

Performance Work Statement
Public Health Surveillance Critical Incident Team
VA Palo Alto Health Care System (VAPAHCS)

Section 1: General Information

1.1 General:

- A. This is a non-personal services contract to provide a Public Health Surveillance Critical Incident Team for the Veterans Health Administration (VHA) in conjunction with the Public Health Surveillance and Research (PHSR) office located at VAPAHCS. The Government shall not exercise any supervision or control over the contract service providers performing the services herein. Such contract service providers shall be accountable solely to the Contractor who, in turn is responsible to the Government.

1.2 Background:

- A. The PHSR program office aligns with the Office of Quality, Safety and Value's (QSV) mission to enhance the quality, safety, reliability, and value of VHA's clinical systems in numerous ways.
- B. PHSR Core Functions:
 - 1) Conduct ongoing VHA system-wide public health surveillance, thereby serving as the early warning system to VHA of impending public health emergencies;
 - 2) Promote and support public health surveillance and reporting by VHA facilities by maintaining close ties with local, state and federal agencies, including CDC, FDA, DoD, DHS;
 - 3) Conduct epidemiological investigations and lookbacks (lookbacks are an organized process for identifying patients and/or staff with exposure to potential risk);
 - 4) Operate the Public Health Reference Laboratory (PHRL) which enables VA to rapidly conduct specialized and/or high volume lab diagnostic tests with little lead time notice in response to clinical care needs, public health investigation and/or health emergencies;
 - 5) Provide subject matter expertise and scientific research on a wide variety of public health issues, and develop products to inform and instruct VA staff on public health policies and procedures
- C. Critical Incident Teams are established to investigate emergent epidemiologic outbreaks and lookbacks. The composition of the team will depend on the circumstances of the particular case including the nature of incident involved and the number of people affected and the type of facility, but the following points are to be taken into consideration at all times:
 - 1) Must be sufficiently representative of parties involved to ensure expert advice is available or able to be sought and efficient communication is achieved.

2) Should be of a size that facilitates effective and appropriate action.

1.3 Period of Performance:

Base Year: February 1, 2017 to January 31, 2018
Option Year 1: February 1, 2018 to January 31, 2019
Option Year 2: February 1, 2019 to January 31, 2020
Option Year 3: February 1, 2020 to January 31, 2021
Option Year 4: February 1, 2021 to January 31, 2022

1.4 Place of Performance: The primary location will be the Palo Alto Medical Center but this contract will involve travel to the other locations within the VAPAHCS as follows:

Medical Centers

Palo Alto Medical Center 3801 Miranda Ave. Palo Alto, CA 94304	Livermore Medical Center 4951 Arroyo Rd. Livermore, CA 94550	Menlo Park Medical Center 795 Willow Rd. Menlo Park, CA 94025
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Community Based Outpatient Clinic

Capitola CBOC 1350 41 st Ave., Ste 102 Capitola, CA 95010	Fremont CBOC 39199 Liberty Street Fremont, CA 94538	Monterey CBOC 3401 Engineer Lane Seaside, CA 93955
San Jose CBOC 80 Great Oaks Blvd. San Jose CA 95119	Sonora CBOC 13663 Mono Way Sonora, CA 95370	Stockton CBOC 7777 South Freedom Rd. French Camp, CA 95231
Modesto CBOC 1225 Oakdale Rd. Modesto CA 95355		

1.5 Hours of Operation: Work will be performed during regular administrative working hours from 8:00 a.m. to 6:00 pm, Monday through Friday, excluding federal holidays.

1.6 Type of Contract: The government will award a Firm Fixed Price contract.

1.7 Invoicing: All invoices from the contractor shall be submitted electronically in accordance with VAAR Clause 852.232-72 Electronic Submission of Payment Requests.

VA's Electronic Invoice Presentment and Payment System – The FSC uses a third-party contractor, Tungsten, to transition vendors from paper to electronic invoice submission. Please go to this website: <http://www.tungsten-network.com/US/en/veterans-affairs/> to begin submitting electronic invoices, free of charge.

More information on the VA Financial Services Center is available at <http://www.fsc.va.gov/einvoice.asp>.

Vendor e-Invoice Set-Up Information:

Please contact Tungsten at the phone number or email address listed below to begin submitting your electronic invoices to the VA Financial Services Center for payment processing, free of charge. If you have question about the e-invoicing program or Tungsten, please contact the FSC at the phone number or email address listed below:

- Tungsten e-Invoice Setup Information: 1-877-489-6135
- Tungsten e-Invoice email: VA.Registration@Tungsten-Network.com
- FSC e-Invoice Contact Information: 1-877-353-9791
- FSC e-invoice email: vafscshd@va.gov

Section 2: Definitions & Acronyms

2.1 Definitions:

Contractor. A supplier or vendor awarded a contract to provide specific supplies or service to the government. The term used in this contract refers to the prime.

Subcontractor. One that enters into a contract with a prime contractor. The Government does not have privity of contract with the subcontractor.

Work Day. The number of hours per day the Contractor provides services in accordance with the contract.

Work Week. Monday through Friday, unless specified otherwise.

2.2 Acronyms:

CDC	Centers for Disease Control and Prevention
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments
CSCA	Contractor Security Control Assessment
DoD	Department of Defense
DHS	Department of Homeland Security
HIPAA	Healthcare Insurance Portability and Accountability Act
FDA	Food and Drug Administration
FISMA	Federal Information Security Management Act
NIST	National Institute of Standards and Technology
OMB	Office of Management and Budget
PHRL	Public Health Reference Laboratory

PHSR	Public Health Surveillance and Research
QSV	Quality, Safety and Value
VA	Veterans Affairs
VAPAHCS	Veterans Affairs Palo Alto Health Care System
VAAR	Veterans Affairs Acquisition Regulation

Section 3: Government Furnished Property, Equipment, and Services

3.1 The contractor will be working with VA staff in the performance of the Public Health surveillance activities. The VA staff working on this project includes:

- A. Infection Control/Infectious Diseases/Microbiology staff
- B. Clinicians from relevant specialties/departments
- C. Executive representative from VAPAHCS (particularly important where members of the public will be contacted and/or asked to present to the facility as part of a look back exercise)
- D. Independent Public Health Physician
- E. Four Independent Infectious Disease Epidemiologists

3.2 GFE – Contract Staff Computers

VA will provide Dell Optiplex 9010 series desktop (with 8GB of RAM and 3.6GHz cpu, and 500GB drives) for each contract staff member participating in this project.

Section 4: Contractor Furnished Items and Services

4.1 PHSR conducts disease surveillance and public health response activities within VHA focusing on public health surveillance. Public health surveillance includes activities such as detection and tracking progression of disease outbreaks, monitoring disease trends across VA and early warning of bioterrorist and other health-related events. Upon request from the VA Undersecretary for Health, a Critical Incident Team should be established. Composition will depend on the circumstances of the particular case including the nature of incident involved, the number of people affected and the type of facility, but the following points are to be taken into consideration:

- Must be sufficiently representative of parties involved to ensure expert advice is available or able to be sought and efficient communication is achieved.
- Should be of a size that facilitates effective and appropriate action.

4.2 Despite ongoing efforts to make health care as safe as possible, the process of delivering care carries an inherent risk that patients may be exposed to potentially harmful situations. Any health care system that aspires to transparency must acknowledge this fact, and it is in the best interest of patients and the health care systems to proactively establish a system to respond when such situations are identified. Response must be in a manner that is effective, efficient, timely and sensitive to the needs of affected patients and caregivers.

4.3 Situations in which a potential exposure to risk occurs during care delivery may be identified through a number of sources, from routine patient safety rounds to standard reporting systems to ad hoc reports from individual staff members. These investigations have as their starting point the time immediately

following an organizational decision that patient notification is warranted, and does not replace or amend directives, policies or procedures related to determining the need for such a program. A look-back program is an organized effort whose objective is to identify patients with evidence of exposure to potential risk during past clinical procedures in order to notify affected patients, offer them appropriate care and document what has been done. One aspect of this project focuses on operational aspects of implementing a look-back program.

4.4 The second aspect of this project focuses on what is needed at the facility and within VHA in order for an epidemiological investigation to occur. A team of epidemiologists from the Office of Public Health and Environmental Hazards will conduct an epidemiologic investigation into the likelihood that the adverse event was related to any new diagnosis that was identified during the look-back.

4.5 The scope of patient notification may vary from a single patient or site to the entire system, but essential components will remain the same regardless of the scope.

Section 5: Tasks to be performed

PHSR surveillance activities are continuous and ongoing. In accordance with VHA Look-Back Program Operations Manual, the Critical Incident Team shall provide support for PHSR epidemiologic investigations and lookback activities by providing the following tasks:

5.1 Task 1

5.1.1 Develop and maintains legal strategy to analyze complex and highly visible actions such as public health legislation, executive directives, departmental policy issuances, as well as other influential statements of policy with the potential to impact the activities of the division, center, and/or coordinating center.

5.1.2 Develop reports that reflect in-depth analysis and interpretation of policy matters involving relevant public health issues. Presents expert analysis on such factors as well as advice to senior leadership on the impact of these highly visible policy actions.

5.1.3 Write new internal and external policies or recommendations based on changes in legislation, executive directives, departmental issuances, or other key changes in voluntary practices.

5.1.4. Deliverables:

5.1.4.1 Monthly Progress Report

5.1.4.2 Policy and Guidance Reports

5.2 Task 2

5.2.1 Manage and evaluate procedures, and provide technical assistance to public health epidemiologist and attorneys. Areas of investigation include chronic diseases, environmental health, infectious diseases,

injury prevention and control. Particular attention will be required to both electronic and paper chart review and conducting staff interviews.

5.2.2. Deliverables:

5.2.2.1 Monthly Progress Reports

5.2.2.2 Interim Project Progress Reports

5.2.2.3 Final Project Progress Report

5.3 Task 3

5.3.1 Direct and manage multi-disciplinary teams in the development of plans, goals, objectives, policies, and procedures for completion of an investigation

5.3.2 Review project proposals and plans to determine time requirements and allotment of available resources to various phases of the project;

5.3.3. Establish work plan and staffing for each phase of the project, confer with project staff to outline work plan and to assign duties, responsibilities, and scope of authority

5.3.4. Deliverables:

5.3.4.1 Monthly Progress Reports

5.3.4.2 Staffing Plan

5.3.4.3 Project Plan

5.4 Task 4

5.4.1 Develop communication plan, including writing and editing planning documents, correspondence, briefing materials, speeches, talking points, introductory remarks, and other communications on behalf of PHSR

5.4.2 Drafts, as requested, messages from the PHSR to members of the community, congress, VHA leadership. Coordinate with central office communication directorate staff to ensure wide-spread recognition of important events, press releases

5.4.3. Prepare, compile, and design comprehensive reports and presentations to professionally communicate outcomes and recommendations resulting from analytical studies, impact analysis.

5.4.4. Deliverables

5.4.4.1 Weekly status reports on assigned communications

5.4.4.2 Drafts of required communications materials

5.4.4.3 Comprehensive outcome reports and presentations.

5.5 Task 5

5.5.1 Provide authoritative advice and consultation for difficult, complex, or unique tests utilizing special knowledge (e.g. PCR, Specialized tests or microbiology automation). Utilize specialized Clinical Microbiology laboratory knowledge (hospital, clinic or reference lab) to process patient specimens.

5.5.2 Provide authoritative advice to staff microbiologists and troubleshooting ability for more markedly difficult, unique, and/or emerging tests utilizing specialized knowledge. Examples are, but not limited to, molecular testing using the Cepheid Infinity; bacterial identification, and susceptibility testing using Biomerieux Vitek and blood culture detection using BacTAlert.

5.5.3 Perform validations of new methods to determine accuracy, precision, sensitivity, specificity, normal ranges and interfering substances in area of responsibility.

5.5.4 Conduct studies and recommends changes to correct deficiencies and improve the specialty area. Recommends new/replacement instrumentation.

5.5.5 Designs work flow to accomplish objectives in the clinical specialty area.

5.5.6 Advise director and providers on various aspects of the specialized testing, including the appropriateness of specific tests and takes into consideration the clinical context and usefulness of the test information. Recommend alternate testing to overcome ambiguity in the clinical diagnoses.

5.5.7 Identifies training needs appropriate for the type and complexity of the laboratory services performed.

5.5.8 Identifies, defines, and resolves laboratory issues associated with complex aspects of data or unique or controversial aspects of the testing where no direct precedent exists.

5.5.9 Improve and maintains laboratory process control in a specialty area using quality improvement monitors.

5.5.10 Analyze emerging laboratory trends and technology and adopt appropriate methods and testing.

5.5. 11 Apply laws, policies, and clinical laboratory accrediting requirements to establish, monitor, and maintain the specialized testing.

5.5.12 Deliverables

5.5.12.1 Monthly testing reports

5.5.12.2 Monthly laboratory certification reports

5.5.12.3 Standard Operating Procedure Guides for all laboratory activities

5.6 Task 6

5.6.1 Develop and implement comprehensive data analysis strategy

5.6.2 Develop and maintain automated data processing systems

5.6.3 Develop specifications for database, communication systems, security, and data storage

5.6.4 Serve as data analysis liaison with users concerning requests, usage, standards, security, and other developmental and production matters.

5.6.5 Develops guidelines and upgrade techniques of new operational procedures for the support of databases

5.6.6 Evaluates, implement, and provides data analysis customer support for epidemiologists

5.6.7 Deliverables

5.6.7.1 Report detailing the maintenance of records.

5.6.7.2 Prepare reports and correspondence related to the project data analysis.

5.6.7.3 Develop, compile, maintain documents for databases, statistical packages and communication systems.

Section 6: Security Requirements

6.1 The Contractor and their personnel shall be subject to the same Federal laws, regulations, standards and VA policies as VA personnel, regarding information and information system security. These include, but are not limited to Federal Information Security Management Act (FISMA), Appendix III of OMB Circular A-130 and guidance and standards, available from the Department of Commerce's National Institute of Standards and Technology (NIST). This also includes the use of common security configurations available from NIST's Web site at: <http://checklists.nist.gov>.

6.2 The Contractor shall comply with all applicable requirements as outlined in VA Handbook 6500.6 "Contract Security." The Contractor and their personnel shall be subject to the Federal laws, regulations, standards, and VA Directives and Handbooks regarding information and information system security as delineated in this contract.

6.3 The Contractor is required to complete and submit the Contractor Security Control Assessment (CSCA), version 1.2, dated 05/15/2009, or the latest version available.

6.4 Privacy Act: The Contractor shall be responsible for safeguarding all confidential information. The Contractor shall keep all information confidential pursuant to, and comply with all provisions of, the Privacy Act of 1974, HIPAA, the Freedom of Information Act, M-1, Part 1, Chapter 9 and other VA regulations.

6.5 Violation of the Privacy Act of 1974 may involve the imposition of criminal penalties. The Contractor shall protect against loss or misuse of all dictated and transcribed documents. The documents described in this solicitation are irreplaceable medication information. The Contractor shall insure the confidentiality of all patient information, and shall be held liable in the event of breach of confidentiality.

6.6 The Contractor shall ensure the confidentiality of all patient and provider information. The Contractor shall not retain information longer than herein required for sensitive or patient identifying data and shall comply with all directives and regulations pertaining to the Privacy Act of 1974, Freedom of Information Act, and VHA Lookback Manual Program Operations Manual. Contractor and all contract employees shall be required to sign confidentiality statements.

6.7 The Contractor shall adhere to the following policies and laws applicable to all services to be provided under this contract. These policies and laws are retrievable via the worldwide web.

- A. Healthcare Insurance Portability and Accountability Act of 1996 (HIPPA)
- B. Fraud and Related Activity in Connection with Access Devices and Computers, 18 U.S.C. 1029-1030
- C. Electronic Communications Privacy Act of 1986, PL 99-508
- D. Title 38, U.S.C. 5701, VA Claims Confidentiality Statute
- E. Title 38, U.S.C. 5705, Confidentiality of Healthcare Quality Assurance Records
- F. Title 38, U.S.C. 7332, Confidentiality of Certain Medical Records

6.8 VHA Business Associate Agreement (BAA): The Contractor shall execute a BAA upon award of the contract.

6.9 The Contractor shall have and maintain a VA-approved site-to-site virtual private network (VPN) connection for remote service.

Section 7: Attachments

Attachment #1: Sample Business Associate Agreement

Attachment #2: Security Requirements

Attachment #3: VHA Look-Back Program Operations Manual