STATEMENT OF WORK
Mobile Magnetic Resonance Imaging (MRI) Trailer Lease
CENTRAL TEXAS VETERANS HEALTH CARE SYSTEM

1. **SCOPE:** This is a services contract to provide all the necessary personnel, supervision, equipment, transportation, and materials, for a Mobile MRI Leased Trailer and Technologist Services at the Department of Veterans Affairs, Central Texas Veterans Health Care System (CTVHS), Austin Outpatient Clinic. The contractor shall comply with applicable Federal, State, and local laws, regulations, codes, technical manuals, recommendations, and acceptable commercial practices in the delivery of required services.

   The government shall not exercise any supervision or control over the contract service providers performing the services. Such contract service providers shall be accountable solely to the contractor, who in turn is responsible to the government.

2. **GENERAL REQUIREMENTS:** The contractor shall provide a mobile 1.5T MRI unit and Technologist Services for the CTVHCS, Austin OPC, TX, in accordance with the SOW.
   Address:
   Central Texas Veterans Health Care System
   Austin VA Outpatient Clinic
   7901 Metropolis Dr.
   Austin, TX 78744-3111

a. Schedule: Services shall be required five (5) days per week.

b. Hours of Service: The contractor's mobile unit and personnel shall be on site to perform exams eight (8) hours per day, Monday - Friday, between the hours of 7:30 AM and 4:30 PM, excluding Federal holidays. The first MRI will begin at 7:30 AM with the last patient being seen, such that the exam is completed no later than 4:30 PM.

c. Pro-rated Monthly Rental Fee: The contractor shall prorate the monthly rental fee when the MRI unit is not functioning following prescribed guidelines. The monthly fee shall be prorated based on the number of hours the coach is out of service during regularly scheduled clinic hours Monday - Friday, 7:30 AM – 4:30 PM. The contractor will pro-rate the hourly rate in the amount of:

   $_____

4. CONTRACTOR RESPONSIBILITIES:

a. Contractor shall provide one (1) certified technologist for the operation of the MRI equipment. Contractor shall be solely responsible for all driver and technologist staffing issues related to the operation of the mobile system.
   i. Contractor shall also provide an alternate certified technologist that will only be needed to provide coverage for the primary technologist to take vacation and/or sick time.

b. Contractor shall provide a mobile 1.5T MRI unit (5 years old or newer) (including scanner, acquisition and processing station, and physician viewing stations) with a high-performance

gradient system for use at the CTVHCS. Specific equipment requirements include:

(1) The operating system must be Windows 10 or newer/ Lynux
(2) MRI system minimum requirements:
    a. 45 mT/m gradient strength "minimum prerequisites"
    b. 200 T/m/s Slew rate [T/m/s} "minimum prerequisites"
    c. 70 cm Bore dimensions.
    d. 550 lbs or greater scanner table weight limit
    e. Minimum number of receiver channels – 45
    f. Motorized table with integrated coil design and ports
    g. Patient positioning and support aids
    h. MRI compatible dual head injector pedestal or ceiling mounted.
    i. Zero boil-off cryogen technology
    j. Vendors are expected to provide and install all cryogens.
    k. Chiller must meet or exceed MRI and location needs.
        i. Central Texas temperature can exceed 100 deg F
    l. All phantoms that are required for calibration and performance verification.
        i. Vendor must provide ACR compliant phantom for system QA.

(3) Software minimum requirements:
    a. Motion correction technology
    b. Magnetic Artifact Reduction
    c. Noise reduction
    d. ECG (VCG), respiratory, and peripheral pulse gating/triggering
    e. Real-time MIP, MPR, and 3D surface rendering
    f. Advanced non-contrast MRA imaging technology
    g. Bolus tracking capabilities
    h. Integrated communication system to include:
        i. Direct communication and audio for patients
        ii. MRI safe headphones

(4) Advanced Applications requirements:
    a. 3D processing for all modality datasets
    b. Neuro package
    c. Ortho package
    d. Body package with respiratory navigator
    e. Musculoskeletal software package
    f. Oncology package
    g. Vascular package
    h. MRA package
    i. Elastography package
    j. MRI spectroscopy package that includes single voxel, 2D/3D chemical shift imaging
    k. FAT analysis calculation including iron analysis
    l. Phase contrast MRI and flow analysis
    m. Parametric prostate imaging package
    n. Diffusion Brain, whole body, computed, microview, and FSE
    o. Diffusion B value capabilities from 0-35000
    p. Diffusion computed B-values 0-2500
    q. Water/Fat shift Imaging

r. Blood oxygen level dependent imaging

(5) Processing Workstation minimum requirements:

a. Stitching
b. Dynamic evaluation
c. Brain perfusion
d. Advanced neuro (DTI, tractography, BOLD)
e. Breast evaluation
f. Vessel analysis
g. Workstation computer with (minimum 23-inch) LCD Monitor

(6) The RF coils supplied with the system will include at a minimum:

a)	Phased Array NV/Head/Neck Coil	Minium 24 Channels
b)	Phased Array Spine coil Table integrated assembly	Minium 32 Channels
c)	Phased Array Body Array	Minium 12 Channels
d)	Phased Array Shoulder	Minium 12 Channels
e)	Phased Array Knee Coil	Minium 12 Channels
f)	Phased Array Wrist/Hand Coil	Minium 12 Channels
g)	Phased Array Foot/Ankle Coil	Minium 24 Channels
h)	Phased Array Blanket style Super flex Body Coil	Minium 24 Channels
i)	Phased Array Super flex small Coil	Minium 12 Channels
j)	Phased Array Run-off compatible Coil	Minium 8 Channels
k)	Prostate imaging compatible Coil	Minium 8 Channels
l)	Elbow Imaging compatible Coil	Minium 4 Channels

(5) A power injector for intravenous contrast administration must be included.

(6) The scanner must be able to scan:

a) Cervical, thoracic, and lumbar spines continuously without requiring patient movement
b) Liver Elastography
c) Prostate Imaging
d) Rectal Imaging
e) Breast Imaging
f) General Body Imaging

(7) The system must be capable of performing 2D, 3D TOF & PCA, and total Body contrast enhanced MRA (intracranial and body) studies.

(8) The scanner must include some form of effective noise abatement system for the patients.

(9) The scanner must offer a patient entertainment system that enables the patient to experience digital media during the MRI scan procedures.

c. Contractor shall be responsible for the transportation of the Mobile MRI coach to and from CTVHCS. The cost of transportation shall be included in the monthly rate. Austin facility is gated and locked after hours. The facility is open from 6:30 AM through 6 PM, Monday through Friday for the removal of trailers for other assignments.

d. Delivery and Set-up of Contractor Equipment: The contractor shall be responsible for the proper installation/set-up of the contractor's furnished equipment including the mobile trailer.

Installation/setup shall be accomplished following industry standards, all OSHA regulations, and applicable manufacturer's recommendations.

(1) Medical Physicist - shielding analysis/ requirements for new MRI system with an overlay of the room diagram. The analysis must include above, below and any adjacent areas. This shall be specific to the manufacture and model of the MRI system. This must be completed prior to starting any renovations. (Requirements: Joint Commission and ACR)

(2) Medical Physicist-Pre-construction/ renovation shielding verification of current shielding meets requirements of new MRI system. The analysis must include above, below and any adjacent areas. (Requirements: Joint Commission and ACR)

(3) Medical Physicist- Review and approval of MRI zones. This shall include a diagram of the MRI zones

(4) Medical Physicist-Post-construction/ renovation shielding verification of shielding meeting requirements of new MRI system. The analysis must include above, below and any adjacent areas. (Requirements: Joint Commission and ACR)

(5) Medical physicist- MRI system initial compliance testing. This shall be conducted after final installation, but before the first patient. (Requirements: Joint Commission and ACR)

e. Contractor's Equipment: The contractor shall be responsible for the following daily functions:

(1) Transmit completed electronic data after each exam. Ensure that all of the day's exam data is completely transferred to the CTVHCS computer systems.

(2) Any patient data archived to a magnetic optical disk (MOD) or DVD is handed to a designated VA staff member for storage on-site at CTVHCS. The MOD and/or DVD shall be the property of CTVHCS. All patient information required for the Contractor's records shall be secured following HIPAA guidelines.

(3) All connections from the trailer to CTVHCS property are properly disconnected from the trailer when moved from CTVHCS' site.

(4) Any temporary site preparations are removed upon completion of services.

(5) The contractor shall ensure mobile MRI is maintained in optimum working condition to always ensure the highest level of patient safety. Maintenance documents shall be made available to CTVHCS upon request

f. Contractor shall ensure each patient arriving for a mobile MRI exam has a written or electronic medical record physician order to receive services and a completed MRI Screening Checklist.

g. Contractor shall use appropriate screening devices to ensure the patient has no ferromagnetic materials on or in his/her body.

h. Contractor shall be responsible for adhering to all Federal regulations regarding patient care, patient safety, medical practice, and operation of mobile MRI.

i. The contractor shall provide a copy of a current, comprehensive MRI Safety Program policy

to which each technologist is expected to comply. MRI Technologist is required to complete CTVHCS MRI Safety Training yearly.

j. Contractor shall be responsible for the patient after picking up at the designated area, while on the mobile unit, and during the entire scanning procedure up to the patient's release.

k. In the event a patient is injured while in the contractor's care, the contractor shall immediately notify the assigned nurse or a designated VA physician and complete a written report.

l. Contractor shall be responsible for providing a qualified MRI Technologist(s) to perform services defined herein. The MRI Technologist shall be required to provide all scanning services specified in the SOW. Any training needed for the MRI Technologist(s) shall be provided at no additional cost to the government. If the MRI Technologist is unable to come in to work as per the schedule, the contractor shall provide an alternate MRI Technologist to cover the shift and prevent rescheduling patients. All MRI Technologists, to include alternates, must complete the credentialing requirements established by the CTVHCS prior to performing scanning services.

m. Environment of Care Rounds shall be conducted quarterly by the Contracting Officer's Representative (COR) and CTVHCS Austin Administrator. All identified deficiencies shall be corrected by the contractor before the next scheduled day of service.

5. MAINTENANCE REQUIREMENTS:

a. Contractor shall be responsible for all maintenance of the unit including all PMs as required by the manufacturer's literature. The contractor shall assume all costs for labor and parts including glassware and will make all arrangements for service upon notification of failure. The contractor shall communicate these occurrences and progress promptly with Imaging Service staff and Biomedical Staff. Anyone performing maintenance on the unit shall be factory-trained by the manufacturer on this specific unit. Any FDA alerts or recalls associated with this equipment will be ameliorated on time.

b. All PMs shall be done after normal operating hours, Monday – Friday.

c. Contractor shall ensure a 95% or better up-time based upon the normal operation hours, Monday – Friday, 7:30 AM – 4:30 PM.

d. If the system breaks down, the MRI Technologist is responsible for informing the Imaging Service representative and Bio Medical of the issue immediately upon determining there is a problem. The MRI Technologist will contact the vendor immediately if an on-site service technician is needed. It is expected that the on-site service technician will respond within 2 hours to determine what the problem is and a proposed timeframe of how long the machine is expected to be down. Repairs and delays that will be beyond two working days will require a replacement trailer to be brought in.

6. CTVHCS RESPONSIBILITIES:

a. CTVHCS shall provide a covered walkway, utility connections, and an appropriate computer line(s) for use by the contractor.

b. CTVHCS shall be responsible for scheduling exams for the mobile MRI unit.

c. CTVHCS shall transport patients to the VA furnished waiting area.

d. CTVHCS shall identify patients and provide and administer prescribed sedation which patients may require prior to the scans provided by the Contractor. Sedated patients shall be identified and given special care by the Contractor during the performance of procedures. A CTVHCS registered nurse shall monitor sedated patients in the Contractor's trailer. Conscious sedation/moderate sedation will not be used for these exams.

e. CTVHCS employee assistant.

1. The CTVHCS shall provide a VA employee to assist the vendor MRI technologist to satisfy the requirements of VHA directive 1101.05-10. The VA employee is responsible for escorting patients throughout the Imaging Service and transporting patients to and from wards when necessary. Escorts patients from the Imaging Service waiting room to a dressing area and, if necessary, helps patients get appropriately dressed for their procedure. Assist patients in getting on and off examination tables if required. If necessary, assist patients to a bathroom following their examination. Helps clean patients in the event of spills and assists patients with changing gowns. Assists the x-ray, Ultrasound, CT, or MRI technologists in cleaning and disinfecting x-ray tables and other equipment after patient use. Assists in monitoring wheelchair and litter bound patients and helps ensure these patients' needs are met while in the Imaging Service.

7. CONTRACTOR PERSONNEL QUALIFICATIONS/POLICIES:

a. The contractor's Technologist shall possess a current Radiologic Technologist (RT) license. A copy of all applicable operators' license(s) shall be provided with the proposal along with a copy of the updated license immediately upon renewal. The contractor shall ensure that a copy of the technologist's current license is always provided to the COR for inclusion in CTVHCS' 6-part folder.

b. The contractor shall be responsible for ensuring that contractor employees providing work on this contract are fully trained and completely competent to perform the required work. Evidence of the contractor's Technologist's competency review shall be provided with the proposal. Competency checklists must contain evidence of supervisory review at least annually and must contain the written signature of the supervisory official performing the review. A current copy of the employee's competency checklist shall be maintained in CTVHCS' 6-part folder at all times. Competency checklists shall be resubmitted to CTVHCS each time the checklist is updated, no more than 12 months beyond the original date of review.

c. The contractor shall be required to maintain documentation and provide copies, with their proposal, of the following for each employee working under the contract:

(1) credentials and qualifications for the job

(2) a current competency assessment checklist (an assessment of knowledge, skills, abilities, and behaviors required to perform a job correctly and skillfully; includes age-specific knowledge and skills required to provide care for certain patient populations, as appropriate.)

(3) a listing of relevant continuing education for the last two years

(4) health examination records of all individuals performing work under this contract to include:
(a) Annual TB Skin Test and recent (within the last year) chest X-ray if there is a history of positive TB skin test

(b) evidence of Hepatitis B immunity (hepatitis immune titer, if provider has had the series of shots; if no immunity, evidence that provider has started the Hepatitis B vaccination series.)

(c) Varicella titer if provider has not had chicken pox and has direct patient contact.

d. This is a non-personal health care service contract under which the Contractor is an independent contractor. Contractor employees shall not be considered VA employees for any purpose.

8. MOBILE UNIT EQUIPMENT SPECIFICATIONS: The following minimum performance characteristics of the equipment are required:

a. Contractor shall make whatever adaptations are necessary so that the Contractor's equipment is compatible with the CTVHCS data network as specified in Paragraph 14, Telecommunications.

b. Mobile Trailer minimum requirements:
   a. 12’ x 46’.
   b. 12’ x 60’ is preferred: The larger trailer size better facilitates compliance with the national VHA Directive 1105.05 guideline that two MRI staff must be present in Zones 3 and 4 when a patient is being scanned.
   c. 42” wide stairs with handrails on both sides of step
   d. Americans with Disabilities Act Compliant Aluminum lift assembly for entering and exiting of the MRI Trailer
   e. 40” Minimum width RF Scan Room Door
   f. Patient Changing Room with locking storage for valuables.
   g. Patient Hydraulic Lift
   h. Patient stairs & Landing
   i. Handwashing facilities

c. The Mobile MRI unit shall be ready for use regardless of outside environmental conditions.

d. The Mobile MRI unit shall maintain a temperature to ensure proper operation of the scanner and provide for patient comfort.

e. The Mobile MRI unit shall include a private dressing area with secured cabinets for patient use.

f. Contractor shall provide an MRI-compatible Automatic External Defibrillator (AED). The system must contain the minimum characteristics:

(1) AED Unit with LCS Screen showing voice prompt messages, device advisory messages, elapsed time, shock count and chest compression graph, Operator's Guide, and Carrying Case.

(2) Two (2) Sets of CPR-D Pads, one piece defibrillation and CPR system with compression, depth, and rate sensors, supplies with gloves, barrier mask, scissors, razor, wet wipes, and dry wipes;

(3) Two (2) Sets of Type 123 Lithium Batteries with storage sleeve.

9. CONFORMANCE STANDARDS/REGULATORY ADHERENCE:

a. Contractor shall perform the required services in accordance with the following:

(1) the standards of the Joint Commission for the Accreditation of Healthcare Organizations (JC) to include Patient Safety Standards (a copy of these standards may be obtained from the Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Blvd., Oakbrook Terrace, IL 60181)

(2) the established principles and ethics of the medical profession established by the AMA and ACEP and is responsible for the quality of care rendered to all patients.

(3) all relevant Federal and State regulations regarding patient care, medical practice, operation of MRI equipment; to include but not be limited to

Occupational Safety and Health Act (OSHA)
The Joint Commission (JC)
Veterans Health Administration (VHA)
United States Department of Transportation (US DOT)
Health Information Portability and Accountability Act (HIPAA)
VHA Automated Information Security (AIS)
Privacy Act
CTVHCS Medical Staff Bylaws

b. Contractor shall ensure that the equipment/system functions in conformance with the latest published edition of OSHA and the manufacturer's specifications.

c. Contractor shall adhere to the provisions of Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the National Standards to Protect the Privacy and Security of Protected Health Information (PHI). As required by HIPAA, the Department of Health and Human Services (HHS) has promulgated rules governing the security and use and disclosure of protected health information by covered entities, including the Department of Veterans Affairs Veterans Health Administration (VA).

10. MRI STUDY INTERPRETATION: A CTVHCS radiologist shall read/interpret all MRI studies and dictate all required study reports.

11. MRI DATA OWNERSHIP: CTVHCS shall maintain sole ownership of all data of studies performed on the mobile MRI under this contract. The contractor may not use any portion of imaging data obtained from patient studies under the contract. The contractor may not use any portion of imaging data obtained from patient studies for quality control or educational purposes without written consent of CTVHCS.

12. EMERGENCIES ON MOBILE MRI UNIT: Emergency 911 shall handle all medical emergencies occurring on the mobile coach. The contractor shall maintain a written emergency plan addressing emergencies such as patient codes, personal injury, fire, and disruptive behavior.

13. MRI POINT OF CONTACT: The Contracting Officer will designate an individual as the Contracting Officer's Representative (COR) will be the primary point of contact at the

CTVHCS for communication between the CTVHCS and the contractor with regards to the technical aspects of imaging protocols and medical aspects of MRI studies. The contractor shall communicate to the COR any possible and actual disruptions of MRI service. Upon becoming aware of possible or actual disruption of MRI service, the contractor shall communicate such service-disruption information to the COR in a timely manner so that patient and service schedules can be appropriately modified with as little inconvenience as possible to patients and services. The contractor shall provide contact information with their solicitation proposal and provide an update to CTVHCS immediately upon any change in the designation(s).

14. TELECOMMUNICATIONS:

a. The mobile unit shall be equipped with an outlet connection capable of transmitting data and voice through a government provided network interface jack (RJ11 Analog Voice and RJ45 IEEE 803.x). The government shall provide the necessary network services required for the transmission of images, data and voice. The contractor's mobile unit shall be able to connect to VISTA Imaging Network and to transmit all images to VISTA Imaging to include being compatible to DICOM 3.0 imaging standards. (PACS interface contact person shall be provided to the Contractor during the post-award orientation).

b. The contractor shall be responsible for all expenses incurred to interface the MRI Scanner OEM using the DICOM 3.0 network with the existing VISTA RAD (soon to be McKesson PACs system). System must be compatible with HL7 – V2.3 soon to be V2.4.

15. QUALITY ASSURANCE MONITOR:

a. The contractor shall have a Quality Assurance Program in place at the time of contract award.

b. The contractor's Quality Assurance Program Plan shall be in accordance with all JC and HIPAA standards.

c. The contractor shall maintain equipment service records to document performance reports.

d. Quality Improvement: The government may evaluate the quality of professional and administrative services provided but retain no control over the medical, professional aspects of services rendered (e.g., professional judgments, diagnosis for specific medical treatment), in accordance with FAR 37.401.b. unless otherwise stated herein.

e. The results of all Quality Improvement activities performed by the contractor involving CTVHCS patients shall be provided to the COR. This shall include, but not be limited to, quality improvement plans, minutes of staff meetings where quality improvement has been discussed and which include practitioner-specific findings, conclusions, recommendations, written plans for actions taken in response to such conclusions and recommendations, and evaluation of those actions taken. It will also include the annual evaluation required by JCAHO. The monitors should reflect, at a minimum, issues related to quality of care and appropriateness of referral. The contractor shall submit Quality reports by the 10th workday of the first month of each Government fiscal quarter (i.e., October, January, April, July).

f. At the end of each scheduled day of scanning, the contractor shall provide a log of patients who were scanned on that date and all diagnostic information regarding each patient scanned that day.

16. CONFIDENTIALITY OF PATIENT RECORDS:

a. The contractor, as a VA provider, shall assist in the provision of health care to patients seeking such care from or through VA. As such, the contractor is considered as being part of the Department health care activity. Contractor is considered to be a VA provider for purposes of the Privacy Act, Title 5 U.S.C. 552a. Further, for the purpose of VA records access and patient confidentiality, contractor is considered to be a VA provider for the following provisions: Title 38 U.S.C. 5701, 5705, and 7362. Therefore, contractor may have access, as would other appropriate components of VA, to patient medical records including patient treatment records pertaining to drug and alcohol abuse, HIV, and sickle cell anemia, to the extent necessary to perform its contractual responsibilities. However, like other components of the Department, and not withstanding any other provisions of the contract, the contractor is restricted from making disclosures of VA records, or information contained in such records, to which it may have access, except to the extent that explicit disclosure authority from VA has been received. The contractor is subject to the same penalties and liabilities for unauthorized disclosures of such records as VA.

b. The records referred to above shall be and remain the property of VA and shall not be removed or transferred from VA except in accordance with U.S.C.551 a (Privacy Act), 38 U.S.C. 5701 (Confidentiality of claimants' records), 5 U.S.C. 552 (FOIA), 38 U.S.C. 5705 (Confidentiality of Medical Quality Assurance Records) 38 U.S.C. 7332 (Confidentiality of certain medical records) and Federal laws, rules and regulations. Subject to applicable Federal confidentiality or privacy laws, the contractor, or their designated representatives, and designated representatives of Federal regulatory agencies having jurisdiction over contractor, may have access to VA's records, at VA's place of business on request during normal business hours, to inspect and review as needed in order to perform the examination contracted for but in no case will copies of records be made and/or removed from the VA's place of business.

17. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA): Contractor must adhere to the provisions of Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the National Standards to Protect the Privacy and Security of Protected Health Information (PHI). As required by HIPAA, the Department of Health and Human Services (HHS) has promulgated rules governing the security use and disclosure of protected health information by covered entities, including the Department of Veterans Affairs (VA). Following HIPAA, the contractor may be required to enter into a Business Associate Agreement (BAA) with VA.

18. CONTRACT INFORMATION SECURITY REQUIREMENTS:

a. **GENERAL**: Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security.

b. **CONTRACTOR PERSONNEL SECURITY REQUIREMENTS: LOW RISK**

(1) All contractor employees having or requiring access to the Department of Veterans Affairs' computer systems or sensitive data (including patient or beneficiary records), shall be the subject of a background investigation and must receive a favorable adjudication from the VA Security Investigation Center before contract performance. This requirement applies to all subcontractor personnel requiring the same access.

(1) The COR will provide the appropriate Background Investigation information to the contractor for completion. Required background investigation initiation documentation must be completed and returned within five (5) calendar days after receipt.

(2) Contractor staff shall not begin performance until notification is received indicating that the Security Package has been considered a complete package. It is not necessary that the full investigation be completed prior to commencement of work. However, if the investigation is not completed prior to the start date of the contract, the contractor shall be responsible for the actions of those individuals they provide to perform work for VA.

a. Position Sensitivity - The position sensitivity has been designated as **Low Risk.**

b. Background Investigation - The level of background investigation commensurate with the required level of access is a **National Agency Check with Written Inquiries (NACI)**.

(4) Contractor Responsibilities:

a. The contractor shall bear the expense of obtaining background investigations. The VA shall be responsible for payment to the Security Investigations Center; however, upon final payment, the VA shall submit a Bill of Collections to the Contractor. The contractor shall be responsible for reimbursement to the VA within thirty (30) calendar days. The current cost for a low-risk background investigation is $230 per case.

b. For Low-Risk Sensitivity Designation, each contractor/subcontractor employee must complete the following forms.

i. Standard Form 85, Questionnaire for Non-Sensitive Positions
ii. (ii)Optional Form 306, Declaration for Federal Employment

c. The contractor, when notified of an unfavorable determination by the government, shall withdraw the employee from consideration from working under the contract.

d. Failure to comply with the contractor personnel security requirements may result in termination of the contract for default.

(5) Fingerprinting Requirements – contractor/subcontractor employees will be required to have fingerprints taken as part of the background investigation process. The preferred method of obtaining fingerprints is to have them taken electronically at the Human Resources Service at a VA facility. If fingerprints cannot be obtained at a VA facility the Contracting Officer will provide the contractor with a Form FD258 fingerprint chart, which can be taken to any local police station for fingerprints. However, local entities may assess a fee for this service. The fingerprint chart must accompany the OF 306 when returned by the contractor.

c. **ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS:**

(1) A contractor/subcontractor shall be granted access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order.

(2) All contractor/subcontractors working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for Contractors must be following VA Directive and Handbook 0710, Personnel Suitability and Security Program. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures.

(3) The contractor or subcontractor must notify the Contracting Officer immediately when an employee working on a VA system or with access to VA information is reassigned or leaves the contractor or subcontractor's employ. The Contracting Officer must also be notified immediately by the contractor or subcontractor before an unfriendly termination.

d. **VA INFORMATION CUSTODIAL LANGUAGE:**

(1) Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information development by the contractor/subcontractor in the performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data – General, FAR 52.227-14(d)(1).

(2) VA information should not be co-mingled, if possible, with any other data on the contractors/subcontractor's information systems or media storage systems to ensure VA requirements related to data protection and media sanitization can be met. If co-mingling must be allowed to meet the requirements of the business need, the contractor must ensure that VA's information is returned to the VA or destroyed in accordance with VA's sanitization requirements. VA reserves the right to conduct onsite inspections of contractor and subcontractor IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA directive requirements.

(3) Prior to termination or completion of this contract, contractor/subcontractor must not destroy information received from VA, or gathered/created by the contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, *Records and Information Management* and its Handbook 6300.1 *Records Management Procedures,* applicable VA Records Control Schedules, and VA Handbook 6500.1, *Electronic Media Sanitization.* Self-certification by the contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination or completion of the contract.

(4) The contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of VA information only in compliance with the terms of the contract and applicable Federal and VA information confidentiality and security laws, regulations and policies. If Federal or VA information confidentiality and security laws, regulations and policies become applicable to the VA information or information systems after execution of the contract, or if NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties

agree to negotiate in good faith to implement the information confidentiality and security, laws, regulations and policies into this contract.

(5) The contractor/subcontractor shall not make copies of VA information except as authorized and necessary to perform the terms of the agreement or to preserve electronic information stored on contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.

(6) If VA determines that the contractor has violated any of the information confidentiality, privacy, and security provision of the contract, it shall be sufficient grounds for VA to withhold payment to the contractor or third party or terminate the contract for default or terminate for cause under Federal Acquisition Regulation (FAR) part 12.

(7) If a VA contract is terminated for cause, the associated BAA must also be terminated and appropriate actions taken in accordance with VHA Handbook 1600.01, Business Associates Agreements. Absent an agreement to use or disclose protected health information, there is no business associate relationship.

(8) The contractor/subcontractor must store, transport, or transmit VA sensitive information in an encrypted form, using VA-approved encryption tools that are, at a minimum, FIPS 140-2 validated.

(9) The contractor/subcontractor's firewall and Web services security controls, if applicable, shall meet or exceed VA's minimum requirements. VA Configuration Guidelines are available upon request.

(10) Except for uses and disclosures of VA information authorized by this contract for performance of the contract, the contractor/subcontractor may use and disclose VA information only in two other situations: (i) in response to a qualifying order of a court of competent jurisdiction, or (ii) with VA's prior written approval. The contractor/subcontractor must refer all requests for, demands for production of, or inquiries about, VA information and information systems to the VA Contracting Officer for response.

e. INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE

(1) All electronic storage media used on non-VA leased or non-VA owned IT equipment that is used to store, process, or access VA information must be handled in adherence with VA Handbook 6500.1, *Electronic Media Sanitization* upon: (i) completion or termination of the contract or (ii) disposal or return of the IT equipment by the contractor/subcontractor or any person acting on behalf of the contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the contractors/ subcontractors that contain VA information must be returned to the VA for sanitization or destruction or the contractor/subcontractor must self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination of the contract and becomes the property of the VA.

(2) Bio-Medical devices and other equipment or systems containing media (hard drives,

optical disks, etc.) with VA sensitive information must not be returned to the vendor at the end of lease, for trade-in, or other purposes. The options are:

(a) Vendor must accept the system without the drive;

(b) VA's initial medical device purchase includes a spare drive which must be installed in place of the original drive at time of turn-in; or

(c) VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.

(d) Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is not possible for the VA to retain the hard drive, then;

(3) The equipment vendor must have an existing BAA if the device being traded in has sensitive information stored on it and hard drive(s) from the system are being returned physically intact; and

(4) Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be preapproved and described in the purchase order or contract.

(5) A statement needs to be signed by the Director (System Owner) that states that the drive could not be removed and that (a) and (b) controls above are in place and completed. The ISO needs to maintain the documentation.

f. LIQUIDATED DAMAGES FOR DATA BREACH

(1) Consistent with the requirements of 38 U.S.C. §5725, a contract may require access to sensitive personal information. If so, the contractor is liable to VA for liquidated damages in the event of a data breach or privacy incident involving any SPI the contractor/subcontractor processes or maintains under this contract.

(2) The contractor/subcontractor shall provide notice to VA of a "security incident" as set forth in the Security Incident Investigation section above. Upon such notification, VA must secure from a non-Department entity or the VA Office of Inspector General an independent risk analysis of the data breach to determine the level of risk associated with the data breach for the potential misuse of any sensitive personal information involved in the data breach. The term 'data breach' means the loss, theft, or other unauthorized access, or any access other than that incidental to the scope of employment, to data containing sensitive personal information, in electronic or printed form, that results in the potential compromise of the confidentiality or integrity of the data. Contractor shall fully cooperate with the entity performing the risk analysis. Failure to cooperate may be deemed a material breach and grounds for contract termination.

(3) Each risk analysis shall address all relevant information concerning the data breach, including the following:

(a) Nature of the event (loss, theft, unauthorized access);

(b) Description of the event, including:

(c) date of occurrence;

(d) data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code;

(e) Number of individuals affected or potentially affected;

(f) Names of individuals or groups affected or potentially affected;

(g) Ease of logical data access to the lost, stolen or improperly accessed data in light of the degree of protection for the data, e.g., unencrypted, plain text;

(h) Amount of time the data has been out of VA control;

(i) The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons);

(j) Known misuses of data containing sensitive personal information, if any;

(k) Assessment of the potential harm to the affected individuals;

(l) Data breach analysis as outlined in 6500.2 Handbook, *Management of Security and Privacy Incidents*, as appropriate; and

(m) Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive personal information that may have been compromised.

(4) Based on the determinations of the independent risk analysis, the contractor shall be responsible for paying to the VA liquidated damages in the amount of $37.50 per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:

(a) Notification;

(b) One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;

(c) Data breach analysis;

(d) Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;

(e) One year of identity theft insurance with $20,000.00 coverage at $0 deductible; and

(f) Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

19. SECURITY INCIDENT INVESTIGATION:

(1) The term 'security incident' means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedure. The contractor/subcontractor shall immediately notify the COR and simultaneously, the designated ISO and Privacy Officer for the contract of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/subcontractor has access.

(2) To the extent known by the contractor/subcontractor, the contractor/subcontractor's notice to VA shall identify the information involved, the circumstances surrounding the incident (including to whom, how, when, and where the VA information or assets were placed at risk or compromised), and any other information that the contractor/subcontractor considers relevant.

(3) With respect to unsecured protected health information, the contractor/subcontractor is deemed to have discovered a data breach when the contractor/subcontractor knew or should have known of a breach of such information. Upon discovery, the contractor/subcontractor must simultaneously notify the COR, ISO and Privacy Officer.

(4) In instances of theft or break-in or other criminal activity, the contractor/subcontractor must concurrently report the incident to the appropriate law enforcement entity (or entities) of jurisdiction, including the VA OIG and Security and Law Enforcement. The contractor, its employees, and its subcontractors and their employees shall cooperate with VA and any law enforcement authority responsible for the investigation and prosecution of any possible criminal law violation(s) associated with the incident. The contractor/subcontractor shall cooperate with VA in any civil litigation to recover VA information, obtain monetary or other compensation from a third party for damages arising from any incident, or obtain injunctive relief against any third party arising from, or related to, the incident.

h. **SECURITY CONTOLS COMPLIANCE TESTING:** On a periodic basis, VA, including the Office of Inspector General, reserves the right to evaluate any or all of the security controls and privacy practices implemented by the contractor under the clauses contained within the contract. With 10 working-days' notice, at the request of the government, the contractor must fully cooperate and assist in a government-sponsored security controls assessment at each location wherein VA information is processed or stored, or information systems are developed, operated, maintained, or used on behalf of VA, including those initiated by the Office of Inspector General. The government may conduct a security control assessment on shorter notice (to include unannounced assessments) as determined by VA in the event of a security incident or at any other time.

i. **TRAINING:**

(1) All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete the following before being granted access to VA information and its systems:

(a) Sign and acknowledge (either manually or electronically) understanding of and responsibility for compliance with the Contractor Rules of Behavior training relating to access to VA information and information systems.

(b) Successfully complete the *VA Cyber Security Awareness* and *Rules of Behavior* training and annually complete required security training;

(c) Successfully complete the appropriate VA privacy training and annually completed required privacy training; and

(d) Successfully complete any additional cyber security or privacy training, as required for VA personnel with equivalent information system access as deemed necessary.

(2) The contractor shall provide the contracting officer and/or the COR a copy of the training certificates and certification of signing the Contractor Rules of Behavior for each applicable employee within one week of the initiation of the contract and annually thereafter, as required.

(3) Failure to complete the mandatory annual training and sign the Rules of Behavior annually, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until such time as the training documents are complete.

20. CONTRACTOR REMOTE ACCESS REQUIREMENTS: The Contractor shall be allowed remote access to VA computer systems or network in the performance of the contract. VA has stringent policies and procedures covering remote access, therefore the following responsibilities are outlined below:

a. All remote connections to the VA network shall be through the Office of Cyber and Information Security (OCS) authorized configurations and access points. Contractor's remote access sessions through the Internet or other networks shall be conducted using VA's remote access Virtual Private Network (VPN) Service.

b. The VA shall provide secure and reliable remote access to systems, applications, and information on the VA network to the Contractor.

c. All Contractor personnel requesting remote access shall be required to sign a One-VA VPN Rules of Behavior. The contractor shall be responsible to ensure contractor personnel follow the terms of the agreement.

d. VA shall provide VPN software; host based personal firewall, and anti-virus software to the contractor.

e. The contractor shall install VA provided VPN software, host based personnel firewall, and anti-virus protection software on all contractor computer systems that will connect to the VA network or computer systems.

f. The contractor shall adhere to the remote access requirements, and ensure that systems are properly configured, and appropriately security mechanism and monitoring devices are up to date with best practices and technical standards.

21. PATIENT REFERRAL: The contractor is not authorized to refer any VA patients for

additional medical treatment.

22. **LIABILITY AND INSURANCE COVERAGE:** The Contractor shall provide insurance coverage in accordance with Federal Acquisition Regulation (FAR) Clause 52.228-5, "Insurance - Work On A Government Installation (Jan 1997)" and VA Acquisition Regulation (VAAR) Clause 852.237-7, "Indemnification And Medical Liability Insurance (Oct 1996) incorporated herein under the Clause Section. The Contractor shall furnish a proof of insurance certificate prior to commencement of services under the awarded contract.

23. **POST AWARD REQUIREMENTS:** The contractor shall be responsible to contact the COR upon receipt of Notice of Award to schedule a post-award orientation. This orientation shall be held on a mutually agreed upon date and time to discuss commencement of services, completion of site renovations required to accept the equipment, scheduling of patients and additional services defined in the specifications.

24. **ID BADGES/PARKING/SMOKING POLICY:**

a. BADGES: All contractor personnel are required to wear identification (ID) badges during the entire time they are on the VA grounds.

b. PARKING: It is the responsibility of contractor personnel to park only in designated parking areas. Parking information is available from the VA Security Service. The VA will not invalidate or make reimbursement for parking violations of the contractor's personnel under any circumstances.

c. SMOKING: Smoking is not permitted within or around the VA Healthcare System facilities, except in designated areas.

(END OF SOW)