REQUEST FOR QUOTATIONS
(THIS IS NOT AN ORDER)

THIS RFQ ☐ IS ☒ IS NOT A SMALL BUSINESS SET-ASIDE.

PAGE 1 OF PAGES 50

1. REQUEST NO.	2. DATE ISSUED	3. REQUISITION/PURCHASE REQUEST NO.	4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1	RATING
75D301-20-Q-71199	11/14/2019	000HCPN1-2020-40063	▶	

5a. ISSUED BY
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta GA 303414004

6. DELIVERY BY *(Date)*
See Delivery Schedule

7. DELIVERY
☐ FOB DESTINATION ☒ OTHER *(See Schedule)*

5b. FOR INFORMATION CALL *(No collect calls)*

NAME	TELEPHONE NUMBER	
	AREA CODE	NUMBER
Berta Alldredge	EM: boh9@cdcv.gov	

8. TO:			9. DESTINATION	
a. NAME	b. COMPANY		a. NAME OF CONSIGNEE	
c. STREET ADDRESS			b. STREET ADDRESS	
			c. CITY	
d. CITY	e. STATE	f. ZIP CODE	d. STATE	e. ZIP CODE

10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS *(Date)*
12/2/2019

IMPORTANT: This is a request for information, and quotations furnished are not offers. If you are unable to quote, please so indicate on this form and return it. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or services. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotations must be completed by the quoter.

11. SCHEDULE *(Include applicable Federal, State and local taxes)*

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)
	"See Continuation Page"				

12. DISCOUNT FOR PROMPT PAYMENT ▶	a. 10 CALENDAR DAYS %	b. 20 CALENDAR DAYS %	c. 30 CALENDAR DAYS %	d. CALENDAR DAYS NUMBER	PERCENTAGE

NOTE: Additional provisions and representations ☒ are ☐ are not attached.

13. NAME AND ADDRESS OF QUOTER			14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION	15. DATE OF QUOTATION
a. NAME OF QUOTER				
b. STREET ADDRESS			16. SIGNER	
			a. NAME *(Type or print)*	b. TELEPHONE AREA CODE
c. COUNTY				
d. CITY	e. STATE	f. ZIP CODE	c. TITLE *(Type or print)*	NUMBER

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Prescribed by GSA
FAR (48 CFR) 53.215-1(a)

SECTION B - Line Items

Base Period – Yr 1 Items

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
1000 01	MedMorph Integrated Project Team Support (T&M) Vendor shall assist CDC in developing reference architecture and reference implementations of components of the architecture using exchange standards and technology to improve the availability of clinical EHR data. The work shall be performed as specified in the Statement of Work (SOW), Section C.4, Tasks 1-5. Period of Performance (PoP): 6 months from effective date of award.	1 Job		
1000 02	Other Direct Cost (ODCs) (T&M) Vendor's proposed supplies, equipment, including any software and travel that is required and approved by the COR for the performance of the work. PoP: 6 months from the effective date of award.	1 Job		

Option 1 Yr 1 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
1000 03	Develop Roadmap for Reference Architecture Adoption and Sustainability (T&M) Vendor shall assist CDC in developing reference architecture and reference implementations of components of the architecture using exchange standards and technology to improve the availability of clinical EHR data. The work shall be performed as specified in the Statement of Work (SOW), Section C.4, Task 6. PoP: Within 6 months from the effective date option is exercised	1 Job		

Option 2 Yr 2 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
2000 01	MedMorph Integrated Project Team Support (T&M) Vendor shall assist CDC in developing reference architecture and reference implementations of components of the architecture using exchange standards and technology to improve the availability of clinical EHR data. The work shall be performed as specified in the Statement of	1 Job		

	Work (SOW), Section C.4, Tasks 1-5. PoP: Within 12 months from date option is established to be exercised.			
2000 02	Other Direct Cost (ODCs) (T&M) Vendor's proposed supplies, equipment, including any software and travel that is required and approved by the COR for the performance of the work. POP: Within 12 months from date option is established to be exercised.	1 Job		
2000 03	Develop Roadmap for Reference Architecture Adoption and Sustainability (T&M) Vendor shall assist CDC in developing reference architecture and reference implementations of components of the architecture using exchange standards and technology to improve the availability of clinical EHR data. The work shall be performed as specified in the Statement of Work (SOW), Section C.4, Task 6. PoP: within 12 months from the effective date of award.	1 Job		

Option 3 Yr 3 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
3000 01	MedMorph Integrated Project Team Support (T&M) Vendor shall assist CDC in developing reference architecture and reference implementations of components of the architecture using exchange standards and technology to improve the availability of clinical EHR data. The work shall be performed as specified in the Statement of Work (SOW), Section C.4, Tasks 1-5. PoP: Within 12 months from date option is established to be exercised.	1 Job		
3000 02	Other Direct Cost (ODCs) Vendor's proposed supplies, equipment, including any software and travel that is required and approved by the COR for the performance of the work. PoP: Within 12 months from date option is established to be exercised.	1 Job		
3000 03	Develop Roadmap for Reference Architecture Adoption and Sustainability (T&M)	1 Job		

	Vendor shall assist CDC in developing reference architecture and reference implementations of components of the architecture using exchange standards and technology to improve the availability of clinical EHR data. The work shall be performed as specified in the Statement of Work (SOW), Section C.4, Task 6. PoP: within 12 months from the effective date of award.			

Notes:

1. This task order will be placed against GSA Schedule 70, GENERAL PURPOSE COMMERCIAL INFORMATION TECHNOLOGY EQUIPMENT, SOFTWARE, AND SERVICES.

2. The total anticipated period of performance, inclusive of options, is 2.5 years as follows:

   Year 1 – Base Period: 6 months from date of award
   Year 2 – Option Period 2: 12 months from date option is established to be exercised.
   Year 3 – Option Period 3: 12 months from date option is established to be exercised.

3. Award will be made on the basis of Time and Materials (T&M) IAW/FAR 52.216-31 Time-and-Materials/Labor-Hour Proposal Requirements—Commercial Item Acquisition.

4. Prices will be established at a ceiling, which, if the vendor exceeds, it would be at its own risk. Payment will be made on a monthly basis of in accordance with FAR Clause 52.212-4 Alternate I (JAN 2017), (i) Payments (1) i, Hourly rate, which requires the vendor to show clearly the level of effort provided per month, i.e., number of labor hours, number of days and labor categories employee.

5. ODC's are anticipated for the performance of this contract. The cost of travel ODCs including travel is considered "Materials" (see FAR Clause 52.212-4 Alternate I (JAN 2017), (i) Payments, (1) ii, Materials. All travel is to be performed in accordance with Federal Travel Regulations and/or the Joint Travel Regulation. The vendor may be required to submit evidence supporting any claim for travel related expenses. All requests for federally reimbursable travel shall be pre-approved by the Contracting Officer Representative and reimbursed to the extent that it is reasonable and supported. The FTR can be located at: http://www.gsa.gov/portal/content/104790?utm_source=OGP&utm_medium=print-radio&utm_term=ftr&utm_campaign=shortcuts

6. Notwithstanding Clause *352.227-70 Publications and Publicity*, located in Section D, page 26 below, the vendor shall not publish any article resulting from this work prior to CDC review and approval of the article. The vendor shall obtain approval by the CDC Contracting Officer Representative prior to publication.

7. To ensure payment, invoice must reference the PO# _____, DUNS, and Tax ID Number.

8. Invoice/Payment information: for inquiring about payment status contact ocfoservicedesk@cdc.gov or call 678-475-4510.

9. Send Invoices to FAX: 404-638-5324 or Email at fmoapinv@cdc.gov

10. The Government has identified several contract line item numbers (CLINs) above as options. Exercise of optional CLINs will be made by written unilateral modification to the contract IAW/Option Clauses in Section 10 below.

11. Vendor Point of Contact (POC): To be determined (TBD)

12. Government (POC): The government point of contact or Contracting Officer Representative (COR) will provide general instructions on limitations and deadlines and is responsible for administration of the contract to include inspection and acceptance of deliverables.

    CDC COR: (TBD)

SECTION C – STATEMENT OF WORK

Title of Project: Making Electronic Health Record (EHR) Data Available for Public Health and Research (MedMorph)

C.1 Background

This Statement of Work (SOW) describes the terms of the agreement between the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) at the U.S. Centers for Disease Control and Prevention (CDC) and a pre-vetted General Services Administration (GSA) Information Technology vendor (later referred as Contractor) for the work required to complete the project Making Electronic Health Record (EHR) Data Available for Public Health and Research (MedMorph).

Within the U.S. Department of Health and Human Services (HHS), the CDC is the primary federal agency responsible for safeguarding national public health through the control and prevention of disease, injury, and disability. To accomplish its mission, CDC conducts critical surveillance, performs analysis, provides health information that protects the nation against dangerous health threats, and responds when threats arise. CDC depends heavily on sound data to perform its public health and scientific duties, as one of its pledges to the American people is to base all public health decisions on the highest quality scientific data that is derived openly and objectively.

The CSELS [1] leads the agency efforts at the intersection of public health, healthcare, and health IT to advance agency-wide science, surveillance, and data priorities and strategies in order to help CDC unlock the full potential of data for disease detection, prevention, and elimination [2].

The MedMorph project fits within the CDC strategic imperative of transforming how data are collected, used and shared through modern IT capabilities to save lives and improve health. It is an initiative funded by the HHS Assistant Secretary for Planning and Evaluation (ASPE) Patient-Centered Outcomes Research Trust Fund [3] and executed by CSELS to advance research and public health goals. The background, project objective, and project overview sections of this SOW provide information on the entire project to help establish context, but the Contractor is expected to complete the portions of the project outlined in the Scope of Work (section C.3) and described in each of the tasks (section C.4 and its subsections).

Patient-centered outcomes research (PCOR) is a field of investigation that studies the safety and effectiveness of preventive and curative healthcare services by integrating clinical and biological data with patient's perspectives, experiences, preferences and values [4].

For researchers and public health, the wide spread adoption of electronic health records (EHRs) across the U.S. health care system provides a promising opportunity to access both patient level and aggregate data needed to perform their duties. Many initiatives are currently underway to capture or integrate patient-reported outcomes within EHRs [5, 6], or to improve the usefulness of EHRs for public health reporting and programmatic needs. However, these efforts are not uniform across the variety of EHRs systems currently available and interoperability challenges [7-11] preclude a consistent and reliable standard method of moving relevant patient data, when they are available, from EHRs to the various receiving systems where they are needed for research and public health purposes. Those receiving systems include public health surveillance and information systems, specialized registries, national health care surveys, and research information systems. They exist at the local, regional, state, and federal levels. In addition, fulfilling the diversity of patient data requests from research and public health and sending data from clinical settings to research and public health settings is often a labor-intensive, manual process. As a consequence, researchers and

public health experience difficulties in obtaining quality patient data from EHRs in a timely and efficient fashion and need better ways to receive data from different EHRs systems without posing additional burden on health care providers and patients.

In recent years, the emergence of new health data exchange methods, based on application programming interfaces (APIs), web services, and internet communication protocols – supporting frequent, real-time or bidirectional communications between applications – have created new possibilities to overcome

interoperability challenges and break down closed health information exchange systems and siloed data stores. In 2014, Health Level Seven International (HL7), one of the leading health information technology (IT) standards development organizations, launched Fast Healthcare Interoperability Resources (FHIR), its next generation standards framework for electronic exchange of health information. FHIR is both a data model and a messaging specification for the design of applications and other technical solutions. FHIR leverages web standards and is intended to reduce the need to solve EHRs' interoperability challenges with complex and expensive custom extensions [12].

The adoption of FHIR by EHR vendors is strongly supported by the Office of the National Coordinator for Health IT (ONC) as part of its Health IT certification program. In addition, in order to facilitate greater interoperability, ONC is working towards extending the core data that EHRs will be required to make exchangeable. In its 2015 Edition Health IT Certification Criteria, ONC stipulated the 2015 Edition Common Clinical Data Set (CCDS) [13], an evolution from the initial "Meaningful Use Common Dataset" that ONC adopted in 2012. As part of the 21st Century Cures Act's (Cures Act) implementation, the ONC draft US Core Data for Interoperability (USCDI), released in 2018, and its proposed expansion process is another step forward towards the ability to exchange all patient information that is stored electronically. The USCDI builds on the CCDS definition by gradually including new data classes that will be required for nationwide exchange.

The maturation of standards such as FHIR and the Health IT industry adoption of the latest ONC requirements for certification such as CCDS, USCDI, and open APIs, are creating a health IT environment that is ripe for developing scalable and extensible solutions to overcome interoperability challenges and for enabling researchers and public health to answer critical questions that could lead to better, more patient-centered care and leverage patient-level data for public health action. Indeed, in 2018, 32% of the health IT developers certified published that they are using FHIR, specifically FHIR Release 2; nearly 51% of health IT developers appear to be using a version of FHIR combined with OAuth 2.0; and about 82% of hospitals and 64% of clinicians use these FIHR certified products [14].

C.2 **Project Objective**: The goal of this project is to leverage the FHIR, CCDS, USCDI, and other relevant existing health data and exchange standards to improve patient data exchange from different EHR platforms to various receiving systems in order to improve the timeliness and completeness of data received by public health and research and reduce the burden on health care providers and patients.

Standards like FHIR contain extensive optionality (i.e., some data elements within the standard could be "optional", which means that may either be populated with information or left NULL in a conformant message) to accommodate the development of a variety of health IT solutions across the health care industry. This inherent optionality could become an important barrier to effective implementation and to the design of interoperability architectures or of APIs that will fulfill the information needs of a specific community. Therefore, interested parties can develop an implementation guide (IG) to clearly define the rules dictating how FHIR resources are used in a particular context. These IGs can be presented to the HL7 community for informative purposes, to receive feedback and comments, or to become normative through a voting process. IGs that are HL7 normative standards can later be submitted for consideration as an American National Standards institute (ANSI) standard, which greatly improves their usefulness and likelihood of implementation. The process of having an IG approved by the HL7 community is called "balloting," and balloted IGs are often published for use after ballot comments are reconciled.

Similarly, the CCDS and USCDI standards have been developed to accommodate a variety of health data needs across the health care industry. Further specifying the core data can reduce the time and effort needed to develop FHIR-based solutions for a specific community while lessening the data collection burden on health care providers and patients.

Reference architectures are an additional step towards the design of a FHIR-based solution aiming at sharing data from EHRs to receiving systems. They are extremely useful, especially for organizations that lack the appropriate in-house IT skills. They capture the subsystems and components, the relationships between these subsystems and components, the information workflows, and the technologies of the

solution. Subsequent guidance on how to implement these components might be needed to fully enable implementation.

Many HL7 supported initiatives are currently underway to leverage the FHIR standards and improve health information exchange. For example, the Argonaut Project, is a private sector initiative to advance industry adoption of modern, open interoperability standards. The purpose of the Argonaut Project is to rapidly develop a first-generation FHIR-based API and core data services specification to enable expanded information sharing for EHRs and other health IT based on internet standards and architectural patterns and styles [15]. The Da Vinci project focuses on meeting the needs of the value-based care community including health plans, care providers, and vendor organizations. The project aims to minimize the development and deployment of one-off solutions between partners with a goal to the value-based community better deliver on clinical quality, cost, and care management outcomes [16, 17]. SMART on FHIR provides a platform for the development of FHIR-based third party applications that can run unmodified on different EHR platforms [18].

While FHIR IGs have been developed for some research and public health use cases, they have typically been developed for a specific use case without regard for a common architecture that can help minimize efforts for both the senders and receivers of data. As such, the standards specified in the IGs have limited ability to reduce burden because each one has a siloed approach to its architecture. The combination of industry-accepted standards such as FHIR and a common architecture can bring together disparate approaches to meet the needs for specific use cases while minimizing burden on senders and receivers of data. MedMorph seeks to develop a reference architecture that will provide a common reporting framework for public health and research use cases and will complement initiatives such as Digital Bridge.

Therefore, the specific objectives of this project are to:

1. Identify common data from the current standards (CCDS, USCDI) that will fulfill the needs of Research and Public Health;
2. Develop FHIR IG(s) based on the defined common data and submit the IG(s) to the HL7 ballot process;
3. Design and develop a reference architecture for the exchange of EHR data for both public health and research use;
4. Create reference implementations for components of the reference architecture that fall outside the common FHIR capabilities of EHR commercial solutions;
5. Pilot the designed reference architecture in both research and public health uses of the Hepatitis C use case (as described in the sections below);
6. Evaluate the reference architecture and provide recommendations for scalability of the solution,
7. Make the IGs, reference architecture, and reference implementations freely available.

The ultimate goal is to improve the availability of EHR data for research and public health.

Project Overview: Figure 1 below illustrates the full scope of the overall initiative. The subsequent sections elaborate on the use cases, the technical expert panel (TEP), the National Test Collaborative, and the principles guiding the project.

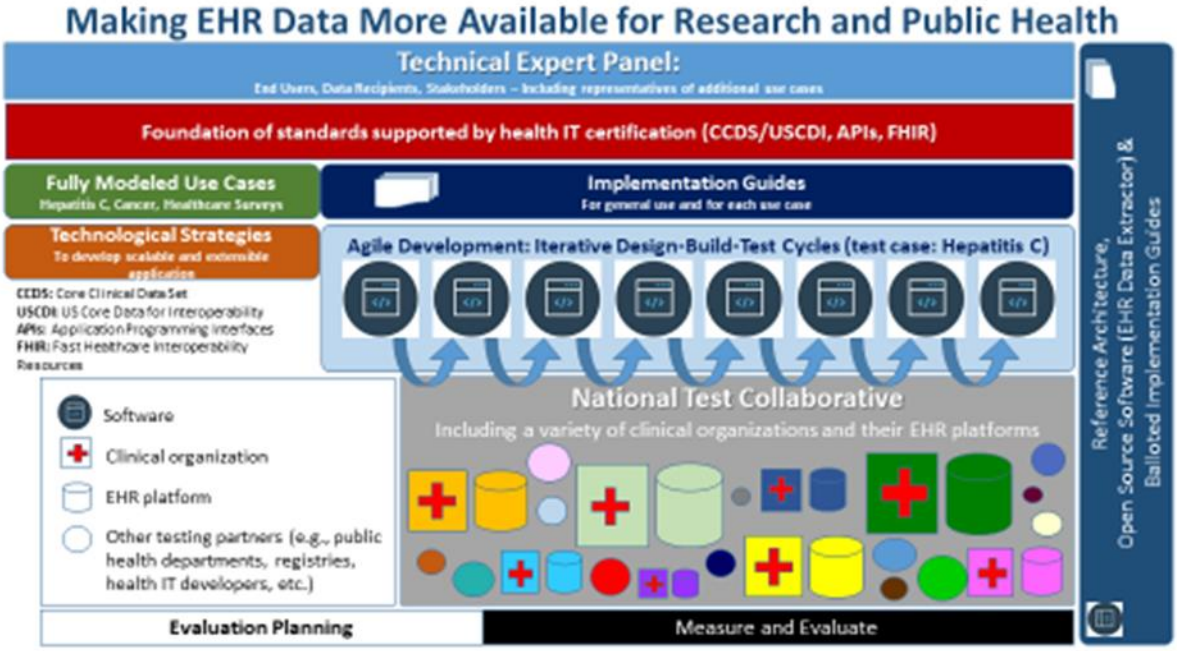

Figure 1: Project Overview

Use Cases: In order to achieve the specific objectives, the project has selected three use cases that are representative of data needs and receiving systems within the Research and Public Health communities, while being different enough to address generalizability for broader use:

- **Hepatitis C**

Patient data from EHRs about Hepatitis C are needed for research and to improve the monitoring of diagnosis, linkage to care and treatment using registries for persons with hepatitis C infection. A registry is a database of identifiable persons containing a clearly defined set of health and demographic data collected for a specific public health purpose. In the context of the current project, the solution should consider the ability for these registries to be used across different organizations to help track patients who may receive care at multiple organizations, may relocate, or otherwise may require the need for multiple organizations to track the same patient's data. The published IGs, reference architecture, and reference implementations could then be used to scale.

- **Cancer**

This use case will focus on the transmission of cancer case information from EHRs to Central Cancer Registries (CCRs). CCRs are established at the state level in public health departments (or bona fide agents of public health departments. They collect detailed information about cancer patients and the treatments they receive [19, 20]. The CDC National Program of Registries, in collaboration with the cancer registry community, has developed and published an HL7 Clinical Document Architecture (CDA) IG. This IG identifies the content and structure for reporting from physician EHRs to CCRs, but it does not use FHIR [21]. HL7 International has also published two FHIR IGs for Cancer, the Breast Cancer FHIR IG [22] and the minimal Common Oncology Data Elements (mCODE) FHIR IG [23]. These IGs aim to capture data elements used for breast cancer staging and research-quality data from the treatment of all cancer patients respectively. They do not specifically address public health information needs. This use case will help assess whether the data and workflow needs of Public Health and Research are adequately covered by the existing IGs and propose relevant additions.

- **National Healthcare Surveys**

This use case will focus on sending EHR data to a system hosted at the federal level. National Health Care Surveys are nationally-representative surveys of healthcare utilization across hospitals, provider/clinician

practices, and long-term care settings. The National Health Care Surveys Registry is a public health reporting registry that facilitates U.S. healthcare providers' participation in the National Health Care Surveys [24]. This use case will help define how EHR data can be used in more automated data collection for healthcare surveys, thus helping reduce reporting burden on healthcare organizations.

Together, the selected use cases will assist in defining data needs and information workflows related to acute and chronic diseases, healthcare services utilization, and to a variety of receiving systems at the local, regional, state, and federal levels. The use cases will inform the development of FHIR IGs and a reference architecture for the exchange of EHR data for both public health and research use.

Technical Expert Panel: The project will also set up a technical expert panel (TEP) composed of research, public health and clinical experts, and other relevant stakeholders. The TEP will include both technical and subject matter experts to ensure that the use cases, used to inform the IGs as well as the design and development of the reference architecture, are modeled with scientific rigor, accuracy, and precision. The TEP will also include representatives of other possible use cases to ensure generalizability of the final products.

The TEP will be instrumental in delineating the core data needed by Research and Public Health by:

- Developing and modeling the three selected use cases (i.e., Hepatitis C, Cancer, and National Healthcare Surveys) with scientific rigor, accuracy, and precision;
- Identifying the research questions relevant to the Hepatitis C use case;
- Identifying and integrating additional use cases that could help comprehensively model the needs of research and public health;
- Evaluating the completed modeled use cases for broad usefulness, applicability, and implementation;
- Determining the type of data (e.g., longitudinal) needed for the research and public health communities.

The TEP will contribute to the creation of the FHIR IGs as well as to the design and development of the reference architecture by:

- Assessing the relevance of existing FHIR IGs;
- Helping to identify the appropriate standards required to support data exchange for the modeled use cases;
- Providing requirements and feedback based on data needs across use cases and sending and receiving systems' characteristics;
- Identifying roles privacy and security requirements needed for handling patient data;
- Participating in the testing and the piloting of the reference architecture and developed components;
- Participating in the final evaluation of the reference architecture and the IGs.

The TEP will participate in the creation of the project artifacts and in the development of a plan for broad use and long-term sustainability of the project's solutions.

National Test Collaborative: The development of the reference architecture will take place in a sandbox environment. However, to fully test at least one use case (i.e., Hepatitis C) for both research

and public health uses, the project will leverage the notionally named National Test Collaborative (NTC). The concept of an NTC was included in a Request for Information (RFI) [25] to external stakeholders and followed up with a multi-agency federal discussion on what such an NTC, designed to most effectively provide a real-world national testbed infrastructure, should consist of. The idea of the NTC is that a representative sample of different kinds of testing partners, including but not limited to clinical organizations, EHR and other health IT vendors, public health agencies, and research networks, would be available to accomplish real-world testing needs for a variety of use cases as the need arises without the

need to find such testing partners each and every time the testing needs arise. For this project, existing mechanisms to find appropriate testing partners for both the research and public health uses for the Hepatitis C use case will be identified by CDC and supported by the Contractor (details provided in Task 4). The purpose of the real-world testing is to help ensure that the developed reference architecture and component solutions work when applied in actual systems. The types of testing partners could include:

- Clinical providers
- Clinical and public health informaticists
- EHR and other health IT developers
- Health information exchanges (HIEs)
- Federal, state, local, tribal, and territorial agencies (including public health departments)
- Research sites or networks
- Patients and patient advocacy groups
- Payors
- Professional associations (e.g., American Medical Association, American Hospital Association, Federation of American Hospitals)
- Standards developers

The composition of the testing partners for this project will be determined based on the needs to execute and test the Hepatitis C use case for research and public health purposes.

Guiding principles: The project will comply with the following guiding principles:

- Harmonize with national health IT policies
    - Align with data content standards (i.e., CCDS, USCDI)
    - Align with interoperability standards (e.g., FHIR, APIs)
- Build on a policy and data authorities architecture
- Reuse instead of de novo development, wherever possible
    - Align with existing initiatives as much as possible
- Build capacity in public health and research
- Work towards flexibility or “as needed” workflows

MedMorph Solution Initial Concept of Operations: The architecture developed throughout this project will describe the structure, components, and information workflows of a cutting-edge FHIR-based technical solution designed to move patient data from EHRs systems to various receiving systems used for research and public health.

Currently, two fundamental ways are used to incorporate FHIR in solution architecture. The first one consists of FHIR-enabling existing solutions and the second one consists of using FHIR as the central design element of a new type of healthcare data technology [26, 27]

The solution envisioned for this project belongs to the second category, and will incorporate the following characteristics:

- Agnostic to EHR platforms;
- Support data exchange between EHRs and receiving systems;
- Support bidirectional communication between EHRs and receiving systems (e.g. through the inclusion of standards such as Structured Data Capture (SDC) [28], etc.) as allowed by applicable laws and regulations;
- Have extensibility built in to support the evolution of interoperability and healthcare data standards as well as the inclusion of additional data elements to support research and public health information needs;
- Support various organizational reporting patterns between EHRs and receiving systems (e.g. include standards such as Data Access Framework (DAF)[29], etc.)

In addition, as healthcare information will not be limited to exchange across RESTful APIs. The architecture should accommodate and include, if necessary, other exchange paradigms [27, 30].

C.3 Scope of Work: This SOW delineates the tasks and associated activities that CDC requires from the Contractor, in support of the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) mission and the project, Making EHR Data Available for Public Health and Research (MedMorph). The contractor will be a member of the MedMorph Integrated Project Team, and as such its work, activities and deliverables shall be integrated into an overarching plan and schedule that includes collaboration with the Technical Expert Panel (TEP). The scope of work is to assist CDC in developing a reference architecture and reference implementations of components of the architecture using exchange standards and technology to improve the availability of clinical EHR data. The total timeframe of this contract (including base and option periods of performance) is expected to be 30 months (2.5 years).

To accomplish the scope of this work, CDC requires the Contractor technical and project management expertise and services in the following areas:

- Task 1: Refine Use Cases, Gather and Document Requirements
- Task 2: Design a Reference Architecture
- Task 3: Build Reference Implementations of Components
- Task 4: Support Pilot Implementation to test Reference Architecture
- Task 5: Project Management
- Optional Task 6: Develop Roadmap for Reference Architecture Adoption and Sustainability

C.4 Technical Requirements: The Contractor will perform the tasks listed below under this task order. The Contractor is a committed partner that is expected to help achieve outcomes integral to the mission and operation of CDC and CSELS.

4.1 Refine Use Cases, Gather and Document Requirements

The Contractor shall draft the use cases, initial requirements and support the CDC team in engaging the TEP to review and gather input on the use case and document the technical and program requirements.

4.1.1 Model and Refine the Use Cases

The contractor shall identify and present to CDC team, a standardized use case development framework and methodology that are suitable for the project. The Contractor shall then adopt the framework and engage with each of the three TEP use case subcommittees to refine CDC provided draft use cases and fully model the three use cases.

Deliverables:

a. Use case Definition Document for each of the three areas (Hepatitis C, Cancer, Health Survey)

b. Use case development framework and associated documentation

4.1.2 Gather and Analyze Requirements

The contractor shall develop an initial set of data (with focus on developing towards USCDI) and technical requirements by reviewing existing documentation and working with the CDC project team. The contractor shall then engage with the each of the three TEP use case subcommittees in refining the requirements for each use case. The Contractor shall help analyze and identify common requirements across the use case domain areas for the development of a foundational reference architecture that is generalizable and can address a variety of research and surveillance needs.

The contractor shall review the draft common technical requirements with the broader TEP to inform the design of the reference architecture. The technical requirements should include data authorities, privacy and security requirements needed for the different use cases.

Deliverables:

a. Initial and Final Requirements Document
b. Technical Paper documenting use cases and results of Task 4.1.1

c. Technical Considerations Briefing

4.2 Design a Reference Architecture

Using the outputs of Task 1, the Contractor, in collaboration with CDC and the TEP, shall develop a reference architecture. The architecture will be based on FHIR standards and will support the requirements for the three use cases defined in Task 4.1.

4.2.1 Landscape Analysis

The Contractor shall review CDC-provided landscape analysis report for known approaches to get data out of EHRs and, as needed, conduct assessments on additional existing efforts or more in depth assessments on already reviewed efforts, including but not limited to: Electronic Case Reporting (eCR);Emerging Infections Program (EIP), Chronic Population Health Informatics Framework ; Common Data Model Harmonization (CDMH) Project; National Quality Registry Network (NQRN) with Registries on FHIR; a Duke Clinical Research Institute project called "Improving Healthcare Data Interoperability" on harmonizing data elements across registries funded by Pew Charitable Trust; NCATS -FDA Clinical Adapter Project; and potentially others.

Deliverables:

a. Briefing presentation and white paper on the additional landscape considerations to the CDC Team and, if necessary, the TEP

4.2.2 Design and Document the Reference Architecture

The Contractor shall design and document the reference architecture to support the use cases identified in Task 4.1. The Contractor shall deliver the Concept of Operations (ConOps) and identify the appropriate available and to be developed technical standards required to support data exchange for the modeled use cases. The Contractor shall need to consider relevant policies to facilitate the adoption and execution of the technological strategies.

Deliverables:

a. ConOps
b. Architecture Design Document
c. List of Standards required

4.3 Build Reference Implementations of Components

Based on the EHR Vendor Landscape Analysis and Capability Crosswalk document provided by CDC (from section 4.2.1), the contractor shall prioritize and, with review and approval of the priorities with the CDC team, build a set of components required to implement the reference architecture.

Some examples components may include:

- Policy and trust services
- Clinical reasoning services
- FHIR server components

Where possible, components shall be built using existing open source libraries and applications. The contractor shall work with the CDC team to scope the minimum of 5 components needed to demonstrate the use cases defined in Task 4.1.

4.3.1 Develop Draft FHIR IGs

The contractor shall use the requirements gathered in Task 4.1 and Sub-task 4.2.2 to develop a draft FHIR IG for the reference architecture and in sub-task 1.2 to develop draft FHIR IGs, one for each of the three identified use cases. The contractor shall engage HL7 working group(s) (e.g., Public Health workgroup, CDS workgroup) and follow the process to ballot and publish the IGs. The contractor will review existing FHIR IGs e.g., ECR, BSeR and use US Core (CCDS/USCDI) as a baseline to assure that new IGs are complementary.

The draft FHIR IGs will capture the data elements required to be exchanged for each use case and will be mapped to appropriate FHIR resources.

Deliverables:

a. Draft FHIR IG for the reference architecture
b. Draft FHIR IGs for each of the three use cases
c. Published Standard for Trial Use (STU) FHIR IG for the reference architecture
d. Published STU FHIR IGs for each of the three identified use cases

4.3.2 Agile Development and Test

The Contractor, using agile methods, shall engage end-users and partners (e.g., SMEs, pilot sites, TEP members) to design, build, and test reference implementations of components required to test the reference architecture at pilot sites.

The Contractor shall use approved requirements to inform the design and functionality of the components:

- Iteratively develop components (sprint planning).
- Iteratively test the components (e.g., integration, validation or unit testing).
- Establish benchmarks for evaluating the components (e.g., usability, performance, etc.)
- The Contractor shall participate in up to three FHIR Connectathons to test the architecture components and/or IGs

The Contractor shall recommend and, with review and approval from the CDC team, establish the infrastructure and technology stack required for developing and testing the reference implementation. The contractor shall also establish the required collaborative platform for CDC and the TEP members to be engaged throughout the project lifecycle.

As required by the Federal Source Code Policy set out in OMB Memo M-16-21, all computer software produced in the performance of this contract shall be open source software and shall be available for Government-wide use and for use by the public with data use rights under FAR 52.227-14 Rights in Data - General, unless otherwise specified in writing by the contract officer. The Contractor (and/or any subcontractor) shall maintain, at all times, a working, current and fully-documented copy of all project or activity custom-developed source code in a repository from the CDC Recognized List of Source Code Repositories. The Contractor shall advise on the appropriate licensing agreement and publish the source code in accordance with that licensing agreement.

Deliverables:

a. Component Source code
b. Documentation and configuration files
c. Publish final Reference Implementation Source Code

4.4 Support Pilot Implementations of the Reference Architecture

The contractor shall assist CDC and the TEP in the recruitment or assessment of the sites to pilot the implementation and end-to-end testing of the reference architecture. The contractor shall work with CDC-selected pilot sites (contracted separately by CDC for implementation – e.g., AHRQ Action Network sites). The Contractor shall support these two differently configured sites, and if budget and schedule allow, a third uniquely configured site will be supported, as agreed upon by CDC. The contractor shall develop and maintain an updated version of the pilot site candidate requirements document throughout the development sprint cycles. The document will address topics including technical capability and readiness needed.

The Contractor shall perform a crosswalk analysis of FHIR compliance required by the reference architecture to FHIR APIs and features supported by pilot site's EHR vendors to further inform the development of the components under Task 4.3.

The Contractor shall help coordinate, support and test the reference implementation for one use case (e.g., hepatitis C) for both clinical research and public health surveillance contexts. The Contractor shall provide hands-on technical support and coordination to install, configure and test the appropriate components at the pilot sites as allowed.

The Contractor shall use the experience gained during test and implementation and testing to refine the draft FHIR IG as described in Task 3.1.

The Contractor shall prepare an adoption guide that will include documentation of steps involved in implementing the reference architecture for the use case

The Contractor shall address any issues or deficiencies related to implementing and testing the reference architecture at the pilot site(s).

The contractor shall deliver a draft manuscript that will be cleared and submitted by CDC for publication in a peer-reviewed journal summarizing the work of building the extensible application and designing and implementing the reference architecture as well as the fully implemented test case for both research and public health aspects.

Deliverables:

a. Pilot site candidate requirements document
b. Technical Support for software installation, configuration, and test at Pilot Sites
c. Draft Manuscript to Summarize the reference Implementation and Use Case Results
d. Adoption Guide
e. Documentation of findings from pilot implementations to inform development of a roadmap to scale the use of the reference architecture
f. Refine draft FHIR IG from Task 3.1

4.5 Project Management

The Contractor shall manage its work and provide the government necessary feedback regarding progress. The Contractor shall assign a Project Lead (PL) for this task. The PL shall be responsible for creating and maintaining project management plans and associated timelines that will ensure cost, schedule, and scope are in alignment with the CDC's requirements. The PL shall be responsible for monthly progress reports and other status reporting, as agreed to by the PL and CDC Team. The contractor shall provide and use a project collaboration software solution (e.g., Atlassian Confluence) to manage the project and the TEP through the period of performance. The Contractor shall complete the following sub-tasks to manage this project.

4.5.1 Project Management Plan and Reporting

The Contractor shall follow the proposed product delivery schedule and provide a high-level project management plan that includes collaboration with the TEP.

The CDC shall approve the project management plan or provide comments for revision within ten (10) government business days of delivery. The project management plan may be revised as needed throughout the period of delivery; however, the project management plan may not be revised more than monthly, as mutually agreeable to the CDC and the Contractor.

The Contractor shall provide monthly progress reports to ensure that the expenditure of resources is consistent with and will lead toward successful completion of all tasks within projected cost and schedule limitations. Monthly status reports will detail progress made during the prior month, progress expected during the next month, resources expended, any significant problems or issues encountered, recommended actions to resolve identified problems, and any variances from the proposed schedule and discussed during a monthly briefing. In coordination with the CDC leadership and pending the content approval of the government's Contracting Officer's Representative (COR), the monthly status reports may take the form of a PowerPoint briefing to expedite the identification and resolution of issues.

Each monthly progress report shall be submitted electronically within twenty (20) days following the close of the reporting month and one (1) copy will accompany the Contractor invoice that is sent to the CDC COR.

Deliverables:

a. Kickoff Meeting Agenda
b. Project Management Plan
c. Monthly Progress Reports and briefing

4.5.2 Support TEP

The Contractor shall support the development of materials and facilitate discussion and review by the TEP. The Contractor shall provide and/or manage shared workspace (e.g., Atlassian Confluence) and meeting collaboration platforms (e.g., WebEx) to support the TEP. The TEP shall include technical and subject matter experts from research, public health, clinical end users, and other relevant stakeholders to guide the project in refining use cases and ensure the reference architecture design is modeled with scientific rigor, accuracy and precision.

Deliverables: Materials to support and facilitate TEP meetings and discussions

4.6 Develop Roadmap for Reference Architecture Adoption and Sustainability

The Contractor shall develop a plan for broad use and long-term sustainability of the reference architecture.

The Contractor shall leverage the Technical Expert Panel from Task 4.1 to develop high-level strategic guidance and recommendations for the following:

- Blueprint for adapting the technical architecture to support other use cases
- Consider business model and funding mechanisms
- Maintenance, operations, and expansion
- Governance
- Communication and dissemination

The Contractor shall document our findings in a high-level strategic roadmap.

Deliverables: High-level Reference Architecture Adoption and Sustainability Roadmap**:** Includes blueprint for expanding use of the Reference Architecture

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C.5 Post Award Orientation/Kick-Off meeting

Within five (5) business days following the task award date, the contractor shall attend a Post award Orientation meeting to review the task order goals and objectives. The contractor shall be prepared to discuss the technical requirement, administrative matters, security requirements, project transition Government Furnished Information/Materials/Equipment (GFI/GFM/GFE), milestone schedule, review cycles, and invoicing. The meeting shall be attended by all contractor identified Key personnel, Contracting Officer (CO) and Contracting Officer Representative (COR). The meeting location and time will be determined by the Government. The contractor shall record detailed minutes of this meeting and provide a completed copy to the CO and COR within five (5) business days after the post award meeting is held.

C. 6 Deliverables/Delivery Schedule

All deliverables shall be submitted to the government task lead (GTL) and COR via email unless otherwise agreed upon. Unless otherwise specified, the Government will have a maximum of ten (10) working days from the day the deliverable is received to review the document, provide comments back to the contractor, approve or disapprove the deliverable(s). The contractor will also have a maximum of ten (10) working days from the day comments are received to incorporate all changes and submit the final deliverable to the Government. All days identified below are intended to be workdays unless otherwise specified.

All Task Order related reports shall be submitted to the Government via email. The contractor shall conduct Progress Review as required by the COR.

The following table provides the list of deliverables:

No.	Task #	Deliverable	Deliverable Schedule	Frequency	Deliver To
1-1	1	Use case development framework and associated documentation	2 months after award	Once	One electronic copy to the COR
1-2	1	Initial Requirements Document	3 months after award	Once	One electronic copy to the COR
1-3	1	Use case Definition Document for each of the three areas (Hepatitis C, Cancer, Health Survey)	Within 5 months after award	Once	One electronic copy to the COR
1-4	1	Final Requirements Document	5 months after award	Once	One electronic copy to the COR and Contracting Officer
1-5	1	Technical Paper documenting the use cases and results of Task 1	6 months after award	Once	One electronic copy to the COR
1-6	1	Technical Considerations Briefing	6 months after award	Once	One electronic copy to the COR
2-1	2	Briefing on the additional landscape considerations to the CDC Team and, if necessary, the TEP	1 month after award, and if new considerations arise throughout the project	Once	One electronic copy to the COR
2-2	2	Reference Architecture Concept of Operations	8 months after award	Once	One electronic copy to the COR
2-3	2	Architecture Design Document	10 months after award	Once	One electronic copy to the COR
2-4	2	List of Standards required	10 months after award	Once	One electronic copy to the COR
3-1	3	Publish draft FHIR IG for the reference architecture	14 months after award	Once	Electronically on build.fhir.org and provide URL to the COR
3-2	3	Publish draft FHIR IGs for each of the three use cases	14 months after award	Once	Electronically on build.fhir.org and provide URL to the
3-3	3	Published STU FHIR IG for the reference architecture	24 months after award	Once	Electronically on build.fhir.org and provide URL to the COR
3-4	3	Published STU FHIR IGs for each of the three identified use cases	24 months after award	Once	Electronically on build.fhir.org and provide URL to the COR

No.	Task #	Deliverable	Deliverable Schedule	Frequency	Deliver To
3-5	3	Component Source code	1 week from end of each sprint cycle	Each Sprint	Electronically on a repository from the CDC Recognized List of Source Code Repositories and provide URL to the COR and Contracting Officer
3-6	3	Documentation and configuration files	15 days from end of each sprint cycle	Each Sprint	One electronic copy to the COR and from a repository from the CDC Recognized List of Source Code Repositories
3-7	3	Publish Final Reference Implementation Source Code	26 months after award	Once	Electronically on a repository from the CDC Recognized List of Source Code Repositories and provide URL to the COR
4-1	4	Pilot site candidate requirements document	1 week from the end of each sprint cycle as applicable	Each Sprint	One electronic copy to the COR
4-2	4	Technical Support for software installation, configuration, and test at Pilot Sites with written update after each sprint	3 weeks after pilot sites are identified and 1 week from the end of each sprint cycle	Throughout pilot implementation Project Phase, Each Sprint	Pilot sites with regular (i.e., each sprint) reports to COR
4-3	4	Draft Manuscript to Summarize Reference Implementation & Use Case Results	26 months after award	Once	One electronic copy to the COR
4-4	4	Adoption Guide	1 weeks from the end of each sprint cycle as applicable	Each Sprint	One electronic copy to the COR
4-4	4	Documentation of findings from pilot implementations to inform development of a roadmap to scale the use of the reference architecture	26 months after award	Once	One electronic copy to the COR
5-1	5	Kick-off Meeting Agenda for orientation meeting and briefing between Contractor and CDC	Within four (4) business days of government award	Once	One electronic copy to the COR
5-2	5	Kick-off Meeting for orientation meeting and briefing between Contractor and CDC	Within five (5) business days of government award	Once	Contractor and CDC project team

No.	Task #	Deliverable	Deliverable Schedule	Frequency	Deliver To
5-3	5	Kick-off Meeting Minutes	Within five (5) business days after kick-off meeting is held	Once	One electronic copy to the COR
5-4	5	Project Management Plan	Within ten (10) government business days of the project kick-off	Updated at each sprint cycle as needed	One electronic copy to the COR
5-5	5	Monthly Progress Reports and briefing	15th of the month, most months, but within twenty (20) days of start of new month	Monthly	One electronic copy to the COR
5-6	5	Materials to support and facilitate TEP meetings and discussions	2 days prior to each TEP meeting	Weekly to Monthly based on project phase	One electronic copy to the COR
6-1	6	High-level Reference Architecture Adoption and Sustainability Roadmap	30 months after award	Once	One electronic copy to the COR

C.7 Government Furnished Property

The CDC expects all work for this contract to be completed offsite. If onsite work is determined necessary, CDC shall provide onsite contractor personnel with adequate work space and materials. The contractor shall supply property and equipment to their employees who are working offsite. Only CDC-furnished equipment may be connected to the CDC network or to CDC-owned devices.

C.8 Period of Performance: The total period of performance will not exceed 30 months, based and options included. *(specific dates will be established after award.)*

C.9 Place(s) of Performance

Most of the work is offsite CDC premise; however, vendor's employees may be required to work at the CDC on-site location in the Atlanta metro areas on CDC Campus. A workspace will be provided by the CDC for vendor employee's when they are required to work onsite.

C.10 Access Requirements

Wearing and prominent display of the CDC identification badge (HHS 576 CDC) is mandatory during tours of duty if working onsite. Exception: The ID badge will not be worn in work areas when it will obstruct or interfere with the wearing of safety equipment/clothing or when the working environment is not conducive to support this requirement.

C.11 Transition and Succession

The Contractor shall have a transition and succession plan that demonstrates the capability to ensure a smooth transition with current contracts and/or successor contracts with a minimum of disruption to customer services. At the end of the contract period, the Contractor may be required to continue performance to complete tasks issued prior to the effective date of any successor contract, unless

terminated by the Contracting Officer. The Contractor shall also be expected to work with the follow-on Contractor(s) to ensure a smooth transition.

C.12 Specific Requirements

a. Contract Management and Control - the Contractor shall provide the planning, coordination, technical direction, and surveillance of the activities necessary to assure disciplined work performance to accomplish all work under the contract. The Contractor shall be responsible for maintaining communication with the Contracting Officer (CO) and Contracting Officer's Representative (COR), and to immediately notify both the CO and the COR of any problems that would prevent timely performance of work issued under this contract.

b. The Contractor shall prepare and submit badge ID, cardkey request forms, etc. for all Contractor staff on-boarding and/or changing locations, if requested by the GTL or COR. Any update information should be provided in the monthly reports or in the monthly meetings with management and the COR.

c. Contractor Training – except for certain Government required training, the contractor at his own expense shall provide training as necessary for the contractor's personnel.

d. Contract Closeout - The contractor shall submit a final invoice within forty-five (45) calendar days after the end of the Performance of Period. After the final invoice has been paid the contractor shall furnish a completed and signed Release of Claims to the Contracting Officer. This release of claims is due within fifteen (15) calendar days of final payment.

e. Continuity of Support - Personal services shall not be performed under this contract. Although the Government may provide sporadic or occasional instructions within the scope of the contract, the Contractor is responsible for control and supervision of its employees. If the Contractor (including its employees) believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

f. The contractor shall comply with, and ensure their employees and subcontractors comply with, CDC Policy titled "Identification of Contractors' Employees and Safeguarding Government Information." No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. The contractor is limited to performing the services identified in the contract statement of work and shall not interpret any communication with anyone as a permissible change in contract scope or as authorization to perform work not described in the contract. All contract changes will be incorporated by a modification signed by the Contracting Officer.

g. The Contractor shall ensure that all of its employees and subcontractor employees working on this contract are informed of the substance of this clause. The Contractor agrees that this is a non-personal services contract; and that for all the purposes of the contract, the Contractor is not, nor shall it hold itself out to be an agent or partner of, or joint venture with, the Government. The Contractor shall notify its employees that they shall neither supervise nor accept supervision from Government employees. The substance of this clause shall be included in all subcontracts at any tier.

h. Nothing in this clause shall limit the Government's rights in any way under any other provision of the contract, including those related to the Government's right to inspect and accept or reject the services performed under this contract.

C.13 Overtime: Overtime is not authorized.

C.14 Disposition and Use of Data

All materials developed or information of whatever nature resulting from work being performed under this contract shall not be submitted for publication or dissemination without the prior review and written approval of the Contracting Officer's Representative.

C.15 Access to HHS Electronic Mail

If it determined that Contractor staff will need access to HHS electronic mail, all Contractor staff that have access to and use of HHS electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

C.16 Support Hours

When working at CDC facilities or telecommuting, the contractor's support services shall be provided for an 8-hour period (excluding lunchtime), including the core hours of 9:00 am and 3:00 pm Eastern Time, Monday through Friday, excluding Federal holidays.

Federal Holidays are:

New Year's Day	Labor Day
Martin Luther King's day	Columbus Day
President's Day	Veteran's Day
Memorial Day	Thanksgiving Day
Independence Day	Christmas Day

SECTION D – ADDITIONAL APPLICABLE CLAUSES

52.204-14 Service Contract Reporting Requirements (Oct 2016)

(a) Definition.

"First-tier subcontract" means a subcontract awarded directly by the Contractor for the purpose of acquiring supplies or services (including construction) for performance of a prime contract. It does not include the Contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies that benefit multiple contracts and/or the costs of which are normally applied to a Contractor's general and administrative expenses or indirect costs.

(b) The Contractor shall report, in accordance with paragraphs (c) and (d) of this clause, annually by October 31, for services performed under this contract during the preceding Government fiscal year (October 1-September 30).

(c) The Contractor shall report the following information:

(1) Contract number and, as applicable, order number.

(2) The total dollar amount invoiced for services performed during the previous Government fiscal year under the contract.

(3) The number of Contractor direct labor hours expended on the services performed during the previous Government fiscal year.

(4) Data reported by subcontractors under paragraph (f) of this clause.

(d) The information required in paragraph (c) of this clause shall be submitted via the internet at www.sam.gov. (See SAM User Guide). If the Contractor fails to submit the report in a timely manner, the contracting officer will exercise appropriate contractual remedies. In addition, the Contracting Officer will make the Contractor's failure to comply with the reporting requirements a part of the Contractor's performance information under FAR subpart 42.15.

(e) Agencies will review Contractor reported information for reasonableness and consistency with available contract information. In the event the agency believes that revisions to the Contractor reported information are warranted, the agency will notify the Contractor no later than November 15. By November 30, the Contractor shall revise the report, or document its rationale for the agency.
(f)
(1) The Contractor shall require each first-tier subcontractor providing services under this contract, with subcontract(s) each valued at or above the thresholds set forth in 4.1703(a)(2), to provide the following detailed information to the Contractor in sufficient time to submit the report:

(i) Subcontract number (including subcontractor name and unique entity identifier); and

(ii) The number of first-tier subcontractor direct-labor hours expended on the services performed during the previous Government fiscal year.

(2) The Contractor shall advise the subcontractor that the information will be made available to the public as required by section 743 of Division C of the Consolidated Appropriations Act, 2010.

(End of clause)

Option for Increased Quantity – Separately Priced Line Items

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written

notice to the contractor within the period of performance of the CLIN being affected. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

FAR 52.217-8 Option to Extend Services. (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days prior to the ending period of performance.

FAR 52.217-9 Option to Extend the Term of the Contract. (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days prior to contract ending; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36 months.

HHSAR 352.203-70 Anti-Lobbying. (DEC 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

(End of clause)

352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations. (Dec. 18, 2015)

(a) In addition to complying with the clause at FAR 52.222-26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (Agency) in investigations of Equal

Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614. For purposes of this clause, the following definitions apply:

(1) **Complaint** means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction.

(2) **Contractor employee** means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees~~,~~ who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide the Agency with that employee's last known mailing address, e-mail address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(3) **Good faith cooperation** cited in paragraph (a) includes, but is not limited to, making Contractor employees available for:

(i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints;

(ii) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(iii) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during the course of EEO investigations;

(iv) Producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and

(v) Preparing for and providing testimony in depositions or in hearings before the MSPB, EEOC and U.S. District Court.

(b) The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded at any tier under this contract.

(c) Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default.

(End of clause)

352.227-70 Publications and Publicity (December 18, 2015)

(a) Unless otherwise specified in this contract, the Contractor may publish the results of its work under this contract. The Contractor shall promptly send a copy of each article submitted for publication to the Contracting Officer's Representative. The Contractor shall also inform the Contracting Officer's Representative when the article or other publication is published and furnish a copy of it as finally published.

(b) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo including Operating Division or Staff Division logos on any publications.

(c) The Contractor shall not reference the product(s) or service(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies HHS approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract.

(End of clause)

352.231-70 Salary Rate Limitation (Dec 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management Web site for Federal Executive Schedule salary levels.

(End of clause)

352.233-71 Litigation and Claims (December 18, 2015)

(a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost and Payment."

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent documents received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by other terms or conditions of this contract, by law or regulation, or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

352.237-75 Key Personnel. (DEC 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days' notice, the contractor shall provide the maximum notice practicable under the circumstances. The contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause)

CDC0.H049 Non-Disclosure Agreement for Contractors and Contractor's Employee (May 2009)

(a) The contractor shall prepare and submit a Non-Disclosure Agreement (NDA) to the Contracting Officer prior to access of government information or the commencement of work at CDC.

(b) The NDA made part of this clause, exhibit I and II, is required in service contracts where positions and/or functions proposed to be filled by contractor's employees will have access to non-public and procurement-sensitive information. The NDA also requires contractor's employees properly identify themselves as employees of a contractor when communicating or interacting with CDC employees, employees of other governmental entities (when communication or interaction relates to the contractor's work with the CDC), and members of the public. The Federal Acquisition Regulation (FAR) 37.114 (c), states "All contractor personnel attending meetings, answering Government telephones, and working in other situations where their contractor status is not obvious to third parties are required to identify themselves as such to avoid creating an impression in the minds of members of the public or Congress that they are Government officials, unless, in the judgment of the agency, no harm can come from failing to identify themselves. They must also ensure that all documents or reports produced by contractors are suitably marked as contractor products or that contractor participation is appropriately disclosed."

(c) The Contractor shall inform employees of the identification requirements by which they must abide and monitor employee compliance with the identification requirements.

(d) During the contract performance period, the Contractor is responsible to ensure that all additional or replacement contractors' employees sign an NDA and it is submitted to the Contracting Officer prior to commencement of their work with the CDC.

(e) Contractor employees in designated positions or functions that have not signed the appropriate NDA shall not have access to any non-public, procurement sensitive information or participate in government meeting where sensitive information may be discussed.

(f) The Contractor shall prepare and maintain a current list of employees working under NDA's and submit to the Contracting Officer upon request during the contract period of performance. The list should at a minimum include: contract number, employee's name, position, date of hire and NDA requirement.

(End of Clause)

CDCA_H040 Government Property (Jul 2017)

(a) Government-Furnished Property (GFP). In accordance with the terms of FAR 52.245-1, Government Property, the Government reserves the right to supply the Contractor, as Government-furnished property, any additional

supplies, equipment, and materials determined by the Contracting Officer to be necessary and in the best interest of the Government.

(b) Contractor-Acquired Property (CAP). The Contractor must receive written consent from the Contracting Officer prior to purchase of any CAP not expressly identified in the contract, and as defined in FAR 52.245-1.

(c) Accountable and Sensitive Government Property. The Government will provide property labels and other identification for contractor-acquired Government property that is considered Accountable as defined in the HHS Logistics Management Manual (LMM) https://intranet.hhs.gov/abouthhs/manuals/lmm/index.html or considered Sensitive as defined in CDC's Sensitive Items List (http://intranet.cdc.gov/ofr/documents/contracts/Authorized-Prohibited-List.pdf)

(d) The contractor shall be responsible for the control and accountable record keeping of any Government property used in the performance of this contract predominately outside the confines of a Government controlled workspace in accordance with the HHS Contracting Guide found on the OSSAM Government Property and Contractors Property intranet page. (http://intranet.cdc.gov/ossam/property-shipping-receiving/property-management/government-property-contractors/index.html)

(e) The Chief of the Office of Safety, Security and Asset Management (OSSAM), Asset Management Services Office, Centers for Disease Control and Prevention (CDC), is hereby designated as the Property Administrator for this contract. The Contractor shall identify each item of equipment furnished by the Government to the Contractor or acquired by the Contractor using contract funds, with a suitable decal, tag, or other marking, as prescribed by the Property Administrator, and shall follow the guidance set forth in the HHS Contracting Guide.

(End of Clause)

CDCA.H037 Observance of Legal Holidays and Facility Closure (Government Facilities Performance (Feb 2011)

(a) Holidays
Government personnel observe the following listed days as holidays:
Washington's Birthday
Memorial Day
Independence Day
Labor Day
Veterans' Day
Thanksgiving Day
Christmas Day
New Year's Day
Columbus Day
Martin Luther King Day
Any other day designated by Federal Statute
Any other day designated by Executive Order
Any other day designated by Presidential proclamation

For purposes of contract performance, the Contractor shall observe the above holidays on the date observed by the Government. Observance of such days shall not be cause for an additional period of performance or entitlement to compensation except as otherwise set forth in the contract. No form of holiday or other premium compensation will be reimbursed; however, this does not preclude reimbursement for overtime work authorized in writing by the Contracting Officer.

(b) Unscheduled Facility Closures
In the event Government facilities are closed due to inclement weather, potentially hazardous or unsafe conditions, or other special circumstances, contractor personnel assigned to work within those facilities are automatically dismissed. Notwithstanding the terms of this clause, the contractor shall comply with any specific contract terms

that require a level of ongoing support for critical operations during times of facility closure. The contractor may also continue to provide support under a scheduled telework arrangement in accordance with the terms of the contract if the contract expressly authorizes telework in writing.

(c) Cost Impact
Accounting for costs associated with an unscheduled facility closure is unique to each contract and depends upon a number of factors such as:
i) Contract type, e.g. Fixed Price, Time and Materials, or Cost Reimbursement.
ii) Contractor's established management and accounting practices for unproductive time.
iii) The inclusion and applicability of other contract clauses.
iv) The ability of the contractor to mitigate costs by reassigning employees to work on other contracts, to work from a different facility, or to work remotely from home in accordance with contract telework provisions.

(End of Clause)

CDC0.H022 Smoke Free Working Environment (May 2009)

In compliance with Department of Health and Human Services (DHHS) regulations, all contractor personnel performing work within CDC/ATSDR facilities shall observe the CDC/ATSDR smoke-free working environment policy at all times. This policy prohibits smoking in all CDC/ATSDR buildings and in front of buildings which are open to the public. This policy is also applicable to contractor personnel who do not work full-time within CDC/ATSDR facilities but are attending meetings within CDC/ATSDR facilities.

(End of Clause)

CDC37_0001 Non-Personal Services (Apr 2015)

(a) Personal services shall not be performed under this contract. Although the Government may provide sporadic or occasional instructions within the scope of the contract, the Contractor is responsible for control and supervision of its employees. If the Contractor (including its employees) believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

(b) The contractor shall comply with, and ensure their employees and sub-contractors comply with, CDC Policy titled “Identification of Contractors' Employees and Safeguarding Government Information.” No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work.

(End of Clause)

CDCP.G009 Contracting Officer (Jul 1999)

(a) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

(b) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

(End of Clause)

CDC0_G008 Contracting Officer's Representative (COR) (Jul 2017)

Performance of the work hereunder shall be subject to the technical directions of the designated COR for this contract.

As used herein, technical directions are directions to the Contractor which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof.
In the event that the Contractor believes full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer, immediately or as soon as possible, in a letter or e-mail separate of any required report(s). No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government COR is not authorized to change any of the terms and conditions of this contract. Contract changes shall be made only by the Contracting Officer by properly written modification(s) to the contract.

The Government will provide the Contractor with a copy of the COR delegation memorandum upon request.

(End of Clause)

CDC-42.0002 Evaluation of Contractors Utilizing CPARS (Apr 2015)

In accordance with FAR 42.15, the Centers for Disease Control and Prevention (CDC) will review and evaluate contract performance. FAR 42.1502 and 42.1503 requires agencies to prepare evaluations of contractor performance and submit them to the Past Performance Information Retrieval System (PPIRS). The CDC utilizes the Department of Defense (DOD) web-based Contractor Performance Assessment Reporting System (CPARS) to prepare and report these contractor performance evaluations. All information contained in these assessments may be used by the Government, within the limitations of FAR 42.15, for future source selections in accordance with FAR 15.304 where past performance is an evaluation factor.

The CPARS system requires a contractor representative to be assigned so that the contractor has appropriate input into the performance evaluation process. The CPARS contractor representative will be given access to CPARS and will be given the opportunity to concur or not-concur with performance evaluations before the evaluations are complete. The CPARS contractor representative will also have the opportunity to add comments to performance evaluations.

The assessment is not subject to the Disputes clause of the contract, nor is it subject to appeal beyond the review and comment procedures described in the guides on the CPARS website. Refer to: www.cpars.gov for details and additional information related to CPARS, CPARS user access, how contract performance assessments are conducted, and how Contractors participate. Access and training for all persons responsible for the preparation and review of performance assessments is also available at the CPARS website.

The contractor must provide the CDC contracting office with the name, e-mail address, and phone number of their designated CPARS representative who will be responsible for logging into CPARS and reviewing and commenting on performance evaluations. The contractor must maintain a current representative to serve as the contractor representative in CPARS. It is the contractor's responsibility to notify the CDC contracting office, in writing (letter or email), when their CPARS representative information needs to be changed or updated. Failure to maintain current CPARS contractor representative information will result in the loss of an opportunity to review and comment on performance evaluations.

[End of Clause]

Homeland Security Presidential Directive – 12 (HSPD-12) Requirements

(a) To perform the work specified herein, contractor personnel are expected to have routine 1) physical access to an HHS-controlled facility; 2) logical access to an HHS controlled information system; or 3) access to sensitive HHS data or information, whether in an HHS controlled information system or in hard copy. This contract/order will entail the following position sensitivity level(s): Non-sensitive

(b) To gain routine physical access to an HHS facility, logical access to an HHS controlled information system, and or access to sensitive data or information, the contractor and its employees shall comply with Homeland Security Presidential Directive 12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); Federal Information Processing Standards Publication Number 201; and with the personal identity verification and investigation procedures contained in the following documents:

(1) HHS Information Security Program Policy

(2) HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005

(3) HHS HSPD-12 Policy Document, v. 2.0

(4) "IN- AND OUT-PROCESSING OF CDC FTEs, PSCs, CONTRACTORS, AND OTHER NON-FTEs" Policy

(5) "VISITORS AND FOREIGN NATIONALS IN THE WORKPLACE AT CDC" Policy

(c) The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (with fingerprinting). More restricted positions, above non-sensitive, require more extensive documentation and investigation. The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

(d) Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays--see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

(e) Multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the extra investigation(s).

(f) Language similar to this Security section shall be included in any subcontracts which require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; or (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; access to an information system, access to sensitive data, regular or prolonged access to an HHS-controlled facility.

(g) Inquiries on matters that affect contract compliance or terms and conditions should be directed to the Contracting Officer or designee.

(h) Within seven (7) calendar days after final acceptance of the work specified herein, the contractor shall return all identification badges in accordance with CDC's Policy titled "In- And Out-Processing of CDC FTEs, PSCs, Contractors, and Other Non-FTEs Policy". Contractor employees who separate from service under the contract prior to final acceptance shall be out processed in accordance with that same policy.

Baseline Security Requirements

1) **Applicability.** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

   a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

   b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) employee will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

   2) **Safeguarding Information and Information Systems.** In accordance with the Federal Information Processing Standards Publication (FIPS)199, *Standards for Security Categorization of Federal Information and Information Systems*, the Contractor (and/or any subcontractor) shall:

   a. Protect government information and information systems in order to ensure:
      - **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
      - **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
      - **Availability**, which means ensuring timely and reliable access to and use of information.

   b. Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less**, bring the situation to the attention of the other party.

   c. Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov.

   d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.

3) **Controlled Unclassified Information (CUI).** CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with *Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR,* part 2002*)* when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "h*andling"* refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

   a. marked appropriately;

b. disclosed to authorized personnel on a Need-To-Know basis;

c. protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations* applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations* if handled by internal Contractor system; and

d. returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, *Guidelines for Media Sanitization*.

4) **Protection of Sensitive Information**. For security purposes, information is *or* may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, *Protection of Sensitive Agency Information* by securing it with a FIPS 140-2 validated solution.

5) **Confidentiality and Nondisclosure of Information**. Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and *[CDC]* policies. Unauthorized disclosure of information will be subject to the HHS/*[CDC]* sanction policies and/or governed by the following laws and regulations:

a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

6) **Internet Protocol Version 6 (IPv6).** All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, *Transition Planning for Internet Protocol Version 6 (IPv6)*.

7) **Government Websites.** All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

8) **Contract Documentation**. The Contractor shall use provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.

See **Appendix D** *for baseline deliverables.*

9) **Standard for Encryption.** The Contractor (and/or any subcontractor) shall:

a. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information.

b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI],

proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.

c. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and CDC-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR *[CDC-provided delivery date]*.

e. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to CDC Office of Chief Information Security Officer (OCISO).

10) **Contractor Non-Disclosure Agreement (NDA)**. Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the CDC non-disclosure agreement, as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

See Appendix C *for the HHS Contractor Non-Disclosure Agreement.*

11) **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)** – The Contractor shall assist the CDC Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

The Contractor shall assist the CDC SOP or designee in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the CDC SOP that a review is required based on a major change to the system (e.g., new uses of information collected, changes to the way information is shared or disclosed and for what purpose, or when new types of PII are collected that could introduce new or increased privacy risks), whichever comes first.

Training

1) **Mandatory Training for All Contractor Staff.** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/CDC Contractor Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees shall complete *CDC Security Awareness Training (SAT)* and Records Management training at least ***annually***, during the life of this contract. All provided training shall be compliant with HHS training policies.

2) **Role-based Training.** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training (RBT) ***within 60 days*** of assuming their new responsibilities. Thereafter, they shall complete RBT at least ***annually*** in accordance with HHS policy and the *HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum*.

All HHS employees and contractors with SSR who ***have not*** completed the required training within the mandated timeframes shall have their user accounts disabled until they have met their RBT requirement.

3) **Training Records.** The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall

be provided to the CO and/or COR within ***30 days*** after contract award and ***annually*** thereafter or upon request.

Rules of Behavior

1) The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the *HHS Information Technology General Rules of Behavior*.

2) All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least ***annually*** thereafter, which may be done as part of annual *CDC Security Awareness Training*. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

Incident Response

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines incidents as events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose.
OMB Memorandum M-17-12, "Preparing for and Responding to a Breach of Personally Identifiable Information" (03 January 2017) states:

> **Definition of an Incident:**
> *An occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.*
>
> **Definition** of a **Breach:**
> *The loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for another than authorized purpose.*
>
> It further adds:
>
> A breach is not limited to an occurrence where a person other than an authorized user potentially accesses PU by means of a network intrusion, a targeted attack that exploits website vulnerabilities, or an attack executed through an email message or attachment. A breach may also include the loss or theft of physical documents that include PU and portable electronic storage media that store PU, the inadvertent disclosure of PU on a public website, or an oral disclosure of PII to a person who is not authorized to receive that information. It may also include an authorized user accessing PU for another than authorized purpose.

The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines a breach as "a suspected or confirmed incident involving PII".

Contracts with entities that collect, maintain, use, or operate Federal information or information systems on behalf of CDC shall include the following requirements:

1) The contractor shall cooperate with and exchange information with CDC officials, as deemed necessary by the CDC Breach Response Team, to report and manage a suspected or confirmed breach.

2) All contractors and subcontractors shall properly encrypt PII in accordance with OMB Circular A-130 and other applicable policies, including CDC-specific policies, and comply with HHS-specific policies for protecting PII. To this end, all contractors and subcontractors shall protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.

3) All contractors and subcontractors shall participate in regular training on how to identify and report a breach.

4) All contractors and subcontractors shall report a suspected or confirmed breach in any medium as soon as possible and without unreasonable delay, consistent with applicable CDC IT acquisitions guidance, HHS/CDC and incident management policy, and United States Computer Emergency Readiness Team (US-CERT) notification guidelines. To this end, the Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC) or CDC Computer Incident Response Team (CSIRT) within 24 hours via email at cdc@csirt.gov or telephone at 866-655-2245, whether the response is positive or negative.

5) All contractors and subcontractors shall be able to determine what Federal information was or could have been accessed and by whom, construct a timeline of user activity, determine methods and techniques used to access Federal information, and identify the initial attack vector.

6) All contractors and subcontractors shall allow for an inspection, investigation, forensic analysis, and any other action necessary to ensure compliance with HHS/CDC Policy and the HHS/CDC Breach Response Plan and to assist with responding to a breach.

7) Cloud service providers shall use guidance provided in the FedRAMP Incident Communications Procedures when deciding when to report directly to US-CERT first or notify CDC first.

8) Identify roles and responsibilities, in accordance with HHS/CDC Breach Response Policy and the HHS/CDC Breach Response Plan. To this end, the Contractor shall NOT notify affected individuals unless and until so instructed by the Contracting Officer or designated representative. If so, instructed by the Contracting Officer or representative, all notifications must be pre-approved by the appropriate CDC officials, consistent with HHS/CDC Breach Response Plan, and the Contractor shall then send CDC-approved notifications to affected individuals; and,

9) Acknowledge that CDC will not interpret report of a breach, by itself, as conclusive evidence that the contractor or its subcontractor failed to provide adequate safeguards for PII.

Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR).

*The requiring activity representative, in conjunction with Personnel Security, shall use the OPM Position Sensitivity Designation automated tool (*https://www.opm.gov/investigations/*) to determine the sensitivity designation for background investigations. After making those determinations, include all applicable position sensitivity designations.*

Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*; HHS HSPD-12 policy; and *Executive Order 13467, Part 1 §1.2.*

.

For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12)

Roster. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO by the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted immediately upon change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

If the employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level.

Contract Initiation and Expiration

1) **General Security Requirements.** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Guide (2012).

   HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

2) **System Documentation.** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, *Security Considerations in the System Development Life Cycle*, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

3) **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, *Guidelines for Media Sanitization*.

4) **Notification.** The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO before an employee stops working under this contract.

5) **Contractor Responsibilities Upon Physical Completion of the Contract**. The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or *CDC* policies.

6) The Contractor (and/or any subcontractor) shall perform and document the actions identified in the CDC Out-Processing Checklist (http://intranet.cdc.gov/od/hcrmo/pdfs/hr/Out_Processing_Checklist.pdf) when an employee terminates work under this contract. All documentation shall be made available to the CO and/or COR upon request.

Records Management and Retention

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS policies and shall not dispose of any records unless authorized by HHS.

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS policies.

EXHIBIT I
Centers for Disease Control and Prevention (CDC)
Contractor Non-Disclosure Agreement

I. Non-public Information

[Name of contractor] understands that in order to fulfill the responsibilities pursuant to **[Contract name and number]** between the Centers for Disease Control and Prevention and **[Name of CDC contractor] dated [date],** employees of **[contractor]** shall have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or will not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

In order to properly safeguard non-public information, **[contractor]** agrees to ensure that prior to being granted access to government information or the commencement of work for the CDC, whichever is applicable, all employees shall sign a Non-Disclosure Agreement (NDA) provided by the CDC prior to beginning work for the CDC. Contractor agrees to submit to the contracting official the original signed copies of NDAs signed by the contractor's employees in accordance with the instructions provided by the contracting official. Failure to provide signed NDAs in accordance with this agreement and instructions provided by the contracting official could delay or prevent the employee from commencing or continuing work at the CDC until such agreement is signed and returned to the contracting official.

Contractor further agrees that it shall not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee any non-public information that the employee may obtain in connection with the performance of the employee's responsibilities to the CDC.

II. Procurement-Sensitive Information

Contractor further agrees that it shall not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual, other than an authorized Government employee, any procurement-sensitive information gained while in connection with fulfilling the employee's responsibilities at the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Requests for Contract (RFC), and Requests for Proposal (RFP); Responses to RFPs, including questions from potential offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personal involved in the solicitation; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

Contractor understands and agrees that employee access to any procurement-sensitive information may create a conflict of interest which shall preclude contractor from becoming a competitor for any acquisition(s) resulting from this information. Therefore, if an employee participates in any discussions relating to procurement-sensitive information, assists in developing any procurement-sensitive information, or otherwise obtains any procurement-sensitive information during the course of performing duties at the CDC, contractor understands and agrees that contractor may be excluded from competing for any acquisition(s) resulting from this information.

III. Identification of Non-Government Employees

Contractor understands that its employees are not agents of the Government. Therefore, unless otherwise directed in writing by the CDC, contractor agrees to assist and monitor employee compliance with the following identification procedures:

A. At the beginning of interactions with CDC employees, employees of other governmental entities, members of the public, or the media (when such communication or interaction relates to the contractor's work with the CDC), contractors' employees shall identify themselves as an employee of a contractor.

B. Contractors' employees shall include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages, in connection with contractual duties to the CDC:

Employee's name
Name of contractor
Center or office affiliation
Centers for Disease Control and Prevention

C. At the beginning of telephone conversations or conference calls, contractors' employees shall identify themselves as an employee of a contractor.

D. Contractors should not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises. The only other exception is when a CDC management official has granted permission to use the CDC logo.

E. Contractors' employees shall program CDC voice mail message to identify themselves as an employee of a contractor.

I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. Contractor acknowledges that contractor has read and fully understands this agreement.

Name of contractor: _____

Signature of Authorized Representative of Contractor: _____

Date: _____

Copies retained by: contracting official and contractor

EXHIBIT II

Centers for Disease Control and Prevention (CDC)
Contractors' Employee Non-Disclosure Agreement

I. Non-Public Information

I understand that in order to fulfill my responsibilities as an employee of **[Name of CDC contractor],** I shall have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or shall not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

I **[Name of Employee],** agree to use non-public information only in performance of my responsibilities to the CDC. I agree further that I shall not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any non-public information that I may obtain in connection with the performance of my responsibilities to the CDC.

II. Procurement-Sensitive Information

I further agree that unless I have prior written permission from the CDC, I shall not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any procurement-sensitive information gained in connection with the performance of my responsibilities to the CDC. I specifically agree not to disclose any non-public, procurement-sensitive information to employees of my company or any other organization unless so authorized in writing by the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Requests for Contract (RFC), and Requests for Proposal (RFP); Responses to RFPs, including questions from potential offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personal involved in the acquisition; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

I understand and agree that my access to any procurement-sensitive information may create a conflict of interest which shall preclude me, my current employer, or a future employer from becoming a competitor for any resulting government acquisition derived from this information. Therefore, if I participate in any discussions relating to procurement-sensitive information, assist in developing any procurement-sensitive information, or otherwise obtain any procurement-sensitive information during the course of performing my duties at the CDC, I understand and agree that I, my current employer, and any future employer(s) may be excluded from competing for any resulting acquisitions.

III. Special Non-Disclosure Clause for Contractors with Access to CDC Grants Management and Procurement-Related Information Technology Systems

In addition to complying with the non-disclosure requirements and safeguards stated above, I understand that my authorization to use CDC's grants management and procurement systems is strictly limited to the access and functions necessary for the performance of my responsibilities to the CDC and which have been approved in advance by the CDC. I understand that I am not authorized to enter procurement requests for any requirements pertaining to contracts or subcontracts held by me or my employer.

IV. Identification as a Non-Government Employee

I understand that as an employee of a government contractor, I represent an independent organization and I am not an agent of the Government. Therefore, I agree that unless I have prior written authorization from the CDC, I will, at the beginning of interactions with CDC employees, employees of other governmental entities, members of the public, or the media (when such communication or interaction relates to the contractor's work with the CDC), identify myself as an employee of a contractor. I further agree to use the following identification procedures in connection with my work at the CDC:

A. I shall include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages:

Employee's name
Name of contractor
Center or office Affiliation
Centers for Disease Control and Prevention

B. I shall identify myself as an employee of a contractor at the beginning of telephone conversations or conference calls;
C. I shall not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises; the only other exception is when a CDC management official has granted permission to use the CDC logo.
D. I shall program my CDC voice mail message to identify myself as a contractors' employee.

I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. I acknowledge that I have read and fully understand this agreement.

Name of contractor: _____

Name of Employee: _____

Signature of Employee: _____

Date: _____

Copies retained by: contracting official, contractor, and Employee

(End of Clause)

SECTION E- INSTRUCTIONS FOR SUBMISSION OF QUOTES

The following are instructions for submission of quotes:

a. Quotes are due **2 pm (EST), December 2nd, 2019**

b. The deadline for submission of questions about this requirement is 2pm (EST), **November 21, 2019** Questions will be compiled and the answers to the questions will be sent back in a single document to all interested parties by COB **November 22, 2019.**

c. Quotes shall be submitted electronically (via e-mail) in MS Word or MS Excel files to both yrj7@cdc.gov and boh9@cdc.gov.

The following format is required as e-mail subject: The RFQ No: **75D301-20-Q-71199 KT.doc** or .xls (Where "75D301-20-Q-71199" is the respective RFQ No. and "KT" are the first two letters of the respective Vendor's name; and ".doc" and ".xls" are the format extensions.)

d. Quoters are responsible for providing accurate and complete information for evaluation. (Failure to do so may rule the quote unacceptable.)

Quotes shall be submitted in two severable parts: Part I - Technical and Part II - Business

Part I – Technical: The following information shall be included as part of the Technical quote:

1. **Experience (page limit: 3)**

Quoters shall provide a description of three (3) projects completed within the past three years that clearly demonstrates the Offeror's experience in performing projects of similar scope, size and complexity to the requirements described in the PWS. The following information shall be provided for each project reference:

- Contract number, customer/agency name and contract title;
- Brief narrative description of the work performed for each of those contracts, including a discussion of any problems encountered/corrective actions and significant accomplishments;
- Dollar value, contract type, period of performance, place of performance, and the number and types of personnel used in the performance of the contract; and
- Name, address and phone number of at least two (2) customer contacts (Contracting Officer and COR) for each of the identified contracts.

2. **Technical Approach (page limit: 7)**
Quoters are to provide a written report of their technical approach for providing the services required for this procurement. The technical approach shall include descriptions of the performance techniques and methodologies to be used and should include a milestone and/or phasing chart to illustrate a logical sequence of proposed events, including:

a. Address each of the requirements specified in the Statement of Work. Provide evidence of specific methods and techniques for completing each discrete task, to include such items as quality assurance, technology use, innovation opportunities; include the methods to be utilized, (e.g., production, quality control), and the identification of potential challenges to successful completion of the project; be consistent with the stated project goals and objectives.
b. The proposed approach must ensure the achievement of timely and acceptable performance and will include a milestone and/or phasing charts to illustrate a logical sequence of proposed events.

3. **Staffing and Management Plan (page limit: 4)**

The Staffing and Management Plan shall:

a. include a description of the project's organization to include the labor-mix and person hours for all personnel and matching skillsets.

b. include a staffing matrix showing type and number of staffing resources readily available, including breakdowns by skill sets, security clearances and any related certifications. The matrix of proposed personnel shall also include their experience, education, skills, and qualifications to do the job. The backgrounds of the personnel will reflect the length and variety of experience and expertise in tasks similar to the tasks required by this project and any relevant training. The percentage of time each staff member shall contribute to the program will be adequately identified. The extent to which outside consultants or specialists will be used and evidence of availability shall be indicated.

c. provide a description of the Offeror's approach to rapidly obtain and/or replace qualified staffing resources to support existing and new task order work and to meet changing workload requirements, including a table showing employee turnover rates for each of the past three years; and resumes for proposed Key Personnel (limited to two (2) pages per resume).

d. document the decision-making authority of the project manager as related to other elements of the organization. Including a description of how the Offeror will interface with CDC, as well as a clear delineation of staff authorities and line of responsibility with special emphasis on relationships with subcontractors, other Contractors, and CDC partners.

e. If subcontractors are proposed, provide information to support their qualifications as well. The Offeror shall identify any portions of the task that will be performed by subcontractors. This information must include the subcontracting firm and the specific duties and labor categories that will be performed by the subcontractor. The Offeror shall also furnish a written copy of the draft subcontracting agreement. The Offeror shall also provide copies of any Service Level Agreements.

4. **Transition and Succession (page limit: 2)**

The Contractor shall propose a transition and succession plan that demonstrates the capability to ensure a smooth transition with current contracts and/or successor contracts with a minimum of disruption to customer services.

(Quoters are required to observe the page limitation indicated. Failure to provide to do so may render the quote unacceptable.)

Part II - The Business Quote:

Quoters shall include the proposed labor categories, estimated labor hours and rates for each of the **proposed task** (i.e., there are 6 tasks identified in this project.) Include discounted labor rates, if any, and then calculate the total amount in the right hand column.

Labor Category	Rate	Discounted Rate	Hours	Total Amount

Other Direct Costs (ODCs), such as the estimated travel and materials, are to be proposed and identified separately. Provide support documentation for any associated ODC to be quoted.

Estimated Level of Effort: From previous CDC contractual history, the following table demonstrates suggested skill labor categories and hours. This table is only an example for the purpose of indicating the initial scope of work and the workload expressed as skill labor categories and number of estimated hours using the base year as an example: **This table is not a mandatory requirement**.

Government Estimate of Skill Categories and Support Hours

Year 1 (Base and Options)

Labor Categories	Support Hours
Business Analyst	1306
Clinical Information Data Analyst	0
Implementation Specialist	0
Network Security Engineer II	0
Project Manager	156
Software Architect	94.80
Software Engineer	26
Software Engineer IV	120
Subject Matter Expert II	224.80
System Analyst III	0
Total	**1927.60**

Year 2

Labor Categories	Support Hours
Business Analyst	1436.80
Clinical Information Data Analyst	436
Implementation Specialist	436
Network Security Engineer II	132
Project Manager	313.20
Scrum Master	436
Software Architect	228
Software Engineer	1744
Software Engineer IV	848
Subject Matter Expert II	1821.20
System Analyst III	436
SMEs lin-kind – federal – incl clinical	0
Total	**8267.20**

Year 3

Labor Categories	Support Hours
Business Analyst	313.20
Clinical Information Data Analyst	104.40
Implementation Specialist	104.40
Network Security Engineer II	313.20
Project Manager	208.80
Scrum Master	104.40
Software Architect	0
Software Engineer	104.40
Software Engineer IV	1044
Subject Matter Expert II	62.64
System Analyst III	0
SMEs lin-kind – federal – incl clinical	0
Total	**2359.44**

Note: This estimate is only an example and is not intended to be the only possible solution to the requirement. Given the dynamic nature of the mission, the actual workload may vary significantly during the period of performance and the task or may be modified accordingly. The labor categories and number of hours established in the task order may be modified during the period of performance to reflect current mission requirement.

Past performance is one indicator of the vendor's ability to perform the contract successfully. The government will evaluate different customers' opinions about how well (quality) the vendor has satisfied their requirements. Information on vendor's performance history will be retrieved from the Past Performance Information Retrieval System (PPIRS).

FAR 52.216-1 Type of Contract (Apr 1984)

The Government is awarding a Time and Materials contract.

[End of Provision]

CDC-42.0001 Contractor's Performance Assessment System (CPARS) Requirements (Apr 2015)

In accordance with FAR 42.15, the Centers for Disease Control and Prevention (CDC) will review and evaluate contract performance. FAR 42.1502 and 42.1503 requires agencies to prepare evaluations of contractor performance and submit them to the Past Performance Information Retrieval System (PPIRS). The CDC utilizes the Department of Defense (DOD) web-based Contractor Performance Assessment Reporting System (CPARS) to prepare and report these contractor performance evaluations. All information contained in these assessments may be used by the Government, within the limitations of FAR 42.15, for future source selections in accordance with FAR 15.304 where past performance is an evaluation factor.

The CPARS system requires a contractor representative to be assigned so that the contractor has appropriate input into the performance evaluation process. The CPARS contractor representative will be given access to CPARS and will be given the opportunity to concur or not-concur with performance evaluations before the evaluations are

complete. The CPARS contractor representative will also have the opportunity to add comments to performance evaluations.

The assessment is not subject to the Disputes clause of the contract, nor is it subject to appeal beyond the review and comment procedures described in the guides on the CPARS website. Refer to: www.cpars.gov for details and additional information related to CPARS, CPARS user access, how contract performance assessments are conducted, and how Contractors participate. Access and training for all persons responsible for the preparation and review of performance assessments is also available at the CPARS website.

The contractor must provide the CDC contracting office with the name, e-mail address, and phone number of their designated CPARS representative who will be responsible for logging into CPARS and reviewing and commenting on performance evaluations. The contractor must maintain a current representative to serve as the contractor representative in CPARS. It is the contractor's responsibility to notify the CDC contracting office, in writing (letter or email), when their CPARS representative information needs to be changed or updated. Failure to maintain current CPARS contractor representative information will result in the loss of an opportunity to review and comment on performance evaluations.

Provide the current CPARS representative information below.

_____
PRINT OR TYPE NAME

_____
EMAIL ADDRESS AND PHONE NUMBER

HHSAR 352.239-73 Electronic and Information Technology Accessibility Notice (Dec 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/standards.htm.

(c) The Section 508 accessibility standards applicable to this contract are: 1194.
205 WCAG 2.0 Level A & AA Success Criteria
302 Functional Performance Criteria
502 Inoperability with Assistive Technology
503 Applications
504 Authoring Tools
602 Support Documentation
603 Support Services

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and documentation detail -

whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://hhs.gov/web/508.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(e) Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at http://508.hhs.gov/, or from the Section 508 Coordinator listed at https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

(End of provision)

SECTION F - EVALUATION CRITERIA

a) The following factors, listed in descending order or importance, will be used to evaluate quotes:

i. Experience
ii. Technical Approach
iii. Staffing and Management Plan
iv. Transition and Succession Plan

(b) Price is an important factor for award; however, the non-price factors above, are more important than price. The Government reserves the right to award the order to a vendor who may not be the lowest in price as quotes will be evaluated on the basis of "best value".

(c) Quoters are encouraged to provide their best prices with the initial quote as award may be made without discussions.

d) Options. The Government will evaluate quotes for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that a quote is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

e) Past performance will be evaluated based on information retrieved from the Past Performance Retrieval System (PPIRS).