

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA260-17-AP-6163

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 20, VA Puget Sound Healthcare System (VAPSHCS).
- 2. Nature and/or Description of the Action Being Processed:** Justification and Approval (J&A) for the "Brand name" selection of the items listed in Table 1 below. This action will be awarded as a new Firm-Fixed-Price contract with an estimated value of \$459,182.57. The requested contract covers goods & services to supply the Government with the above listed systems with options that enables biomedical research capabilities. These Fisher Scientific models have been used and validated for protocol compliance. Rigorous protocol compliance and its associated instrumentation, equipment characteristics and dimensions are required to establish an essential research capacity that, in part, fulfills the VAPSHCS VISN20 MIRECC's Congressionally-mandated investigation of posttraumatic stress disorder (PTSD) and its comorbidities which includes, but is not limited to, traumatic brain injury (TBI). Estimated award date: September 2017.

Table 1: Fischer-Scientific Brand Name Items

Item #	Description/Part Number*	Qty	Price
1	TSX600A ULT FZ TSX600A 115V/50-60HZ	13	
2	1950520 SIDE RACK 25-2 BX 4 DOOR	234	
3	13 998 123 FORMA SERIES 3 WJ CO2 W TC 12	4	
4	13 998 215 HERA 160I CO2 CU 1-21 TC 120V	1	
5	13 998 216 HERA 160I CO2 CU 5-90 TC 120V	1	
6	13 998 147 STAND WITH CASTORS FOR 160L C	1	
7	11 676 071 MAXQ 4450 DIGITAL PROMO PKG	1	
8	75 393 839 SORVLEGXFR120V TC28/56	1	
9	75 003 624 M-20 MICROPLATE ROTOR	1	
10	75 003 723 27 X 5/7 ML ADAPTERS 4/PK	1	

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11	75 003 643 4 X 50 ML ADAPTER	1
12	75 004 521 CENTF SORVALL XTR 120V 60HZ	1
13	75 003 642 9 X 15 ML ADAPTER	1
14	75 003 643 4 X 50 ML ADAPTER	1
15	75 006 590 LYNX 6000 200-240V 50/60 HZ EA	1
16	09 606 1075 ROTOR LYNX F9-6X1000 LEX EA	1
17	09 614 5075 ROTOR LYNX F14-14X50CY EA	1
18	09 648 4075 ROTOR LYNX F23-48X1.5 EA	1
19	75 003 004 ROTOR LYNX A21-24X15C EA	1
20	75 003 000 ROTOR LYNX BIOFLEX HC 4X1L EA	1
21	75 007 309 TX-1000 BIOCONTAINMENT LIDS	1
22	75 007 301 ADAPTER TX-1000, 1X1000 ML (SE	1
23	75 003 674 10 X 50 ML ADAPTER 4PK	1
24	75 007 306 ADAPTER TX-1000, 15 ML CONICAL	1
25	75 003 671 49 X 5/7 ML ADAPTER 4PK	1
26	12 463 377 EVOS FL AUTO	2
27	12 563 550 EVOS ON STAGE INCUBATOR	2
28	12 563 536 OBJ: 10X PLAN LWD FL/PH 0.25NA	2
29	12 563 537 OBJ: 20X PLAN LWD FL/PH 0.40NA	2
30	12 563 467 OBJECTIVE: 40X FL PLAN/0.65NA	2
31	12 563 468 OBJECTIVE: 60X FL PLAN/0.75NA	2
32	12 563 469 DAPI FLUORESCENT LIGHT CUBE	2
33	12 563 470 GFP FLUORESCENT LIGHT CUBE	2
34	12 563 474 TX RED FLUORESCENT LIGHT CUBE	2

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35	AMQAF1000 COUNTESS II FL	1	
36	A25750 COUNTESS II FL REUSABLE SLIDE	1	
37	R10477 MOLECULAR PRO CELL IMAGING KIT	2	

3. Description of Supplies/Services Required to Meet the Agency's Needs: The VISN 20 VAPSHCS MIRECC requires the following pieces of equipment that are defined by their key required "Salient characteristics" that are listed as associated bullet points:

a. Evos FL Auto Microscope / Imaging system: CLINs 26-34

The Government requires expanded imaging capability to serve 3 physically separated and functionally distinct tissue culture rooms (which prevent the import / export of outside materials) to perform live cell fluorescence imaging of primary nervous cells, immortalized mammalian cells, c. elegans, stem cells (iPSC, etc.) and tissue. The Government requires compact fluorescence microscopes with the capability to perform automated time-lapse imaging under incubator conditions of gas and temperature maintenance capable of being sustained inside of a biosafety cabinet. This compact automated fluorescence microscope shall be able to perform time-lapse imaging with the added benefit of 3-gas environmental control and the potential to fit inside of a biosafety cabinet. Thermo Fisher's EVOS FL Auto Cell Imaging System is the only system capable of meeting this requirement. The EVOS FL Auto includes the required compact integrated unit with microscope, digital camera, computer, and high-power LED fluorescence illumination. It can be operated in any location, due to its provided light-shielding. This is critical because our lab space does not allow the set-up of a dedicated dark room that would be required to operate almost all other fluorescence microscopes. The LED "light cubes" for the microscope are interchangeable with the Countess II FL cell counter, which we are also planning to purchase. Being able to exchange the light cubes between the two instruments will save the lab \$6,000. We're also planning to purchase the EVOS onstage incubator, which will allow automated control of gas exchange for studies of hypoxia, exposure to ozone, biomolecules, and other harmful volatilized substances. The three-line gas control of the onstage incubator, integrated with the time-lapse software, provides the unique ability to study live cells under highly controlled atmospheric conditions that would be difficult or impossible to achieve with conventional live-cell imaging microscopes. The EVOS FL Auto environmental chamber has a much smaller volume than any other on the market and moves with the stage top. Access to the chamber is provided with a simple lid that's held in place with magnets, allowing the user to quickly open the chamber, switch out live cell plates, and close it while retaining most of the atmospheric environment. The EVOS FL Auto environmental chamber volume can be switched to fully hypoxic conditions in less than two minutes. Other

competing systems use a large clamshell chamber that opens completely, which immediately loses all the atmospheric conditions inside the chamber. Re-establishing the atmospheric conditions with these clamshell chambers takes much longer. In terms of utility and convenience, the EVOS FL Auto environmental chamber is much better suited for studies involving critical atmospheric manipulations, and the extra gas line is essential for flexibility in providing different atmospheres compared to the standard two lines (O₂ and CO₂) commonly used for mammalian cells. For these reasons, we require the unique capabilities of the EVOS FL Auto microscope, and request a sole-source waiver for its purchase.

- b. Thermo Scientific Forma Series 3 Water Jacketed CO₂ Incubator is required to meet the following user defined criteria: CLIN 3
- The incubator chamber must be constructed entirely of polished, corrosion resistant stainless steel with coved corners to simplify cleaning and decontamination practices to minimize the potential for unwanted contamination.
 - Needs to have triple wall water jacket construction which surrounds sides, back, top, and bottom of chamber with thermally conditioned water to provide superior temperature stability, particularly during power outages or failures
 - Interior chamber capacity of 6.5 cu. ft. (184 liters).
 - Footprint of 26"W x 25" D
 - Incubator stainless steel shelving and supports which can be readily assembled and removed without use of tools, to facilitate cleaning or adjustment
 - An in-chamber HEPA filtered airflow system within the culture environment to continuously filter the entire chamber air volume every 60 seconds to insure continuous protection against unwanted microbial contaminants which could enter upon routine door openings, minimizing the associated risk of product loss or inconvenient downtime
 - Superior Class 100 cleanroom air quality achieved within the culture chamber in under 5 minutes following a typical door closing to prevent the opportunity for invading contaminants to settle on interior surfaces where they can pose a threat to valuable cultures.
 - The incubators on-board contamination control technologies have been validated by independent third party testing facilities.
 - A filtered air exchange system within the incubator that minimizes the risk of condensation, a common breeding ground for contamination within a humid culture environment
 - A heated dual inner glass door design to facilitate quick recovery to desired set temperature following door openings while minimizing resultant condensation.

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- High quality microbiological filters on all gas inlets, outlets and sample ports, to eliminate the potential of contamination into the chamber from these entry points.
 - Capable of being supplied with a choice of either highly stable and long lasting TC gas sensor or enhanced sensitivity IR sensors.
 - Unit needs to have touch screen user interface to simplifying daily operation for researchers with improved access to incubator functions and information to include specific performance or operational data, data and error logging, on-screen operational prompts, user specific electronic security.
 - Control and measurement probes and sensors located directly inside the culture chamber to provide true and accurate process data and foster faster parameter recovery times than possible with remotely located sensors outside the chamber.
 - Incubator provides field reversible inner and outer doors.
 - Units are readily stackable.
 - Incubator is equipped with programmable tracking alarms for critical temperature and CO2 control parameters that can be custom configured to meet the needs of changing research requirements
 - Incubator is UL listed. CSA certified, and CE marked.
 - A relative humidity monitoring system and display with an alarm function that alerts to the need to add humidification water supply to the incubator
 - An 8-segment inner glass door to allow selective access to culture samples while restricting the exposed area, thus reducing parameter recovery time and minimizing access to potential airborne contaminants.
 - A tri-gas configuration with a control range of 1-20% O2, to enable hypoxic experimentation, with independent oxygen measuring sensors and control/display.
- c. 3) Sorvall Legend XF/Sorvall Legend XFR Centrifuges and their rotors are required to meet the following user defined needs: CLINs 8-10
- The Centrifuge must be Floor Standing (22.2" width) with locking and unlocking castor wheels so centrifuge can be moved easily.
 - The centrifuge must offer at least 8 swing-out rotor configurations and various angle rotors to meet current and future sample processing needs of the lab.

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- The angle rotors must be manufactured from a highly corrosion and fatigue resistant material – Carbon Fiber.
- The buckets and rotor sealing lids must be certified for bio-containment by a 3rd party lab of worldwide recognition.
- The bucket lids must operate in a safe manner without spring clips or metal components.
- The centrifuge must be capable of running up to 196 x 5 ml or 7 ml blood collection tubes and 144 x 10 ml blood collection tubes in certified sealed conditions.
- The centrifuge must be capable of running up to 40 x 50 ml or 88 x 15 ml disposable conical tubes in certified sealed conditions.
- The centrifuge must be capable of running up to 8 x 250 ml bottles in swing-out configuration and in certified sealed conditions.
- The centrifuge must be capable of running a minimum of 6 x 250 ml disposable bottles at speeds of at least 18500 x g (230v) or 15300 x g (120v).
- The centrifuge must be capable of running a minimum of 6 x 94-85 ml disposable tubes at speeds of at least 24000 x g.
- The centrifuge must be capable of running a minimum of 14 x 50 ml disposable conical tubes at speeds of at least 17000 x g (230v) or 14600 x g (120v).
- The centrifuge must be capable of running a minimum of 8 x 50 ml disposable conical tubes at speeds of at least 24000 x g.
- The centrifuge must be capable of running a minimum of 48 x 2 ml disposable microtubes at speeds of at least 25000 x g in certified sealed conditions.
- The centrifuge must be capable of running a minimum of 28 microplates of standard footprint and height.
- The centrifuge must be capable of running two deepwell filtration plates (85 mm high) under certified sealed conditions at above 6000 x g.
- The centrifuge must have a sealed swingout rotor capable of spinning samples above 7000 x g. • The centrifuge must not require bolting to laboratory benching to meet CE, CSA or UL requirements for safety containment in case of rotor accident.
- The centrifuge must be able to display distance of at least 5 meters.

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- The centrifuge must have a mset parameters together with actual values, and parameters must be readable at a minimum of 5 “direct recall” program keys, and capability for up to 99 programs.
 - The centrifuge must have an option for automatic lid opening at the end of the run.
 - The centrifuge must have capability of password protection for the programs.
 - The centrifuge must have capability of password protection for lid opening.
 - The centrifuge must be able to display both air/chamber temperature as well as temperature in the sample.
 - The rotor shall be installed and removed with no tool in less than 5 seconds.
 - The centrifuge must be able to display messages in at least 5 languages.
 - The centrifuge should have advanced imbalance technology that adapts for specific rotors
 - The centrifuge must be able to utilize the standard 120V / 60 Hz receptacle that are found
 - in every lab in the US and still maintain a < 57 dBA sound level performance.
- d. Thermo Scientific Sorvall Legend XT/Sorvall Legend XTR Centrifuges and their rotors are required to meet the following user defined needs: CLINs: 11-14
- The centrifuge must offer at least 8 swing-out rotor configurations and various angle rotors to meet current and future sample processing needs of the lab.
 - The angle rotors must be manufactured from a highly corrosion and fatigue resistant material – Carbon Fiber.
 - The buckets and rotor sealing lids must be certified for bio-containment by a 3rd party lab of worldwide recognition.
 - The bucket lids must operate in a safe manner without spring clips or metal components.
 - The centrifuge must be capable of running up to 196 x 5 ml or 7 ml blood collection tubes and 144 x 10 ml blood collection tubes in certified sealed conditions.
 - The centrifuge must be capable of running up to 40 x 50 ml or 88 x 15 ml disposable conical tubes in certified sealed conditions.
 - The centrifuge must be capable of running up to 8 x 250 ml bottles in swing-out configuration and in certified sealed conditions.

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- The centrifuge must be capable of running a minimum of 6 x 250 ml disposable bottles at speeds of at least 18500 x g (230v) or 15300 x g (120v).
- The centrifuge must be capable of running a minimum of 6 x 94-85 ml disposable tubes at speeds of at least 24000 x g.
- The centrifuge must be capable of running a minimum of 14 x 50 ml disposable conical tubes at speeds of at least 17000 x g (230v) or 14600 x g (120v).
- The centrifuge must be capable of running a minimum of 8 x 50 ml disposable conical tubes at speeds of at least 24000 x g.
- The centrifuge must be capable of running a minimum of 48 x 2 ml disposable microtubes at speeds of at least 25000 x g in certified sealed conditions.
- The centrifuge must be capable of running a minimum of 28 microplates of standard footprint and height.
- The centrifuge must be capable of running two deepwell filtration plates (85 mm high) under certified sealed conditions at above 6000 x g.
- The centrifuge must have a sealed swingout rotor capable of spinning samples above 7000 x g.
- The centrifuge must have a low profile (not to exceed 14.2"/36 cm) for easy access by end-user.
- The centrifuge must not require bolting to laboratory benching to meet CE, CSA or UL requirements for safety containment in case of rotor accident.
- The centrifuge must be able to display set parameters together with actual values, and parameters must be readable at a distance of at least 5 meters.
- The centrifuge must have a minimum of 5 "direct recall" program keys, and capability for up to 99 programs.
- The centrifuge must have an option for automatic lid opening at the end of the run.
- The centrifuge must have capability of password protection for the programs.
- The centrifuge must have capability of password protection for lid opening.
- The centrifuge must be able to display both air/chamber temperature as well as temperature in the sample.
- The rotor shall be installed and removed with no tool in less than 5 seconds.
- The centrifuge must be able to display messages in at least 5 languages.

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- The centrifuge should have advanced imbalance technology that adapts for specific rotors.
- The centrifuge must be able to utilize the standard 120V / 60 Hz receptacle that are found in every lab in the US and still maintain a < 65 dBA sound level performance.
- e. THERMO SCIENTIFIC SORVALL LYNX 6000 SUPERSPEED CENTRIFUGE and its rotors are required to meet the following user defined needs: CLINs: 15-25
 - The refrigerated superspeed floor model centrifuge must be able to run carbon fiber rotors to:
 - Provide the lowest weight available for better ergonomics.
 - Provide a full 15-year warranty, with no end of life.
 - Provide corrosion resistance to chemicals used with the separation samples.
 - Provide resistance to fatigue failure typical of metal rotors.
 - Provide the highest Relative Centrifugal Force (RCF) performance for samples run in tubes and bottles with fill volumes of 1000 mL, 500 mL, and 50 mL (conical tubes), without the need for canisters or other additional sub-assemblies.
 - The centrifuge must provide a fast, simple, and secure push-button rotor exchange mechanism to automatically lock the rotor onto the drive adapter, eliminating the need for a tool or to hand tighten.
 - The centrifuge must provide automatic and instant rotor identification, completed upon installation of the rotor into the centrifuge and before the run is started, to ensure safe and convenient operation by eliminating the need to manually input a rotor code and avoiding aborted or changed runs due to rotor misrecognition.
 - The centrifuge rotor lid locking mechanism must include a special handle to make loading and unloading the rotors, as well as carrying them to and from the centrifuge, easier and safer.
 - The centrifuge must have a partial vacuum system, with a HEPA filter option, which only operates when needed and can be user selected for high performance or for energy saving.
 - The centrifuge must be able to provide the following performance:
 - The centrifuge must have swinging bucket rotor capacities of 4 x 1000 mL bottles, 40 x 50 mL conical tubes, and 24 microplates, with an overall maximum speed of 5,500 Revolutions per Minute (rpm) and Relative Centrifugal Force (RCF) of 7,000 x g. The rotor cross must be Teflon-coated for improved corrosion resistance and for smooth bucket operation without the use of additional lubrication.

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- The centrifuge must have swinging bucket rotor capacities of 4 x 400 mL and 4 x 250 mL conical at 7,000 rpm and 10,025 x g.
- The centrifuge must have swinging bucket rotor capacities of 4 x 1000 mL and 4 x 400 mL with a simple one-touch biocontainment system without an integrated HEPA filter.
- The centrifuge must have swinging bucket rotor capacities of 4 x 1000 mL and 4 x 400 mL that must always run without the use of a partial vacuum to protect sensitive samples in microplates, as well as other tubes and bottles.
- The centrifuge must have fixed angle rotor capacities of 6 x 1000 mL at 9,000 rpm and 17,568 x g and 4 x 1000 mL at 10,500 rpm and 20,584 x g.
- The centrifuge must have fixed angle rotor capacity of 8 x 50 mL at 29,000 rpm and 100,605 x g.
- The centrifuge must have continuous flow and zonal rotor capacity of 1350 mL at 20,000 rpm and 42,913 x g.
- The centrifuge must offer a temperature set range of -20 °C up to +40 °C, with a temperature control accuracy of +/-2 °C.
- The centrifuge must be microprocessor-controlled, with touch screen operating controls that can be used with a gloved hand, and which displays both set and actual run conditions simultaneously during operation, and enlarges automatically during a run to enhance visibility from across a room.
- The centrifuge must allow setting and controlling in both rpm and RCF directly for any selected rotor.
- The centrifuge must have 9 acceleration profiles and 10 deceleration profiles to support optimal reorientation of phases for different run conditions, which is especially important for gradient separations to minimize pellet re-suspension and preserve the gradient resolution.
- The centrifuge must have the capability to store up to 99 programs, and provide easy operation and run customization for multiple users.
- The centrifuge must have in-use training with on-board tutorial videos and a quick-start manual.
- The centrifuge must have an on-board rotor calculation feature that allows the comparison of run times between two different sets of rotors and/or run conditions.
- The centrifuge must have a multilingual keyboard.
- The centrifuge must have run logging and reports for enabling GMP compliance.
- The centrifuge must have user access control with optional password protection.

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- The centrifuge must have a built-in integrator (w²t) that provides exact run-to-run reproducibility by controlling the accumulating w²t; operation in the w²t mode allows the centrifuge to accurately reproduce critical runs.
- The centrifuge door must open fully and automatically, even when a user's hands are full, using an easy to see and reach button near waist height.
- The centrifuge must have a place to store the rotor lid while the rotor is being accessed by the user.
- The centrifuge must be designed with a space for feet to be placed under the front of the unit to allow the user to stand closer to the instrument for easier lifting of rotors in and out of the unit.
- The centrifuge must have a "lift over" profile no greater than 860 mm (33.9 in), providing a safe working height for instrument users.
- The centrifuge must run quietly, at less than 59 dBA.
- The centrifuge must have an imbalance tolerant drive up to 5% of opposing loads.
- The centrifuge must have an energy savings mode ("sleep mode") to reduce power consumption up to 15% by turning itself off if idle after a period of time.
- The centrifuge must contain a built-in electrical management system to ensure instrument performance, even under poor power supply condition and must accept +/- 10% fluctuations in input line voltage.
- The centrifuge must be able to satisfy cULus and CE safety requirements without being bolted to the floor, to greatly simplify installation and provide flexibility to relocate within the facility.
- The centrifuge must have the following to minimize unnecessary service expense and downtime:
 - Employ a brushless, high-frequency, direct drive motor with a 3-year non-prorated warranty to eliminate service maintenance due to service issues related to belt-driven drive systems.
 - Employ a hermetically sealed refrigeration system that is protected by a 5-year nonprorated warranty; the refrigerant should be CFC-free.
 - Select rotors must have been independently tested for biocontainment by the Public Health Laboratory Service, Microbiology Services, Porton Down, UK.
 - Select rotors must be certified as autoclavable to 121 °C.
- The centrifuge must have a floor-mounted configuration, not exceeding dimensions (H x D x W) of 930 mm x 805 mm x 700 mm (36.6 in x 31.7 in x 27.6 in).

- f. HERACELL VIOS 160i CO2 INCUBATOR TRI-GAS are required to meet the following user defined needs: CLINs: 4-6
- Reliable, clean and easy-to-use in vitro environment with both event based and continuous contamination control solutions for optimized growth and security.
 - Approximate 5.8 cu ft (165 L) chamber
 - Interior components constructed of electropolished stainless steel or 100% solid copper, with rounded corners, to minimize potential for unwanted contamination and simplify cleaning.
 - Stackable cabinet design
 - Small relative footprint not to exceed 26" width, 36" height or 32" depth and reversible door swing.
 - Modular shelving and supports that can be readily assembled and removed without use of tools, to facilitate simplicity of cleaning or adjustment.
 - Direct air jacketed heating design featuring high quality thermal jacket insulation and fan assisted circulation, allowing recovery under 10 minutes of all parameters (temperature, CO2, and relative humidity) following a 30 second door opening.
 - Integrated humidification design, a water reservoir that is in direct contact with a heated surface to maximize humidification efficiency as opposed to removable water pans which impede heat transfer.
 - Covered humidity reservoir design to keep contaminants from breeding in the water.
 - Water level sensor and alarm to alert user when humidification water refill is required. Water level is monitored and displayed on the touch screen at all times with advanced notice of refill needed.
 - Humidity reservoir may be filled without the removal of shelves or cultures and easily drained through built-in copper drain.
 - CO2 and optional N2/O2 gases are pre-humidified before entering the chamber to provide a more constant, uniform environment.
 - All control and measurement probes and sensors are located inside the culture chamber to provide true and accurate values and foster faster parameter recovery times than is possible with sensors remotely located outside the chamber.

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- Independent over-temperature protection function with independent back-up temperature sensor, to protect valuable cultures from potential damage in the event of an unexpected failure in the primary temperature control system.
- Availability of either humidity compensated thermal conductivity (TC) or bulbless IR CO₂ gas sensor technology.
- An in-chamber HEPA filtered airflow system within the culture environment continuously filters the entire chamber air volume every 60 seconds for continuous protection against unwanted microbial contaminants.
- ISO 5 clean room air quality achieved within the culture chamber within 5 minutes following a 30 second door opening, minimizing the opportunity for contaminants to settle on interior surfaces.
- Touch screen user interface
- On-board graphics capability, via the controller, enabling users to obtain historical performance by parameter or specified time periods to allow greater understanding of culture growth dynamics and usage patterns, enhancing research results.
- Interface logs and displays all user interactions with the incubator (e.g. door openings, parameter changes) facilitating the identification of important changes in the culture environment.
- Automated overnight (under 12 hours) high temperature sterilization cycle that ensures full chamber sterilization and meets the 12D true standard of sterilization.
- A fully automatic AutoStart routine to reliably calibrate and verify proper operation of all electronic measuring within hours to simplify incubator set-up and speed the availability for culturing use.
- High quality microbiological filters on all gas inlets, outlets and sample ports, to eliminate the potential of contamination entering the chamber from these points.
- The incubator includes a standard USB port with software for data downloading and reporting in Windows Excel format.
- 4-20mA signal output for interfacing with external data collection systems.
- Control of O₂ concentration in a range of 1-21% or 5-90% utilizing a zirconium oxide sensor requiring no electrolyte refill or membrane replacement ensuring long term stability at varied O₂ concentrations.

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- A 3-door gas tight inner glass door assembly with each door panel individually gasketed, to allow selective access to incubator shelves, without opening the entire chamber, limiting disturbance to the controlled environment, and enabling rapid recovery times for incubation parameters following door openings.
- Incubator is CSA certified and CE marked, demonstrating that stringent testing procedures have been undertaken by independent agencies to provide the customer's best assurance of unquestioned quality and suitability for function.
- g. Thermo Scientific MaxQ 4450 (SHKE4450) Small Digital Incubated Bench Top Shaker are required to meet the following user defined needs: CLIN: 7
 - A temperature range of 5C above ambient to 80C with a control of plus/minus 0.1C at 37C (in flask) over complete temperature range, uniformity of plus/minus 0.5C at 37C (in flask).
 - The temperature indicator is a digital LED electronic display with 0.1C increments with ½" character height and has a PID microprocessor control.
 - The unit must have a secondary back-up independent thermostat for heating if the main controller fails.
 - Audible and visual temperature alarm signals will alert the user to temperature deviations and the heat should turn off if the temperature deviates over/under 1C of set point.
 - Shaking speed range of 15 to 500 RPM with a control of plus/minus 1 RPM and display the speed with a LED display of RPM.
 - The shaker will stop rotating and provide audible/visual alarm signals if unit operates over/under 10% of set speed preventing shaker from walking off bench.
 - The shaker will have a user adjustable speed calibration that can be performed using a digital hand held tachometer where verification is required and protocols can be standardized.
 - An unbalanced load sensor should stop the platform motion when excess vibration is detected due to an unbalanced load.
 - The unit will have a RS232 interface for remote monitoring of speed, time and temperature.
 - The shaker will have a built-in recorder jack to monitor temperature via a chart recorder for a permanent record.
 - The shaker will rotate in an orbital fashion with a circular orbit diameter of 3/4" (1.9cm).
 - The shaking incubator will have a timer from 0.1 hour up to 999 hours or 0.1 minute up to 999 minutes or continuous operation.

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- The time indicator is a digital LED electronic display that displays time in 0.1 hours or 0.1 minutes with ½" character height.
 - The unit will have a safety interlock that will stop the platform rotation when the lid is ajar but the blower and heat remain on to maintain temperature.
 - Temperature and speed set points are retained by non-volatile memory and will automatically restart after power has been restored.
 - The shaker will have a soft start feature that contains software algorithms to prevent sudden starts and stops.
 - The unit is designed to operate in a 0C to 40C and 20% to 80% non-condensing humidity environment.
 - Further user needs are driven by the following physical specifications:
 - The unit will have a triple eccentric steel drive shaft and can hold a load capacity of 35 lbs. (15.9kg). The unit will use a solid-state DC brushless motor.
 - The incubated shaker will have a 11" x 13" universal platform and accommodate any combination of flask holders and tube racks.
 - The platform and flask clamps should be constructed out of stainless steel.
 - Unit should have a polycarbonate lid with complete view of cultures through the top, front and sides of the shaker and be able to withstand temperatures up to 80C.
 - The shaker exterior is constructed of cold-rolled, powder coated steel and has exterior dimensions of 27.2" Lx14.1" Wx15.8"H (69.1 x 35.8 x 40.1cm) and interior/chamber dimensions of 17.3" Lx13.3" Wx9.0"H (43.9 x 33.8 x 22.9cm).
 - An ABS control housing surrounds a polyester control panel. The shaker has a shipping weight of 77 lbs. (35kg).
- h. Thermo Scientific TSX Series ULT freezer with racks are required to meet the following user defined needs: CLINs: 1 & 2

CONSTRUCTION

- The freezer must be constructed using 1" thick vacuum panel insulation in conjunction with environmentally-friendly water blown foam

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- Door Gasket must provide 7 independent insulation zones along with 4 points of contact to ensure sample security.
- Freezer shall be painted with high-impact, scratch resistant powder coat finished interior and exterior to ensure long term viability and maximum interior temperature uniformity.
- The perimeter heater to reduce condensation shall be on the door side not on the cabinet size to limit heat introduction into the sample storage area.
- The thermal break shall be made of plastic to limit heat leakage into the cabinet
- Door latch allows one-handed opening and closing. Handle must include door key lock as well as padlock provision for added security.
- Freezer shall have 4 or 5 internal storage compartments with a minimum of 2 polystyrene insulated inner doors to ensure sample security. Inner doors should have no latches or external magnets and must be removable for easy cleaning without the use of tools.
- Freezer shall have an automatic heated pressure equalization port allows rapid re-entry to cabinet.
- Freezer shall have two, 1 inch access ports
- Freezer shall have a RS485 output, Dry Contacts and 4-20mA output for remote monitoring purposes
- Freezer the door must open at least 180 degrees for easy sample access.

CAPACITY

- Freezer shall hold 600 2" boxes or 60,000 2ml Vials with a vial to footprint ration of 4,272 2m vials per square foot of floor space.

4. **Statutory Authority Permitting Other than Full and Open Competition: FAR13.5 Simplified Procedures for Certain Commercial Items:** This acquisition is being conducted under FAR 13 – Simplified Acquisition Procedures. The authority for restricting competition under simplified acquisition procedures is 41 U.S.C. 1901, as implemented by FAR 13.5
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The Government must establish or maintain an essential capability for theoretical analyses, exploratory studies, and experiments in research of PTSD and or TBI at the VISN20 MIRECC, as mandated by Congress. This capacity must be consistent with the department's existing research development of various clinical, preclinical and molecular biological research protocols while leveraging equipment modernization. This request is for "Brand-name" procurement. Only the items listed above satisfy the Government's requirements as listed under the "salient characteristics" listed in Section 3 above, meet the performance history

and standards of the research unit and are consistent with brands used to establish the research program.

The VA Northwest Network (VISN-20) Mental Illness Research, Education, and Clinical Center (MIRECC). The MIRECC is a neuroscience research facility with a Congressionally-mandated focus in military posttraumatic stress disorder (PTSD) and its complex comorbidities. Among the comorbidities included are repetitive blast concussion mild traumatic brain injury (the “signature injury” of the wars in Afghanistan and Iraq), alcohol misuse, and chronic post concussive symptoms. The Seattle MIRECC has particular strength in blast concussion mTBI and its sequelae – both in the short term (e.g., chronic post concussive migraines, irritability and anger dyscontrol) and long-term (potential neurodegeneration and dementia). This research program comprises 24 VAPSHCS Investigators, 30 funded research projects (3 of which are DoD grants), and is intimately partnered with local and national DoD, VA, and academic affiliates. In conjunction with the VA GRECC here at VA Puget Sound and with the Neuropathology Division of the Dept. of Pathology at the University of Washington (among a number of UW departments), we have a very robust research program in living Veterans with mild TBI, a corresponding clinically-relevant translational animal research program, and an innovative and successful program to obtain autopsy brain tissue from active duty service members and Veterans with TBI. These research foci are of high value to VHA (as well as DoD).

The Northwest MIRECC applies modern genetic, neurobiological and clinical trial methodology to the discovery and development of new and more effective treatments for major and often treatment resistant mental disorders afflicting Veterans and the active duty combat personnel who will become Veterans. Pertinent to this request, these equipment items include, but are not limited to ultra-low temperature freezers for biological sample and reagent storage, tissue culture incubators, orbital shakers, various high speed and low speed centrifuges with a variety of rotors and adaptors to fit dynamic research needs, and live cell-culture compatible fluorescence imaging system packages.

The Northwest MIRECC’s existing Standard Operating Procedures are based on the performance characteristics of the listed Fisher Scientific equipment. Acquisition of dissimilar equipment would require extensive revalidation and protocol refinement, jeopardize budget and project milestone timelines. The Government has spent 5 – 20 years (depending on the project) developing exacting protocols and methodologies which have cost hundreds of thousands to millions of dollars in development and validation. The Government estimates it would cost up to \$400,000 in man-hours to revalidate equipment alone. In addition, some experiments would need to be run over again. Samples would have to be regenerated or purchased depending on the case. In some situations the samples cannot be rederived or replaced because the samples were unique and consumed. The Government estimates it would take one year to revalidate existing protocols and methodologies using dissimilar equipment. This could negatively impact MIRECC’s ability to compete for grants and could cost an additional \$3.5 million in lost funding opportunities. Additionally, the estimated one year delay and potential for lost funding could reduce the capacity for the Government to make timely translational research insights impacting clinical care of traumatic brain injury, post-traumatic stress disorder and broader Veteran mental health care delivery. However, this is difficult to know or quantify in advance as some aspects of this work are immediately impactful on healthcare and other aspects take 20 years.

To accomplish the Government's goals, the Government elects a brand name justification of the above listed items. The above listed items accomplish the Government's performance requirements. By extension, other methodologies are as yet unproven, would require substantial duplication of cost to vet feasibility and adaptability and would contribute unacceptable delays in fulfilling the agency's immediate requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This requirement is for Fisher Scientific Brand Name items. These items are available from multiple sources (see section 8 below) including several Service-Disabled Veteran-Owned Small Businesses. To align with VA's small business contracting goals, the resulting solicitation will be a 100% set-aside for SDVOSB firms.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer will compare the proposed price submitted by the offeror to the IGE. In addition, the Contracting Officer compared the IGE to the items pricing on the GSA schedule. It is anticipated that the items quoted should be the same or less than those prices on the GSA schedule.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** In accordance with FAR Part 10, market research has been conducted for this acquisition. The following techniques were used:

Medical Surgical Prime Vendor (MSPV) Contracts: A search was conducted on the National Acquisition Center's MedSurg Catalog search located at <http://www.va.gov/nac/MedSurg/List> for a list of nationally awarded contractors and/or prime vendor contracts. The MSPV for Seattle is Cardinal Health. Cardinal Health was contacted (Anna Crocker) via phone to verify if this equipment was on their formulary. They do not provide this equipment on the formulary. MSPV is not appropriate at this time for this requirement.

Mandatory BPA VA119-16-A-00411: VWR LLC received a single award Blanket Purchase Agreement (VA119-16-A-00411) to provide centrifuges. However, VWR only provides Beckman Coulter centrifuges which do not meet the end user's requirements for this procurement package. This BPA is therefore not a suitable vehicle for this requirement.

GSA eLibrary: <https://www.gsaelibrary.gsa.gov/ElibMain/home.do>. A search for "GS-07F-161BA" (identified by the program on the J&A for pricing) was conducted. This search produced 1 result. This result is the manufacturer, a Large Business and has been referenced in the Market Research Findings section below. Additionally, searching "fisher scientific" as the manufacturer, 1 other result (Franklin Young International) has a GSA schedule and is a verified SDVOSB. This vendor has been referenced in the Market Research Findings section below. GSA is not an appropriate source as there are not two or more VOSBs on GSA.

SDVOSB/VOSB Sources via VetBiz (VIP): In Accordance with VAAR Subpart 819.7004, 819.7005, 819.7006 - <https://www.vip.vetbiz.gov/>. A search on Vetbiz.gov was conducted in an attempt to locate Service-Disabled-Veteran-Owned-Small-Business (SDVOSB) and Veteran-Owned-Small-Business (VOSB) concerns utilizing NAICS code 334516 (this search provided 58 results). From these results, all vendors were contacted via email (Attachment VIP Email on P02 Market Research doc).

Many vendors (SDVOSB) and responded as being able to meet the specifications of the requirement. These SDVOSBs and have been referenced in the Market Research Findings section below.

Request for Information (RFI): An RFI (VA701-17-N-0021) was posted on FBO. 1 vendor responded to VA701-17-N-0021 as being able to meet the specifications of the requirements. This vendor has been referenced in the Market Research Findings section below.

Solutions for Enterprise-Wise Procurement (SEWP): <https://www.sewp.nasa.gov/>. A search was conducted for “Fisher Scientific” as a provider. The search produced 0 results. The conclusion of this search effort is that SEWP does not have the provider and is not a source for acquiring the Da Vinci Dual Console System at this time. (Attachment – SEWP MR on P02 Market Research doc)

Small Business Administration (SBA) – Dynamic Small Business Search (DSBS):

http://dsbs.sba.gov/dsbs/search/dsp_dsbs.cfm. SBA DSBS market research was conducted utilizing NAICS code 334516 and the keywords “fisher scientific”. The search produced 4 results. From these results, all vendors were contacted via email (Attachment SBA Email on P02 Market Research doc). 0 vendors responded as being able to meet the specifications of the requirement.

Table 2: Summary of Available Sources

Vendor	DUNS	Socioeconomic Category	Authorized
Franklin Young International, Inc.	113785385	SDVOSB	Yes
Bennettsan Consulting LLC	078305080	SDVOSB	Yes
Veterans Healthcare Supply Solutions	964899483	SDVOSB	Yes
TEVET LLC	149433844	SDVOSB	Yes
Comtel Corporation	003897550	SDVOSB	Yes
Fisher Scientific LLC	004321519	Other than Small	OEM
Attain It	104178756	8a & HubZone	Yes

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This requirement for the brand name items listed above satisfy the Government’s requirements as listed under the “salient characteristics” listed in Section 3 above, meet the performance history and standards of the MIRECC research unit and are consistent with brands used to establish the research program. Acquisition of dissimilar items would require extensive revalidation and protocol refinement, jeopardize budget and project milestone timelines and reduce the capacity for the department to make timely translational research insights impacting clinical care of traumatic brain injury, post-traumatic stress disorder and broader Veteran mental health care delivery.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** See Table 2 in Section 8 above.
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** No

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

further actions are planned for future acquisitions of this nature. The current approval is sought for a single requirement / fulfillment that is associated with building activation.

- 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.

James S. Meabon
561132

Digitally signed by James S. Meabon 561132
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Date: 2017.09.06 09:48:15 -07'00'

James Meabon, PhD
R&D
663 VA Puget Sound Health Care System

Date

Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.

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

Sandra J. Johnson 749522

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749522
Date: 2017.09.06 10:30:09 -04'00'

Sandra Johnson
Contracting Officer
Program Contracting Activity - Central

Date

- b. **One Level Above the CO /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Grace E. Kelly-
Burnsworth 1384242

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Grace Kelly-Burnsworth
Supervisory Contracting Officer
Program Contracting Activity - Central

Date