

DEFENSE HEALTH AGENCY
Quality Assurance Surveillance Plan (QASP)
Version 1

For
Clinical Blood Processing
Contract Number: TBD
Contractor's Name: TBD

Contract Description: This is to establish a bridge contract between the end of FAR 52.217-8 six month extension of the previous award and the award of the follow-on contract.

1. Objective:

The contractor shall provide non-personal laboratory support services to pick up and process study participant blood samples for a variety of tests.

2. Background:

Since 1893, the WRAIR has been a leader in solving the most significant threats to soldier readiness and lethality such as disease and battle injury. WRAIR's broad research capabilities afford soldiers the best medical protection and support possible before, during, and after deployment by addressing both longstanding and emerging threats. Though the WRAIR's research is focused on soldier health, its products have important civilian applications responsible for saving countless lives around the world.

The WRAIR aims to conduct biomedical research that is responsive to Department of Defense (DoD) requirements and to deliver life-saving products including knowledge, technology, and medical material that sustain the combat effectiveness of the warfighter. The WRAIR headquarters is in Silver Spring, MD, and is the largest biomedical research facility currently serving the DoD. The WRAIR's Research and Development (R&D) activities reach around the world to include forward laboratories in locations such as the Republic of Georgia, Thailand, and Kenya.

The WRAIR's vision is to be the premier DoD biomedical research organization that executes constantly relevant, integrated basic research and advanced technology that protects, projects, and sustains the warfighter today, invents global medical solutions for the future, and keeps the warfighter on point for the Nation. The WRAIR hosts three Centers: The Center for Military Psychiatry and Neuroscience (CMPN), the Center for Infectious Disease Research (CIDR), and the Center for Enabling Capabilities (CEC) with efforts ranging from blast induced neurotrauma to infectious disease vaccine development.

Standing at the forefront of safeguarding and enhancing Soldier health, WRAIR created the Division of Neuropsychiatry and Neurophysiology in 1950. In the ensuing decades, that effort grew to become today's Center for Military Psychiatry and Neuroscience (CMPN).

CMPN is a translational and expeditionary effort to identify and eliminate brain health threats to Soldiers. CMPN investigates and manipulates the relationship between sleep and performance, performs mental health assessments to inform unit Commanders on Soldier mental health needs, and develops and implements resilience trainings. On a parallel track are efforts to identify and treat traumatic brain injury as well as understand the impact of repeated blast exposure.

With more than 3,000 publications, numerous patents, and many products, CMPN is an internationally recognized leader in brain health and mental health, developing evidence-based strategies to diagnose, prevent, and mitigate the psychological demands of war, continuous operations, and brain trauma associated with military service.

3. Purpose:

This Quality Assurance Surveillance Plan (QASP) is a Government-developed document used to determine if the contractor's performance meets the performance standards contained in the contract. The QASP establishes procedures on how this assessment/inspection process will be conducted. It provides the detailed process for a continuous oversight process:

- A. What will be monitored
- B. How monitoring will take place
- C. Who will conduct the monitoring
- D. How monitoring efforts and results will be documented

The contractor is responsible for implementing and delivering performance that meets contract standards using its Quality Control Plan (QCP). The QASP provides the structure for the government's surveillance of the contractor's performance and their Quality Assurance/Quality Control (QA/QC) actions to assure they meet contract standards. It is the Government's responsibility to be objective, fair and consistent in evaluating contractor performance.

The QASP is not part of the contract nor is it intended to duplicate the contractor's QCP. This QASP is a living document. Flexibility in the QASP is required to allow for an increase or decrease in the level of surveillance necessary based on contractor performance.

The government may provide a copy of the QASP to the contractor to facilitate open communication. In addition, the QASP should recognize that unforeseen or uncontrollable circumstances might occur that are outside the control of the contractor.

Bottom line, the QASP should ensure early identification and resolution of performance issues to minimize impact on mission performance.

4. Authority:

Authority for issuance of this QASP is provided under Part 46 of the Federal Acquisition Regulation (FAR), Inspection of Services clauses, which provides for inspection, acceptance and

documentation of the service called for in the contract or order. This acceptance is to be executed by the Contracting Officer (CO) or a duly authorized representative.

5. Roles and Responsibilities:

The following personnel shall oversee and coordinate surveillance activities.

Program/Project Manager (PM) or Functional Services Manager (FSM): The PM/FSM provides primary program oversight, nominates the Contracting Officer's Representative (COR), ensures the COR is trained before performing any COR duties and supports the COR's performance assessment activities. While the PM/FSM may serve as a direct conduit to provide Government guidance and feedback to the contractor on technical matters, they are not empowered to make any contractual commitments or any contract changes on the government's behalf.

Assigned PM/FSM: ***enter name***
 Organization or Agency: ***Branch***, WRAIR
 Telephone: ***enter number***
 Email: ***enter address***

Contracting Officer (CO): The CO 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 (U.S.) in the contractual relationship. The CO shall also ensure that the contractor receives impartial, fair, and equitable treatment under this contract. The CO shall also determine the final assessment of the contractor's performance.

Additionally, the CO shall include a requirement in the QASP to revalidate all key personnel annually to determine whether the contractors meet the labor categories specified in the contract.

The CO shall maintain documentation in the contract files that demonstrates their review and approval of initial and replacement contractor employees in key personnel positions.

The CO shall include a requirement in information technology service contracts QASPs to review a sample of non-key personnel quarterly to determine whether the contractor personnel meet the labor categories specified in the contract.

Assigned CO: <enter name>
 Organization or Agency: Defense Health Agency (DHA) Contracting Activity (DHACA)
 Telephone: <enter number>
 Email: <enter address>

Contracting Officer's Representative (COR): The COR is responsible for providing continuous technical oversight of the contractor's performance. The COR uses the QASP to conduct the oversight/surveillance process. The COR shall keep a Quality Assurance file that accurately documents the contractor's actual performance. The purpose is to ensure that the

contractor meets the performance standards contained in the contract. The COR is responsible for reporting early identification of performance problems to the CO. The COR is required to provide an annual performance assessment to the CO which will be used in documenting past performance. The QASP is the primary tool for surveillance of the contractor's quality program and help the COR to document contractor performance. The COR is not empowered to make any contractual commitments or to authorize any contractual change on the Government's behalf.

Assigned COR: Ruthie H. Ratcliffe

Organization or Agency: Center for Military Psychiatry and Neurosciences Research (CMPN), WRAIR

Telephone: (301) 319-3131

Email: ruthie.h.ratcliffe.civ@health.mil

Contractor Representatives: The following employees of the contractor serve as the contractor's Program Manager and Task Manager for this contract. **(Complete this section after the contract award)**

Contractor Program Manager - <upon award, enter name>

Telephone: <enter number>

Email: <enter address>

Contractor Task Manager - <upon award, enter name>

Telephone: <enter number>

Email: <enter address>

Other Key Contractor Personnel - <upon award, enter name or delete these lines if not applicable>

Title: <enter title>

Telephone: <enter number>

Email: <enter address>

6. Performance Requirements and Method of Surveillance:

6.1. Contract Surveillance: The goal of QASP is to ensure that contractor performance is effectively monitored and documented. The COR's contribution is their professional, non-adversarial relationships with the CO, PM and the contractor, which enables positive, open and timely communications. The foundation of this relationship is built upon objective, fair, and consistent COR evaluations of contractor performance against contract requirements. The COR uses the methods contained in this QASP to ensure the contractor is in compliance with contract requirements. The COR function is responsible for a wide range of surveillance requirements that effectively measure and evaluate the contractor's performance. Additionally, this QASP is based on the premise that the contractor, not the Government, is responsible for management and QA/QC actions to successfully meet the terms of the contract.

6.2. Surveillance Matrix: The Surveillance Matrix (see sample at Attachment 1) is the list of performance objectives and standards that must be performed by the contractor. This matrix details the method of surveillance and frequency the COR will use to validate and inspect these performance elements. Inspection of each element will be documented in the COR file.

Defense Federal Acquisition Regulation Supplement (DFARS) 222.17 mandates including surveillance for ensuring compliance with Combatting Trafficking in Persons (CTIP) in the QASP. Use the CTIP sample checklist from DFARS Procedures, Guidance and Information (PGI) 222.17. See the DoD CTIP website.

Performance objectives define the desired outcomes. Performance Standards define the level of service required under the contract to successfully meet the performance objective. The inspection methodology defines how, when, and what will be assessed in measuring performance. The Government performs surveillance, using this QASP, to determine the quality of the contractor's performance as it relates to the performance element standards. The Performance Requirement Summary (PRS) should be used to form the foundation of the COR's inspection checklist.

6.3. Performance Rating Definitions: The performance ratings below reflect definitions at FAR 42.1503 Table 42-1. The COR will use these rating to evaluate the quality of contractor's performance.

Performance Rating	Definition
Exceptional	Performance meets contractual requirements and exceeds many to the government's benefit. The contractual performance of the element or sub-element being evaluated was accomplished with few minor problems for which corrective actions taken by the contractor were highly effective.
Very Good	Performance meets contractual requirements and exceeds some to the Government's benefit. The contractual performance of the element or sub-element being evaluated was accomplished with some minor problems for which corrective actions taken by the contractor were effective.
Satisfactory	Performance meets contractual requirements. The contractual performance of the element or sub-element contains some minor problems for which corrective actions taken by the contractor appear or were satisfactory.
Marginal	Performance does not meet some contractual requirements. The contractual performance of the element or sub-element being evaluated reflects a serious problem for which the contractor has not yet identified corrective actions. The contractor's proposed actions appear only marginally effective or were not fully implemented.
Unsatisfactory	Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element or sub-element contains a serious

	problem(s) for which the contractor's corrective actions appear or were ineffective.
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Note 1: Plus or minus signs may be used to indicate an improving (+) or worsening (-) trend insufficient to change the evaluation status.

Note 2: N/A (not applicable) should be used if the ratings are not going to be applied to a particular area for evaluation.

7. Performance Reporting:

- 7.1. Corrective Action Report (CAR):** Describes how discrepancies are reported and resolved (see sample CAR below).
- 7.2. Customer Complaint Form:** (See sample customer complaint form below)
- 7.3. Performance Assessment Report (PAR):** (See sample customer PAR page 11)

Appendix 1 - Surveillance Matrix

M1: Inspection of Reports. All reports shall be reviewed upon receipt. The reviewer will report any flaws in the document and categorize the flaws (Editorial, Format, and/or Substance).

Performance Requirements Summary (PRS) Table:

Performance Objective	PWS Reference	AQL	Method of Surveillance	Incentive
PRS - 1 Responsive Customer Support (Business Acumen) The contractor shall seek to ensure customer satisfaction and professional and ethical behavior of all contractor personnel.	Paragraph 5.1	The Government will perform random sampling (reviews) to gauge the contractor's responsiveness and professionalism. The Government will receive no more than three complaints or negative reviews denoting a customer support or business acumen deficiency during the contractor's performance of the entire contract. A get-well plan shall be provided within five days of identification of deficiency.	Random sampling (reviews) and receipt of validated complaints	Past performance
PRS - 2 Pick up and processing of samples.	Paragraph 5.1.1 - 5.1.3	95 percent compliance with the following: -Samples shall be picked up the same day requested during WRAIR business hours as provided in Part 1 of this PWS. -Results shall be electronically within 72 hours from sample pick-up.	Direct COR observation	Past performance
PRS - 3 Quality Deliverables	Part 7, Attachment 2	95 percent compliance with deliverable requirements. The contractor shall submit all deliverables as instructed by the established schedule (due date). The COR will have 10 days to review draft deliverables and make comments. A revised deliverable shall be submitted within five days. of identification of deficiency.	Random sampling	Past performance

DHA QASP Template V1

CUSTOMER COMPLAINT RECORD			DATE/TIME OF COMPLAINT
SOURCE OF COMPLAINT			
ORGANIZATION	BUILDING NUMBER	INDIVIDUAL	PHONE NUMBER
NATURE OF COMPLAINT			
CONTRACT REFERENCE			
VALIDATION			
DATE/TIME CONTRACTOR INFORMED OF COMPLAINT			
ACTION TAKEN BY CONTRACTOR			
RECEIVED/VALIDATED BY			

PERFORMANCE ASSESSMENT REPORT (PAR)

(If more space is needed, use reverse and identify by number)

1. CONTRACT/TASK ORDER NUMBER	2. CONTRACTOR	3. TYPE OF SERVICES
4. QUALITY ASSURANCE PERSONNEL (COR) SIGNATURE AND DATE		5. COR PHONE
		6. SUSPENSE DATE

I. PERFORMANCE

7. ☐ DEFICIENCY (CHECK ALL BOXES THAT APPLY) ☐ NEW ☐ REPEAT ☐ NO DEFICIENCY NOTED	8. SERVICES SUMMARY or PWS PARAGRAPH ITEM REVIEWED
9. BRIEF DESCRIPTION OF DEFICIENCY (IF DEFICIENCY BOX WAS CHECKED)	10. DETAILED PERFORMANCE ASSESSMENT

II. CONTRACTOR VALIDATION

11. CONTRACTOR REPRESENTATIVE ☐ CONCUR ☐ NON-CONCUR	12. CORRECTIVE ACTION ESTIMATED COMPLETION DATE
13. CONTRACTOR REPRESENTATIVE CORRECTIVE ACTION AND PREVENTION OF RECURRENCE <u>OR</u> REASON FOR NON-CONCURRENCE OF COR CITED DEFICIENCY	

III. ACTION CORRECTED

14. ☐ CONCUR ☐ NON-CONCUR	COR SIGNATURE AND DATE
15. COR REMARKS (REQUIRED)	
16. CONTRACTOR REPRESENTATIVE REMARKS	