CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

BROAD AGENCY ANNOUNCEMENT (BAA) 75D301-21-R-71738

ISSUANCE DATE: **December 16, 2020**
CLOSING DATE: **January 13, 2021**

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PART I - INTRODUCTION

Authority

The Centers for Disease Control and Prevention (CDC), the Office of Science (OS) issues this Broad Agency Announcement (BAA) under the provisions of FAR 35.016 and FAR 6.102(d)(2) which provides for the competitive selection of research proposals. Contracts that are awarded based on responses to this BAA are as a result of full and open competition and therefore in full compliance with the provisions of PL 98-369, "The Competition in Contracting Act of 1984."

The CDC may award contracts with educational institutions, nonprofit organizations, not for profit organizations, state and local government, and private industry for research and development (R&D) in those areas covered in Part II of this BAA.

Within the meaning of FAR 6.102 and 35.016, this announcement constitutes the government's solicitation for this effort. There will be no other solicitation issued in regard to this requirement. Offerors should be alert for any BAA amendments that may be posted on beta.SAM.gov.

Process

Funding of research within CDC will be determined by funding constraints and research priorities set during each fiscal year. Therefore, those contemplating submission of a white paper are encouraged to contact the CDC BAA technical point of contact as noted below to determine whether the research warrants further inquiry. If the research warrants further inquiry and if funding is available, then submission of a white paper/proposal will be entertained. **For all email inquiries to the Subject Matter Expert Technical POC, please copy the CDC BAA Technical Coordinator as well.**

The following four-step sequence is established for offerors contemplating submission of a white paper or a proposal under this BAA. This sequence allows for an early determination of the potential for interest based on technical merit, applicability to CDC and projected funding. This process is designed to limit offeror and Government expenditure of effort to prepare and review formal proposals for research that may have little chance of being funded.

Step 1 – Email Contact (Technical Dialogue)

Once the BAA is issued, technical dialogue can began. Technical dialogue between the Government and the potential offeror is the first step. The initial point of contact may direct offerors to a specific scientific/technical point of contact based on the topic area and specifics of the proposed research project. The initial contact points for each area of research interest identified in Part II is listed below.

Research Interests	SME Point of Contact (POC)	SME POC e-mail address
Topic #1: Innovative methods for maternal and infant health surveillance		
1.1: Development, piloting, and evaluation of innovative methods, tools, and strategies for maternal and infant health surveillance capable of producing jurisdiction population-based estimates rapidly (<3 months) in up to 2 jurisdictions.	Shanna Cox	CIO8@cdc.gov
1.2: Development, piloting, and evaluation of innovative methods, tools, and strategies to collect longitudinal data for women of reproductive age across the lifespan (e.g., adolescents, pregnancy, postpartum period) in up to 2 jurisdictions.	Shanna Cox	CIO8@cdc.gov
1.3: Development and evaluation of innovative methods, tools, and strategies to increase representation of surveillance system respondents to sampled population of interest (e.g., women with livebirths or still births).	Shanna Cox	CIO8@cdc.gov

1.4 Development, piloting and evaluation of innovative tools, methods and strategies to create multi-level data sets linking individual (e.g. birth certificate, PRAMS, early intervention data, hospital discharge data) and socio-contextual data (e.g., provider and health system characteristics, community-level indicators of social determinants of health, geo-spatial data)	Shanna Cox	CIO8@cdc.gov
Topic #2: Leveraging Technology and Systems to increase enrollment of underserved persons living with diabetes, prediabetes or at high risk for developing type 2 diabetes		
2.1: Leveraging Technology and Systems to Increase Enrollment of Underserved Persons Living With Prediabetes or at high risk for developing type 2 diabetes in National Diabetes Prevention Program (National DPP) Lifestyle Change Programs.	Bryce Smith	Bsmith6@cdc.gov
2.2:Leveraging Technology and Systems to Increase Enrollment of Underserved Persons Living With Diabetes in Diabetes Self-Management Education and Support (DSMES) services.	Bryce Smith	Bsmith6@cdc.gov
Topic #3: Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection and preparedness through the Laboratory Response Network (LRN)		
3.1: Validation and deployment of existing innovative technologies for immediate implementation within the Laboratory Response Network community to detect and characterize existing and novel pathogens that are associated with a biothreat event or could cause a novel EID outbreak and/or public health emergency. Solutions should include a framework for data reporting and analytics necessary for determination of public health action.	Julie Villanueva	Jfv3@cdc.gov
3.2: Develop and evaluate rapid, flexible, and scalable novel technologies for implementation into the Laboratory Response Network to improve the network capability to detect, report, and analyze results for existing and novel pathogens that are associated with a biothreat event or could cause a novel EID outbreak and/or public health emergency. Solutions should include a framework for data reporting and analytics necessary for determination of public health action.	Julie Villanueva	Jfv3@cdc.gov
Topic #4: International Transmission, Colonization, and Prevention of Antibiotic Resistant Pathogens		
4.1: Improved plasmid classification to understand antibiotic resistance epidemiology and ecology	Jason Folster Kaitlin Tagg	bhx1@cdc.gov nnp2@cdc.gov
4.2: Building whole genome sequencing capacity in PulseNet Asia Pacific and Middle East regions to improve detection and surveillance of emerging multi-drug resistant enteric bacteria	Jason Folster	bhx1@cdc.gov
4.3: Estimating the prevalence of antifungal-resistant *Aspergillus fumigatus* in low- and middle-income countries	Shawn Lockhart	gyi2@cdc.gov
4.4: Evaluate the Relatedness of Colonizing Multidrug Resistant Organism Isolates	Rachel Smith	vih9@cdc.gov
4.5: Evaluation of Metrics of Admission Among Patients Colonized with Carbapenem-resistant Enterobacteriaceae (CRE)	Rachel Smith	vih9@cdc.gov
4.6: Assessing Antimicrobial Stewardship Practices Internationally	Fernanda Lessa	dta3@cdc.gov
4.7: Review of Infection Prevention and Control (IPC) Guidelines, Policies, and Practices Implemented in Healthcare Facilities	Elizabeth Bancroft	emb6@cdc.gov
4.8: Development of Operational Guidance for Hospital IPC Committees	Elizabeth Bancroft	emb6@cdc.gov
4.9: Development of a curated international antibiotic resistant gonorrhea specimen bank	Brian Raphael	elx9@cdc.gov
Topic #5: Comparing the effectiveness of different vaccine types against laboratory-confirmed influenza outcomes		
5.1: Compare laboratory-confirmed influenza among older adults (65+years of age).	Lenee Blanton	acy9@cdc.gov
5.2: Compare laboratory-confirmed influenza among adults (18-64 years of age).	Lenee Blanton	acy9@cdc.gov
Topic #6: Monitoring Trends in Healthcare Utilization and Detection of Influenza and Other Respiratory Infections		

6.1: Develop innovative strategies to use electronic data to monitor trends in healthcare utilization and laboratory testing for influenza and other respiratory infections.	Carrie Reed	ggj2@cdc.gov
Topic #7: Advancing vaccines through in-depth virus characterization and by identifying/selecting optimal candidate vaccine viruses		
7.1: Map/define epitopes targeted by human antibodies and develop strategy to rapidly identify and characterize antigenic drift.	John Steel Rebecca Kondor	pdx1@cdc.gov dqy5@cdc.gov
7.2: Exploit new techniques to establish virus neutralization assays to directly antigenically characterize influenza viruses present in human specimens.	John Steel John Barnes	pdx1@cdc.gov fzq9@cdc.gov
7.3: Develop bioinformatics techniques for fitness forecasting to identify virus groups/clades that will predominate in humans 1 year in advance.	Rebecca Kondor	dgy5@cdc.gov
7.4: Create strategy to experimentally identify antigenically advanced influenza A viruses likely to predominate in the human population in future influenza seasons.	Bin Zhou	nmb7@cdc.gov
Topic #8: Genomic sequencing of SARS-CoV-2 to investigate viral evolution, and emergence and spread of infections in communities and populations.		
8.1: Incorporate viral genomic data with host genomic, immunogenetic, serologic, demographic and other relevant data to better understand patient risk factors and clinical outcomes, especially suspected cases of SARS-CoV-2 reinfection or severe clinical outcomes such as multisystem inflammatory syndrome.	Duncan MacCannell	fms2@cdc.gov
8.2: Conduct studies that compare SARS-CoV-2 sequence diversity and viral phylodynamics within and between regions with different public health response timelines and strategies, especially studies that evaluate changes in viral diversity in the context of vaccination campaigns.	Duncan MacCannell	fms2@cdc.gov
8.3: Develop or enhance open source bioinformatic software, databases, and visualization tools that improve the availability, utility and impact of SARS-CoV-2 sequence data in the public domain, and facilitate the use of molecular epidemiology for state and local response activities.	Duncan MacCannell	fms2@cdc.gov
Topic #9: COVID-19 and Evaluating Effectiveness of Respiratory Virus Vaccines		
9.1: Prospective observational cohort study to assess the effectiveness of SARS-CoV-2 vaccines against infection and infectiousness with SARS-CoV-2.	Sharon Saydah	zle0@cdc.gov
9.2: Develop innovative methods, tools and strategies to evaluate effectiveness of influenza and COVID-19 vaccines in preventing laboratory-confirmed illness.	Brendan Flannery	bif4@cdc.gov
9.3:Development and evaluation of innovative methods to estimate the secondary attack rate of respiratory virus-associated illness within a household.	Melissa Rolfes	ydi8@cdc.gov
Topic #10: COVID-19 and Acute otitis media (AOM)		
10.1: Prevalence of nasopharyngeal carriage of common otopathogens and etiology of Acute otitis media (AOM) before and during the COVID-19 pandemic	K. Flemming-Dutra	ftu2@cdc.gov
Topic #11: COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C)		
11.1: Evaluation of Risk Factors for development of MIS-C among those infected with SARS-CoV-2.	Angela Campbell	app4@cdc.gov

Step 2 – Submission of Informal White Paper (Technical Dialogue)

This step is a continuation of the technical dialogue for projects of interest. Submission of a white paper **does not require an explicit request or invitation from CDC**. Offerors may submit a white paper even if there was no technical dialogue with the SME. Additionally, from time to time, the scientific point of contact may request that an offeror submit an informal white paper. The white paper can be **no more than 4 pages in length, all inclusive.** The purpose of the white paper is to facilitate the SME's understanding of the scientific and technical aspects of the

proposed research project. Use of the white paper is intended to determine which efforts are of sufficient scientific and technical merit prior to submission of a formal research proposal as described in Part IV; therefore, informal white papers should not be so lengthy or detailed as to constitute a formal proposal (see Part IV). Informal white papers should contain a Rough Order of Magnitude (ROM) (e.g. "Estimated Cost"). A ROM **is NOT** a full blown business proposal. Instead, it is merely a "statement or a range" that provides a high level estimate of what the offeror believes the project will cost.

NOTE: CDC cannot discuss budget estimates or number of awards expected and cannot review draft white papers prior to submission.

Please note that the Government may use non-Government participants during the white paper review process (See Part III – Use of Non-Government Personnel).

All submitted white papers will undergo an initial review for technical merit and program applicability. **See Part III for specific evaluation criteria.**

NOTE: Once white papers are submitted technical dialogue STOPS!

Step 3 - Submission of Formal Research Proposal

If there is sufficient interest in a proposed research project, the Contracting Officer will invite the offeror to submit a formal research proposal (see Part IV). **During the preparation of the offeror's proposal, technical dialogue may resume.** The purpose of the technical dialogue is to facilitate the Government's understanding of the scientific and technical aspects of the proposed research project. **However, once proposals are submitted, communication between scientific personnel and the technical review team STOPS!**

Please note that the Government may use non-Government participants during the evaluation of the proposals technical section (See Part III – Use of Non-Government Personnel).

Step 4 - Contract Award for Selected Projects

All proposals will receive an initial review (see Part V) and the Contracting Officer will notify the offeror, in writing, whether the proposal will be processed for award. The primary basis for selecting proposals for award shall be scientific/technical merit, importance to agency programs, corporate capabilities, and personnel. Cost realism, reasonableness and fund availability will also be considered to the extent appropriate. Past performance will also be considered. **Any contract resulting from this process will include all standard FAR clauses or the appropriate alternates applicable to the contract type for the proposed project and offeror institution. See Part V for specific evaluation criteria.** The Government has the right to make multiple awards.

NOTE: Projects will be funded as contracts, NOT GRANTS.

Government obligation

Persons submitting white papers and proposals are cautioned that only a Contracting Officer may obligate the Government to any contract involving expenditure of Government funds. **The Government is under no obligation to pay for the cost of for the development of white papers or proposals. Furthermore, there is no commitment on behalf of the Government to fund any proposal.** Contractors are caution that the submission of a white paper and a proposal is submitted strictly on a voluntary bases.

BAA POINTS OF CONTACT

CDC's BAA Technical Coordinator and point of contact is Diana Bartlett, MPH, MPP who may be reached by email at dbartlett@cdc.gov.

Based on the research topic area, CDC has multiple contractual points of contact. The POCs and the research areas they are responsible for is listed below.

Name	Research Topic Area	Email
Mr. Tray Burch	#1, #6	vwa8@cdc.gov
Ms. Latoya Hill	#2	mdx7@cdc.gov
Ms. Jasmine Powell	#3	qes1@cdc.gov
Mr. Ronnie Williams	#4, #7	oga3@cdc.gov
Mr. Tim Williams	#5	tpw8@cdc.gov
Steve Lester	#8, #9	svl3@cdc.gov
Pellumbeshe Hoxhaj	#10, #11	kfx2@cdc.gov

PART II - CDC RESEARCH INTERESTS

Overview

The Centers for Disease Control and Prevention (CDC) works to protect the U.S. from health, safety and security threats, both foreign and domestic. Specifically, CDC works with its partners to monitor health, detect and investigate health problems, conduct research to enhance and implement prevention strategies, develop and promote sound public health policies, promote healthy behaviors, foster safe and healthful environments, respond to current and emerging threats, and

CDC's role as the nation's health protection agency is to operate 24/7 in order to keep people healthy and safe. The agency accomplishes this goal by working to: detect and respond to new and emerging health threats; address the biggest health problems causing death and disability; move science and advanced technology into actions to prevent disease; promote health and safe behaviors, communities and environments; develop leaders by training the public health workforce; and understand the health pulse of the nation.

For this announcement, CDC is requesting white papers for the following areas, which are further described below:

Topic #1: Innovative methods for maternal and infant health surveillance

Maternal and infant health surveillance can be used to monitor the prevalence of maternal behaviors and experiences and assesses progress of health status over time (e.g., Healthy People 2030 targets); investigate emerging issues in the field of reproductive health (e.g. opioid use, effects of COVID-19); and assess impacts of programs and policies aimed at reducing health problems among mothers and babies.

Jurisdiction-based systems of maternal and infant health surveillance, such as the Pregnancy Risk Assessment Monitoring System (PRAMS), use self-reported survey data collected by mixed-mode methods (i.e., mailing, telephone calls). PRAMS is an ongoing multi-jurisdictional maternal and infant surveillance system with current participation by forty-seven states, New York City, Puerto Rico, and the District of Columbia, representing approximately 83% of all U.S. live births. Data collection procedures and instruments are standardized to allow comparisons between states and over time. Respondents are selected through a stratified systematic sample pulled monthly from the vital records (birth certificate or fetal death files) in each participating jurisdiction. PRAMS sampling strategies have been adapted for emergency response activities; for example, for rapid data collection to inform the response to the Zika outbreak in Puerto Rico, a hospital-based sampling strategy was used. Point in time surveys for one year of data collection have been fielded in collaboration with Tribal organizations to collect robust data on Native populations.

To improve accuracy of estimates, representation from source populations is crucial to address nonresponse bias as respondents may vary from respondents in a way that cannot be controlled for with statistical methods.

Development and evaluation of strategies to increase representation of respondents to source population of interest are needed. Researchers may request access to PRAMS data to answer research and programmatic questions of interest to the field of maternal and child health using analytical techniques, such as econometric or epidemiological modeling. However, multi-state research data files available by request from CDC, and included in publications released by CDC for states, must meet a response rate threshold, which has been set at ≥ 55% beginning in 2015. While this threshold incentivizes states to maintain one indicator of representativeness of this data, some populations are still less likely to respond such as mothers who are younger, Black, or of lower educational or socio-economic status. It is unclear whether the addition of a web-based option for response or innovative incentives for survey completion can address differential participation by demographic groups. Information Technology solutions which support modes of data collection without multiple steps of data entry can improve efficiency and reduce burden on grantees. Other federal surveys such as the National Survey of Family Growth (NSFG), perform intensive follow up with a sub-sample of initial non-responders to validate assumptions for statistical weighting.

Internet Panel Surveys are also often used for rapid collection and dissemination of maternal and infant health indicators. For example, the Vanderbilt Child Health COVID-19 Poll conducted from June 5 to June 10, 2020 used the Ipsos Knowledge Panel, a large online research panel created using probability-based address sampling of US households to collect and rapidly disseminate data (October 2020) on how pandemic and mitigation efforts affected the physical and emotional well-being of parents and children in the United States. Internet panel surveys are routinely used to collect and disseminate rapid data on maternal immunization practices. Limitations to generalizability include characteristics of who opts into these panels, with lower representation from hard to reach populations. Lack of jurisdiction-based data and linkage to other sources of information like the birth certificate data impact the utility of these approaches.

Collection of multi-level indicators may further contribute to the robustness of maternal and infant health surveillance. Data on patient-centered outcomes such as respectful care and social context (e.g., participation in home visiting or WIC programs) and system level indicators (e.g., facility characteristics such as Baby Friendly Hospital designation, Perinatal Quality Collaborative participation, and care received in facilities with appropriate levels of maternal and infant care) may allow for multilevel research. Linkages of existing data systems (e.g. Medicaid claims data, birth certificate, PRAMS, early intervention data, hospital discharge data, and community level social determinants of health, such as poverty rates and neighborhood violence) can enhance the ability to answer key questions for multiple stakeholders. Methods for small area estimates for geographic areas smaller than states (e.g., 500 cities, Census Tract) further allow for aligning of contextual community data jurisdictions.

Maternal and infant outcomes are not only influenced by experiences around the time period of pregnancy. Longitudinal cohorts are uniquely poised to answer research question on influences across the lifespan on maternal and infant health. Key reproductive health indicators of interest include preventative care, such as quality and postpartum contraceptive care, chronic condition diagnosis and care, infertility diagnosis and treatment, and pregnancy care utilization and outcomes. Web-based models of longitudinal data collection and follow up, such as the evaluation of the Zika Contraceptive Access Network, demonstrate the feasibility of long-term participant retention.

Addressing these key gaps in maternal and infant health surveillance will inform the Division of Reproductive Health immediate surveillance strategies and improve the ability of data to inform programs and policies that address health inequities.

Innovative methods for maternal and infant health surveillance are needed to include:

1.1: Development, piloting, and evaluation of innovative methods, tools, and strategies for maternal and infant health surveillance capable of producing jurisdiction population-based estimates rapidly (<3 months) in up to 2 jurisdictions.

1.2: Development, piloting, and evaluation of innovative methods, tools, and strategies to collect longitudinal data for women of reproductive age across the lifespan (e.g., adolescents, pregnancy, postpartum period) in up to 2 jurisdictions.
1.3: Development and evaluation of innovative methods, tools, and strategies to increase representation of surveillance system respondents to source population of interest (e.g., women with livebirths or still births).
1.4: Development, piloting and evaluation of innovative tools, methods and strategies to create multi-level data sets linking individual (e.g., birth certificate, PRAMS, early intervention data, hospital discharge data) and socio-contextual data (e.g., provider and health system characteristics, community-level indicators of social determinants of health, geo-spatial data).

Topic #2: Leveraging Technology and Systems to increase enrollment of underserved persons living with diabetes, prediabetes or at high risk for developing type 2 diabetes

Approximately 88 million Americans have prediabetes, nearly 1 in 3 adults. Prediabetes is characterized by blood glucose levels that are higher than normal but not high enough to be diagnosed as type 2 diabetes. People with prediabetes have an increased risk of developing type 2 diabetes, heart disease, and stroke.

The CDC-led National Diabetes Prevention Program (National DPP: http://www.cdc.gov/diabetes/prevention/index.html) is a public/private partnership working to scale and sustain an evidence-based lifestyle change program (LCP) for people with prediabetes to prevent or delay onset of type 2 diabetes. The LCP is founded on the Diabetes Prevention Program research study and subsequent translation studies which showed that making achievable behavior changes helped participants lose 5% to 7% of their body weight and reduced the risk of developing type 2 diabetes by 58% (by 71% for people 60 years and older). The CDC-recognized LCP consists of a minimum of 16 weekly, then a minimum of six monthly group sessions conducted over a year. A trained lifestyle coach facilitates the sessions to guide people in changing their lifestyle and losing weight.

Since the National DPP was launched in 2012, over 1,700 organizations have provided the lifestyle change program to almost 500,000 people at high risk for type 2 diabetes. But with 88 million people living with prediabetes, we need to reach millions of participants to stem the tide of type 2 diabetes.
Given the vast number of people living with prediabetes and the availability of an effective intervention, CDC is seeking the development and evaluation of innovative methods, tools, and strategies to leverage technology to increase enrollment into the National DPP Lifestyle Change Program and Diabetes Self-Management Education and Support (DSMES) services, particularly for underserved populations.

2.1: Leveraging Technology and Systems to Increase Enrollment of Underserved Persons Living With Prediabetes or at high risk for developing type 2 diabetes in National Diabetes Prevention Program (National DPP) Lifestyle Change Programs.

2.2: Leveraging Technology and Systems to Increase Enrollment of Underserved Persons Living With Diabetes in Diabetes Self-Management Education and Support (DSMES) services.

Topic #3: Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection and preparedness through the Laboratory Response Network (LRN)

With more than 120 national, state, and local laboratories, the Laboratory Response Network (LRN) is an integral part of the National Response Framework. The LRN ensures consistent, high confidence results by developing and distributing laboratory assays, offering specialized training, and supporting secure data reporting. In the 20 years since its creation, the LRN has played an instrumental role in boosting laboratory capacity and building a domestic public health infrastructure for response.

In order to maintain response readiness, and to support day-to-day critical, time-sensitive EID testing needs, the LRN is pursuing cutting edge technologies that can strengthen, expand or enhance the LRN's existing capabilities and inform public health policies and decisions. Whether a single suspect case of a novel EID or a

public health emergency, authorities need to know what pathogen is causing illness for a fast response. Rapid, accurate laboratory identification and characterization of pathogens from clinical specimens or environmental samples provides public health authorities the data necessary to deploy subject matter experts, provide appropriate medical countermeasures, facilitate rapid evaluation and tracing of potentially exposed contacts, and communicate potentially lifesaving information to the public as well as decision makers.

CDC is interested in the development and evaluation of innovative methods, tools, and strategies for deployment to the LRN for detection and characterization of existing and novel pathogens that are associated with a biothreat event or could cause a novel EID outbreak and/or public health emergency. The first area of interest is in existing innovative technologies for identification and/or characterization of rare and emerging infectious disease pathogens that can be fully validated, manufactured, and deployed to LRN laboratories within a one- to two-year timeframe. The second area of interest is the development of novel strategies for identification and/or characterization of rare and emerging infectious disease pathogens that may require a longer time period for development, validation, and deployment. All solutions should include plans for automatic and/or simplified data transfer of test results to public health officials.

3.1 Validation and deployment of existing innovative technologies for immediate implementation within the Laboratory Response Network community to detect and characterize existing and novel pathogens that are associated with a biothreat event or could cause a novel EID outbreak and/or public health emergency. Solutions should include a framework for data reporting and analytics necessary for determination of public health action.

3.2 Develop and evaluate rapid, flexible, and scalable novel technologies for implementation into the Laboratory Response Network to improve the network capability to detect, report, and analyze results for existing and novel pathogens that are associated with a biothreat event or could cause a novel EID outbreak and/or public health emergency. Solutions should include a framework for data reporting and analytics necessary for determination of public health action.

Topic #4: International Transmission, Colonization, and Prevention of Antibiotic Resistant Pathogens

4.1: Improved plasmid classification to understand antibiotic resistance epidemiology and ecology
NARMS-CDC is interested in continuing this collaboration by utilizing this newly validated tool to investigate the distribution and diversity of plasmids in international strains of concern .A sequence-based plasmid speciation tool generating discrete clusters of plasmid taxonomic units (PTUs) has recently been published and offers improved granularity for plasmid analysis (Redondo-Salvo et al. 2020. Pathways for horizontal gene transfer in bacteria revealed by a global map of their plasmids. *Nat Commun*, doi:10.1038/s41467-020-17278-2). This tool forms the basis of an existing collaboration between University of Cantabria, Spain and CDC-NARMS (2019 BAA), which is due to end December 2020. Examples include multidrug resistant (MDR) *Shigella sonnei* and extensively-drug resistant (XDR) *Salmonella* Typhi, both responsible for widespread outbreaks domestically and internationally. Understanding plasmid dynamics in these pathogens can help define risk estimates for the emergence and persistence of MDR and XDR strains both regionally and globally.

4.2: Building whole genome sequencing capacity in PulseNet Asia Pacific to improve detection and surveillance of emerging multi-drug resistant enteric bacteria
CDC is interested in developing and improving capacity for WGS in the PulseNet Asia Pacific (PNAP) region and ensuring that data are comparable. This region consists of 14 countries that are actively engaged in transitioning their molecular subtyping techniques to whole genome sequencing (WGS). The main objectives for this project are to:

1. Develop an action plan in collaboration with PNAP members to implement and validate WGS as a subtyping method and tool to monitor emerging antibiotic resistance mechanisms
2. Build laboratory and analysis capacity by providing training and technical assistance for PNAP member countries

3. Launch a pilot project to demonstrate the value of using WGS to characterize emerging MDR enteric bacteria

4.3: Estimating the prevalence of antifungal-resistant *Aspergillus fumigatus* in low- and middle-income countries

The fungal pathogen *Aspergillus fumigatus* is the leading cause of invasive mold infections, which have high mortality rates. Although most patients who develop aspergillosis are immunocompromised, increasing evidence suggests that people with chronic lung disease and severe respiratory viral infections are also at risk of this deadly infection, which are typically acquired by breathing in fungal spores. The primary treatments for A. fumigatus infections are azole antifungals, primarily voriconazole, which have substantially improved survival over the older amphotericin B, a drug known for its severe side effects. However, strains of *A. fumigatus* resistant to azole antifungals have emerged over the last decade that carry specific mutations (known as TR34/L98H and TR46/Y121F/T289A). Many of these strains are resistant to all azole antifungals and have been associated with treatment failure and higher mortality. Several lines of evidence suggest that these resistance mechanisms are linked to use of azole fungicides, which are highly similar to medical azoles, in plant agriculture.

A. fumigatus strains carrying these resistance genotypes have been identified across the world, but much remains unknown about their prevalence in low- and middle-income countries. This topic requests projects that will provide better data on the prevalence of antifungal-resistant *A. fumigatus* in the environment and/or in patients in these settings. Examination of antifungal and fungicide use practices within the region is encouraged but not required.

Methods will include laboratory surveillance. Broth microdilution is optimal but agar plate screening and gradient diffusion (Etest) are acceptable.

Regions: Asia and Latin America. Brazil found their first case recently in Campinas.

4.4: Evaluate the Relatedness of Colonizing Multidrug Resistant Organism (MDRO) Isolates
Evaluate the relatedness of colonizing MDRO isolates (of particular interest CRE, ESBL, MRSA) collected from community dwellers and hospitalized patients in the same catchment area, via whole genome sequencing.

4.5: Evaluation of Metrics of Admission Among Patients Colonized with Carbapenem-resistant Enterobacteriaceae (CRE)
In countries with substantial burden of CRE among hospitalized patients, evaluate how metrics of admission CRE colonization prevalence and prevalence of CRE colonization among already admitted patients can be assessed and tracked to monitor infection prevention and control practices.

4.6: Assessing Antimicrobial Stewardship Practices Internationally
To assess current antimicrobial stewardship practices and needs in multiple institutions in various countries and regions globally to inform targeted interventions to reduce antimicrobial consumption, including:

- Develop survey/assessment tool based on guidance documents from CDC, WHO, and existing literature
- Assess variation in antimicrobial stewardship practices within and across countries
- Understand existing resources, training-level of personnel, daily activities/interventions around antibiotic use surveillance, and perceived needs
- Determine perceived successes/failures of implementation of antimicrobial stewardship interventions

4.7: Review of Infection Prevention and Control (IPC) Guidelines, Policies, and Practices Implemented in Healthcare Facilities
The extent to which IPC guidelines, policies, and practices have been implemented in healthcare facilities is largely unknown for most countries in Latin America. This information is critical to identify gaps, inform interventions, measure the impact of interventions, and develop evidence-based guidance. This proposed project

involves a national survey of healthcare facilities in 2-3 countries in Latin America (*preferably at least one country in Central America and one in South America*) to assess implementation of IPC policies and practices and identify factors associated with guideline implementation.

4.8: Development of Operational Guidance for Hospital IPC Committees
Experiences in a number of East African countries have shown that Hospital IPC Committees, if they exist, are not functional or do not understand what their expected duties are. This project would result in the development of a manual or guidance for the establishment, implementation, and operations of a model IPC committee at a hospital in a LMIC. It would include composition, roles and responsibilities, expected level of authority, interactions with other groups, routine activities (*including data collection and dissemination, IPC observations, interactions with microbiology, pharmacy, and clinicians*), and additional activities based on need (*e.g. inputs on facility renovations for patient flow, building materials, etc.*).

4.9: Development of a curated international antibiotic resistant gonorrhea specimen bank
Development of an international specimen bank representing residual clinical specimens and *Neisseria gonorrhoeae* isolates to validate novel molecular methods and expand testing capacity for detection and characterization of antibiotic resistant gonorrhea cases.

Topic #5: Comparing the effectiveness of different vaccine types against laboratory-confirmed influenza outcomes

Comparing the effectiveness of different vaccine types against laboratory-confirmed influenza outcomes. Vaccines are the primary tool to prevent influenza. CDC seeks to improve the overall preventive benefit of the U.S.'s influenza vaccination program. First-generation standard-dose egg-based inactivated influenza vaccines (sIIV) have been used for many decades. In the past decade, second-generation IIVs with distinctly different immune responses compared with sIIV have been licensed for use including higher antigen dose IIV (HD-IIV), adjuvanted IIV (aIIV), recombinant protein IIV (rIIV), and cell-culture derived IIV (ccIIV). The U.S. Advisory Committee on Immunization Practices has recommended these vaccine products with varying age indications during the 2020-2021 influenza season. However no preferential recommendations exist.

Understanding whether some vaccines offer advantages over others is urgently needed among adults. Several phase III clinical efficacy trials have shown comparative advantages of some of the second-generation vaccines compared with sIIV. Among older adults, studies have compared incidence of laboratory-confirmed influenza-associated illness between those receiving HD-IIV or aIIV vs. sIIV; among younger adults, studies have evaluated rIIV vs sIIV. Also, immunogenicity studies have compared differences in antibody titers between different influenza vaccine types. Some of these studies have found higher performance of second-generation vaccines. However, post-licensure observational comparative evaluations have shown inconsistent findings possibly due to study design related confounding, outcome differences, variations in circulating viruses and vaccine viruses, repeated vaccination, or inadequate power.

In addition, no study has compared laboratory-confirmed outcomes between second-generation egg-based vs. nonegg-based vaccines. Innovative post-licensure evaluations are needed to better understand potential differences and advantages of second-generation influenza vaccines.

5.1: Compare laboratory-confirmed influenza among older adults (65+). CDC seeks to expand the current knowledge base of benefits offered by different vaccine types through creative and innovative methods to compare laboratory-confirmed influenza among older adults randomized to receive different second-generation influenza vaccines over a two-year period. The objectives are to:

- Determine relative vaccine effectiveness against laboratory-confirmed influenza
- Determine impact of prior history of vaccination and type of vaccine
- Determine if sequential order of vaccination is impactful
- Enhance the understanding of cellular immunity after receipt of different vaccine types

5.2: Compare laboratory-confirmed influenza among adults (18-64 years of age). CDC seeks to expand the current knowledge base of benefits offered by different vaccine types through creative and innovative methods to Compare laboratory-confirmed influenza among adults (18-64 years of age) randomized to receive different second-generation influenza or standard dose egg-based inactivated influenza vaccines over a two-year period. The period of interest to CDC is June 2021 to August 2025. The objectives are to:

- Determine relative vaccine effectiveness against laboratory-confirmed influenza
- Determine impact of prior vaccine history and history of prior vaccine type
- Enhance the understanding of cellular immunity after receipt of different vaccine types

Priority will be given to offerors who establish:

- A track record of successful implementation of similar evaluation activities with working-age and older adults;
- Capacity to enroll and maintain large cohorts that include diversity in sociodemographic characteristics while minimizing selection and participation biases;
- Experience designing and implementing surveillance systems to identify acute illness;
- Capacity to collect sera from participants and conduct all steps of specimen processing and management;
- Capacity to collect, process, and recover peripheral blood mononuclear cells;
- Capacity to collect and manage the data required by this effort;
- The overall likelihood that they can initiate and implement the study in a timely manner.
- Offeror's should describe the influenza outcomes they propose will best distinguish the preventive value of alternative influenza vaccines.

Topic #6: Monitoring Trends in Healthcare Utilization and Detection of Influenza and Other Respiratory Infections

Each year, CDC monitors the impact of seasonal influenza and other respiratory viruses in the U.S. population and uses mathematical and statistical models to estimate the broader disease burden from these infections in the population. Not all persons seek medical care for respiratory illnesses, and not all those who do are tested to confirm infection with a specific pathogen. There are a variety of viral and bacterial respiratory illnesses that are clinically compatible with each other, however, complicating diagnosis based on symptoms or clinical findings alone. Laboratory testing for specific pathogens may be more or less common in certain care settings, for different age groups, and at differing levels of disease severity. To account for the incomplete detection of influenza and other respiratory infections through clinical testing in healthcare settings, methods to model the disease burden incorporate age-specific information on healthcare utilization and laboratory testing for respiratory viruses. CDC seeks to explore innovative methods to monitor these factors throughout the year.

6.1: Development of innovative strategies to use electronic data to monitor trends in healthcare utilization and laboratory testing for influenza and other respiratory infections. CDC seeks to explore the use of electronic health information that can be followed on a weekly basis throughout the year to monitor illness rates, the use of health services, laboratory testing, and clinical diagnosis for influenza and other respiratory viruses. Toward this objective, CDC is interested in creative solutions to monitor the following:

- Healthcare visits for different clinical syndromes (e.g., acute respiratory illnesses, specific signs and symptoms, systemic complications or exacerbations of chronic conditions that could be influenced by a respiratory infection, etc.)
    - The ability to stratify on patient characteristics such as age, sex, race and ethnicity.
    - Characterization of the type of provider seen (e.g., telemedicine, outpatient medical clinic, urgent care provider, emergency department, inpatient hospitalizations with and without ICU admission, etc.)
    - Preference for sources that can define an active user base to calculate rates of illness and healthcare visits in addition to counts

- The proportion of patient encounters with laboratory tests performed for influenza and other respiratory viruses and the results of those tests, stratified by patient characteristics such as age group, healthcare setting, clinical syndrome, etc.

- Patient encounters with a clinical diagnosis of influenza or other specific respiratory virus, with or without laboratory testing.
- Consideration will be made to ensuring geographic representativeness across contributing data sources. Respondents should describe the geographic coverage of their system and the smallest geographic scale available for data reporting.

Topic #7: Advancing vaccines through in-depth virus characterization and by identifying/selecting optimal candidate vaccine viruses

Under this Area of Interest, the Virology, Surveillance and Diagnosis Branch (VSDB) in the Influenza Division, NCIRD, CDC is seeking technologies that will advance vaccines through in-depth virus characterization and by identifying/selecting optimal candidate vaccine viruses. Offerors for these VSDB areas of interest should have demonstrated expertise in the proposed techniques/approaches. Additionally the techniques/approaches should have a maturity level that illustrates objectives can be met within 1-2 years of the award. Successful offerors will provide evidence that the proposed plan is achievable, and the product represents a transformative and deployable improvement compared to techniques/approaches currently used for each of the topics below.

7.1: Map/define the epitopes targeted by human antibodies upon infection by contemporary A and B viruses and develop a sustainable strategy to rapidly identify and characterize antigenic drift. Typically, ferrets are immunized with influenza viruses and the antisera is used to antigenically characterize influenza viruses. Reference viruses with specific amino acid substitutions are used to generate many different antisera that are used to characterize co-circulating antigenic variants. However, ferrets don't always produce antisera that effectively differentiates contemporary viruses); the VSDB wants to develop system(s) that use human antibodies generated by natural infection to characterize viruses circulating in our population on an annual basis. For example, respondents may use new technologies to identify/generate human monoclonal antibodies (Mab), which target multiple epitopes on the hemagglutinin. Projects need to be scaled for a 12-24 month period of performance.

7.2: Exploit new techniques to establish virus neutralization assays to directly antigenically characterize influenza viruses present in human specimens. This goal is to exploit new techniques to establish virus neutralization assays to directly antigenically characterize influenza A (H1N1)pdm09, A/(H3N2) and/or influenza B viruses present in human specimens (i.e., avoid need for virus culture). CDC seeks to partner with organizations to develop a sustainable approach, capable of analyzing each specimen with up to 14 different antisera. Grantee(s) will work closely with VSDB to develop rapid nanoscale/microfluidic, or similar, approaches that conserve sera and antigen are optimal. Projects need to be scaled for a 12-24 month period of performance.

7.3: Develop bioinformatics techniques for fitness forecasting. Develop bioinformatics techniques for fitness forecasting to identify virus groups/clades that will predominate in humans 1 year in advance. CDC seeks to partner with organizations to develop and implement. bioinformatics that efficiently predicts optimal vaccine targets for each of the four subtypes/lineages of influenza viruses circulating in humans and would be deployable within VSDB's informatics infrastructure. Projects need to be scaled for a 12-24 month period of performance.

7.4: Create strategy to experimentally identify antigenically advanced influenza viruses likely to predominate in the human population in future influenza seasons. CDC seeks to explore the use of experimental approaches to complement the current vaccine strain selection process, by using human convalescent sera to select antigenic variants from human influenza virus populations. Grantee(s) will work closely with VSDB to identify specific progenitor viruses based on surveillance data. Projects need to be scaled for a 12-24 month period of performance.

COVID-19: The following areas of interest focus on SARS-CoV-2 virus /Coronavirus Disease 2019 (COVID-19).

Topic #8: Genomic sequencing of SARS-CoV-2 to investigate viral evolution, and emergence and spread of infections in communities and populations.

8.1: Incorporate viral genomic data with host genomic, immunogenetic, serologic, demographic and other relevant data to better understand patient risk factors and clinical outcomes, especially suspected cases of SARS-CoV-2 reinfection or severe clinical outcomes such as multisystem inflammatory syndrome.
Studies of SARS-CoV-2 infection that include both viral genomics and detailed host profiling to help define the host-pathogen interface, risk factors that mediate the pathogenic process, and variables that may influence both typical and atypical phenotypes and presentations. Proposals may include the study of rare or unusual outcomes and syndromes (such as MIS-C/MIS-A), investigations of suspected cases of SARS-CoV-2 reinfection, or studies that assess the role of viral genomics and coinfection among specific patient groups, using metagenomics or other broad-based molecular technologies and approaches.

8.2: Conduct studies that compare SARS-CoV-2 sequence diversity and viral phylodynamics within and between regions with different public health response timelines and strategies, especially studies that evaluate changes in viral diversity in the context of vaccination campaigns.
As states implement safe re-open strategies and prepare for large-scale vaccination campaigns, monitoring circulating viruses and patterns of transmission will help adjust the timing and nature of public health prevention and mitigation efforts. Studies that establish sustainable, population-based surveillance of circulating SARS-CoV-2 sequence variants within a state or region, and assess patterns of regional introductions and transmission over time, are of particular interest. Studies that assess changes in circulating viral diversity and characteristics, particularly in the context of vaccine delivery are also strongly encouraged.

8.3: Develop or enhance open source bioinformatic software, databases, and visualization tools that improve the availability, utility and impact of SARS-CoV-2 sequence data in the public domain, and facilitate the use of molecular epidemiology for state and local response activities.
The SARS-CoV-2 pandemic has led to unprecedented viral genomic sequence data sharing from laboratories throughout the world. CDC is soliciting the development or enhancement of open source tools, databases, standards and curation efforts that improve the overall accessibility, quality and usefulness of publicly-shared sequence data in public repositories, such as GISAID EpiCoV and NCBI GenBank and SRA. Data visualization and dashboarding tools that improve the interpretation and reporting of public domain/public access sequence data are encouraged, as are those that facilitate the linking and deduplication of sequence records between public repositories, and simplify association to clinical electronic laboratory reporting and medical records systems. Priority will be given to proposals that facilitate and enable the use of molecular epidemiologic data for state and local investigations and response activities.

Topic #9: COVID-19 and Evaluating Effectiveness of Respiratory Virus Vaccines

CDC seeks to improve the overall preventive benefit of the U.S.'s influenza vaccination program and improve pandemic preparedness, specifically through understanding the role of vaccines in preventing influenza illness. Many studies have described the vaccine effectiveness (VE) of seasonal influenza vaccine formulations against laboratory-confirmed symptomatic and medically attended outpatient influenza illness. Influenza vaccines provide moderate protection against illness requiring outpatient medical visits and inpatient care. In recent seasons, effectiveness of influenza vaccines has varied by illness severity, influenza virus type and subtype or lineage, antigenic match between vaccine and circulating viruses, patient characteristics including age and prior vaccination history. More recently, increasing use of vaccine products with distinct mechanisms of protection are being used with substantial heterogeneity in temporal and geographic usage patterns. This has complicated the evaluation of seasonal influenza VE and urgent efforts are needed for comparative post-licensure evaluations of these products. Through previous collaborations and research efforts, CDC has developed study protocols for assessing VE through observational designs. However, the COVID-19 pandemic has changed the nature of healthcare encounters, including increased use of telemedicine for evaluation of individuals with mild illness, decreased in-person health facility consultations and use of testing centers not directly linked to health facilities or healthcare systems, and resulted in changes in laboratory testing for acute and severe illness. These changes will affect the ability of research institutions to evaluate the effectiveness of both COVID-19 and seasonal influenza vaccines against illness in the outpatient setting. To leverage these experiences and address critical knowledge gaps regarding effectiveness of influenza and COVID-19 vaccines (and future vaccines against other respiratory viruses), CDC seeks partners who can apply innovative and efficient methods to:

- Establish networks of study sites or collaborating institutions in the US that would refine and apply common protocols and case-definitions to facilitate the evaluation of influenza and COVID-19 VE, focusing on the outpatient setting.
- Develop innovative methods, tools and strategies to estimate the effectiveness of seasonal influenza between product types and COVID-19 vaccination to prevent infection and secondary transmission of respiratory viruses in household settings.
- Develop and implement a strategy for collecting blood and respiratory research specimens from patients and household members to facilitate the evaluation of susceptibility to infection and illness, duration of infection and contagiousness and immune responses to infection (e.g., antibody kinetics, correlates of protection, cellular immunity, microbiome differences, proteomics).

While novel approaches and methods are welcome, the use of a test-negative study design for VE and household cohort or case-ascertained study design for household transmission studies and length of the evaluation (12 months) cannot be changed as those are established approaches to evaluate VE and assess household transmission of influenza and SARS-CoV-2. CDC seeks partners to evaluate effectiveness of respiratory virus vaccines for the prevention of acute illness and secondary transmission in household settings.

9.1: Prospective observational cohort study to assess the effectiveness of SARS-CoV-2 vaccines. Understanding SARS-CoV-2 vaccine effectiveness (VE) against infection with SARS-CoV-2, and respiratory and extrapulmonary manifestations, would assist in prioritizing vaccine coverage and in informing public health strategies. Approaches should include a cohort that is nationally representative by age strata, race/ethnicity, and socio-economic status (SES).

- Sites will implement a harmonized protocol that includes consistent enrollment criteria, collection of information on factors potentially influencing VE, weekly syndromic surveillance for COVID-19-like symptoms and vaccination, and respiratory or mucosal sample collection for testing of SARS-CoV-2 (ideally twice weekly).
- Methods for testing for SARS-CoV-2 should include the use of a single, high performing molecular assay for detection of RNA, an ability to estimate viral load (such as by using real time quantitative RT-PCR), and a marker of infectiousness, such as culture of viable virus.
- Molecular screening for respiratory viruses, including SARS-CoV-2, and further evaluation will be considered for participants reporting acute respiratory illness. Additional testing of respiratory or mucosal sample for other respiratory viruses can be considered.
- For participants reporting symptomatic illness, additional clinical information may be collected (e.g. symptom type, illness duration, severity indicators).

- Collection of blood specimens, for serologic and cellular analyses, at enrollment and at additional time points should be considered to support study objectives.
- Additional outcomes can include measures of clinical disease, other clinical diagnoses that could be sequelae of COVID-19 (e.g., endovascular, neurologic, or other sequelae), and healthcare utilization.
- Detailed information on vaccine received, such as manufacturer, lot number, date, number of doses, is necessary.
- Additional information on demographics (age, sex, race/ethnicity, SES, occupation, geographic area), clinical risk factors for severe COVID-19 (e.g. obesity, diabetes), smoking, and preventive behaviors (e.g., wearing a mask, avoiding close contact with non-household members, avoiding attendance in congregate settings).

The cohort should have sufficient sample size to assess primary endpoints/estimates for one or more possible vaccine products with ≥80% power, and by demographic subgroups of age and race/ethnicity and possibly underlying conditions.

Priority will be given to offerors with demonstrated experience in designing, implementing and maintaining large cohorts (including minimizing selection and participation biases and loss to follow-up); capacity to collect biological samples from participants for standardized analysis and uniform testing through a central lab; demonstrated experience providing infrastructure for standardized approaches, data collection and management, blood specimen (including serum/plasma and PBMCs) processing, laboratory analysis and processing, analytical methods, and outcome measures. CDC's needs are primarily focused on US populations. The period of interest to CDC is June 2021 to August 2025.

The primary objective is to assess the effectiveness of vaccines against molecularly-confirmed infection (asymptomatic or symptomatic) with SARS-COV-2. Secondary objectives could include:
- Assess the effectiveness of vaccines against infectiousness of SARS-CoV-2 (during asymptomatic or symptomatic infection).
- Compare, by vaccination status, the duration and load of detectable SARS-CoV-2 RNA and on the duration and viral load of infectious SARS-CoV-2
- Access the vaccine-preventable burden of acute respiratory illness from any cause
- Assess the vaccine-preventable burden of extrapulmonary sequelae of SARS-CoV-2 infection
- Assess serologic and cellular immune correlates of protection against primary and secondary endpoints

9.2: Development of innovative methods, tools, and strategies to evaluate effectiveness of vaccines in preventing outpatient, laboratory-confirmed illness. Innovative approaches will be needed to evaluate both influenza and COVID-19 VE during periods when both viruses circulate. Symptoms of the two viral illness broadly overlap, and persons infected with influenza or SARS-CoV-2 viruses may present for medical attention with the same principal complaints. In contrast to previous studies of influenza VE, systematic testing for more than one virus among patients meeting pre-defined clinical criteria for mild illness (such as the presence of fever, cough or decreased sense of taste or smell) will be required. The test-negative control group of patients may be restricted to those patients that test negative for both influenza and SARS-CoV-2 infection. Innovative molecular assays such as multiplex SARS-CoV-2/influenza A and B RT-PCR may be employed for this purpose. Innovative strategies may also be needed for enrollment of patients with mild illness seeking healthcare remotely, via telemedicine or from testing sites for SARS-CoV-2. In addition, alternative strategies besides respiratory specimen collection may be needed to obtain specimens from all study participants for viral testing.

Improved analytic approaches are needed for addressing the heterogeneity in usage patterns and risk of disease between populations receiving different vaccine products. Efforts to understand these factors as they relate to observational TND are needed. Estimation of influenza and COVID-19 VE will depend upon detailed information to determine vaccination status. This is particularly challenging for determining product type and product specific comparative evaluations. Date(s) of vaccination, number of doses and types of vaccines received will require documentation from a variety of sources, including electronic medical records, state and provider immunization information systems, public health departments, occupational health, pharmacies and non-traditional providers. Parent report or participant self-report of vaccination may be needed to determine the

completeness of electronic data sources but will not by themselves provide sufficient documentation of vaccination status.

9.3: Development and evaluation of innovative methods to estimate the secondary attack rate of respiratory virus-associated illness within a household. CDC seeks to partner with organizations in the development and evaluation of innovative methods to estimate the secondary attack rate of influenza, COVID-19 or other respiratory virus-associated illness within a household, describe factors associated with respiratory virus infection and transmission, and estimate the effectiveness of vaccination against virus transmission. Households provide excellent environments for influenza, SARS-CoV-2, and other respiratory viruses to transmit, as contact among household members is exceptionally high. Various non-pharmaceutical measures, such as home isolation and school closures, have been outlined as methods of to prevent and control the spread of influenza and SARS-CoV-2, not only during pandemics but also during the periods of seasonal circulation. The potential utility and impact of these preventive measures hinge on the dynamics of transmission, especially in households. Innovative approaches will be needed to estimate the secondary attack rate of influenza and other respiratory viral diseases. Case-ascertained household transmission studies, in which patients presenting at healthcare facilities with laboratory confirmed disease are enrolled and their household members are followed for respiratory virus infection, provide a resource-efficient study design to systematically understand the clinical spectrum of viral infection and measure influenza transmission dynamics. Innovative approaches to identify index cases will be needed during the COVID-19 pandemic due to changes in healthcare seeking behavior and collection of respiratory specimens for laboratory confirmation.

Innovative household cohort studies will also be needed to describe the full breadth of naturally acquired influenza infections that occur, largely unrecognized, within the community. Much of our understanding of influenza transmission, its patterns and timing, comes from household-based studies because the household provides a strategic setting to track influenza infections among close contacts of cases. In a home, the denominator is well-defined, exposure is similar, and follow-up of household contacts is feasible. Household studies can provide useful information about the range of clinical presentations of influenza, including the risk of asymptomatic and symptomatic influenza, and how that varies by age, influenza virus type and subtype, influenza vaccination, influenza antiviral treatment, and other covariates. Collection of respiratory specimens is required from all household studies to explore emerging questions about the evolution and transmission of influenza genetic diversity. Blood collection may also be considered to study natural and vaccine-induced immunity and immune responses to infection.

Topic #10: COVID-19 and Acute otitis media (AOM)

Otitis media is a group of inflammatory diseases of the middle ear. Acute otitis media (AOM) is an infection of rapid onset that usually presents with ear pain. The cause of AOM is related to childhood anatomy and immune function. Either bacteria or viruses may be involved. Risk factors include exposure to smoke, use of pacifiers, and attending daycare. A number of measures decrease the risk of otitis media including pneumococcal and influenza vaccination, breastfeeding, and avoiding tobacco smoke.

10.1: Prevalence of nasopharyngeal carriage of common otopathogens and etiology of Acute otitis media (AOM) before and during the COVID-19 pandemic. AOM is the most common reason children receive antibiotics in the United States. Streptococcus pneumoniae, Haemophilus influenzae, and Moxerella catarrhalis are the three most common bacteria that cause AOM. New higher valency pneumococcal conjugate vaccines are expected to be licensed in the next few years and have the potential to reduce incidence of pneumococcal AOM, including disease resistant to commonly prescribed antibiotics. Understanding of the vaccine preventable burden of AOM is important to inform vaccine policy decisions. Early evidence from Massachusetts indicates that AOM decreased substantially in children once social distancing and school closures were implemented due to the COVID-19 pandemic (Hatoun J et al. Social Distancing for COVID-19 and Diagnoses of Other Infectious Diseases in Children. Pediatrics. 2020 Oct;146(4):e2020006460. doi: 10.1542/peds.2020-006460. Epub 2020 Sep 2.). It is unknown how often COVID-19 infection co-occurs with AOM and the role the COVID-19 pandemic has played in the etiology of AOM. Understanding the impact of the COVID-19 pandemic on nasopharyngeal carriage of common otopathogens and on the etiology of AOM is important to inform treatment

guidelines and vaccine policy in the coming years. This project would aim to assess the prevalence of nasopharyngeal carriage of common otopathogens, including Streptococcus pneumoniae, Haemophilus influenzae, and Moxerella catarrhalis, and etiology of AOM before and during the COVID-19 pandemic and to assess patterns of co-infections of COVID-19 and AOM in young children.

Topic #11: COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C)

MIS-C is a condition where different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. We do not yet know what causes MIS-C. However, many children with MIS-C had the virus that causes COVID-19, or had been around someone with COVID-19. As of October 14, 2020, ~1,100 confirmed cases of MIS-C have been reported by health departments to CDC national surveillance from 44 states, New York City, and Washington, DC.

11.1: Evaluation of Risk Factors for MIS-C through the development of prospective case-control study to identify potential host, environmental, and viral risk factors for development of MIS-C among those infected with SARS-CoV-2. It is not clear why certain children and young adults develop MIS-C, although it appears that the significant systemic inflammation is linked to antecedent SARS-CoV-2 infection. It has been hypothesized that a post-infectious dysregulated immune response is causing this condition. Understanding why some children and young adults with SARS-CoV-2 infection develop MIS-C and others do not will help with targeting prevention and treatment strategies for those at highest risk. We hypothesize that MIS-C is associated with SARS-CoV-2 infection, but that there may be additional host, environmental, or viral risk factors that contribute to the development of MIS-C. CDC has developed a draft study protocol and tools including parent interviews to perform a prospective case-control study to elucidate risk factors for MIS-C. Due to the complicated nature and evolving understanding of MIS-C, this innovative approach to understanding risk factors would improve our understanding of MIS-C. To address this critical knowledge gap, CDC seeks partners who can apply efficient and novel methods to:

- Establish new network of tertiary care pediatric hospitals (or build upon existing networks) in the U.S. that would refine and apply common protocol to identify possible host, environmental and viral risk factors for MIS-C.
- Develop efficient and novel methods to enroll cases of MIS-C and identify and enroll SARS-CoV-2-positive controls matched by age brackets who are not hospitalized for COVID-19 and do not develop MIS-C; conduct medical record abstraction and interviews of parents/guardians of cases and controls regarding potential risk factors (e.g., medical history including vaccination history, family history, symptoms/severity of acute COVID-19 illness, medications, household risk factors).
- Develop a strategy to collect stored or salvaged respiratory specimens from cases and controls for additional virologic characterization to evaluate viral risk factors for MIS-C.
- Develop innovative methods and tools to characterize long-term outcomes and clinical sequelae of MIS-C, and risk factors for prolonged and/or severe sequelae, through medical record review, parent interview(s) and/or electronic survey(s).

PART III - WHITE PAPER SUBMISSION

Steps 1 and 2 provide for technical interchange prior to the submission of a formal proposal. Any questions or clarification of project objectives or methods may be directly discussed between the Government technical representatives and the potential offerors during the Technical Dialogue. The purpose of the Technical Dialogue is to obviate excessive expenditure of resources for projects that do not warrant consideration based on insufficient technical merits or funding limitations.

Use of Non-Government Personnel

Offerors are hereby notified that non-Government participants may have access to the offerors' white papers and that providing a white paper shall constitute consent to the disclosure of proprietary information to all non-Government participants in the white paper review process. The non-Government participants are employees of commercial firms under contract to the Government and they will be authorized access to only those portions of the white paper and discussions that are necessary to enable them to provide specific technical advice on specialized matters or on particular problems, and for tracking and recording purposes. All non-Government participants have executed a Certificate of Non-Disclosure.

WHITE PAPER EVALUATION CRITERIA

White papers will be reviewed to determine if the proposed effort supports the research interest identified in Part II of this BAA. White papers will be evaluated by a technical review team using the following criteria:

- Technical Merit (Novelty, Impact, Scientific Rigor)
- Program Applicability (Priority, Gap)
- Timeframe Feasibility (Risk, Experience, Resource)

Offerors receiving a **favorable review** of their white paper will be requested to submit a formal proposal. Offerors receiving an **unfavorable review** of their white paper will not receive a request to submit a formal proposal. To be eligible for award a white paper must be submitted.

Upon completion of white paper evaluations, offerors will be notified whether or not their white paper was favorably received. Favorable review of a white paper does not constitute selection of the proposed effort for contract award and will not establish a binding commitment for the Government to fund the effort in whole or in part.

The Government will not offer debriefs to offerors whose white papers are deemed unfavorable.

WHITE PAPER FORMAT AND CONTENT

Each white paper must adhere to all of the following requirements and should be no more than 4 pages (all inclusive) in length per subtopic area. The email subject line for the white paper shall include research topic number and subtopic title.

- White Paper must be written in the following format:
    a. Font size: 12-point, unreduced
    b. Single-spaced
    c. Paper size: 8.5 by 11 inches
    d. Page Margin Size: One inch
    e. Printed only on one side of page
    f. Descriptive Title of the Proposed Project
    g. BAA Number

- White paper submissions shall be unclassified.

- Project description addressing in sufficient detail the characteristics identified in **Part II.** The offeror may submit an individual white paper for any or all of the topic areas under Part II.

- Point of contact.

- A rough order of magnitude (ROM) cost estimate to implement the research effort.

- An estimated timeline to complete the project.

WHITE PAPER SUBMISSION

This BAA is open and in effect for 28 days from the date of release **(December 16, 2020 through January 13, 2021). THIS IS AN IMMEDIATE CALL FOR WHITE PAPERS.** Prior to submission of a white paper offerors are strongly encouraged to contact the CDC BAA technical point of contact for the research topic/subtopic of interest. White papers must be received electronically by 3:00 PM EST for **January 13, 2021** in order to be considered for further evaluation. White papers should be submitted electronically to the mailbox at oadsbaaprojects@cdc.gov with a copy to the BAA Technical Coordinator, Diana Bartlett at dbartlett@cdc.gov, and with a copy to Dr. Mim Kelly at Mkelly2@cdc.gov.

***Please allow adequate time for your submission to get through the CDC firewall. We highly recommend allowing 5 or more minutes for this process. All white papers received after the 3:00 p.m. deadline will not be considered for review**

PART IV - PROPOSAL PREPARATION AND SUBMISSION

General Information

This section is intended to provide information needed in preparing research proposals for submission to CDC. Proposals submitted under this BAA must contain technical, administrative, cost, and other supporting information as described below.

Most of the information needed to prepare a proposal will be found within this section. Blank proposal forms are included in Part VI and are designed to provide the required information needed for contracting purposes. Use of the enclosed proposal forms will expedite award of the research contract.

All proposals should include the information specified in this announcement in order to avoid delays in evaluation.

CDC encourages nonprofit organizations, educational institutions, small business, small disadvantaged business concerns, HubZones, Service-Disabled Veteran-Owned Small Businesses (SDVOSBS) and Woman Owned Small Businesses (WOSB) concerns to submit white papers for consideration.

This announcement is an expression of interest only and does not commit the Government to reimburse any proposal preparation cost for responding. The cost of the proposal preparation in response to this announcement is not considered an allowable expense to the normal bid and proposal indirect costs as specified in FAR 31.205-18. Any request for white paper or submission of a full proposal does not guarantee award. The Government reserves the right to cancel this requirement at any time and shall not be liable for any cost of proposal preparation or submission.

Any contractual questions concerning the preparation or content of the research proposal should be directed to:

Name	Research Topic Area	Email
Mr. Tray Burch	#1, #6	vwa8@cdc.gov
Ms. Latoya Hill	#2	mdx7@cdc.gov
Ms. Jasmine Powell	#3	qes1@cdc.gov
Mr. Ronnie Williams	#4, #7	oga3@cdc.gov
Mr. Tim Williams	#5	tpw8@cdc.gov
Steve Lester	#8, #9	svl3@cdc.gov
Pellumbeshe Hoxhaj	#10, #11	kfx2@cdc.gov

Eligibility

To be eligible for award of a contract, a prospective contractor (except other Governments, including State and Local Governments) must meet certain minimum standards pertaining to financial resources, ability to comply with the performance schedule, prior record of performance, integrity, organization, experience, operational controls, technical skills, facilities, and equipment.

Post-Employment Conflict of Interest

There are certain post-employment restrictions on former federal officers and employees, including special Government employees (Section 207 of Title 18, United States Code). If a prospective offeror believes that a conflict of interest may exist, the situation should be brought to the attention of the Contracting Officer before time and effort is expended in preparing a proposal.

Restrictive Markings on Proposals

Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes shall:

(a) Mark the title page with the following legend: "This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed -- in whole or in part -- for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of -- or in connection with -- the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets];" and

(b) Mark each sheet of data it wishes to restrict with the following legend: "Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal."

All offerors should also complete the Research Proposal Cover Page Attachment (1) and should complete the statements of Attachment (2) indicating their preference for release of information contained in proposals and their understanding of the policy regarding evaluation of the proposals.

The offeror is cautioned, however, that portions of the proposal may be subject to release pursuant to the Freedom of Information Act, 5 U.S.C. 552, as amended.

Reporting Requirements

The contractor will provide a quarterly summary of monthly conference calls. Quarterly Progress reports should include detailed descriptions of activities conducted during the previous quarter, planned activities for the upcoming next three months, and a section on challenges or barriers to meeting timelines and completing tasks, and how the contractor has already or plans to overcome these challenges.

Non-U.S. Citizen Participation

If the proposed research (or a portion of the proposed research) requires access to critical technology, sensitive unclassified information, For Official Use Only material, or intelligence material, non-U.S. citizens may participate in the resultant contract (or portion of the resultant contract) **only** if special written permission is granted by the Contracting Officer. The Contracting Officer will require the review and concurrence of the CDC Foreign Disclosure Officer (FDO) before granting this permission.

If the proposed research (or a portion of the proposed research) requires access to classified information (i.e., confidential or secret), non-U.S. citizens may participate in the resultant contract (or portion of the resultant contract) only if a Limited Access Authorization (LAA) is granted. A LAA can be granted only in the event that there are no U.S. citizens that can perform the effort. Granting of LAAs is not anticipated under this Broad Agency Announcement.

If any non-U.S. citizen requires access to CDC buildings, or other Government facilities, special written permission must be requested and obtained from the Contracting Officer and Security Officer through the

resultant contract's Technical Point of Contact. Requests shall specify purpose, duration, frequency, and location (specific room, lab, etc.).

Period of Performance

The period of performance will be based on the research project. This BAA will include a proposed period of performance which may be negotiated later. In the past, projects have had a period of performance of 12- 24 months or have included options.

Contract Types

For this BAA, offerors can propose firm-fixed price or cost reimbursement [cost plus fixed fee, cost (no fee)].

The contract type should be based on the offerors risk associated with performing the research. As a reminder, per FAR 16.301-3(a)(3), offerors proposing a cost type contracts must have an approved accounting and purchasing system in order to receive a cost contract award. As a result, if proposing a cost type contract, please submit documentation of the approved accounting system along with the proposal.

Cost Certification

Per FAR 15.403-4, certified cost and pricing data are required for offers exceeding $750,000.00 total value. As a result, a Certificate of Current Cost or Pricing Data, in the format specified in FAR 15406-2, shall be submitted along with the offeror's proposal if the work is projected to exceed $750,000.00.

Funding

- Fiscal Year Funds: 2021
- Approximate Total Funding: $30,000,000.00 (This amount is an estimate, it is not intended to be a ceiling, and is subject to availability of funds.)
- Topics 1-4 - Anticipated Award Date: June/July, 2021
- Topics 5-11 – Anticipated Award Date: March/April, 2021
- Period of Performance: TBD (Based on the research project)
- Estimated number of awards: Multiple

Proposal Submission

To be considered for award, an offeror must have submitted a white paper which was favorably reviewed by CDC. Offeror will then be formally notified by the Contracting Officer to submit a formal proposal. The Request for Proposal (RFP) will identify a due date for submitting the proposal. The offeror must follow the proposal submission guideline as identified in this section and the Request for Proposal (RFP) letter.

Follow-On Contracts

A proposal for continuation of a given research project will be considered on the same basis as proposals for new research. The proposal should be submitted sufficiently in advance of the termination of the existing contract so that if it is accepted, contract performance may be continued without interruption.

Proposal Copies

Offerors shall submit copies of their proposal as follows:

Proposal Section	Electronic
Technical Proposal	One
Administrative Proposal	One

Timeline and Cost Proposal	One

All electronic documents electronic must be in a format compatible with Microsoft Office 2016.

PROPOSAL PREPARATION INSTRUCTIONS

The proposal is the only vehicle available to the offeror for receiving consideration for award. The proposal must stand on its own merit; only information provided in the proposal can be used in the evaluation process leading to an award. The proposal shall be prepared simply and economically, providing straightforward, concise delineation of capabilities necessary to perform the proposed work. The technical proposal must be accompanied by a fully supported cost proposal as cost and technical considerations are reviewed simultaneously.

Each proposal shall be submitted under cover of Attachment (1) and shall contain three distinct sections. The first section shall contain the technical approach. The second section shall contain contractual information, certifications, and other documentation. The last section shall contain a breakdown of the anticipated costs.

Section I - Technical Section Contents

The nature of the effort to be performed will determine its acceptability for award under this BAA. Proposed efforts shall be scientific in nature and explore innovative public health practicing concepts. The Technical Section shall contain the following:

Technical Proposal – Limited to 10 Pages

a. **Cover Page**: The cover page shall include the BAA Number, research topic and reference number, name and telephone number for the principal points of contact (both technical and contractual), and any other information that identifies the proposal. The cover page shall also contain the proprietary data disclosure statement, if applicable. **The cover page shall not count as part of your technical proposal page limit.**

b. **Table of Content:** It is highly recommended that the Offeror prepares a table of contents and use it for a final quality-control checklist. **The table of content shall not count as part of your technical proposal page limit.**

c. **List of Illustrations/Tables:** This list is a quick reference of charts, graphs, and other important information. A separate list of Tables is recommended. **List of illustrations/tables shall not count as part of your technical proposal page limit.**

d. **Executive Summary:** The executive summary allows the offeror to present briefly and concisely the important aspects of its proposal to key management personnel. The summary shall present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core issues of the proposed program. **The Executive Summary shall not exceed two pages and shall not count as a part of your technical proposal page limit**.

e. **Technical Approach:** In this section, the Offeror shall provide as much technical detail and analysis as is necessary or useful to support the technical approach they are proposing. One must clearly identify the core of the intended approach. It is not effective to address a variety of possible solutions to the technology methodological problems.

(1) **Technical Discussion:** No technical approach is without its limitations or shortcomings. Every issue shall be identified and compared with the successes/failures of previous approaches. A tradeoff analysis is a good way to make this comparison and shall be supported by theory, modeling, experimental data, or other sound scientific practices. If the offeror has a "new and creative" solution to the problem(s), that solution shall be developed and analyzed in this section. The preferred technical approach shall be described in as much detail as is necessary or useful to establish confidence in the approach.

(2) **Technical Program Summary:** This section summarizes the above technical discussion in an orderly progression through the program, emphasizing the strong points of the proposed technical approach.

(3) **Potential Contribution:** Discuss the potential contribution to research programs relating to CDC initiatives, including the topic areas of interest

***In addition to the information above, your response in this area shall also focus on the information provided in Part II of this BAA.**

(4) **Risk Analysis and Alternatives:** Every technical approach has its limitations and shortcomings. The proposal evaluator(s) will formulate a risk assessment and it is in the best interest of the Offeror to have its own understanding of the risk factors presented. Critical approaches shall be identified along with their impact on the overall program as well as fallback positions that could still improve on existing approaches.

(5) **References**: Any good technical discussion must present the basis for and reference the findings cited in the literature.

f. **Special Technical Factors:** In this section, the Offeror shall describe any capabilities it has that are uniquely supportive of the topic areas described in Part II of this BAA. The following subparagraphs are offered as possible areas to be addressed:

(1) Capabilities and Relevant Experience of the staff
(2) Previous or Current Relevant Public Health Practices
(3) Identification of well-defined statistical principles and methods as applied to prediction and modeling techniques for public health, and
(4) Information on facilities/resources that will be used to accomplish the proposed effort and an explanation of why they are adequate to conduct a successful program.

g. **Schedule**: The schedule represents the Offeror' s commitment to perform the program tasks in an orderly, timely manner.

(1) **Time Line Chart by Task:** Each major task identified in the SOW must appear as a separate line on the program schedule. Planned meetings, such as kick-off, presentations (including final), Technical Interchange Meetings, etc., must be included in the time line. The time line must also indicate the anticipated meeting site.

h. **Program Organization:** In this paragraph, the Offeror shall present its organization's ability to conduct difficult technical programs. Any pertinent or useful information may be included in this paragraph, but a minimum recommended response shall address the following subparagraphs:

(1) **Organizational Chart(s) with Key Personnel**: Include prime contractor and subcontractor organization charts, principal investigator (PI), and additional key staff who are involved in this project

(2) **Management and Technical Team:** This shall specifically identify what tasks will be performed by which party and why each subcontractor, if any, was selected to perform its task(s).

(a) Prime Contractor Responsibilities
(b) Subcontractor(s) Responsibilities
(c) Consultant(s) Responsibilities

(3) **Resumes of Key Personnel:** Key personnel are those skilled, experienced, professional and technical personnel essential for successful accomplishment of the proposal objectives, such as the principal investigator, team leader, etc. Information regarding the qualifications, capabilities, and experience of the proposed key personnel shall be addressed. Include the resumes of the prime contractor, subcontractor, and consultant personnel to include the names, brief biography, and list of recent publications of the offeror's key personnel. Documentation of previous work or experience in the field of the proposer is especially important. **Resumes shall not exceed 2 pages and shall not count as a part of your technical proposal page limit**

i. **Appendix(es):** Appendices may include technical reports, published papers, and referenced material. A listing of these reports/papers with short descriptions of the subject matter is usually adequate. Do not provide commercial product advertising brochures; these are unwanted.

Offeror's Statement of Work (SOW)- No page limit

a. It is the intent of the Government to use the Offeror' s SOW, as written, provided that the Offeror' s SOW accurately describes the work to be performed, is enforceable, and is void of inconsistencies. If, in the Government's opinion, the Offeror's SOW does not reflect these requirements, the Government will prepare a SOW using information available in the offeror's proposal; this process may delay the award.

b. **The SOW shall be a separate word document that is a distinct part of the proposal. Do not include any proprietary information in the SOW. To ensure all technical proposals receive proper consideration, the Government requires that the SOW format below be strictly adhered to.**

c. Below is the required format for the SOW. Begin this section on a new page with the Title of the Project at the top of the page. Start your SOW at Paragraph C.1.

STATEMENT OF WORK

C.1 Background and Need – (*Describes the requirements in general, non-technical terms. This section should explain why the acquisition is being pursued and how it relates to past, current, or future projects. Include a summary of statutory program authority and any regulations that are applicable. If any of the techniques have been found to be tried and been found to be effective, they should be included here.)*

C.2 Project Objective – (*A succinct statement of the purpose of the acquisition. It should outline results that the Government expects and may also identify the benefits to the program that is contemplated.)*

C.3 Scope of Work – (*An overall, non-technical description of the work to be performed. It expands on the projected objectives, but does not attempt to detail all of the work required. It must be consistent with the detailed requirements.)*

C.4 Technical Requirements – (*Spells out precisely what is expected of the contractor in the performance of the work.*

- *Describes the specific tasks and phases of the work*
- *Deliverables to be generated from the described tasks must be clearly defined*
- *Specifies the total effort each task or phase is to receive*
- *Considerations that may guide the contractor in its analysis, design, or experimentation on the designated problems*
- *Identifies the requirements and indicates the scope of each)*

C.5 Reporting Schedule – *(Describes any reporting requirements including content and format.)*

C.6 Special Considerations – *(Information that does not fit neatly or logically into one of the other sections. For example, it may be used to explain any special relationships between the contractor and other contractors working for the government.)*

C.7 Government Furnished Property

C.8 Travel – *Describes any travel that is projected to take place during the period of performance. Travel may include in-person kick-off meetings or final meetings, attendance at conferences, travel to present deliverables, etc.*

C.9 References – *(Describes any reference materials that may be relevant to the work being performed.)*

Deliverables – *(Defines and describes the deliverables, the quantity required, the recipient(s), and the schedule should be attached to the SOW.*
NOTE: Deliverables included in Deliverables table must correspond to the tasks outlined under "Technical Requirements"

Section II - Administrative Section Contents – No page limit

This portion of the proposal shall contain the completed certifications and applicable forms contained in this BAA and shall include the following:

Contract Type

Identify the type of completion contract proposed. (**Note**: Offers proposed on a cost-reimbursement basis **MUST** contain evidence that the offeror' s accounting system is approved for such type contracting; i.e., provide identification of audit agency and dates last accounting and estimating system audits were performed. If approval was not obtained before submission of the proposal, the proposal shall address how the offeror will obtain the required approvals. Evidence of an approved accounting system **MUST** be obtained prior to contract award.)

Environmental Considerations

Discuss all applicable environmental and energy conservation objectives associated with the acquisition (see FAR Part 23), the applicability of an environmental assessment or environmental impact statement (see 40 CFR 1502), the proposed resolution of environmental issues, and any environmentally-related requirements to be included in the resultant contract.

Organizational Conflicts of Interest

Identify any members of the offeror's organization or team with potential conflicts of interest. Possible conflicts of interest include any people with prior federal employment, including employment of the Principal Investigator as a special Government employee (duties, agency with whom employed, dates of employment) within two years from the date of proposal submission. If none, so state.

Disclosure Requirement

Completion of Attachment (2) is prerequisite for evaluation of the proposal under this BAA.

Understanding of Evaluation Policy

Completion of Attachment (2) is prerequisite for evaluation of the proposal under this BAA.

Representations, Certifications and Other Statements of Offerors

Attachment (3) is provided for **information only**. Each offeror is required to complete the Online Representations and Certifications prior to submission of proposal and verification/validation is a prerequisite to award under this BAA. (**Note**: Online Representations and Certifications Applications (ORCA), an e-Government initiative has replaced the paper based Representations and Certifications (Reps and Certs) process. The ORCA site can be found by going to http://www.sam.gov/SAM and clicking on "Online Reps and Certs Application" on the left side of the screen.)

Contractors' Performance Assessment Reporting System (CPARS) Ratings

Completion of Attachment (4) is prerequisite for evaluation of the proposal under this BAA.

Past/Present Performance Reference Questionnaire

Completion of Attachment (5) is prerequisite for evaluation of the proposal under this BAA.

Subcontracting Plan (Only Applicable to Large Businesses)

In accordance with FAR 19.702, if the total amount of the proposal exceeds $750,000 and the offeror is a large business, the offeror shall prepare and submit a Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan. A mutually agreeable Subcontracting Plan will be included in and made a part of the resultant contract. The contract cannot be executed unless the Contracting Officer determines that the Subcontracting Plan provides the maximum practicable opportunity for small, small disadvantaged and women-owned small business concerns to participate in the performance of the contract.

As stated in 15 U.S.C. 637(d) (8), any contractor or subcontractor failing to comply in good faith with the requirements of the subcontracting plan is in material breach of its contract. Further, 15 U.S.C. 637(d) (4) (f) directs that a contractor's failure to make a good faith effort to comply with the requirements of the subcontracting plan shall result in the imposition of liquidated damages.

Title to Equipment

Title to equipment or other tangible property purchased with contract funds will be disposed of in accordance with Contracting Officer instructions at the time of contract completion.

Section III - Cost Section Contents – No page limit

In accordance with FAR 15.403-3 (under FAR 15.408 Table 15.2 when submission of Cost or Pricing Data is required), a detailed cost proposal shall be submitted with the research proposal and shall include, as a minimum, the following information (contractor's format is acceptable):

Period of Performance

Identify the proposed duration of the effort.

Direct Labor

Provide a list of participants, by category (and name, if appropriate), showing the hours and labor rates to be charged for each and the total amount per year proposed to be paid for each. Do not propose labor costs as percentages of time over the duration of the period of performance. Labor costs should be calculated by multiplying each proposed employee's labor rate by the amount of labor hours that they will work. Please disclose and explain the basis of any potential escalation factors utilized. Please refer to Attachment 9 for clarity.

Materials

Provide an itemized list of permanent equipment showing the cost of each item and the basis for the proposed cost. Provide a general description and total estimated cost of expendable equipment and supplies. Permanent equipment is any article of non-expendable tangible personal property having a useful life of more than two (2) years and an acquisition cost of $500 or more per unit. Permanent equipment costs shall not be fee/profit bearing.

Other Direct Costs

Travel

Include contemplated expenditures for travel with explanations for each trip and its proposed length and number of participants. The breakdown of these costs shall show the airfare, per diem rates, car rental rate, and any other travel expenses (such as parking fees, etc.) and shall be in accordance with the Joint Travel Regulations (JTR).

Subcontracts

Subcontractor cost proposals shall meet all of the requirements stated herein for the prime contractor. Subcontractor cost breakdowns may be submitted under separate cover.

Consultants

Provide a breakdown of any costs for consulting services showing number of days, daily rates, and estimated travel/per diem costs to the level of detail described in the travel narrative above. The need for consulting services must be explained and the basis for the daily rates must be provided.

Miscellaneous

Miscellaneous costs may include such items as publication charges, copying, subscriptions, photography, graphics, etc., only if they are consistent with and allowable under the offeror' s cost accounting system.

Indirect Costs

Indirect rates (overhead, G&A, etc.) utilized must be disclosed. Indicate whether any indirect rates used are fixed or provisional and the time frames to which they are applicable (e.g., a fixed rate may apply until a specified date, after which the rate becomes provisional). Proposals for contracts subject to FAR Subpart 31.2 shall complete Attachment (4). Facilities capital cost of money (FCCM) will not be an allowable cost in any resulting contract if the offeror's proposal fails to identify or propose FCCM (see FAR 15.408(i)).

Fee/Profit

The offeror must explain their proposed fee or profit, if any, which the organization proposes to assess the research project and how the fee/profit was derived. Reminder: Permanent equipment costs and the cost of facilities when purchased for the account of the Government (i.e., charged as a direct cost) shall not be fee/profit bearing.

PART V - PROPOSAL EVALUATION

INITIAL REVIEW

Upon receipt of a proposal, the Government will perform an initial review of the proposal's scientific/technical merit and potential contribution to CDC's mission. The Government will also determine if funds are expected to be available based on the proposed cost for the effort. Proposals not considered having sufficient scientific/technical merit or relevance to the CDC's mission or those in areas for which funds are not expected to be available, may be declined without being subject to the detailed scientific review described below. Scientific/technical merit, relevance to the research to CDC's mission, and availability of funding are of equal importance.

SCIENTIFIC REVIEW

Formal proposals not declined as a result of the initial review will be subject to a detailed extensive scientific review by highly qualified personnel.

Proposals submitted in response to this BAA will be evaluated in accordance with the following criteria:

Proposed Research

The overall scientific and/or technical merits of the proposed research, including the adequacy and effectiveness of any analysis and/or testing required to substantiate the methodology being developed.

Potential Contribution

The potential contributions of the effort to the CDC's mission and the extent to which the research effort will contribute to balancing the overall CDC's Research.

Offeror's Qualifications

The offeror's capabilities, related experience, facilities, techniques, or the unique combinations of any of these qualifications are integral factors for achieving the proposal objectives.

Personnel

The qualifications, capabilities, and experience of the proposed key personnel, such as the contractor manager, team leader, etc. Key personnel are those skilled, experienced, professional and technical personnel essential for successful accomplishment of the proposal objectives.

Cost Realism

In accordance with FAR 15.404-1 Proposal analysis techniques, the Government will evaluate the reasonableness and realism of proposed costs.

Administrative Proposal

The Contracting Officer will review the administrative section of the proposal for compliance.

PROPOSAL COMPARISONS

Each proposal will be evaluated based on the merit and relevance of the specific research proposed as it relates to the overall CDC mission rather than against other proposals for research in the same general area.

PART VI - PROPOSAL FORMS & ATTACHMENTS

Number of Pages

Attachment 1: To be included with proposal as Cover Page
Attachment 2: To be included with proposal
Attachment 3: Included for offeror's information and concurrence
Attachment 4: Included for offeror's information and concurrence
Attachment 5: To be completed by references
Attachment 6: Included for offeror's information
Attachment 7: Included for offeror's information
Attachment 8: To be completed after contract award
Attachment 9: Included as a Sample

ATTACHMENT 1

RESEARCH PROPOSAL COVER PAGE

1. To:

CDC Office of Acquisition Services (OAS)
2900 Woodcock Blvd
Atlanta, GA 30341

2. CDC Research Topic Area

☐ Research Topic 1
☐ Research Topic 2
☐ Research Topic 3
☐ Research Topic 4
☐ Research Topic 5
☐ Research Topic 6
☐ Research Topic 7
☐ Research Topic 8
☐ Research Topic 9
☐ Research Topic 10
☐ Research Topic 11

3. From *(name and address of offeror):*

4. Government Point of Contact During Technical Dialog

5. Type and Size of Business:

☐ Large
☐ Individual
☐ Partnership
☐ Small Business
☐ SDB
☐ Women-Owned SB
☐ Corporation, incorporated in state of:

6. CAGE:	7. DUNS:	8. TIN:
9. Proposal Title:	10. Requested Start Date:	11. Total Proposed Contract Value:
	12. Requested Duration:	13. Proposal Valid Until (*minimum nine months*):
	14. Type of Contract Proposed: ☐ Firm Fixed Price ☐ Cost Plus Fixed Fee ☐ Cost, No Fee	15. Address to Which Payment Shall Be Mailed (*if different from Block 4*):

16. Offeror' s technical representative authorized to conduct negotiations (Principal Investigator):		17. Offeror' s administrative representative authorized to conduct negotiations:	
Name	Telephone No.	Name	Telephone No.
Primary		Primary	
Alternate		Alternate	

18. Proposal Contents (*if not applicable, enter "N/A" under Page*):

Page	Technical Section	Page	Administrative Section	Page	Cost Section
	Proposed Research		Contract Type		Detailed Cost Estimate Breakdown
	Potential Contribution		Organizational Conflicts of Interest		
	Offeror' s Qualifications		Security Issues		
	Personnel		Disclosure Requirement and Evaluation Policy Understanding: Policy Statement, Statement of Disclosure Concurrence, and Statement of Evaluation Policy Understanding (see Attachment (2))		
	Past Performance				
	Draft Description of Work				
			Representations, Certifications and Other Statements of Offerors or Quoters (see Attachment (3))		

19. Authorized Representative:

Typed Name: _____ Signature: _____

Title: _____ Date signed: _____

ATTACHMENT 2

DISCLOSURE REQUIREMENT AND EVALUATION POLICY UNDERSTANDING

POLICY STATEMENT

CDC has a continuing interest in receiving and evaluating proposals containing new ideas, suggestions for researching ways to enhance the state-of-the-art in public health. However, Government personnel and contractors are constantly engaged in R&D activities, and the substance of your proposal may already be known to Government employees or contractors, or may even be in the public domain. For such reasons it is desirable, when receiving proposals for evaluation, to insure that the persons submitting them are aware of the conditions under which the CDC will consider them.

It must be understood that the receipt and evaluation of the proposal by CDC does not imply a promise to pay, recognition of novelty or originality, or any relationship, which might require the Government to pay for use of information to which it is otherwise lawfully entitled.

Due care will be exercised to ensure that, in addition to technical design or concept data submitted, administrative and cost data will not be used by the Government for any purpose other than evaluation of the proposal. Administrative and cost data will not be disclosed to non-Government participants. Additionally, such data will not be disclosed outside the Government or be duplicated, used or disclosed in whole or in part by the Government, except for tracking and record purposes or to evaluate the proposal. This restriction does not limit the Government's right to use information contained in such data if it is obtained from another source, or is in the public domain.

All research proposals will be treated as privileged information before award and contents will only be disclosed for purposes of evaluation. Your voluntary submission will be handled in accordance with established Government procedures for safeguarding such articles or information against unauthorized disclosure. All Government reviewers will be made aware that proposals sent to them are not to be duplicated, used, or disclosed in whole or in part for any purpose other than to evaluate the proposal, without the written permission of the offeror.

You should be aware that, despite all precautions, we may be able to protect the confidentiality of proposal only to the extent that it is exempt from disclosure under the Freedom of Information Act (see FAR Subpart 24.2).

Upon receipt, your proposal will be submitted to the appropriate technical experts for evaluation. Your proposal will undergo initial review within one hundred and twenty (120) days after receipt. If additional time for this review is required, you will be notified in writing. Processing of proposals not declined as a result of the initial review may require as much as 180 days.

Having read and understood the above policy, please execute and submit the following statements:

STATEMENT OF DISCLOSURE PREFERENCE	**STATEMENT OF UNDERSTANDING OF EVALUATION POLICY**
☐ This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed -- in whole or in part -- for any purpose other than to evaluate this proposal. If, however, if a contract is awarded to this offeror as a result of – or in connection with -- the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. ☐ The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]: _____ _____ _____. ☐ All data contained in this proposal are subject to this restriction. ☐ Permission is hereby granted to CDC to evaluate this proposal, which may include evaluation by evaluators both within and outside the Government, with the understanding that written agreement not to disclose this information shall be obtained from any non-Government evaluator.	It is understood that CDC has accepted the above proposal for the purpose of evaluating it and advising of any possible interest. It is further understood that such acceptance does not imply or create a promise to pay; an obligation to give up any legal right or to assume any duty; a recognition of novelty, originality or priority; or any relationship, contractual or otherwise, such as would render the Government liable to pay for or give up any legal right or assume any obligation for disclosure or use of any information in the proposal to which the Government would otherwise lawfully be entitled.

Company or Corporation Name:	
Proposal Title:	
Signature:	
Name and Title/Position of Authorized Rep Signing:	
Date:	
BAA Number:	
Topic/Subtopic #	
DUNS Number	
NAICS Code	

ATTACHMENT 3

REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR QUOTERS

A. The following FAR provision must be completed ONLY if the proposed contract type is firm fixed price:

52.203-2 CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APR 1985)

(a) The offeror certifies that

(1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to (i) those prices, (ii) the intention to submit an offer, or (iii) the methods or factors used to calculate the prices offered;

(2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and

(3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory

(1) Is the person in the offeror' s organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above; or

(2)(i) Has been authorized, in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above _____
(insert full name of person(s) in the offeror' s organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror' s organization);

(ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) above have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above; and

(iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a) (1) through (a) (3) above.

(c) If the offeror deletes or modifies subparagraph (a) (2) above, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.
{End of provision}

B. The following FAR provisions must be completed by ALL offerors.

52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEP 2007)

(a) *Definitions.* As used in this provision—"Lobbying contact" has the meaning provided at 2 U.S.C. 1602(8). The terms "agency," "influencing or attempting to influence," "officer or employee of an agency," "person," "reasonable compensation," and "regularly employed" are defined in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12).

(b) *Prohibition.* The prohibition and exceptions contained in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12) are hereby incorporated by reference it his provision.

(c) *Certification.* The offeror, by signing its offer, hereby certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with the awarding of this contract.

(d) *Disclosure.* If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(e) *Penalty.* Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by 31 U.S.C. 1352. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure required to be filed or amended by this provision, shall be subject to a civil penalty of not less than $10,000, and not more than $100,000, for each such failure.

(End of Provision)

52.204-3 TAXPAYER IDENTIFICATION (OCT 1998)

(a) Definitions.

Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C.7701(c) and 3325(d), reporting requirements of

26 U.S.C.6041, 6041A, and 6050M, and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C.7701(c) (3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror' s TIN.

(d) Taxpayer Identification Number (TIN).

☐ TIN: _____
☐ TIN has been applied for.
☐ TIN is not required because:
☐ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;
☐ Offeror is an agency or instrumentality of a foreign government;
☐ Offeror is an agency or instrumentality of the Federal Government.

(e) Type of organization.

☐ Sole proprietorship;
☐ Partnership;
☐ Corporate entity (not tax-exempt);
☐ Corporate entity (tax-exempt);
☐ Government entity (Federal, State, or local);
☐ Foreign government;
☐ International organization per 26 CFR 1.6049-4;
☐ Other _____

(f) Common parent.

☐ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.
☐ Name and TIN of common parent:

Name _____

TIN _____
{End of provision}

52.204-5 <u>WOMEN-OWNED BUSINESS (OTHER THAN SMALL BUSINESS) (OCT 2014)</u>

a) Definition. "Women-owned business concern," as used in this provision, means a concern that is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

(b) Representation. [Complete only if the offeror is a women-owned business concern and has not represented itself as a small business concern in paragraph (c)(1) of FAR 52.219-1, Small Business Program Representation, of this solicitation.] The offeror represents that it [ ] is a women-owned business concern.

(End of Provision)

52.204-6 UNIQUE ENTITY IDENTIFER (OCT 2016)

(a) Definitions. As used in this provision--

"Electronic Funds Transfer (EFT) indicator" means a four-character suffix to the unique entity identifier. The suffix is assigned at the discretion of the commercial, nonprofit, or Government entity to establish additional System for Award Management records for identifying alternative EFT accounts (see subpart 32.11) for the same entity.

"Unique entity identifier" means a number or other identifier used to identify a specific commercial, nonprofit, or Government entity. See www.sam.gov for the designated entity for establishing unique entity identifiers.

(b) The Offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "Unique Entity Identifier" followed by the unique entity identifier that identifies the Offeror's name and address exactly as stated in the offer. The Offeror also shall enter its EFT indicator, if applicable.

(c) If the Offeror does not have a unique entity identifier, it should contact the entity designated at www.sam.gov for establishment of the unique entity identifier directly to obtain one. The Offeror should be prepared to provide the following information:

(1) Company legal business name.

(2) Tradestyle, doing business, or other name by which your entity is commonly recognized.

(3) Company physical street address, city, state and Zip Code.

(4) Company mailing address, city, state and Zip Code (if separate from physical).

(5) Company telephone number.

(6) Date the company was started.

(7) Number of employees at your location.

(8) Chief executive officer/key manager.

(9) Line of business (industry).

(10) Company headquarters name and address (reporting relationship within your entity).

(End of Provision)

52.204-24 REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.

As prescribed in 4.2105(a), insert the following provision:

Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (OCT 2020)

The Offeror shall not complete the representation at paragraph (d)(1) of this provision if the Offeror has represented that it "does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument" in paragraph (c)(1) in the provision at 52.204-26, Covered Telecommunications Equipment or Services—Representation, or in paragraph (v)(2)(i) of the provision at 52.212-3, Offeror Representations and Certifications-Commercial Items. The Offeror shall not complete the representation in paragraph (d)(2) of this provision if the Offeror has represented that it "does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services" in paragraph (c)(2) of the provision at 52.204-26, or in paragraph (v)(2)(ii) of the provision at 52.212-3.

(a) **Definitions.** As used in this provision—

Backhaul, covered telecommunications equipment or services, critical technology, interconnection arrangements, reasonable inquiry, roaming, and substantial or essential component have the meanings provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) **Prohibition**.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Nothing in the prohibition shall be construed to—

(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(ii) Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract or extending or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. This prohibition

applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract. Nothing in the prohibition shall be construed to—

(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(ii) Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) **Procedures.** The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

(d) **Representation.** The Offeror represents that—

(1) It □ will, □ will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation. The Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that—

It □ does, □ does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds "does" in paragraph (d)(2) of this section.

(e) **Disclosures.**

(1) Disclosure for the representation in paragraph (d)(1) of this provision. If the Offeror has responded "will" in the representation in paragraph (d)(1) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment—

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(ii) For covered services—

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(2) Disclosure for the representation in paragraph (d)(2) of this provision. If the Offeror has responded "does" in the representation in paragraph (d)(2) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment—

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(ii) For covered services—

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(End of provision)

52.204-25 PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.

As prescribed in 4.2105(b), insert the following clause:

Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)

(a) **Definitions.** As used in this clause—

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (**e.g.**, connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (**e.g.**, fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means–

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (**e.g.**, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (**e.g.**, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) **Prohibition**.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) **Exceptions.** This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) **Subcontracts.** The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

52.209-5 CERTIFICATION REGARDING OTHER RESPONSIBILITY MATTERS

As prescribed in 9.104-7(a), insert the following provision:

Certification Regarding Responsibility Matters (Aug 2020)

(a)

(1) The Offeror certifies, to the best of its knowledge and belief, that—

(i) The Offeror and/or any of its Principals–

(A) Are □ are not □ presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have □ have not □, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if offeror checks "have", the offeror shall also see 52.209-7, if included in this solicitation);

(C) Are □ are not □ presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision;

(D) Have □, have not □, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds the threshold at 9.104-5(a)(2) for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) **The tax liability is finally determined**. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) **The taxpayer is delinquent in making payment**. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) **Examples**.

(i) The taxpayer has received a statutory notice of deficiency, under I.R.C. § 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. § 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. § 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has □ has not □, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principal," for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (**e.g.**, general manager; plant manager; head of a division or business segment; and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

52.209-11 REPRESENTATION BY CORPORATIONS REGARDING DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW. (FEB 2016)

As prescribed in 9.104-7 (d), insert the following provision:

Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law (Feb 2016)

(a) As required by sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), and similar provisions, if contained in subsequent appropriations acts, the Government will not enter into a contract with any corporation that–

(1) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or

(2) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(b) The Offeror represents that–

(1) It is ☐ is not ☐ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; and

(2) It is ☐ is not ☐ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

(End of provision)

52.215-6 PLACE OF PERFORMANCE (OCT 1997)

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, ☐ intends, ☐ does not intend [check applicable block] to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of performance (Street address, City, County, State, Zip code)	Name and address of owner and operator of the plant or facility if other than offeror or quoter

{end of provision}

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS

As prescribed in 19.309(a)(1), insert the following provision:

Small Business Program Representations (Nov 2020)

(a) **Definitions**. As used in this provision-

"Economically disadvantaged women-owned small business (EDWOSB) concern" means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

Service-disabled veteran-owned small business concern-

(1) Means a small business concern-

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) "Service-disabled veteran" means a veteran, as defined in 38 U.S.C.101(2), with a disability that is service-connected, as defined in 38 U.S.C.101(16).

Small business concern—

(1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (b) of this provision.

(2) **Affiliates**, as used in this definition, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

Small disadvantaged business concern, consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that-

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by-

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States, and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

"Veteran-owned small business concern" means a small business concern-

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C.101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern" means a small business concern-

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

"Women-owned small business (WOSB) concern eligible under the WOSB Program" (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b)

(1) The North American Industry Classification System (NAICS) code for this acquisition is– ***541715***.

(2) The small business size standard is ***1000***.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture (i.e., nonmanufacturer), is 500 employees.

(c) Representations.

(1) The offeror represents as part of its offer that it □ is, □ is not a small business concern.

(2) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it □ is, □ is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it □ is, □ is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(3) of this provision.] The offeror represents as part of its offer that-

(i) It □ is, □ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (c)(4) of this provision.] The offeror represents as part of its offer that-

(i) It □ is, □ is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it □ is, □ is not a veteran-owned small business concern.

(7) [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(6) of this provision.] The offeror represents as part of its offer that it □ is, □ is not a service-disabled veteran-owned small business concern.

(8) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, as part of its offer, that-

(i) It □ is, □ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It □ is, □ is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Under 15 U.S.C.645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall-

(1) Be punished by imposition of fine, imprisonment, or both;

(2) Be subject to administrative remedies, including suspension and debarment; and

(3) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

Alternate I (Sep 2015). As prescribed in **19.309**(a)(2), add the following paragraph (c)(9) to the basic provision:

(9) [Complete if offeror represented itself as disadvantaged in paragraph (c)(2) of this provision.] The offeror shall check the category in which its ownership falls:

___ Black American.

___ Hispanic American.

___ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians).

___ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, Republic of Palau, Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).

___ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

___ Individual/concern, other than one of the preceding.

52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEB 1999)

The offeror represents that –

(a) It ☐ has, ☐ has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;

(b) It ☐ has, ☐ has not filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.16.
{end of provision}

52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 1984)

The offeror represents that (a) it ☐ has developed and has on file, ☐ has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of

the Secretary of Labor (41 CFR 60-1 and 60-2), or (b) it ☐ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

{end of provision}

52.226-2 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION (OCT 2014)

(a) *Definitions.* As used in this provision --

"Historically Black College or University" means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2.

"Minority Institution" means an institution of higher education meeting the requirements of Section 365(3) of the Higher Education Act of 1965 (20 U.S.C. 1067k, including a Hispanic-serving institution of higher education, as defined in Section 502(a) of the Act (20 U.S.C. 1101a).

(b) *Representation*. The offeror represents that it --

* is * is not a historically black college or university;

* is * is not a minority institution.

(End of Provision)

52.227-6 ROYALTY INFORMATION (APR 1984)

(a) *Cost or charges for royalties.* When the response to this solicitation contains costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers, patent application serial numbers, or other basis on which the royalty is payable.
(4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.
(5) Percentage or dollar rate of royalty per unit.
(6) Unit price of contract item.
(7) Number of units.
(8) Total dollar amount of royalties.

(b) *Copies of current licenses.* In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

{end of provision}

52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION

As prescribed in 30.201-3 (a), insert the following provision:

Cost Accounting Standards Notices and Certification (Jun 2020)

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS coverage pursuant to 48 CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement-Cost Accounting Practices and Certification

(a) Any contract in excess of the lower CAS threshold specified in Federal Acquisition Regulation (FAR) 30.201-4(b) resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR chapter 99must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) □ **Certificate of Concurrent Submission of Disclosure Statement**. The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) Original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable; and

(ii) One copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official.)

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) □ **Certificate of Previously Submitted Disclosure Statement**. The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) □ **Certificate of Monetary Exemption**. The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling $50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) □ **Certificate of Interim Exemption**. The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under paragraph (c)(1) or (c)(2) of PartI of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of $50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

II. Cost Accounting Standards-Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

□ The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status

changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of $50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with paragraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

□ Yes □ No

(End of provision)

ATTACHMENT 4

CONTRACTORS' PERFORMANCE ASSESSMENT REPORTING SYSTEM (CPARS) RATINGS

This assessment will be performed electronically at least annually or as required by www.cpars.gov.

1. **Block 18a - Quality of Product or Service**.

Assess the contractor's conformance to contract requirements, specifications and standards of good workmanship (e.g. commonly accepted technical, professional, environmental, or safety and health standards). MANDATORY.

- For example: Are reports/data accurate? Does the product or service provided meet the specifications of the contract? Does the contractor's work measure up to commonly accepted technical or professional standards? Assess the degree of Government technical direction required to solve problems that arise during performance.
- For Operations Support: Assess how successfully the contractor meets program quality objectives such as ability to produce, reliability, maintainability and ability to inspect. The Assessing Official must be flexible in how contractor success is measured (e.g. using data from field reliability and maintainability and failure reports, user comments and acceptance rates, and scrap and rework rates). These quantitative indicators may be useful later, for example, in source selection evaluations, in demonstrating continuous improvement, quality and reliability leadership that reflects progress in total quality management. Assess the contractor's control of the overall production process to include material control, shop planning and control, and status.

2. **Block 18b - Schedule**.

Assess the timeliness of the contractor against the completion of the contract, task orders, milestones, delivery schedules, and administrative requirements (e.g. efforts that contribute to or effect the schedule variance). MANDATORY.

- This assessment of the contractor's adherence to the required delivery schedule should include the contractor's efforts during the assessment period that contributes to or effect the schedule variance. This element applies to contract closeout activities as well as contract performance. Instances of adverse actions such as the assessment of liquidated damages, or issuance of Cure Notices, Show Cause Notices, and Delinquency Notices are indicators of problems which may have resulted in variance to the contract schedule and should therefore be noted in the evaluation.

3. **Block 18c - Cost Control (Not required for Firm Fixed Price or Firm Fixed Price with Economic Price Adjustment)**.

4. **Block 18d - Business Relations**.

Assess the integration and coordination of all activity needed to execute the contract, specifically the timeliness, completeness and quality of problem identification, corrective action plans, proposal submittals, the contractor's history of reasonable and cooperative behavior (to include timely identification of issues in controversy), customer satisfaction, timely award and management of subcontracts. MANDATORY

Include, as applicable, information on the following:

- Is the contractor oriented toward the customer?
- Is interaction between the contractor and the government satisfactory or does it need improvement?
- Include the adequacy of the contractor's accounting, billing, and estimating systems and the contractor's management of Government Property (GFP) if a substantial amount of GFP has been provided to the contractor under the contract.
- Address the timeliness of awards to subcontractors and management of subcontractors, including subcontract costs. Consider efforts taken to ensure early identification of subcontract problems and the timely application of corporate resources to preclude subcontract problems from impacting overall prime contractor performance.
- Assess the prime contractor's effort devoted to managing subcontracts and whether subcontractors were an integral part of the contractor's team.

5. Block 18e - Management of Key Personnel (For Services and Information Technology Business Sectors only - Not Applicable to Operations Support).

Assess the contractor's performance in selecting, retaining, supporting, and replacing, when necessary, key personnel. MANDATORY.

- For example, how well did the contractor match the qualifications of the key position, as described in the contract, with the person who filled the key position? Did the contractor support key personnel so they were able to work effectively? If a key person did not perform well, what action was taken by the contractor to correct this? If a replacement of a key person was necessary, did the replacement meet or exceed the qualifications of the position as described in the contract schedule?

6. Block 18f - Utilization of Small Business.

FAR Subpart 19.7 and 15 U.S.C. 637 contains statutory requirements for complying with the Small Business Subcontracting Program. Assess whether the contractor provided maximum practicable opportunity for Small Business (including Alaska Native Corporations (ANCs) and Indian Tribes) (including Small Disadvantaged Businesses (which also includes ANCs and Indian Tribes), Women Owned Small Businesses, HUBZone, Veteran Owned, Service Disabled Veteran Owned Small Business, Historically Black Colleges and Minority Institutions and ANCs and Indian Tribes that are not Small Disadvantaged Businesses or Small Businesses) to participate in contract performance consistent with efficient performance of the contract.

Assess compliance with all terms and conditions in the contract relating to Small Business participation (including FAR 52.219-8, Utilization of Small Businesses and FAR 52.219-9, Small Business Subcontracting Plan (when required)). Assess any small business participation goals which are stated separately in the contract. Assess achievement on each individual goal stated within the contract or subcontracting plan including good faith effort if the goal was not achieved.

It may be necessary to seek input from the Small Business specialist, ACO or PCO in regards to the contractor's compliance with these criteria. For contracts subject to a commercial subcontracting plan, the Utilization of Small Business factor should be rated "satisfactory" as long as an approved plan remains in place, unless liquidated damages have been assessed by the contracting officer who approved the commercial plan (see FAR 19.705-7(h)). In such case, the Utilization of Small Business area must be rated "unsatisfactory."

This area must be rated for all contracts and task orders that contain a small business subcontracting goal.

Ratings for the Utilization of Small Business evaluation area will be in accordance with the definitions described below. Ratings for the other CPAR evaluation areas will be in accordance with the ratings described in Block 18 Evaluation Areas.

In accordance FAR 19.705-2(e) a contract may have no more than one subcontracting plan. Evaluations of the Utilization of Small Business are required for contracts and orders placed against basic ordering agreement (BOA) and blanket purchase agreement (BPA) if a subcontracting plan is required. Evaluations of Utilization of Small Business for single-agency task orders and delivery orders (to include FSS) are not required and shall not be accomplished unless the contracting officer determines that such evaluations would produce more useful past performance information for source selection officials than that contained in the overall contract evaluation. Execution of any subcontracting plan may be addressed in block 20.

- **Exceptional.** Exceeded all negotiated subcontracting goals or exceeded at least one goal and met all of the other negotiated subcontracting goals for the current period. Had exceptional success with initiatives to assist, promote, and utilize small business (SB), small disadvantaged business (SDB), women-owned small business (WOSB), HUBZone small business, veteran-owned small business (VOSB) and service disabled veteran owned small business (SDVOSB). Complied with FAR 52.219-8, Utilization of Small Business Concerns. Exceeded any other small business participation requirements incorporated in the contract, including the use of small businesses in mission critical aspects of the program. Went above and beyond the required elements of the subcontracting plan and other small business requirements of the contract. Completed and submitted Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate and timely manner.

Note: To justify an Exceptional rating, identify multiple significant events and state how they were a benefit to small business utilization. A singular benefit, however, could be of such magnitude that it constitutes an Exceptional rating. Ensure that small businesses are given meaningful, innovative work directly related to the project, rather than peripheral work, such as cleaning offices, supplies, landscaping, etc. Also, there should have been no significant weaknesses identified.

- **Very Good.** Met all of the negotiated subcontracting goals in the traditional socio-economic categories (SB, SDB and WOSB) and met at least one of the other socio-economic goals (HUBZone, VOSB, SDVOSB) for the current period. Had significant success with initiatives to assist, promote and utilize SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB. Complied with FAR 52.219-8, Utilization of Small Business Concerns. Met or exceeded any other small business participation requirements incorporated in the contract, including the use of small businesses in mission critical aspects of the program. Endeavored to go above and beyond the required elements of the subcontracting plan. Completed and submitted Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate and timely manner.

Note: To justify a Very Good rating, identify a significant event and state how they were a benefit to small business utilization. Ensure that small businesses are given meaningful, innovative work directly related to the project, rather than peripheral work, such as cleaning offices, supplies, landscaping, etc. There should be no significant weaknesses identified.

- **Satisfactory.** Demonstrated a good faith effort to meet all of the negotiated subcontracting goals in the various socio-economic categories for the current period. Complied with FAR 52.219-8, Utilization of Small Business Concerns. Met any other small business participation requirements included in the contract. Fulfilled the requirements of the subcontracting plan included in the contract. Completed and submitted Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate and timely manner.

Note: To justify a Satisfactory rating, there should have been only minor problems, or major problems the contractor has addressed or taken corrective action. There should have been no significant weaknesses identified. A fundamental principle of assigning ratings is that contractors will not be assessed a rating lower than Satisfactory solely for not performing beyond the requirements of the contract.

- **Marginal.** Deficient in meeting key subcontracting plan elements. Deficient in complying with FAR 52.219-8, Utilization of Small Business Concerns, and any other small business participation requirements in the contract. Did not submit Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate or timely manner. Failed to satisfy one or more requirements of a corrective action plan currently in place; however, does show an interest in bringing performance to a satisfactory level and has demonstrated a commitment to apply the necessary resources to do so. Required a corrective action plan.

Note: To justify Marginal performance, identify a significant event that the contractor had trouble overcoming and how it impacted small business utilization. A Marginal rating should be supported by referencing the actions taken by the government that notified the contractor of the contractual deficiency.

- **Unsatisfactory.** Noncompliant with FAR 52.219-8 and 52.219-9 and any other small business participation requirements in the contract. Did not submit Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate or timely manner. Showed little interest in bringing performance to a satisfactory level or is generally uncooperative. Required a corrective action plan.

Note: To justify an Unsatisfactory rating, identify multiple significant events that the contractor had trouble overcoming and state how it impacted small business utilization. A singular problem, however, could be of such serious magnitude that it alone constitutes an Unsatisfactory rating. An Unsatisfactory rating should be supported by referencing the actions taken by the government to notify the contractor of the deficiencies. When an Unsatisfactory rating is justified, the contracting officer must consider whether the contractor made a good faith effort to comply with the requirements of the subcontracting plan required by FAR 52.219-9 and follow the procedures outlined in FAR 52.219-16, Liquidated Damages-Subcontracting Plan.

NOTE 1: Plus or minus signs may be used to indicate an improving (+) or worsening (-) trend insufficient to change assessment status.

NOTE 2: Generally, zero percent is not a goal unless the Contracting Officer determined when negotiating the subcontracting plan that no subcontracting opportunities exist in a particular socio-economic category. In such cases, the contractor shall be considered to have met the goal for any socio-economic category where the goal negotiated in the plan was zero.

7. Block 18g - Other Areas.

Specify additional evaluation areas that are unique to the contract, or that cannot be captured elsewhere on the form. More than one type of entry may be included, but should be separately labeled. If extra space is needed, use Block 20.

If the contract contains an award fee provision, enter "award fee" in the "Other Areas" block (18g). The Assessing Official should translate the award fee earned to adjective ratings, which could prove more useful for using past performance to assess future performance risk in upcoming source selections. If award fee information is included in the CPAR, use block 20 to provide a description

for each award fee. Include the scope of the award fee by describing the extent to which it covers the total range of contract performance activities, or is restricted to certain elements of the contract.

If any other type of contract incentive is included in the contract (excluding contract shareline incentives on fixed price or cost-type contracts), it should be reported in a manner similar to the procedures described above for award fee.

Use Block 18g in those instances where the Assessing Official believes strongly, either positively or negatively, regarding an aspect of the contractor's performance, but cannot fit that aspect into any of the other blocks on the form.

ATTACHMENT 5

Past/Present Performance Reference Instructions

Instructions: OFFEROR shall complete the PAST/PRESENT PERFORMANCE REFERENCE QUESTIONNAIRE Reference Information Table themselves for the attached questionnaire, identifying the name and other pertinent information for each of your three (3) selected business references. This table, including the name of the offeror, shall be filled out completely by the offeror BEFORE sending it to the customers to respond to the questions. This will ensure the accuracy of the information being provided.

Send the attached questionnaire to each of the customers with a cover letter that:

(a) authorizes the selected customers to discuss the offeror' s performance under the applicable contract with the contracting officer;

(b) requests the customer complete the questionnaire;

(c) instructs the customer to return the completed questionnaire by email:

Email: oadsbaaprojects@cdc.gov

Submit a copy of the customer's cover letter with your business proposal to ensure receipt of questionnaires' responses.

Past/Present Performance Reference Questionnaire

RFP 75D301-21-R-71738

Name of Offeror:

Reference Information Table

Business Name of reference & address	
Point of Contact	
Phone number	
E-mail address	
Contract or Purchase Order Number	
Dollar Value	
Period of Performance	
Description of Services Performed	
Explain any problems and resolutions	

P/U	S	G	VG	E	N
Poor/ Unsatisfactory	**Satisfactory**	**Good**	**Very Good**	**Excellent**	**Neutral**
Does not meet minimum acceptable standards in one or more areas; remedial action required in one or more areas; deficiencies in one or more areas which adversely affect overall performance.	**Meets or slightly exceeds minimum acceptable standards; adequate results; reportable deficiencies with identifiable, but not substantial, effects on overall performance.**	**Effective performance; fully responsive to contract requirements; reportable deficiencies, but with little identifiable effect on overall performance.**	**Very effective performance; fully responsive to contract requirements; contract requirements accomplished in a timely, efficient, and economical manner for the most part; only minor deficiencies with minimal effect on overall performance.**	**Of exceptional merit; exemplary performance in a timely, efficient, and economical manner; very minor (if any) deficiencies with no adverse effect on overall performance.**	**No record of relevant past performance or past performance information is not available**

1. How would you rate the contractor's compliance with the delivery schedule / performance milestones? Comments:	P/U☐ S☐ G☐ VG☐ E☐ N☐
2. How would you rate the contractor's business practices (e.g. maintaining a positive working relationship, business ethics, timely and effectively resolution of any problems etc.)? Comments:	P/U☐ S☐ G☐ VG☐ E☐ N☐
3. How would you rate the contractor's record of conforming to contract requirements and to standards of good workmanship/quality of the product or service? Comments:	P/U☐ S☐ G☐ VG☐ E☐ N☐
4. How would you rate the contractor's overall compliance with the terms and conditions of your purchase order /contract? Comments:	P/U☐ S☐ G☐ VG☐ E☐ N☐
5. How would you rate the contractor's history of reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the contractor's business-like concern for the interest of the customer? Comments:	P/U☐ S☐ G☐ VG☐ E☐ N☐
6. How would you rate the contractor's overall performance? Comments:	P/U☐ S☐ G☐ VG☐ E☐ N☐
7. Would you purchase services from this contractor again? Comments:	☐ YES ☐NO

Please provide any additional comments applicable to the contractor's past performance:	

EVALUATOR'S NAME: _____

TITLE OF EVALUATOR:_____

EVALUATOR'S EMAIL ADDRESS: _____

DATE: _____

ATTACHMENT 6

CONTRACT CLAUSES

Section H- Special Requirement Clauses

H.1 PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM CDC FUNDED RESEARCH (Nov 2018)

All CDC-funded investigators shall submit to the National Institutes of Health Manuscript Submission System the electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services, Centers for Disease Control and Prevention. CDC defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The CDC Stacks and National Library of Medicine's (NLM) PubMed Central (PMC) archives will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and CDC.

H.2 Certificates of Confidentiality (Nov 2018)

Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. Consistent with the statute, research commenced or ongoing after December 13, 2016 and in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate.

Consistent with the statute, CDC considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;

- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46); or

- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some

combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

For research covered by a Certificate and consistent with the statute, Contractor shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Consistent with the statute, disclosure is permitted only in the below circumstances:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

Contractor shall keep records of when such disclosures are made and, upon request by CDC, shall make such information available to CDC.

Contractor shall comply with FAR Part 31, Contract Cost Principles and Procedures, as applicable, and maintain effective internal controls that provide reasonable assurance that the contract is managed in compliance with Federal statutes and regulations. Contractors conducting research covered by a Certificate shall ensure that any company/institution/individual not funded by CDC who receives a copy of identifiable, sensitive information protected by a Certificate is aware of the requirements of subsection 301(d) of the Public Health Service Act with respect to such information. The Contractor will secure an agreement with such company/institution/individual to ensure compliance with the requirements of the Certificate. In addition, Contractor shall ensure that all its employees and subcontractor employees working on this contract are informed of the substance of the abovementioned requirements and agree to comply with subsection 301(d) of the Public Health Service Act.

H.3 PUBLIC ACCESS TO CDC FUNDED DIGITAL PUBLIC HEALTH DATA (Nov 2018)

Public Health Data

Definition: Public Health data means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation
When CDC is funding, in whole or in part, via a contract as defined in FAR 2.101, with respect to public health data, a CDC-approved Data Management Plan (DMP) – a plan for digital data management, sharing, and preservation is required prior to commencing any related services or work. For contracts where public health data collection or generation activities may become necessary during the period of performance (e.g. via contract modification), a DMP will be required to be submitted and evaluated during the period of performance. The DMP is a deliverable and a living document that should be updated throughout the life cycle of data. A final DMP is required at the end of the contract performance that shows where the data are deposited and how they are being made accessible or justification provided for not doing so.

Data Management Plan

A DMP for each collection and/or generation of public health data should include the following information:

- A description of the public health data to be collected or generated in the contract period of performance;
- Standards to be used for the collected or generated public health data;
- Mechanisms for or limitations to providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights) or justification for why data cannot be made accessible. This section should address access to identifiable and de-identified data (see below for additional information about access);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explanation of why long-term preservation and access are not justified. This section should address archiving and preservation of identifiable and de-identified data (see below for additional information regarding archiving).

Examples of Data Management Plan Templates and Tools:

University of California: https://www.cdlib.org/services/uc3/dmpt.html
USGS: http://www.usgs.gov/datamanagement/plan/dmplans.php

Access to and Archiving of the Data

To the extent that is feasible, contractors should make public health data accessible. Rights in Data clauses (FAR 52.227-14 Rights in Data – General, 52.227-16, Additional Data Requirements, FAR 52.227-17 Rights in Data – Special Works, or FAR 52.227-18 Rights in Data-Existing Works), may be applicable and incorporated into contracts, depending on the Statement of Work involved. The data rights

clauses give the government "unlimited rights" in data first produced (when funded by government solely) in the performance of a contract. "Unlimited rights" is an unlimited license to use, disclose or reproduce the data; it does not give the government ownership of the data. Unlimited rights in data would allow the government to archive and make public non-proprietary data first produced in contract performance.

Contracts that do not include terms for submittal of public health data to CDC, are expected to plan and prepare for providing access to, and archiving/long-term preservation of, collected and/or generated data within the contract period of performance, as set forth below. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data, which should be made accessible within a year of the end of a collection cycle. For public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be provided as restricted data upon request under a data-use agreement or onsite controlled use.

For data underlying a scientific publication, the contractor shall make the data available coincident with publication of the paper, at a minimum a machine-readable version of the data tables shown in the paper, unless the data set is already available via a release or sharing mechanism. In addition, contractors should ensure the quality of data they make accessible and seek to provide the data in a machine readable and nonproprietary format. Contractors who fail to release public health data in a timely fashion may be subject to procedures normally used to address failure to comply with the terms and conditions of the contract and may be grounds for the Contracting Officer to terminate the contract for default. Irrespective of whether the data are made accessible or not, Public health data of value should be preserved long-term.

A final DMP is required at the end of the contract performance. The final DMP will indicate the location of the deposited data and the manner of access granted to the data. There needs to be an adequate justification for not making data accessible and this justification must be documented in the DMP and approved by the Contracting Officer's Representative.

Additional information is available at https://www.hhs.gov/open/publicaccess/index.html

Section I Clauses

CLAUSES INCORPORATED BY REFERENCE FAR 52.252-2 (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at the address below:

http://farsite.hill.af.mil/

The following clauses pertains to all contract types

NUMBER	TITLE	DATE
52.202-1	Definitions	NOV 2013
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	SEP 2006
52.203-7	Anti-Kickback Procedures	MAY 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	MAY 2014
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	OCT 2010
52.203-13	Contractor Code of Business Ethics and Conduct	OCT 2015
52.203-14	Display of Hotline Poster(s)	OCT 2015
52.203-15	Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009	JUN 2010
52.203-16	Preventing Personal Conflicts of Interest	DEC 2011
52.203-17	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights	APR 2014
52.204-2	Security Requirements	AUG 1996
52.204-4	Printed or Copied Double-Sided on Recycled Paper	MAY 2011
52.204-7	System for Award Management	JUL 2013
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-19	Incorporation by Reference of Representations and Certifications	DEC 2014
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	OCT 2015
52.204-13	System for Award Management Maintenance	JUL 2013
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	OCT 2015
52.209-10	Prohibition on Contracting with Inverted Domestic Corporation	NOV 2015
52.210-1	Market Research	APR 2011
52.211-11	Liquidated Damages – Supplies, Services, or Research and Development	SEP 2000
52.215-2	Audit and Records – Negotiation	OCT 2010
52.215-8	Order of Precedence – Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Cost or Pricing Data –	AUG 2011

	Modifications	
52.215-13	Subcontractor Cost or Pricing Data – Modifications	OCT 2010
52.215-14	Integrity of Unit Prices	OCT 2010
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications – Alternate IV	OCT 2010
52.215-22	Limitations on Pass-Through Charges—Identification of Subcontract Effort	OCT 2009
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.217-8	Option to Extend Services	NOV 1999
52.219-1	Small Business Program Representations	OCT 2014
52.219-8	Utilization of Small Business Concerns	OCT 2014
52.219-9	Small Business Subcontracting Plan	JAN 2017
52.219-16	Liquidated Damages – Subcontracting Plan	JAN 1999
52,219-28	Post Award Small Business Program Representation	JUL 2013
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition of Segregated Facilities	APR 2015
52.222-26	Equal Opportunity	APR 2015
52.222-35	Equal Opportunity for Veterans	OCT 2015
52.222-36	Affirmative Action for Workers with Disabilities	JUL 2014
52.222-37	Employment Reports Veterans	FEB 2016
52.222-38	Compliance with Veterans' Employment Reporting Requirements	FEB 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	MAR 2015
52.222-54	Employment Eligibility Verification	OCT 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-18	Encouraging Contractor Policies to Ban Text Messaging While Driving	AUG 2011
52.224-1	Privacy Act Notification	APR 1984
52.224-2	Privacy Act	APR 1984
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.225-25	Prohibition on Contracting with Entities in Certain Activities or Transactions Relating to Iran – Representations and Certifications	Oct 2015
52.226-1	Utilization of Indian Organizations and Indian-Owned Economic Enterprises	JUN 2000
52.227-1	Authorization and Consent – Alternate I	APR 1984
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	DEC 2007
52.227-11	Patent Rights-Ownership by The Contractor	MAY 2014
52.227-14	Rights in Data – General	MAY 2014
52.227-14	Rights in Data – General *Alternative IV*	DEC 2007
52.227-17	Rights in Data – Special Works	DEC 2007
52.232-17	Interest	MAY 2014
52.232-18	Availability of Funds	APR 1984
52.232-19	Availability of Funds for the Next Fiscal Year	APR 1984
52.232-23	Assignment of Claims	MAY 2014
52.232-25	Prompt payment	JUL 2013

52.232-33	Payment by Electronic Funds Transfer – System for Award Management	JUL 2013
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.233-2	Service of Protest	SEP 2006
52.233-3	Protest after Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.239-1	Privacy or Security Safeguards	AUG 1996
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-13	Bankruptcy	JUL 1995
52.243-7	Notification of Changes	APR 1984
52.244-2	Subcontracts	OCT 2010
52.244-5	Competition in Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	JUN 2016
52.246-25	Limitation of Liability - Services	FEB 1997
52.249-5	Termination For Convenience of the Government (Educational & Other Nonprofit Institutions	AUG 2016
52.252-4	Alterations in Contract	APR 1984
52.253-1	Computer Generated Forms	JAN 1991

b) The following clauses pertain to Firm-Fixed Price Contracts only (as applicable):

NUMBER	**TITLE**	**DATE**
52.203-6	Restrictions on Subcontractor Sales to the Government	SEP 2006
52.228-5	Insurance - Work on a Government Installation	JAN 1997
52.229-3	Federal, State, and Local Taxes	FEB 2013
52.230-3	Disclosure and Consistency of Cost Accounting Practices	OCT 2015
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-1	Payments	APR 1984
52.232-8	Discount for Prompt Payment	FEB 2002
52.232-11	Extras	APR 1984
52.232-28	Invitation to Propose Performance-Based Payments	MAR 2000
52.232-32	Performance-Based Payments	APR 2012
52.233-3	Protest after Award	AUG 1996
52.243-1	Changes - Fixed-Price – Alternate V	AUG 1984
52.249-9	Default (Research and Development)	APR 1984

c) The following clauses pertain to Cost- Reimbursable Contracts only (as applicable):

NUMBER	**TITLE**	**DATE**
52.216-7	Allowable Cost and Payment	AUG 2018
52.233-3	Protest after Award	AUG 1996
52.242-3	Penalties for Unallowable Costs	MAY 2014
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.243-2	Changes—Cost Reimbursement.	AUG 1987
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984

DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATIONS (HHSAR)

NUMBER	TITLE	DATE
352.211-2	Conference Sponsorship Requests and Conference Materials Disclaimer	DEC 2015
352.215-70	Late Proposals and Revisions	DEC 2015
352.216-70	Additional Cost Principles	DEC 2015
352.223-70	Safety and Health	DEC 2015
352.232-70	Incremental Funding	DEC 2015
352.233-71	Litigation and Claims	DEC 2015
352.239-73	Electronic and Information Technology Accessibility	DEC 2015

Section K Clauses

K.1 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

http://www.acquisition.gov
http://farsite.hill.af.mil

(End of Provision)

FAR SOURCE	TITLE AND DATE
52.204-17	Ownership or Control of Offeror (Nov 2014)
52.204-19	Incorporation by Reference of Representations and Certifications (Dec 2014)

K.2 FAR 52.204-8 Annual Representations and Certifications (MAR 2020)

(a)

(1) The North American Industry classification System (NAICS) code for this acquisition is **541715**.

(2) The small business size standard is **1000**.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)

(1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the provision at 52.204-7, System for Award Management, is not included in this solicitation, and the Offeror has an active registration in the System for Award Management (SAM), the Offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:

[_] (i) Paragraph (d) applies.

[_] (ii) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)

(1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements—Representation. This provision applies to all solicitations.

(iv) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.

(v) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(vi) 52.204-6, Covered Telecommunications Equipment or Services-Representation. This provision applies to all solicitations.

(vii) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.

(viii) 52.209-5; Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(ix) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.

(x) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(xi) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(xii) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(C) The provision with its Alternate II applies to solicitations that will result in a multiple-award contract with more than one NAICS code assigned.

(xiii) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xiv) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xv) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xvi) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xvii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xviii) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA- designated items.

(xix) 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation. This provision applies to solicitations that include the clause at 52.204-7.

(xx) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xxi) 52.225-4, Buy American--Free Trade Agreements--Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225- 3.

(A) If the acquisition value is less than $25,000, the basic provision applies.

(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.

(C) If the acquisition value is $50,000 or more but is less than $83,099, the provision with its Alternate II applies.

(D) If the acquisition value is $83,099 or more but is less than $100,000, the provision with its Alternate III applies.

(xxii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xxiii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.

(xxiv) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certification. This provision applies to all solicitations.

(xxv) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following representations or certifications are applicable as indicated by the Contracting Officer:

[Contracting Officer check as appropriate.]

___ (i) 52.204-17, Ownership or Control of Offeror.

___ (ii) 52.204-20, Predecessor of Offeror.

___ (iii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

___ (iv) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Certification.

___ (v) 52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Certification.

___ (vi) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).

___ (vii) 52.227-6, Royalty Information.

___ (A) Basic.

___ (B) Alternate I.

___ (viii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The Offeror has completed the annual representations and certifications electronically in SAM accessed through https://www.sam.gov. After reviewing the SAM information, the Offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

(End of Provision)

K.3 FAR 52.209-7 Information Regarding Responsibility Matters (OCT 2018)

(a) *Definitions.* As used in this provision—

"Administrative proceeding" means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (*e.g.*, Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceeding at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

"Federal contracts and grants with total value greater than $10,000,000" means—

(1) The total value of all current, active contracts and grants, including all priced options; and

(2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

"Principal" means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (*e.g.*, general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror [_] has [_] does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the offeror checked "has" in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

(i) In a criminal proceeding, a conviction.

(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in—

(A) The payment of a monetary fine or penalty of $5,000 or more; or

(B) The payment of a reimbursement, restitution, or damages in excess of $100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management via https://www.sam.gov (see 52.204-7).

(End of provision)

K.4 Implementation of Executive Order (EO) 13224 Terrorist Financing

The Contractor is reminded that US Executive Orders and US law prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility to ensure compliance with these Executive Orders.

(End of Provision)

K.5 Contact for Negotiation/Administration (May 1998)

Designate a person we may contact for contract administration in the event your firm receives a contract as a result of this solicitation:

Name: _____ Title: _____

Address: _____
(Street) (City) (State) (Zip Code)

Area Code: _____ Telephone: _____

Bidder/Offeror is located in _____ Congressional District.

Contract will be performed in _____
(State) (City) (Congressional District)

(End of Provision)

K.6 Certification (May 1998)

TO BE COMPLETED BY THE OFFEROR: (The Offeror must check or complete all appropriate boxes or blanks in the Representations and Certifications contained herein). The Representations and Certifications must be executed below, by an individual authorized to bind the offeror.

The offeror makes the forgoing Representations and Certifications as a part of its proposal.

_____ _____
(Name of offeror) (Solicitation Number)

_____ _____
(Signature of Authorized Individual) (Date)

_____
(Typed Name of Authorized Individual)

Note: The penalty for making false statements in offerors is prescribed in 18 U.S.C. 1001.

(End of Provision)

K.7 Contractor Performance Assessment Reporting System (CPARS) Requirements (Apr 2013)

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

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

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

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

Provide the current CPARS representative information below.

_____
PRINT OR TYPE NAME

_____
EMAIL ADDRESS AND PHONE NUMBER

(End of Provision)

K.8 Point of Contact

The Contractor shall designate a senior person from the key personnel as the point of contact during normal business hours. This person shall be available for on-site meetings during normal business hours. Should the person be unavailable when scheduled to be on-site, the Contractor shall notify the COR of the name of the designated alternate point of contact. The designated person shall have the authority of the Program Manager to direct personnel and shall be accountable to the directions of the COR. The Contractor shall provide to the COR a contact and backup contact who shall be on-call to make decisions as required during non-business hours.

Name: _____ Title: _____

Address: _____
(Street) (City) (State) (Zip Code)

Area Code: _____ Telephone: _____

(End of Provision)

Attachment 7
Common Required Clearances

The clearances listed below are the most common and are required for procurements that are above $250,000.00. Each clearance that is described below will give you a summary of why they are used.

1. **Human Subjects-** The purpose of this clearance is to make sure that Center for Disease Control and Prevention is in compliance with the Department of Health and Human Services (HHS) policy. The policy is that the contracting officer shall not award a contract involving human subjects until the prospective contractor provides assurance that the activity will undergo initial and continuing review by an appropriate Institutional Review Board (IRB) in accordance with HHS regulations at 45 CFR 46.103. The contracting officer shall require a Federal-wide assurance (FWA), approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or institution engaged in human subjects research in performance of a contract. OHRP administers the assurance covering all HHS-supported or HHS-conducted activities involving human subjects. **(reference HHSAR 370.301)**

2. **Paperwork Reduction-** The purpose of this clearance is to ensure that the Center for Disease Control and Prevention (CDC) is in compliance with the Paperwork Reduction Act of 1995. In addition, it helps determines the applicability for proposed projects.

3. **Information Security and Privacy-** The purpose of this clearance is to determine if the acquisition requires information security, involves personal identifiable information, and is subject to the privacy act.

4. **Section 508-** in compliance with the Department of Health and Human Services (HHS) policy. (a) Electronic and information technology (EIT) supplies and services must comply with Section 508 of the Rehabilitation Act (the Act) of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board (Access Board) Electronic and Information Accessibility Standards (36 CFR part 1194). Requiring activities must consult with their Section 508 Official or designee to determine if the contractor should be responsible for compliance with EIT accessibility standards which apply to website content and communications material.

   (1) When conducting a procurement and employing the best value continuum, the solicitation shall include a separate technical evaluation factor developed by the contracting officer, requiring activity, and the Operating Division (OPDIV) Section 508 Official or designee.

   (2) At a minimum, solicitations for supplies and services shall require the submission of a Section 508 Product Assessment Template (See http://www.hhs.gov/web/508 for the template). Solicitations for services shall include any other pertinent information that the contracting officer deems necessary to evaluate the offeror's ability to meet the applicable Section 508 accessibility standards.
   (Reference HHSAR 339.2)

ATTACHMENT 8

CDC OCFO
REVISED 8/29/13

ACH VENDOR/MISCELLANEOUS PAYMENT ENROLLMENT FORM

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program.

PRIVACY ACT STATEMENT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments.

AGENCY INFORMATION

FEDERAL PROGRAM AGENCY: CENTERS FOR DISEASE CONTROL & PREVENTION		
AGENCY IDENTIFIER: CDC	AGENCY LOCATION CODE (ALC): 7509-0421	ACH FORMAT: ☒ CCD+ ☐ CTX ☐ CTP
ADDRESS: P. O. BOX 15580 MS D06		
ATLANTA, GA 30333		
CONTACT PERSON NAME: Customer Service		TELEPHONE NUMBER: (678) 475-4510
ADDITIONAL INFORMATION		FAX (404) 638-5342

PAYEE/COMPANY INFORMATION

PAYEE/COMPANY NAME:		SSN NO. OR TAXPAYER ID NO.
ADDRESS:		DUNS+4 NUMBER
CITY	STATE	ZIP
CONTACT PERSON NAME:		TELEPHONE NUMBER: ( )

FINANCIAL INSTITUTION INFORMATION

FINANCIAL INSTITUTION NAME:		
ADDRESS (OR BRANCH):		
CITY:	STATE:	ZIP:
NINE-DIGIT ROUTING TRANSIT NUMBER:		
DEPOSITOR ACCOUNT NUMBER:		
TYPE OF ACCOUNT: CHECKING SAVINGS		
ACH COORDINATOR NAME OR AUTHORIZED OFFICIAL AT FINANCIAL INSTITUTION (NOT REQUIRED):		TELEPHONE NUMBER: ( )

ATTACHMENT 9 - COST PROPOSAL (SAMPLE FORMAT)

IMPORTANT NOTE: This is a sample format that is intended to provide guidance to you. **You must tailor the Cost Proposal that you submit to your proposal.** Also, every cost that you submit

must be substantiated in sufficient detail to support the hours, rates and costs included on your Business Proposal and allow the Government to understand how these costs will support the work described in your proposal to successful performance of a contract. The Government cannot evaluate proposals that do not include cost information that is not presented in sufficient detail – so be thorough and complete and include all of your costs (i.e., subcontractors, etc.).

When applicable, this format can be used to report the base period, option years, and a composite for all periods.

Direct Labor

Direct Labor by Category	**Hours**		**Rate**	**Total**
Project Manager	_____	X	$_____	$_____
Principal Investigator	_____	X	$_____	$_____
Total Direct Labor				$_____
Overhead Rate	_____%			$_____
Total Direct Labor + Overhead				$_____
Fringe Rate	_____%			$_____
Total Direct Labor + Overhead + Fringe				$_____
Other Direct Costs:				
Travel and Per Diem *(in accordance with FJTR)*				$_____
Consultants/Subcontractor				$_____
Materials				$_____
Total Other Direct Costs				$_____
Subtotal Cost				$_____
G&A	_____%			$_____
Subtotal Cost (Before Profit)				$_____
Profit	_____%			$_____
TOTAL COST				$_____

NOTE: For positions covered under the Service Contract Act, itemize the fringe rate to identify the H&W component.