PERFORMANCE WORK STATEMENT

1.0 Background: The U.S. Army Institute of Surgical Research (USAISR) is part of the U.S. Army Medical Research and Materiel Command (USAMRMC) and is collocated with the Brooke Army Medical Center (BAMC). The USAISR is dedicated to both laboratory and clinical trauma research. Its mission is to provide requirements- driven combat casualty care medical solutions and products for injured soldiers from self-aid through definitive care across the full spectrum of military operations; provide state-of-the-art trauma, bum, and critical care to Department of Defense beneficiaries around the world; and provide Burn Special Medical Augmentation Response Teams.

2.0 Scope of Work: The contractor shall provide research nursing services in accordance with the ethical,

professional and technical standards of the health care industry, within the established scope of practice and according to the standards set forth in this statement of work. The position is full time. Performance will be at U.S. Army Institute of Surgical Research (USAISR) Combat Critical Care Engineering Task Area of the Research Directorate at Fort Sam Houston, TX 78234.

3.0 Tasks: The following are provided to help potential contractors better understand the task

environment in which the services will be delivered. The following are required to successfully deliver the required service.

3.1 Conduct human research under the USAISR Assurance and. Human Research Protection Program, adhering to all of its requirements. Participates in human research with research staff and other licensed providers.

3.2 Assist the Primary Investigator (P.I.). in the preparation, conduct and documentation of human subjects research, including administrative and clinical support for approved human research conducted at the USAISR (e.g. collection and processing of clinical research samples, maintaining study records and documents, communication, travel support, printing, graphics, library or publication services, and other duties as assigned).

3.3 Review and distribute work in coordination with Research Assistants and other team members, nursing supervisor, research regulatory personnel and program managers to-determine progress of work and completion dates.

3.4 Work with the Institutional Review Board to coordinate the execution of research, report progress and participate in efforts to ensure regulatory compliance; patient safety and scientific .quality.

3.5 Work within the trauma critical care unit, emergency department and bum center critical

care/intermediate care units, and operating room environment to enroll/consent research subjects and collect approved research data

3.6 Work directly with patients for research nursing interventions (e.g. 'administration of medications, blood draws, dressing changes, etc.) that are stated within the approved protocol and obtain informed consent for participation in studies in accordance with the American Nurses Association Nursing Scope of Practice, Texas Board of Nursing Standards, Code of Federal Regulations and Good Clinical Practice Regulations.

3.7 Process and ship specimens.

3.8 Record clinical data to include use of computerized data acquisition systems.

3.9 Review data from a variety of sources to ensure accuracy,

3.10 Develop and use record keeping systems to ensure data integrity.

3.11 Participate in the analysis of reports.

3.12. Possess and maintain all necessary credentials and training required by the USAISR.

3.13 Attend in-house meetings and conferences deemed appropriate by P.I.

4.0 Qualifications -Must be a board certified Registered Nurse; a degree and or 2-5 years of hands on experience in the field or in a closely related area is a major plus.

5.0 Additional Requirements

5.1 Health requirements: Contractor shall comply with safety procedures and infection control/occupational health procedures pertaining to the laboratory, vivarium and animal surgery area, to include documentation of the following: TB Test; Hepatitis B vaccine, titer, or wavier, Tetanus booster within the last 5; HIV titer, as required. Other special exam such as pulmonary function, respirator fit, audiogram, and/or laser vision testing.

5.2 Contractor shall travel to present research data or attend medical/scientific meetings and to obtain education in specialized emerging methodologies and concepts; Travel will be at the discretion of the Primary Investigator and the Commander and Director, USAISR.

5.3 Contractor shall comply with all Army, Institute and other governmental regulatory requirements. Special attention shall be given to Safety and Security requirements.

5.4 Contractor will execute a Non-Disclosure Agreement prior to reporting to the USAISR and a copy of that signed agreement will be provided to the USAISR at the time they in-process.

5.5 Duty hours are from 7:30AM to 4:30 PM, 8 hours a day, on-call and/or a shifting work schedule including evenings, nights, and weekends may be necessary.

5.6 The contractor employee is responsible for maintaining the equipment assigned to them by the Institute for the completion of assigned tasks.

5.7 Contract personnel will report to Building 3611, Room 182-12 for in-processing on their first day of work. On their last day of work, they will complete the out-processing form IAW USAISR Policy Memorandum 01-003, “Clearing USAISR and Turning in Equipment”. All government furnished property will be inventoried prior to departure.

5.8 When required to take government equipment out of Building 3611, the contractor employee must obtain a property pass, Optional Form 7, from the Institutes Logistics Property Book Officer to validate the authorization to do so.

5.9 Contractor’s Employee shall report to the workplace with a Favorable NAC. The security clearance must be submitted and returned by the security office before the employee reports to work.

5.10 Holidays. The following is a list of legal federal holidays. Any of the federal holidays falling on a Saturday will be observed on the preceding Friday, holidays falling on a Sunday will be observed on the following Monday.

 New year’s Day, January 1st

 Martin Luther King’s Birthday, 3rd Monday in January

 President’s Day, 3rd Monday in February

 Memorial Day, Last Monday in May

 Independence Day, July 4th

 Labor Day, 1st Monday in September

 Columbus Day, 2nd Monday in October

 Veteran’s Day, November 11th

 Thanksgiving Day, 4th Thursday in November

 Christmas Day, December 25th

 NOTE 1: Any of the above holidays falling on a Saturday will be observed on the preceding Friday; holidays falling on a Sunday will be observed on the following Monday.

 NOTE 2: Any holidays that are declared by Presidential Executive Order shall be observed in the same manner as the holidays listed above.

5.11 Period of Performance: A base year plus four 1-year options.

5.12 Place of performance: USAISR, Building 3611, 3698 Chambers Pass, Fort Sam Houston, TX 78234

5.13 Authorized use policy agreement: The Contractor shall ensure that the Acceptable Use Policy (AUP) Agreement, outlining the terms and conditions in utilization of government computer and communications systems, is signed by all staff assigned to, including all subcontractors and consultants, or performing on this Task order and adhere to the terms of that AUP. Assignment of staff who has not executed this statement or failure to adhere to this statement shall constitute default on the part of the Contractor.

5.14 Invoicing: The contractor shall submit invoicing through Wide Area Work Flow (WAWF).

5.15 CAC card: The CAC will be issued to eligible DOD contractor personnel. Assistance in obtaining the CAC will be provided by ISR.

5.16 Replacement of Personnel. When personnel leave, the vendor shall fill the vacant position within 15 days of the employee leaving. Replacement personnel shall have equal or better qualifications as the individual being replaced.

5.17 Post closure: When the Post if closed for inclement weather, the employee shall call the company for procedures.

5.18 Contractor identification: Contractor personnel must clearly identify themselves as a contractor employee. The name of their company must be part of their email address, all correspondence and all identification badges, desk plates, etc. Additionally, contractor personnel are required to identify themselves as contractor personnel when attending meetings, answering Government telephones, or working in situations where their status as contractor employees may not be obvious.

## 5.19 Government furnished facilities, supplies, equipment: The Government will provide workspace, working supplies, furniture, desktop computers, and access to business telephones (for business purposes only) and other equipment as needed to perform the tasks specified in this PWS. The government will provide any Government regulations and technical manuals needed*.*

5.20 Government-directed training: Contractors are expected to have the skills to perform their contractual duties. If they must train to maintain the required skills, it is not to be done on Government time. Change in technical requirements and Command determination for total team training are conditions that permit contractor training at Government time or expense.

5.21Department of Defense, Human Protection Program, DOD Individual Investigator Agreement : The Contractor shall ensure that the Agreement, describing the responsibilities of the employee who is engaged in human subject research and is not an employee of the assured institution, but is associated with the assured institution for the purpose of conducting research is signed by the employee. This Agreement becomes part of the institutions Federal Assurance for the Protection of Human Research Subjects. Employees who have not executed this agreement, if required or fail to adhere to this agreement shall not be allowed to perform human subject research and therefore shall constitute default on the part of the Contractor.

5.22 Security

 Category 1: U.S. Citizen

The vendor/contractor must ensure all personnel selected for employment fill out a SF 86. It is the vendor’s/contractor’s responsibility to coordinate and submit the completed SF 86 to the USAISR Security office via email. Once the SF 86 has been properly vetted, the USAISR Security office will notify the vendor/contractor of the results pertaining to the SF 86. Prior to this notification, the employee is not authorized to report for in-processing. For those individuals who claim U.S. citizenship, proof of citizenship will be required prior to the in-processing date. Proof of citizenship can be either a U.S. birth certificate, U.S. Passport, or a Naturalization certificate.

Category 2: Non U.S. Citizen

If a non U.S. citizen is selected to fill this contract position, a Delegation of Disclosure Authority (DDL) is required to be filled out by the gaining Contracting Officer Representative (COR) on the non U.S. citizen. Once that document has been properly vetted, the vendor/contractor will be notified of the results. If the results are favorable, the vendor/contractor must ensure all personnel selected for employment fill out a SF 86. It is the vendor’s/contractor’s responsibility to coordinate and submit the completed SF 86 to the USAISR Security office via email. Once the SF 86 has been properly vetted, the USAISR Security office will notify the vendor/contractor of the results pertaining to the SF 86. Prior to this notification, the employee is not authorized to report for in-processing.

5.23 Conduct of contract personnel: The COR, with the approval of the Contracting Officer, may require the contractor to remove from the job site any employee working under this contract for reasons of misconduct or security, or found or suspected to be under the influence of alcohol, drugs, or other incapacitating agents. Contract employees will be subject to dismissal from the premises upon determination by the COR and the Contracting Officer that such action is in the best interests of the Government.

5.24 The individual is authorized to participate or conduct human subjects’ research under the USAISR Assurance, if applicable.

5.25 All Contract personnel are required to complete Operations Security (OPSEC) training within 30 days of In-Processing and maintain all mandatory OPSEC aspects such as physical security, informational security, awareness and to include adherence to all policies pertaining to OPSEC review of all documents generated for public release.

5.26 **Business Associates**

**Introduction**

In accordance with DOD 6025.18-R "Department of Defense Health Information Privacy Regulation," January 24, 2003, the Contractor meets the definition of Business Associate. Therefore, a Business Associate Agreement is required to comply with both the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Regulations. This clause serves as that agreement- whereby the Contractor agrees to abide by all applicable HIPAA Privacy and Security requirements: regarding health information as defined in this clause, and in DoD 6025.18-R and DoD 8580.02-R, as amended. Additional requirements will be addressed when implemented.

(a) Definitions. As used in this clause generally refer to the Code of Federal Regulations (CFR) definition unless a more specific provision exists, in DOD 6025.18-R or DOD 8580.02-R.

***Individual*** has the same meaning as the term "individual" in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(0.

***Privacy Rule*** means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

***Protected Health Information*** has the same meaning as the term "protected health information" in 45 CFR 160.103, limited to the information created or received by the "Contractor from or on behalf of the Government pursuant to the Contract.

***Electronic Protected Health Information*** has the same meaning as 'the term "electronic protected health information" in 45 CFR 160.103.

***Required by Law*** has the same meaning as the term "required by law" in 45 CFR 164.103.

***Secretary*** means the Secretary of the Department of Health and Human Services or his/her designee.

 ***Security Rule*** means the Health Insurance Reform: Security Standards at.45 CFR part 160, 162 and part 164 subpart C.

Terms used, but not otherwise defined, in this Clause shall have the same meaning as those terms in 45 CFR 160.103, 160.502, 164.103, 164.304, and 164.501.

1. The Contractor shall not use or further disclose Protected Health Information other than as permitted or required by the Contract or as Required by Law.
2. The Contractor shall use appropriate safeguards to prevent use or disclosure' of the Protected Health Information other than as provided for by this Contract.
3. The Contractor agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits in the execution of this Contract.
4. The Contractor shall, at their own expense, take action to mitigate, to the extent practicable, any harmful effect that is known to the Contractor of a use or disclosure of Protected Health Information by the Contracto4 in violation of the requirements of this Clause. These mitigation actions will include as a minimum those listed in the TMA Breach Notification Standard Operating Procedure (SOP), which is available at: [http://www.tricare.mil/tma/privacy/breach.aspx.](http://www.tricare.mil/tma/privacy/breach.aspx.%21)
5. The Contractor shall report to the Government any security incident involving protected health information of which it becomes aware.
6. The Contractor shall report to the Government any use or disclosure of the. Protected. Health Information not provided for by this Contract of which the Contractor becomes aware.
7. The Contractor shall ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Contractor, on behalf of the Government, agrees to the same restrictions and conditions that apply through this Contract to the Contractor with respect to such information. .
8. The Contractor shall ensure that any agent, including a subcontractor, to whom it provides electronic Protected Health Information, agrees to implement reasonable and appropriate safeguards to protect it.
9. The Contractor shall provide access, at the request of the Government, and in the time and manner reasonably designated by the Government to Protected Health Information in a Designated Record Set, to the Government or, as directed by the Government, to an Individual in order to meet the requirements under 45 CFR 164.524.

(k) The Contractor shall make any amendment(s) to Protected Health Information in a Designated Record Set that the Government directs or agrees to pursuant to 45 CFR 164.526 at the request of the Government, and in the time and manner reasonably designated by the Government.

(1) The Contractor shall make internal practices, books, and records relating to the use and disclosure of. Protected Health Information received from, or created or received by the Contractor, on behalf of the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner reasonably designated by the Government or the Secretary, for purposes of the Secretary determining the Government's compliance with the Privacy Rule.

(m) The Contractor shall document such disclosures of Protected Health Information and information related to such disclosures' as would be required for the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528

(n) The Contractor shall provide to the Government or an Individual, in time and manner reasonably designated by the Government, information collected in accordance with this Clause of the Contract, to permit the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

**General Use and Disclosure Provisions**

Except as otherwise limited in this Clause, the Contractor may use or disclose Protected Health Information on behalf of, or to provide services to, the Government for treatment, payment, or healthcare operations purposes, in accordance with the specific use and disclosure provisions below, if such use or disclosure of Protected Health Information would not violate the HIPAA Privacy Rule, the HIPAA Security Rule, DoD 6025.18-R or DoD 8580.02-R if done by the Government.

**Specific Use and Disclosure Provision**

1. Except as otherwise limited in this Clause, the Contractor may use Protected Health Information for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor.

(b) Except as otherwise limited in this Clause, the Contractor may disclose Protected Health Information for the proper management and administration of the Contractor, provided that disclosures are required by law, or the Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

1. Except as otherwise limited in this Clause, the Contractor may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 CFR 164.504(e)(2)(i)(B).
2. Contractor may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

**Obligations of the Government**

Provisions for the Government to Inform, the Contractor of Privacy Practices and Restrictions

1. The Government shall provide the Contractor with the notice of privacy practices that the Government produces in accordance with 45 CFR 164.520.

I

1. The Government shall provide the Contractor with any changes in, or revocation of, permission by Individual to use or disclose Protected Health

Information, if such changes affect the Contractor's permitted or required uses and disclosures.

1. The Government shall notify the Contractor of any restriction to the use on disclosure of Protected Health Information that the Government has agreed to in accordance with 45 CFR 164.522.

**Permissible Requests by the Government**

The Government shall not request the Contractor to use or disclose Protected Health information in any manner that would not be permissible under the HIPAA Privacy Rule, the HIPAA Security Rule, or any applicable Government regulations (including without limitation, DoD 6025.18-R and DoD 8580.02-R) if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Contractor as otherwise permitted by this clause.

**Termination**

(a) Termination. A breach by the Contractor of this clause, may subject the Contractor to termination under any applicable default or termination provision of this Contract.

(b) Effect of Termination

1. If this contract had records management requirements, the records subject to the Clause should be handled in accordance with the records management requirements. If this contract does not have records management requirements, the records should be handled in accordance with paragraphs (2) and (3) below
2. If this contract does not have records management requirements, except as provided in paragraph (3), of this section, upon termination of this Contract, for any reason, the Contractor shall. return or destroy all Protected Health Information received from the Government, or created or received by the Contractor on behalf of the Government. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Contractor. The Contractor shall retain no copies of the Protected Health Information.
3. If this contract does not have records management provisions and the Contractor determines that returning or destroying the Protected Health Information is infeasible, the Contractor shall provide to the Government notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Government and the Contractor that return or destruction of Protected Health Information is infeasible, the Contractor shall extend the protections of this Contract to such Protected': Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Contractor maintains such Protected Health Information.

 **Miscellaneous**

1. Regulatory References. A reference in this Clause to a. section in DoD 6025.18- R, DoD 8580.02-R, Privacy Rule or Security Rule means the section currently in effect or as amended, and for which compliance is required.
2. Survival. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this 'Clause shall survive the termination of this Contract.
3. Interpretation. Any ambiguity in this Clause shall be resolved in favor of a meaning that permits the Government to comply with DOD 6025.18-R, DOD 8580.02-R, the HIPAA Privacy Rule or the HIPAA Security Rule.

**QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)**

1. PURPOSE:

This Quality Assurance Surveillance Plan (QASP) provides a systematic method to evaluate performance for the stated non-personal services contract. This QASP explains the following:

* What will be monitored?
* How monitoring will take place.
* Who will conduct the monitoring?
* How monitoring efforts and results will be documented.

This QASP does not detail how the contractor accomplishes the work. Rather, the QASP is created-with the premise that the contractor is responsible for management and quality control actions to meet the terms of the contract. It is the Government's responsibility to be objective, fair, and consistent in evaluating performance. In addition, the QASP should recognize that nnforeseen and uncontrollable situations may occur.

This QASP is a "living document" and the Government may review and revise it on a regular basis. However, the Government shall coordinate changes with the contractor. Updates shall ensure that the QASP remains a valid, useful, and enforceable document. Copies of the original QASP and revisions shall be provided to the contractor and Government officials implementing surveillance activities.

1. OASP RELATION TO THE SOLICITATION:

QASPs shall be developed and appear in every solicitation, as well as the resultant service contract.

The Government will retain the right to change the surveillance methods and Quality Assurance (QA) procedures, or to increase or decrease the degree of surveillance efforts at any time necessary to assure contract compliance

1. REVISIONS TO THE OASP:

The QASP is a tool for use in Government administration of the Performance Work . Statement/Statement of Won( (PWS/SOW) and remains subject to revision at any time by the Government throughout the contract performance period. Revisions to this surveillance plan are the responsibility of the Contracting Officer's Representative (COR). Changes to the QASP shall be made bilaterally.

* The contractor will assume responsibility for all tasks and deliverables in the PWS under this award.As the performance period progresses, the levels of surveillance may be altered for service areas in cases where performance is either consistently excellent or consistently unsatisfactory. If observations reveal consistently good performance, then the amount of surveillance may be reduced. If observations reveal consistent deficiencies, increased surveillance may be implemented.

2. GOVERNMENT ROLES AND RESPONSIBILITIES:

The following personnel shall oversee and coordinate surveillance activities.

1. Contracting Officer (KO) - The KO shall ensure performance of all necessary actions for effective contracting, ensure compliance with the contract terms, and shall safeguard the interests of the United States in the contractual relationship. The KO shall also assure that the contractor receives impartial, fair, and equitable treatment under this contract. The KO is ultimately responsible for the final determination of the adequacy of the contractor's performance.
2. Contracting Officer's Representative (COR) — The COR will be located at US Army Institute of Surgical Research, Fort Sam Houston, TX. The COR will be responsible for technical administration of the contract, and shall assure proper Government surveillance of the contractor's performance. The COR shall keep a quality assurance file. At the conclusion of the contract or when requested by the KO, the COR shall provide documentation to the KO. A COR is not empowered to make any contractual commitments or to authorize any contractual changes on the Government's behalf. The contractor shall refer any changes they deem may affect contract price, terms, or conditions to the KO for action.
3. CONTRACTOR ROLES AND RESPONSIBILITIES: The contractor is responsible for delivering services in accordance with the Contract. The contractor shall appoint a single off-site point-of-contact to act as a central recipient of communication from the Government
4. CONTRACT QUALITY REQUIREMENTS:

a. Contract quality requirements are the technical requirements in the contract relating to the quality of the

service and those contract clauses prescribing inspection and other quality controls incumbent on the contractor, to assure that the service conforms to the contractual requirements. Government contract quality assurance shall be performed at such times and places as may be necessary to determine that the services conform to the contract requirements. Failure to meet or exceed the contract quality requirements is defined as a "nonconformance" on the part of the contractor. The contractor shall be held responsible for any identified nonconformance, and the government may require the work to be re-performed.

b. The Government's contract quality assurance is defined as follows:

1. "Acceptance" means the act of an authorized representative of the Government by which the Government, for itself or as agent of another, assumes ownership of existing identified supplies tendered or approves specific services rendered as partial or complete performance of the contract.
2. "Conditional acceptance" means acceptance of supplies or services that do not conform to contract quality requirements, or are otherwise incomplete, that the contractor is required to correct or otherwise complete by a specified date.
3. "Minor nonconformance" means a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services.
4. "Major nonconformance" means a nonconformance, other than critical, that is likely to result in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose.
5. "Critical nonconformance" means a nonconformance that is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the supplies or services; or is likely to prevent performance of a vital agency mission.

c. Documentation:

1. Thorough documentation of unperformed or nonconformance is essential for tracking contractor performance throughout the period of performance. The COR will document deficient Work by compiling facts describing the inspection methods and results. The COR will develop documentation to substantiate nonconformance with the Contract.
2. Remedial Action by the Contracting Officer:
3. Shall notify the contractor in writing of the nonconforming service;
4. Shall request that the contractor perform the service, at no cost to the Government;

and

(iii) May accept consideration if offered. For guidance on solicitation of a refund, see Subpart 242:71. In accordance with *FAR 52.246-4: Inspection of Services-Fixed-Price,* the Government may require the contractor to re-perform any services that do not conform to contract requirements: If the defects cannot be corrected by re-performance, the KO may either require the contractor to take the necessary action to ensure that future performance conforms to the requirements, or the KO may reduce the Contract price to

reflect the reduced value of the services performed. At an extreme decision point, penalties may include a-decision not to exercise contract options. The KO will determine the penalty for nonconformance based upon his or her judgment and the severity of the • nonconformance.

5. METHODS OF QUALITY ASSURANCE SURVEILLANCE:

Various methods exist to monitor performance, The COR shall use the surveillance methods listed below in the administration of this QASP.

Regardless of the surveillance method, the COR shall always contact the contractor's point of contact inform the manager of the specifics of the problem. The COR shall be responsible for monitoring the contractor's performance in meeting the contract's quality requirements.

* DIRECT OBSERVATION: (Can be performed periodically or through 100% surveillance.)
* MANAGEMENT INFORMATION SYSTEMS: (Evaluates outputs through the use of management information reports. Best used for general surveillance and may need to be supplemented by periodic inspections.)
* PERIODIC INSPECTION: Uses a comprehensive evaluation of selected outputs. Inspections may be scheduled as required.
* Analysis of contractor's progress reports. (Evaluate cost, schedule, etc.)
* Performance reporting.
* Customer Feedback

Surveillance results may be used as the basis for actions (to include payment deductions) against the contractor. In such cases, the Inspection of Services clause in the Contract becomes the basis for the KO's actions.

**6. FREQUENCY OF MEASUREMENT:** During contract performance, the COR shall periodically analyze whether the frequency of measurement is appropriate for the work being performed.

|  |
| --- |
| **Research Nurse**  |
| Required Service/Deliverable | Performance Standard | Acceptable Quality Level(AQL) | Monitoring Method |
| Conduct human research under the USAISR Assurance and Human Research Protection Program, adhering to-all of its requirements. Participates in human research with research staff and other licensed providers. | Performs as required 100% of the time | Performs as required 100% of the time | Periodic Review |
| Assist the Primary Investigator (P.I.). in the preparation, conduct and documentation of human subjects research, including administrative and clinical support for approved human research conducted at the USAISR | Carries out 100% of the time. | Carries out 98% of the time |  PeriodicReview. |
| Review and distribute work in coordination with Research Assistants and other team members, nursing supervisor, research regulatory personnel and program managers to determine progress of work and completion dates.  | Carries out with 98% accuracy | Carries out with 98% accuracy | PeriodicReview |

|  |  |  |  |
| --- | --- | --- | --- |
| Work with the Institutional Review Board to coordinate the execution of research, report progress and participate in efforts to ensure regulatory compliance, patient safety and scientific quality. | Carries out 100% of the time .. | Carries out 98% of the time. | PeriodicReview |
| Work within the trauma critical care unit, emergency department and bum center critical care/intermediate care units, andoperating room environment to enroll/consent research subjects andcollect approved research data. | Carries out 100% of the time | Carries out 100% of the time. | PeriodicReview |
| Work directly with patients for research nursing interventions(e.g. administration ofmedications, blood draws, dressing changes, etc.) | Carries out 100% of the time  | Carries out 100% of the time. . | PeriodicReview. |
| Process and ship specimens, record clinical data to include use of computerized data acquisition systems. Review data from a variety of sources to ensure accuracy, develop and use record keeping systems to ensure data integrity, participate in analysis of reports. | Carries out 100% of the time.. | Carries out 98% of the time.. | PeriodicReview... |
| Attend in-house meetings and conferences deemed appropriate by P.I | Carries out 100% of the time | Carries out 98% of the time | PeriodicReview |
| Possess and maintain all necessary credentials and training required by the USAISR. | Possess and maintain 100% of the time  | Possess and maintain 100% of the time . | PeriodicReview |