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	Title: Expansion of Active Surveillance for Adverse Events amor Recipients of COVID-19 Vaccines for the National Center Emer Zoonotic Infectious Diseases (in response to RFQ 75D30121Q72					1117					
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	 Contracti	ng Officer's Representative:	Fraci Roberts								
	100	SRoberts1@cdc.gov	Tract Hooding								
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		NE3@cdc.gov									1
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UNITED STATES OF AMERICA: CENTERS FOR DISEASE CONTROL AND PREVENTION

Contracting Officer: Germaine Mullins

Signature: _	Kristopher Lemaster -S	Digitally signed by Kristopher Lemaster -5 Date: 2021.06.04 11:19:34 -04'00'
Date Signed	Į <i>,</i>	

***PLEASE REFERENCE EMAIL AUTHORIZATION TO PROCEED DATED APRIL 19, 2021 BY KRISTOPHER LEMASTER

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

	HONE GOTT ELEG ON GENTIGES AND TH			
ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	VAERS V-Safe Call Center Expansion Base Services		(b)(4)	
	Period of Performance: April 19, 2021 through April 18, 2022			
	Time and Materials Type Order (ERR ID 20-15-3893)			
	Severable Services			
	Line(s) Of Accounting:			
	9390GLY 2512 2021 75-2124-0943 C5B8111101 (b)(4)			the state of the s
0002	VAERS V-Safe Call Center Expansion - Backlog		(b)(4)	
	Period of Performance: April 19, 2021 through April 18, 2022			
	Time and Materials Type Order (ERR 1D 20-15-3893)			
	Severable Services			
	Line(s) Of Accounting:			
	9390GLY 2512 2021 75-2124-0943 C5B8111101 (b)(4)			
0003	VAERS V-Safe Call Expansion- Contract Access Fee (CAF)		(b)(4)	
	Period of Performance: April 19, 2021 through April 18, 2022			
	Firm Fixed Price Fee (ERR ID 20-15-3893)			
	Severable Services			
	Line(s) Of Accounting:			
	9390GLY 2512 2021 75-2124-0943 C5B8111101 (b)(4)			

Total for Contract Line Item Number 0001: Total for Contract Line Item Number 0002: Total for Contract Line Item Number 0003: Overall Total for all Contract Line Item Numbers:	(b)(4)
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This is a Time and Materials type task order.

The Contractor shall not exceed the funded amount on this task order. The funded amount covers the period of performance from April 19, 2021 through April 18, 2022. Performance beyond April 18, 2022 without written authorization from the Contracting Officer is at the Contractor's own risk. The Contractor will be paid only for the actual services it provides and that are accepted by the Government.

"HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System."

LABOR CATEGORY BREAKDOWN

The following labor ca	egories and labor rates are applicable to this task ord	er:
	(bVA)	
	(b)(4)	

STATEMENT OF OBJECTIVES

EXPANSION OF ACTIVE SURVEILLANCE FOR ADVERSE EVENTS AMONG EARLY RECIPIENTS OF COVID-19 VACCINES FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES

1. INTRODUCTION

The mission of the Centers for Disease Control and Prevention (CDC) is to save lives and protect people from health threats and respond to these threats when they arise. CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

The Immunization Safety Office (ISO) is vital in ensuring the CDC's mission of vaccine safety by having sound immunization policies affecting children and adults in the U.S. depend on continuous monitoring of the safety and effectiveness of vaccines. CDC uses many strategies to assess vaccine safety, to identify health problems possibly related to vaccines, and to conduct studies that help determine whether a health problem is caused by a specific vaccine. CDC also works with other federal government agencies and other stakeholders to determine the appropriate public health response to vaccine safety concerns and to communicate the benefits and risks of vaccines. The Immunization Safety Office (ISO) monitors vaccine safety, identifies possible vaccine side effects, and conducts studies to determine whether health problems are caused by a specific vaccine. The Immunization Safety Office regularly reports on vaccine safety monitoring findings and any concerns to CDC's Advisory Committee on Immunization Practices (ACIP). This advisory group develops the recommended vaccine schedule for children and adults in the U.S. ACIP considers the safety and effectiveness of vaccines before making recommendations to the vaccine schedule or changing recommendations for vaccine use.

These missions directly address the current coronavirus disease 19 (COVID-19) pandemic. In December 2019, the Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2) emerged in Wuhan, China. This novel coronavirus was identified as the cause of COVID-19. SARS-CoV-2 has since spread worldwide rapidly: as of this writing, almost 103 million cases of COVID-19 and over 2.2 million deaths from COVID-19 have been reported across the earth (https://coronavirus.jhu.edu/). In the 13 months since SARS-CoV-2 was identified in the United States, over 26.1 million cases and over 441,000 deaths from COVID-19 alone have been reported. COVID-19 represents the most dire pandemic humanity has faced since the 1918–1919 influenza pandemic.

Through unprecedented coordination and effort, two COVID-19 vaccines from Pfizer-BioNTech and Moderna are currently in use under FDA Emergency Use Authorization (EUA), with another manufacturer (Jannsen) anticipated to apply for EUA imminently. It is anticipated that up to 3 additional vaccines may be available over the next 6 months in the United States. In addition, all approved vaccines may have expanded recommendations (i.e. children and teens) As vaccinations increase, public scrutiny and concerns about the safety of these vaccines has accelerated beyond any projections or anticipation. Post-approval/licensure vaccine safety monitoring to detect potential safety concerns with COVID-19 vaccines remain paramount and addressing these concerns in a timely manner is key to reassure the general public of the safety of these vaccines.

V-safe, a voluntary smartphone-based health check-in program established to conduct outreach for VAERS for participants who report medically attended symptoms or health conditions. V-safe enrollees receive daily health check-ins for the 7 days following vaccinations, weekly for 6 weeks, and then at 3, 6, and 12 months. The health

check-in restarts once a second dose is administered. Health check-ins inquire about symptoms or health conditions, with additional questions about specific local injection site and systemic reactions in the first week after each dose of vaccine. Enrollees are asked whether they missed work, were unable to do normal daily activities, and/or receipt of care from a medical professional due to reported symptoms or health conditions. Eurollees who report a medically attended symptom or health conditions are contacted by phone from the VAERS call center and a VAERS report is completed, if appropriate. Non-males are asked to report pregnancy at the time of vaccination upon initial health check-in or a positive pregnancy test after vaccination at the 3 and 6 week health check-in.

The participation in v-safe has been robust, exceeding expectations. In the first 45 days, V-safe has enrolled over 2.5 million participants. Because of this overwhelming participation, the need to increase capacity at the v-safe call center is critical. The purpose of this contract is to increase capacity in order to conduct telephone outreach to v-safe participants who report a medically attended symptom or health condition during v-safe check-ins.

2. SCOPE

The Statement of Statement of Objectives (SOO) describes the scope of work, objectives, tasks and resources needed to successfully fulfill the CDC's active surveillance for adverse events among early recipients of COVID-19 vaccines related responsibilities to advance the organization's mission. Through v-safe, CDC will identify participants that require telephone outreach. The contractor shall provide call center services to conduct telephone-based outreach to v-safe participants in order to facilitate reporting of adverse events to the Vaccine Adverse Event Reporting System (VAERS). The contractor shall provide adequate staffing levels in order to meet the task requirements.

3. TASK OBJECTIVES STATEMENT

The overarching objectives of the support described in the SOO are to:

- i. Provide additional contractor staff as part of the v-safe call center to conduct telephone-based outreach to v-safe participants who report a medically attended symptom or health condition.
- ii. Using developed scripts, determine if a VAERS report should be completed. If deemed appropriate, complete a VAERS reports by telephone with the v-safe participant.

4. TASK REQUIREMENTS

The Contractor shall complete the following task requirements:

- Provide additional staff to initiate new calls to 7,500 v-safe participants (hereafter referred to as participant) per week while also conducting follow-up on those for whom initial outreach was not successful. Overtime is allowed.
- The additional contractor staff shall address the backlog of calls since the inception of v-safe and support timely call outreach to the increasing numbers of participants as vaccine distribution expands in the United States.
- iii. Receive smartphone numbers via secure file transfer daily from v-safe of participants who report a medically attended symptom or health condition, including those who are pregnant.
- iv. Contact participants using a "US GOVERNMENT" number (if possible).
- v. Read a script introducing the purpose for the call, confirming the participant reported a medically attended symptom or health condition in v-safe.
- vi. Determine if the participant already submitted a VAERS report and whether they wish to add additional information. If not completed or more information is required, the contractor shall offer to take a VAERS report over the phone and follow established processes for submitting and editing the VAERS report into the VAERS system. If participants prefer not to complete a VAERS report over the phone, the contractor will record the reason (i.e., needs to schedule another time, wishes to self-report later, refuses to report to VAERS). If the participant wishes to self-report later, the contractor will provide instructions to the v-safe participant.
- vii. Be responsible for following established procedures for telephone outreach as noted below in the breakdown of task requirements.

- viii. Provide reporting as described in the breakdown of task requirements.
- ix. Provide meeting materials and notes, facilitation, and administrative support to conduct meetings on an ad hoc basis. The meetings can be held virtually as an alternative to in-person meetings, with method for virtual meeting shall be approved by the Contracting Officer.

BREAKDOWN OF THE TASK REQUIREMENTS

- 1. Conduct initial contact with participant within 3-5 business days.
 - a. If participant does not answer the call and voicemail is available, the contractor will leave a message including call-back information for the call center and available hours.
 - b. If participant does not answer the call and voicemail is not available, the contractor will make at least one more attempt within 5 business days of the original attempt.
 - c. If additional health impacts are received before contact is made with the participant, the contractor can assess multiple health impacts in a single call and determine whether to complete one or more VAERS reports. (An example requiring two reports would be if the first health impact occurred after a first dose and the second health impact was reported after a second dose.)
- 2. Send data elements captured during follow-up with v-safe participants to CDC on a weekly basis in csv format via secure file transfer (i.e. Epi-X). The cumulative dataset will only include information on participants where the outreach has been completed and the call center final outcome is successful or unsuccessful (unable to reach participant). Additional elements can be added on request by CDC. Data elements include:
 - a. participant v-safe id
 - b. health impact survey id
 - e. original vaccine name
 - d. vaccine validation
 - e. updated vaccine name (if original vaccine name is incorrect)
 - f. dose number
 - g. days since vaccination
 - h. health impact reported date
 - i. call center final outcome (successful, unsuccessful)
 - j. successful completion date
 - k. day I contact date
 - day 1 contact outcome (i.e. successful, requested call back, left voicemail, could not reach participant)
 - m. day 2 contact date
 - n. day 2 contact outcome (i.e. successful, request call back, left voicemail, could not reach participant)
 - o. day X contact date
 - day X contact outcome (I.e. successful, request call back, left voicemail, could not reach participant)
 - q. preferred call back date
 - r. preferred call back time
 - s. current VAERS report outcome (inulti-select: completed over the phone, participant prefers to complete VAERS report online, does not with to fill out VAERS report, not applicable (do not need to complete a VAERS report due to accidental reporting or other reason), reported to VAERS voluntarily prior to contractor contact, reported to VAERS during previous contact from contractor, other)
 - t. current VAERS report outcome other specified
 - u. current VAERS report number (if completed by call center)
 - v. previous VAERS report number
 - w. participant does not wish to be contacted again by call center (yes, null)
 - x. new pregnancy identified during call (yes, null)
 - possible issues with report (yes, null)
 - z. comments

- 3. Provide a weekly progress report via email to CDC (pdf format) that documents current week and cumulative numbers. Content and format of report may be modified at request of CDC but the report should describe the following at a minimum:
 - a. Number of health impact events sent to call center for follow-up
 - b. Call center final outcome status (successful, pending, unsuccessful) of health impact events sent to call center for follow-up
 - c. VAERS report outcome of health impact events sent to call center for follow-up:
 - 1. Participant completed VAERS report over the phone with contractor
 - 2. Participant prefers to complete VAERS report online
 - 3. Participant does not wish to fill out VAERS report
 - 4. Participant reported to VAERS voluntarily prior to contractor contact
 - 5. Participant reports to VAERS during previous contact from contractor
 - 6. Not applicable (do not need to complete a VAERS report due to accidental reporting or other reasons)
 - 7. Other
- **4.** Notify CDC on any barriers or challenges to meeting the requirements on a weekly basis; including increased volume of v-safe participants the call center is required to call daily.
- 5. Identify VAERS reports submitted as a result of the contractor's active outreach by using Box 26 of the VAERS report form. Enter the term "vsafe" to identify these reports when completed during a phone interaction with participant

5. DELIVERABLES

The Contractor shall provide the following deliverable(s) on the due date(s) specified in the chart below:

Deliverable(s)	Frequency	Format/No. of Copies	Submit to
Conduct initial contact with the recipient Documentation of initial contact	Within three to five business days		Contracting Officer's Representative
Document and track all follow-up contact with participants	Continuous	Electronic format	Contracting Officer's Representative
Dataset transmission	Weekly (every 7 days)	Epi-X	Data Manager
Progress report	Weekly (every 7 days)	Electronic mail	Contracting Officer's Representative
Email and/or meetings	Weekly (every 7 days) for 1 ^M month, as needed afterward	Electronic mail	Contracting Officer's Representative
Identification of VAERS reports using Box 26 of the VAERS report form	Continuous		Contracting Officer's Representative

^{**}All deliverables fisted above shall be submitted in an electronic format (MS Word, MS Excel, Adobe Acrobat, SAS, or in a PC/IBM compatible format).

6. TYPE OF ORDER

This is a Time and Materials Type Task Order.

7. PERIOD OF PERFORMANCE

The period of performance for this requirement is April 19, 2021 through April 18, 2022.

8. PLACE OF PERFORMANCE

The place of performance is the Contractor's facility.

 RECOGNIZED HOLIDAYS - See CDCA_H037 Observance of Legal Holidays and Administrative Leave on page 25.

10. GOVERNMENT FURNISHED INFORMATION

The Government will provide the script to be read on all telephone calls with identified numbers of individuals.

11. SECURITY REQUIREMENTS/COMPLIANCE

Standard-1: Procurements Requiring Information Security and/or Physical Access Security

A. 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) Information Security Categorization. In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Appendix C, and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality:	Low x Moderate High
Integrity:	Low x Moderate High
Availability:	[] Low [x] Moderate [] High
Overall Risk Level:	[] Low [x] Moderate [] High
Based on information provided by the ISSO, I	Privacy Office, system/data owner, or other security or
privacy representative, it has been determined	I that this solicitation/contract involves:
[] No PII [x] Yes I	PII

Complete this section using the information obtained from the Security and Privacy Checklist in Appendix A, parts A and B.

- 4) Personally Identifiable Information (PII). Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.
 - PII Confidentiality Impact Level has been determined to be: [] Low [x] Moderate [] High
- 5) 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 32 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling" 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 hasis;
 - 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*.
- 6) **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 aoy 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.
- 7) 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).
- 8) **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)*.
- 9) 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.
- 10) Contract Documentation. The Contractor shall use provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.
- 11) 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 <u>FIPS 140-2</u>. The Contractor shall provide a written copy of the validation documentation to the COR.
 - 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).
- 12) 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.
- 13) Privacy Tbreshold 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.
 - a. 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.

- 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), Privacy, 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.
 - **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.

C. 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.

D. 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 an other than authorized purpose.

It further adds:

A breach is not limited to an occurrence where a person other than an authorized user potentially accesses PII 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 PII and portable electronic storage media that store PII, the inadvertent disclosure of PII 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 PII for an other 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.
- 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 no later than 1 hour of discovery, 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 csirt@cdc.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 CDCapproved notifications to affected individuals; and,
- 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.

E. 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.

F. 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.

G. Contract Initiation and Expiration

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 CDC EPC Requirements: https://www2a.CDC.gov/CDCup/library/other/eplc.htm

- 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 closcout 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.

H. 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.

Standard-2: Requirements for Procurements Involving Privacy Act Records

Appropriate security controls and Rules of Behavior should be incorporated to protect the confidentiality of information, proprietary, sensitive, and Personally Identifiable Information (PII) the Contractor may come in contact with during the performance of this contract.

CDC100_0001 Autodialing Agency Requirement

Independently, and not as an agent of the Government, the Contractor shall furnish the necessary services, personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform this contract.

Notwithstanding the preceding sentence, the contractor shall be an agent of the Government for purposes of placing, in accordance with section C of the SOO/statement of work of this Contract, autodialed, prerecorded, or artificial voice calls, or calls made with equipment capable of making autodialed calls. "Calls" includes text messaging. The Government and the Contractor mutually consent to the creation of such agency, and the Government delegates to the Contractor its prerogative to make such calls. Failure to follow the Government's instructions in or under this Contract, or activity outside the scope of the agency hereby created, may deprive the Contractor of any immunities conferred by such agency.

(End of clause)

CDCA_H005 Data Subject to Privacy Act Requirements (Jul 2017)

- (a) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act.
- (b) In accordance with HHSAR Clause 352.224-70, Privacy Act, which has been incorporated into this contract, certain data provided to the Contractor under this contract shall be treated confidentially. The type(s) of data subject to this clause are as follows: Personally Identifiable Information (PII).
- (c) Following are the requirements for handling this data and the disposition to be made of this data upon completion of contract performance: 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.
- (d) The Contracting Officer's Representative (COR) is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.:

(End of clause)

CDCA_H042 Records Management Obligations (Jun 2020)

A. Applicability

The following applies to all Contractors whose employees create, work with, or otherwise handle Federal records, as defined in Section B, regardless of the medium in which the record exists.

B. Definitions

"Federal record" as defined in 44 U.S.C. § 3301, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of

public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them.

The term Federal record:

- 1. includes Centers for Disease Control and Prevention (CDC) records.
- 2. does not include personal materials.
- 3. applies to records created, received, or maintained by Contractors pursuant to their CDC contract.
- 4. may include deliverables and documentation associated with deliverables.

C. Requirements

- 1. Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chs. 21, 29, 31, 33), NARA regulations at 36 CFR Chapter XII Subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.
- 2. In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552a), as amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended and must be managed and scheduled for disposition only as permitted by statute or regulation.
- 3. In accordance with 36 CFR 1222.32, Contractor shall maintain all records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.
- 4. CDC and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Records may not be removed from the legal custody of CDC or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Head of the Contracting Activity. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, Contractor must report to the Contracting Officer and the Contracting Officer's Representative. The agency must report promptly to NARA in accordance with 36 CFR 1230.
- 5. The Contractor shall immediately notify the appropriate Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the contract. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment is properly protected. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Head of the Contracting Activity. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to CDC control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the contract. Destruction of records is EXPRESSLY PROHIBITED unless in accordance with Paragraph (4).
- 6. The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary

material and/or records generated under, or relating to, contracts. The Contractor (and any sub-contractor) is required to abide by Government and CDC guidance for protecting sensitive, proprietary information, classified, and controlled unclassified information.

- 7. The Contractor shall only use Government IT equipment for purposes specifically tied to or authorized by the contract and in accordance with CDC policy.
- 8. The Contractor shall not create or maintain any records containing any non-public CDC information that are not specifically tied to or authorized by the contract.
- 9. The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.
- 10. Training. All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take CDC-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.
- D. Flowdown of requirements to subcontractors
- 1. The Contractor shall incorporate the entire substance of the terms and conditions herein, including this paragraph, in all subcontracts under this contract, and must require written subcontractor acknowledgment of same.
- 2. Violation by a subcontractor of any provision set forth herein will be attributed to the Contractor.

(End of clause)

CDC0_H049 Non-Disclosure Agreement for Contractor and Contractor Employees (Jun 2020)

- (a) The contractor and contractor employees shall prepare and submit Non-Disclosure Agreements (NDA) to the Contracting Officer prior to access of government information or the commencement of work at CDC.
- (b) The NDAs, at Exhibit I and II, are required in service contracts where contractor's employees will have access to non-public and procurement-sensitive information while performing functions in support of the Government. 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, and members of the public (when communication or interaction relates to the contractor's work with the CDC). 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 contractor 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 meetings where sensitive information may be discussed.
- (f) The Contractor shall prepare and maintain a current list of employees working under NDAs 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, positinn, date of hire and NDA requirement.

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] will 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 contractor employees will sign a Non-Disclosure Agreement (NDA) provided by the CDC prior to beginning work for the CDC. Contractor agrees to submit to the Contracting Officer the original signed copies of NDAs signed by the contractor's employees in accordance with the instructions provided by the Contracting Officer. Failure to provide signed NDAs in accordance with this agreement and instructions provided by the Contracting Officer could delay or prevent the employee from commencing or continuing work at the CDC until such agreement is signed and returned to the Contracting Officer.

Contractor further agrees that it will 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. Procorement-Sensitive Information

Contractor further agrees that it will 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), Procurement Requests (PR), and Requests for Proposal (RFP); Responses to RFPs, including proposals, 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 verhal 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 personnel 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 will 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 while 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, and members of the public (when such communication or interaction relates to the contractor's work with the CDC), contractors' employees will identify themselves as an employee of a contractor.
- B. Contractors' employees will 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 will identify themselves as an employee of a contractor.
- **D.** Contractors' employees 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 will 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 Anthorized Representative of Contractor:	
Date:	

Copies retained by: Contracting Officer 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 will 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.

I, [Name of Employee], agree to use non-public information only in performance of my responsibilities to the CDC. I agree further that I will 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 will 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), Procurement Requests (PR), and Requests for Proposal (RFP); Responses to RFPs, including proposals, 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 personnel 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 will 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 while 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 Agreement 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 (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 will 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 will identify myself as an employee of a contractor at the beginning of telephone conversations or conference calls;
- C. I will 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 will 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 Officer, contractor, and Contractor Employee

CLAUSES IN ADDITION TO THE CLAUSES LISTED IN THE GENERAL SERVICES ADMINISTRATION SCHEDULE FOR ALLIANT 2 CONTRACT NUMBER 47QTCK18D0003 FOR GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.

CDC CLAUSE	TITLE AND DESCRIPTION
52.204-15	Service Contract Reporting Requirements
52,204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or
	Equipment (Aug 2019)
52.232-40	Providing Accelerated Payment to Small Business Subcontractors
52.244-6	Subcontracts for Commercial Items (Aug 2019)
HHSAR CLAUSE	TITLE AND DESCRIPTION
352.203-70	Anti-Lohhying (December 18, 2015)
352,224-71	Confidential Information (December 18, 2015)

HHSAR 352.224-70 Privacy Act (December 18, 2015)

This contract requires the Contractor to perform one or more of the following: (a) design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term **system of records** means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in 45 CFR part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)). The contract work statement:

- (a) Identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and
- (b) Specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

HHSAR 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 indennify 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)

HHSAR 352.231-70 Salary Rate Limitation (December 18, 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 website for Federal Executive Schedule salary levels.

(End of clause)

HHSAR 352.239-74 Electronic and Information Technology Accessibility (December 18, 2015)

- (a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at <a href="http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards/comm
- (b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- (c) The Section 508 accessibility standards applicable to this contract are: 1194.

- 302 Functional Performance Criteria
- 502 Inoperability with Assistive Technology
- 504 Authoring Tools
- 602 Support Documentation
- 603 Support Services
- (d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- (e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(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)

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)

CDCA_G011 Voucher/Invoice Submission - Cost Contracts (March 2021)

- (a) Contractor voucher requests for reimbursement shall conform to the form, format, and content requirements of the **Billing Instructions for Negotiated Cost Type Contracts**, made a part of the contract in Section J, as may be supplemented by specific instructions of the Contracting Officer.
- (b) The Contractor shall submit the original contract invoice/voucher in one of the following ways: 1) mail, 2) facsimile, 3) email:

Mailing Address:

The Centers for Disease Control and Prevention Office of Financial Resources (OFR) P.O. Box 15580 Atlanta, GA 30333

Fax: 404-638-5324

Email: cpbapinv@cdc.gov

NOTE: Submit only one Invoice in PDF format per attachment.

- (c) Subject Line must contain the word "Invoice" Example: Subject: Invoice SAM12345 for Contract 75D30121*********
- (d) The content/details of the email must include the below information provided in the body of the email:
 - · Contract or PO Number:
 - Invoice Number:
 - Amount:
 - Vendor Name:

Only one invoice can be sent to the mailbox with the above relevant details in the body (multiple invoices need to be sent in multiple emails)

- (e) The contractor shall submit 2 copies of the invoice/voucher or progress payment information to the cognizant contracting office previously identified in this contract. These invoices/voucher copies shall be addressed to the attention of the Contracting Officer.
- (f) Do not send Links, Zip Files, or DAT files containing PDF Invoices

The Contractor is \boxtimes , is not \square required to provide a copy of each voucher request for reimbursement to the Contracting Officer's Representative (COR).

(g) In accordance with 5 CFR part 1315 (Prompt Payment), CDC's Office of Financial Resources is the designated billing office for the purpose of determining the payment due date under FAR 32.904.

- (h) The Contractor shall include (as a minimum) the following information on each invoice:
 - (1) Contractor's Name & Address
 - (2) Contractor's Tax Identification Number (TIN)
 - (3) Purchase Order/Contract Number and Task Order Number, if Appropriate
 - (4) Invoice Number
 - (5) Invoice Date
 - (6) Contract Line Item Number and Description of Item
 - (7) Quantity
 - (8) Unit Price & Extended Amount for each line item
 - (9) Shipping and Payment Terms
 - (10) Total Amount of Invoice
 - (11) Name, title and telephone number of person to be notified in the event of a defective invoice
 - (12) Payment Address, if different from the information above
 - (13) DUNS + 4 Number
 - (14) Electronic funds transfer (EFT) banking information
- (g) The Contractor shall, in addition to the above requirements, submit a detailed breakout of costs as supporting backup and shall place the following signed Contractor Certification on each invoice/voucher submitted under this contract:

I certify that this voucher reflects (fill in Contractor's name) request for reimbursement of allowable and allocable costs incurred in specific performance of work authorized under Contract (fill in contract number)/Task (fill-in task order number, if applicable), and that these costs are true and accurate to the best of my knowledge and belief.

(Original Signature of Authorized Official) Typed Name and Title of Signatory

CDC0_G018 Payment by Electronic Funds Trausfer (Feb 2018)

- (a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer –System for Award Management, in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.
- (b) In the case that EFT information is not within the System of Award Management, FAR 52.232-34 requires mandatory submission of Contractor's EFT information directly to the office designated in this contract to receive that information (hereafter: "designated office"); see below. The contractor shall submit the EFT information within the form titled "ACH Vendor/Miscellaneous Payment Enrollment Form" to the address indicated below. Note: The form is either attached to this contract (see Section J. List of Attachments) or may be obtained by contacting the Contracting Officer or the CDC Office of Financial Resources at 678-475-4510.

- (c) In cases where the contractor has previously provided such information, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required unless the designated financial institution has changed.
- (d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

The Centers for Disease Control and Prevention Office of Financial Resources (OFR)
P.O. Box 15580
Atlanta, GA 30333
Or Fax copy to: 404-638-5342

(End of Clause)

CDCA_H037 Observance of Legal Holidays and Administrative Leave (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)

CDC37.0001 Non-Personal Services (Jun 2020)

- (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 subcontractors comply with, CDC Policy titled "Contractor Identification and Safeguarding of Non-Public 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.
- (c) The Contractor shall ensure that all of its employees and subcontractor employees working on this contract are informed of the terms and conditions herein. 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 the terms herein shall be included in all subcontracts at any tier.
- (d) The terms and conditions above do not limit the Government's rights under other terms of the contract, including those related to the Government's right to inspect and accept or reject the services performed under this contract.

(End of Clause)

CDC42.0002 Evaluation of Contractor Performance 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]

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)

AMENDMENT OF SOCIOTATI	ON/MODIFICATION	OF CONTRACT		ONTRACT ID CO		1 1 7		
2. AMENDMENT/MODIFICATION NO. 00001	3. EFFECTIVE DATE 08/05/2021	4. REQUISITION/PURCHAS 0GHCVLDE-202			5. PROJECT	NO. (If applicable)		
CODE Centers for Disease Control an (CDC) Office of Acquisition Services 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004		sease Control and Prevention (CDC) disition Services (OAS) Blvd, MS TCU-4						
8. NAME AND ADDRESS OF CONTRACTOR (No., GENERAL DYNAMICS INFORMATION T. 3150 FAIRVIEW PARK DR STE 100 FALLS CHURCH, VA 22042-4504	Dode)	<u>(√)</u>	9B. DATED (Se	ATION OF CONTRACT/ORDER NO.				
CODE 067641597	FACILITY CODE		X ·	75D30121F10933 10B. DATED (See Item 13) 04/19/2021				
11. THIS	ITEM ONLY APPLIES T	O AMENDMENTS OF S	OLI	CITATIONS				
The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.								
12. ACCOUNTING AND APPROPRIATION DATA (I. N/A		ODJETO A TIONIO OE OOK	ITD	ATO/ODDED	20			
IT MODIF	M APPLIES ONLY TO M FIES THE CONTRACT/O	RDER NO. AS DESCRIE	3ED	IN ITEM 14.	·			
(v) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.								
B. THE ABOVE NUMBERED CONTRACT/ORD etc.) SET FORTH IN ITEM 14, PURSUANT TO C. THIS SUPPLEMENTAL AGREEMENT IS EN	O THE AUTHORITY OF FAR 4	3.103(b).	IGES	(such as change:	s in paying offic	ce, appropriation date,		
X IAW FAR 43.103(a) Bilatera	l Modification	ROTHONITT OF.						
D. OTHER (Specify type of modification and authority)								
E. IMPORTANT: Contractor is not,		his document and return		· .				
14. DESCRIPTION OF AMENDMENT/MODIFICATION	ON (Organized by UCF section f	neadings, including solicitation/c	ontrac	t subject matter w	vhere feasible.,)		
Contractor POC: (b)(6) CDC Project Officer: Traci Sinetta Roberts, xct6@cdc.gov, 404.498.0669 CDC OAS: Sarah Turner, KWP9@cdc.gov, 404-498-5613								
Except as provided herein, all terms and conditions of 15A. NAME AND TITLE OF SIGNER (Type or print)		em 9A or 10A, as heretofore cha			ed and in full f	orce and effect.		
(b)(6)		Sarah Turner		Digitally:	signed by Sa	rah H.		
15B. CONTRACTOR/OFFEROR 15C. DATE SIGNED 16B. OMTED STATES OF AMERICATURE -5 16C. DATE SIGNED 16B. OMTED STATES OF AMERICATURE -5 16C. DATE SIGNED 17 August 2021 17 August 2021 18						6C. DATE SIGNED		

NSN 7540-01-152-8070 PREVIOUS EDITION UNUSABLE

SECTION 2

The purpose of this zero-dollar modification is to:

- A. Update language in the Statemnet of Objectives below regarding prioritization of call outreach and correct number of initiated new and backlog call; and
- B. The total task order value remains unchanged at (b)(4)

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

This is a Time and Materials type task order

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	VAERS V-Safe Call Center - Base Services	(b)(4)		
	Period of Performance: July 1, 2021 through April 18, 2022			
	Time and Materials Type Order			
	Severable Services			
0002	VAERS V-Safe Call Center - Backlog	(b)(4)		
	Period of Performance: July 1, 2021 through April 18, 2022			
	Time and Materials Type Order			
	Severable Services			
0003	VAERS V-Safe Call Center - Contract Access Fee (CAF)		(b)(4)	
	Period of Performance: July 1, 2021 through April 18, 2022			
	Firm Fixed Fee			
	Severable Services			

Total for Contract Line Item Number 0001: Total for Contract Line Item Number 0002:			
Total for Contract Line Item Number 000)3:[(b)(4)	7
Overall Total for all Contract Line Item Numbers:	Ш	(b)(4)	

STATEMENT OF OBJECTIVES

Revised 8/5/2021

EXPANSION OF ACTIVE SURVEILLANCE FOR ADVERSE EVENTS AMONG EARLY RECIPIENTS OF COVID-19 VACCINES FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES

1. INTRODUCTION

The mission of the Centers for Disease Control and Prevention (CDC) is to save lives and protect people from health threats and respond to these threats when they arise. CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to dothe same. CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

The Immunization Safety Office (ISO) is vital in ensuring the CDC's mission of vaccine safety by having sound immunization policies affecting children and adults in the U.S. depend on continuous monitoring of the safety and effectiveness of vaccines. CDC uses many strategies to assess vaccine safety, to identify health problems possibly related to vaccines, and to conduct studies that help determine whether a health problem is caused by a specific vaccine. CDC also works with other federal government agencies and other stakeholders to determine the appropriate public health response to vaccine safety concerns and to communicate the benefits and risks of vaccines. The Immunization Safety Office (ISO) monitors vaccine safety, identifies possible vaccine side effects, and conducts studies to determine whether health problems are caused by a specific vaccine. The Immunization Safety Office regularly reports on vaccine safety monitoring findings and any concerns to CDC's Advisory Committee on Immunization Practices (ACIP). This advisory group develops the recommended vaccine schedule for children and adults in the U.S. ACIP considers the safety and effectiveness of vaccines before making recommendations to the vaccine schedule or changing recommendations for vaccine use.

These missions directly address the current coronavirus disease 19 (COVID-19) pandemic. In December 2019, the Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2) emerged in Wuhan, China. This novel coronavirus was identified as the cause of COVID-19. SARS-CoV-2 has since spread worldwide rapidly: as of this writing, almost 103 million cases of COVID-19 and over 2.2 million deaths from COVID-19 have been reported across the earth (https://coronavirus.jhu.edu/). In the 13 months since SARS-CoV-2 was identified in the United States, over 26.1 million cases and over 441,000 deaths from COVID-19 alone have been reported. COVID-19 represents the most dire pandemic humanity has faced since the 1918 -1919 influenza pandemic.

Through unprecedented coordination and effort, two COVID-19 vaccines from Pfizer-BioNTech and Moderna are currently in use under FDA Emergency Use Authorization (EUA), with another manufacturer (Jannsen) anticipated to apply for EUA imminently. It is anticipated that up to 3 additional vaccines may be available over the next 6 months in the United States. In addition, all approved vaccines may have expanded recommendations (i.e. children and teens) As vaccinations increase, public scrutiny and concerns about the safety of these vaccines has accelerated beyond any projections or anticipation. Post- approval/licensure vaccine safety monitoring to detect potential safety concerns with COVID-19 vaccines remain paramount and addressing these concerns in a timely manner is key to reassure the general public of the safety of these vaccines.

V-safe, a voluntary smartphone-based health check-in program established to conduct outreach for VAERS for participants who report medically attended symptoms or health conditions. V-safe enrollees receive daily health check-ins for the 7 days following vaccinations, weekly for 6 weeks, and then at 3, 6, and 12 months. The health

check-in restarts once a second dose is administered. Health check-ins inquire about symptoms or health conditions, with additional questions about specific local injection site and systemic reactions in the first week after each dose of vaccine. Enrollees are asked whether they missed work, were unable to do normal daily activities, and/or receipt of care from a medical professional due to reported symptoms or heath conditions. Enrollees who report a medically attended symptom or health conditions are contacted by phone from the VAERS call center and a VAERS report is completed, if appropriate. Non-males are asked to report pregnancy at the time of vaccination upon initial health check-in or a positive pregnancy test after vaccination at the 3 and 6 week health check-in.

The participation in v-safe has been robust, exceeding expectations. In the first 45 days, V-safe has enrolled over 2.5 million participants. Because of this overwhelming participation, the need to increase capacity at the v-safe call center is critical. The purpose of this contract is to increase capacity in order to conduct telephone outreach to v-safe participants who report a medically attended symptom or health condition during v-safe check-ins.

2. SCOPE

The Statement of Statement of Objectives (SOO) describes the scope of work, objectives, tasks and resources needed to successfully fulfill the CDC's active surveillance for adverse events among early recipients of COVID-19 vaccines related responsibilities to advance the organization's mission. Through v-safe, CDC will identify participants that require telephone outreach. The contractor shall provide call center services to conduct telephone-based outreach to v-safe participants in order to facilitate reporting of adverse events to the Vaccine Adverse Event Reporting System (VAERS). The contractor shall provide adequate staffing levels in order to meet the task requirements.

3. TASK OBJECTIVES STATEMENT

The overarching objectives of the support described in the SOO are to:

- i. Provide additional contractor staff as part of the v-safe call center to conduct telephone-based outreach to v-safe participants who report a medically attended symptom or health condition.
- ii. Using developed scripts, determine if a VAERS report should be completed. If deemed appropriate, complete a VAERS reports by telephone with the v-safe participant.

4. TASK REQUIREMENTS

The Contractor shall complete the following task requirements:

- i. Starting June 7, 2021, provide additional staff to initiate new calls to 11,000 v-safe participants (hereafter referred to as participant) per week while also conducting follow-up on those for whom initial outreach was not successful. Overtime is allowed. Calls will be prioritized to conduct outreach first to v-safe participants under the age of 18 who report any medically attended symptoms or health conditions and those 18 or older who sought care for medically attended symptoms or health conditions in an emergency room/department or hospital setting.
- ii. Starting June 7, 2021, the additional contractor staff shall initiate 14,000 backlog calls per month and support timely call outreach to the increasing numbers of participants as vaccine distribution expands in the United States. Calls will be prioritized to conduct outreach first to v-safe participants under the age of 18 who report any medically attended symptoms or health conditions and those 18 or older who sought care for medically attended symptoms or health conditions in an emergency room/department or hospital setting.
- iii. Receive smartphone numbers via secure file transfer daily from v-safe of participants who report a medically attended symptom or health condition, including those who are pregnant.
- iv. Contact participants using a "US GOVERNMENT" number (if possible).
- v. Read a script introducing the purpose for the call, coofirming the participant reported a medically attended symptom or health condition in v-safe.
- vi. Determine if the participant already submitted a VAERS report and whether they wish to add additional information. If not completed or more information is required, the contractor shall offer to take a VAERS report over the phone and follow established processes for submitting and editing the VAERS report into the VAERS system. If participants prefer not to complete a VAERS report over the phone, the contractor will record the reason (i.e., needs to schedule another time, wishes to self-report later, refuses to report to VAERS). If the participant wishes to self-report later, the contractor will provide instructions to the v-safe participant.

- vii. Be responsible for following established procedures for telephone outreach as noted below in the breakdown of task requirements.
- viii. Provide reporting as described in the breakdown of task requirements.
- ix. Provide meeting materials and notes, facilitation, and administrative support to conduct meetings on an ad hoc basis. The meetings can be held virtually as an alternative to in-person meetings, with method for virtual meeting shall be approved by the Contracting Officer.

BREAKDOWN OF THE TASK REQUIREMENTS

- 1. Starting June 7, 2021, conduct initial contact with participant within 3-5 business days (for 11,000 calls per week).
 - a. If participant does not answer the call and voicemail is available, the contractor will leave a message including call-back information for the call center and available hours.
 - b. If participant does not answer the call and voicemail is not available, the contractor will make at least one more attempt within 5 business days of the original attempt.
 - c. If additional health impacts are received before contact is made with the participant, the contractor can assess multiple health impacts in a single call and determine whether to complete one or more VAERS reports. (An example requiring two reports would be if the first health impact occurred after a first dose and the second health impact was reported after a second dose.)
- 2. Send data elements captured during follow-up with v-safe participants to CDC on a weekly basis in csv format via secure file transfer (i.e. Epi-X). The cumulative dataset will only include information on participants where the outreach has been completed and the call center final outcome is successful or unsuccessful (unable to reach participant). Additional elements can be added on request by CDC. Data elements include:
 - a. participant v-safe id
 - b. health impact survey id
 - c. original vaccine name
 - d. vaccine validation
 - e. updated vaccine name (if original vaccine name is incorrect)
 - f. dose number
 - g. days since vaccination
 - h. health impact reported date
 - i. call center final outcome (successful, unsuccessful)
 - j. successful completion date
 - k. day 1 contact date
 - day 1 contact outcome (i.e. successful, requested call back, left voicemail, could not reach participant)
 - in. day 2 contact date
 - n. day 2 contact outcome (i.e. successful, request call back, left voicemail, could not reach participant)
 - o. day X contact date
 - day X contact outcome (I.e. successful, request call back, left voicemail, could not reach participant)
 - q. preferred call back date
 - r. preferred call back time
 - s. current VAERS report outcome (multi-select: completed over the phone, participant prefers to complete VAERS report online, does not with to fill out VAERS report, not applicable (do not need to complete a VAERS report due to accidental reporting or other reason), reported to VAERS voluntarily prior to contractor contact, reported to VAERS during previous contact from contractor, other)
 - t. current VAERS report outcome other specified
 - u. current VAERS report number (if completed by call center)
 - v. previous VAERS report number
 - w. participant does not wish to be contacted again by call center (yes, null)
 - x. new pregnancy identified during call (yes, null)
 - y. possible issues with report (yes, null)
 - z. comments

- 3. Provide a weekly progress report via email to CDC (pdf format) that documents current week, backlog, and cumulative numbers. Content and format of report may be modified at request of CDC but the report should describe the following at a minimum:
 - a. Number of health impact events sent to call center for follow-up
 - b. Call center final outcome status (successful, pending, unsuccessful) of health impact events sent to call center for follow-up
 - VAERS report outcome of health impact events sent to call center for follow-up:
 - 1. Participant completed VAERS report over the phone with contractor
 - 2. Participant prefers to complete VAERS report online
 - 3. Participant does not wish to fill out VAERS report
 - 4. Participant reported to VAERS voluntarily prior to contractor contact
 - 5. Participant reports to VAERS during previous contact from contractor
 - 6. Not applicable (do not need to complete a VAERS report due to accidental reporting or other reasons)
 - 7. Other
- 4. Notify CDC on any barriers or challenges to meeting the requirements on a weekly basis; including increased volume of v-safe participants the call center is required to call daily.
- 5. Identify VAERS reports submitted as a result of the contractor's active outreach by using Box 26 of the VAERS report form. Enter the term "vsafe" to identify these reports when completed during a phone interaction with participant

5. DELIVERABLES

The Contractor shall provide the following deliverable(s) on the due date(s) specified in the chart below:

Deliverable(s)	Frequency	Format/No. of Copies	Submit to
Conduct initial contact with the recipient – Documentation of initial contact	Within three to five business days		Contracting Officer's Representative
Document and track all follow-up contact with participants	Continuous	Electronic format	Contracting Officer's Representative
Dataset transmission	Weekly (every 7 days)	Epi-X	Data Manager
Progress report	Weekly (every 7 days)	Electronic mail	Contracting Officer's Representative
Email and/or meetings	Weekly (every 7 days) for 1st month, as needed afterward	Electronic mail	Contracting Officer's Representative
Identification of VAERS reports using Box 26 of the VAERS report form	Continuous		Contracting Officer's Representative

^{**}All deliverables listed above shall be submitted in an electronic format (MS Word, MS Excel, Adobe Acrobat, SAS, or in a PC/IBM compatible format).

6. TYPE OF ORDER

This is a Time and Materials Type Task Order.

7. PERIOD OF PERFORMANCE

The period of performance for this requirement is April 19, 2021 through April 18, 2022.

8. PLACE OF PERFORMANCE

The place of performance is the Contractor's facility.

9. **RECOGNIZED HOLIDAYS** – See CDCA_H037 Observance of Legal Holidays and Administrative Leave on page 25.

10. GOVERNMENT FURNISHED INFORMATION

The Government will provide the script to be read on all telephone calls with identified numbers of individuals.