Will Be Publicized: The COTR and VA investigator will continue to monitor and survey developments in the field of PET in advanced research.

7. Determination Anticipated Cost Will Be Fair and Reasonable: The pricing will be compared to the approximate CPT codes available from the CMS contract intermediary. The pricing is comparative information.

8. Description and Results of Market Research or Statement why Market Research Was Not Conducted:

A review of PET facilities was conducted to determine that Yale PET Center is truly a sole source. A review of local facilities by Dr. Brian Schweinsburg revealed Yale PET Center as the only source capable of providing the requested resources for data collection. The PET Center provides expertise and service for the state-of-the-art scans collected by the NCPTSD, making Yale one of the few places in the world capable of providing all the necessary resources to achieve our scientific aims. The fee for the scan also provides resources for experienced PET technologists that assist in the collection of NCPTSD data. This service is also solely provided by the Yale University PET Center. No other PET supplier is capable or will satisfy the requested contract as it relates the specific scientific aims/objectives. Specifically, the facilities and capabilities of the following local sites were evaluated and determined to not meet the needs for our research studies:

VA Connecticut Healthcare System, 950 Campbell Avenue, West Haven, CT 06516

Saint Raphael Hospital, 1450 Chapel Street, New Haven, CT 06511

Yale-New Haven Hospital, 20 York Street, New Haven, CT 06519

VA Connecticut Healthcare System, 555 Willard Avenue, Newington, CT 06111

9. Any Other Facts Supporting the Use of Other Than Full and Open Competition: There are no other sites available within a reasonable proximity (i.e., driving distance for research volunteers) that provide the full range of services required by the NCPTSD PET studies that the Yale PET Center provides on a regular basis. Further, VA studies ongoing and previous at the NCPTSD have utilized Yale PET Center and the continued use of these services benefits cohesive and consistent research efforts.

10. List Any Other Sources That Expressed Interest in Writing No sources have expressed an interest, in writing, in this acquisition.

11. A Statement of the Actions, if any, the Agency May Take To Remove or Overcome Any Barriers to Competition Before Any Subsequent Acquisition is required. The COTR and VA investigator will continue to monitor and survey developments in the field of PET in advanced research.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Brian Schweinsburg, Ph.D.
Ph.D.

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Brian Schweinsburg, PhD
Research Scientist
National Center for Posttraumatic Stress Disorder
Clinical Neurosciences Division
VA Connecticut Healthcare System

Date

13. Approvals in accordance with FAR 6.304

a. Contracting Officer's Certification: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

John A. Young

Digitally signed by John A. Young
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Contracting Officer
VISN 1 Contracting

- b. **One Level above Contracting Officer: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.**

Kristine Clark

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- c. **QA: I certify the justification meets requirements for other than full and open competition.**

Mary J

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Quality Assurance
VISN 1 Contracting