CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

BROAD AGENCY ANNOUNCEMENT (BAA)

75D301-22-R-72097

"Applied Research to Address Emerging Public Health Priorities"

ISSUANCE DATE:	**December 6, 2021**
CLOSING DATE:	**January 14, 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	Point of Contact (POC)	POC e-mail address
Topic 1. Exploring best strategies to interrupt poliovirus transmission in outbreak-affected countries (CGH)		
1.1. Modeling to inform effective polio outbreak response strategies	Gabe AnayaCGH Extramural Research Program Office	gda1@cdc.gov cgherpo@cdc.gov
Topic 2. Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness (CPR)		
2.1 Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness	Kimberly Leeks	kleeks@cdc.gov
Topic 3. Address critical gaps in knowledge regarding personal protective equipment (PPE) standards in a laboratory setting (CPR)		
3.1. Comparison of PPE used in the United States and globally in terms of physical and barrier resistance using standardized performance tests (e.g., water resistance, viral penetration tests)	Christy Ottendorfer Selcen Kilinc-Balci	uyk0@cdc.gov jcq8@cdc.gov

3.2. Effects of chemical decontamination on the durability and reliability of PPE in standardized performance tests (e.g., water resistance, viral penetration tests)	Christy Ottendorfer Selcen Kilinc-Balci	uyk0@cdc.gov jcq8@cdc.gov
3.3. Effects of reuse of PPE in standardized performance tests (e.g., viral penetration tests)	Christy Ottendorfer Selcen Kilinc-Balci	uyk0@cdc.gov jcq8@cdc.gov
Topic 4. Address Critical Knowledge Gaps related to Emerging and Re-emerging Infectious Diseases During Pregnancy and the Risks, Benefits and Acceptance of Prevention and Treatment Strategies (NCBDDD)		
4.1. Mother-baby linked longitudinal cohort studies to examine the impact of emerging and re-emerging infectious diseases and prevention and treatment strategies on pregnancy, birth, and early childhood outcomes	Suzanne Gilboa Dana Meaney-Delman Van Tong Kara Polen	suz0@cdc.gov vmo0@cdc.gov vct2@cdc.gov fvc1@cdc.gov
Topic 5: Expand the portfolio of effective interventions to prevent or delay type 2 diabetes and manage diabetes among populations who are underserved (NCCDPHP)		
5.1. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in type 2 diabetes prevention.	Bryce Smith	Bsmith6@cdc.gov
5.2. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in diabetes management.	Bryce Smith	Bsmith6@cdc.gov
5.3. Study the effectiveness of various approaches/supports currently used by recognized organizations in the National Diabetes Prevention Program (National DPP) to eliminate or reduce barriers to enrollment and retention in the National DPP lifestyle change program related to the social determinants of health (e.g., food insecurity/limited access to healthy foods, lack of reliable transportation or internet access, lack of safe places to get physical activity, others). Determine which approaches are effective in addressing these barriers for populations currently underrepresented in the program.	Bryce Smith	Bsmith6@cdc.gov
Topic 6. Wastewater Surveillance (NCEZID)		
6.1. Detection and typing of disease targets from wastewater	Rory Welsh	Mpo6@cdc.gov
6.2. Fecal shedding of SARS-CoV-2 RNA	Amy Kirby	Agk1@cdc.gov
Topic 7. Genomic sequencing of SARS-CoV-2 to investigate viral evolution, and emergence and spread of variants in communities and populations. (NCEZID)		
7.1. Incorporate viral genomic data, clinical and demographic data to better predict poor outcomes of SARS-CoV-2 infection, increased likelihood of reinfection and risk factors for vaccine breakthrough.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov fms2@cdc.gov
7.2. 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.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov fms2@cdc.gov
7.3. Adapt and optimize sequencing instrumentation, reagents and workflows for the specific needs of public health infectious disease laboratories and field activities.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov Fms2@cdc.gov
7.4. Develop or enhance open source bioinformatic tools, databases and visualization software that improve the availability, utility, integration and interpretation of genomic data from SARS-CoV-2 and other pathogens of public health concern.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov Fms2@cdc.gov
Topic 8. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness (NCEZID)		
8.1. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness by distributing assays through the Laboratory Response Network (LRN)	Julie Villanueva	Jfv3@cdc.gov
Topic 9. Address gaps in direct detection diagnostic assays for Lyme borreliosis (NCEZID)		
9.1 Investigations to discover chemoattractants for B. burgdorferi in tick saliva for development of a xenodiagnostic-like assay for direct detection of the Lyme spirochete in infected individuals	Bob Gilmore	rbg9@cdc.gov
Topic 10. Address critical gaps in human tick bite prevention (NCEZID)		

10.1. Development and evaluation of human tick bite prevention methods	Lars Eisen	evp4@cdc.gov
10.2. Killing of ticks that go undetected while biting humans	Lars Eisen	evp4@cdc.gov
Topic 11. Novel prevention methods to reduce transmission of Rickettsia rickettsii by brown dog ticks(NCEZID)		
11.1 Development of a canine vaccine against *Rickettsia rickettsii*	William Nicholson	wan6@cdc.gov
Topic 12. Evaluation of novel Aedes aegypti control tools (NCEZID)		
12.1 Evaluate effectiveness of dried attractive bait stations to control Aedes aegypti, the main vector of dengue viruses	Ryan Hemme	rhemme@cdc.gov
Topic 13. Novel Assays for Dengue Vaccine Evaluation (NCEZID)		
13.1. Correlates of protective immunity against dengue	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.2. Measurement of dengue type-specific antibody binding	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.3. Assessments of dengue vaccine immunogenicity	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.4. Dengue immunoassay development or optimization	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.5. Sample collections for test development or validation	Jorge L. Munoz-Jordan	ckq2@cdc.gov
Topic 14. Implementation of Wolbachia-based strategies for dengue control in Central America (NCEZID)		
14.1. Establish surveillance systems to track climate-sensitive mosquito-borne diseases and monitor if they are increasing or shifting over time**.**	Gabriela Paz-Bailey	gmb5@cdc.gov
14.2. Evaluate the implementation and sustainability of *Wolbachia* replacement intervention in Central America	Gabriela Paz-Bailey	gmb5@cdc.gov
14.3. Develop the evidence base for *Wolbachia* replacement implementation in international settings to support implementation of effective strategies in the United States and help reduce risk of importation of vector borne diseases to the U.S.	Gabriela Paz-Bailey	gmb5@cdc.gov
Topic 15. Towards dengue elimination: enhanced vector control and surveillance in Puerto Rico (NCEZID)		
15.1. Develop and implement methods for enhanced surveillance and response to dengue hotspots in Puerto Rico	Gabriela Paz-Bailey	gmb5@cdc.gov
15.2. Evaluate the effectiveness of hotspot responses in preventing additional disease spread	Gabriela Paz-Bailey	gmb5@cdc.gov
Topic 16. Research to inform optimal approaches to environmental sampling and understanding of the prevalence and distribution of pathogenic fungi in healthcare settings (NCEZID)		
16.1. Develop innovative methods for detection and surveillance of pathogenic fungi in healthcare environments	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.2. Quantify baseline levels of pathogenic fungi within healthcare environments	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.3. Correlate fungal quantitative data with episodes of fungal infections or transmission in patients.	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.4. Pilot early detection and surveillance methods for invasive mold and other fungi in patients and in the environment to guide public health efforts.	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.5. Evaluate the feasibility and utility of different environmental sampling approaches for pathogenic fungi in healthcare environments.	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
Topic 17. Understanding the impact of climate change and other predictors on the distribution and severity of fungal diseases (NCEZID)		
17.1. Evaluate the influence of climate on diversity and abundance of human-pathogenic fungi in the environment -	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.2. Model geographic spread of fungal diseases based on predicted and observed climate changes	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.3. Understand the effect of severe weather events on the incidence of fungal infections	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.4. Assess role of social factors (e.g., health disparities) in determining severity of fungal diseases.	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.5. Assess role of host factors on determining severity of fungal diseases.	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
Topic 18. Development of rapid point-of-care (POC) syphilis diagnostic tests (NCHHSTP)		

18.1 Development of a rapid point-of-care combo treponemal/ nontreponemal antibody test for active syphilis diagnosis	Mayur Shukla Kim Kitzler	Iun9@cdc.gov nin1@cdc.gov
18.2 Development of a direct detection test for *T. pallidum,* ideally for all stages of syphilis	Allan Pillay Kim Kitzler	ajp7@cdc.gov nin1@cdc.gov
Topic 19. Decreasing disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, other sexually transmitted infections (STIs), tuberculosis and adolescent health (NCHHSTP).		
19.1 Develop, implement, and/or evaluate innovative evidence-based interventions to reduce population-level disparities in the incidence, morbidity and mortality associated with HIV, viral hepatitis, STIs, or tuberculosis.	Kirk Henny Harrell Chesson	KHenny@cdc.gov HChesson@cdc.gov
Topic 20. Influenza and Other Acute Respiratory Infections (NCIRD)		
20.1. CRISPR-Based Diagnostic Assays for Multi-Pathogen and Multi-Analyte Detection	Marie K. Kirby	pbi0@cdc.gov
20.2. Assessing the role of non-pharmaceutical interventions (NPI) in preventing influenza	Sonja Olsen	sco2@cdc.gov
Topic 21. SARS-CoV-2 (COVID-19) and Children (NCIRD)		
21.1. Describing respiratory virus transmission in educational settings.	Hannah Kirking	hrj7@cdc.gov
21.2 Evaluating COVID-19 vaccine effectiveness in schools.	Hannah Kirking	hrj7@cdc.gov
21.3. Children 5-17 years: Evaluating the duration of immune protection following COVID-19 vaccination	Hannah Kirking	hrj7@cdc.gov
21.4. Children 0-17 years: Estimating COVID-19 vaccine effectiveness in ambulatory healthcare settings	Leora Feldstein	nqw5@cdc.gov
21.5. COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C)	Angela Campbell	app4@cdc.gov
21.6. COVID-19 and Acute Otitis Media (AOM)	Katherine Fleming-Dutra	ftu2@cdc.gov
Topic 22. Bacterial Respiratory and Vaccine-Preventable Diseases (NCIRD)		
22.1. Assessing the molecular epidemiology of group A Streptococcus (GAS) isolates among children.	Katherine Fleming-Dutra	ftu2@cdc.gov
22.2. Understanding the spectrum of clinical pertussis.	Susan Hariri	bse4@cdc.gov
22.3. Understanding immune response to pertussis infection.	Susan Hariri	bse4@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. Timothy Barnes	1	krz3@cdc.gov
Mr. Tray Burch	5, 6	vwa8@cdc.gov
Elizabeth Cole Greenblatt William O'Bryan	3	qst7@cdc.gov rvq0@cdc.gov
Ms. Latoya Hill	7, 8, 9	mdx7@cdc.gov
Mr. Kristopher Lemaster	10	ene3@cdc.gov
Ms. Marva D. Lewis	2	knn5@cdc.gov
Mr. Marty Nemec	18, 19	oga2@cdc.gov
Ms. Jasmine Powell	11, 12, 13	qes1@cdc.gov
Ms. Denedra Threatt	4	qfa5@cdc.gov
Mr. Ronnie Williams	14, 15, 16, 17	oga3@cdc.gov
Mr. Tim Williams	20, 21, 22	tpw8@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. Exploring best strategies to interrupt poliovirus transmission in outbreak-affected countries (CGH)

1.1. Modeling to inform effective polio outbreak response strategies

Wild poliovirus type 2 was declared eradicated in 2015 and thereafter in April of 2016, routine immunization (RI) programs across the globe switched ("global switch") from the trivalent oral poliovirus vaccine (tOPV; contains types 1, 2, and 3) to the bivalent vaccine OPV (bOPV; contains types 1 and 3). In addition, a single dose of the trivalent inactivated poliovirus vaccine (IPV) was introduced into routine immunization programs to provide protection against type 2 paralysis which does not lead to intestinal immunity necessary to stop virus transmission like OPV. A second dose is being introduced into routine immunization programs in OPV-using low and lower-middle income countries to increase the proportion protected. Outbreaks of circulating vaccine-derived poliovirus (cVDPV) result from use of OPV in under-immunized and unimmunized populations, permitting the vaccine virus to spread among susceptible individuals for prolonged periods, increasing the chance for the virus to revert and re-acquire the ability to cause paralysis. Despite intentions to boost type 2 intestinal immunity ahead of the global switch in 2016, pockets of susceptible children remained in countries with chronically low polio vaccination coverage. The increasing number of susceptible cohorts of infants without type 2 intestinal immunity increases the risk and spread of virus. As of 14 October 2021, cVDPV2 outbreaks have been detected in 19 countries, affecting 333 individuals. Responding to cVDPV2 outbreaks requires the use of monovalent Sabin strain oral poliovirus vaccine type 2 (mOPV2) in Supplementary Immunization Activities (SIAs) to quickly increase type 2 population intestinal immunity and halt the spread of the virus. When high quality SIAs are not achieved, the mOPV2 virus continues to spread unabated, increasing the potential for emergence of a new VDPV, and transmission of the originally detected cVDPV2 continues.

To respond to cVDPV2 outbreaks effectively, policy makers must weigh response scenarios to inform optimal response strategies to quickly interrupt virus transmission. For example, the promptness in which SIAs are conducted (i.e., time between initial virus detection and first SIA), quality of the SIAs (i.e., true coverage effectiveness vis-á-vis performance indicators assessing vaccine coverage), number of SIA rounds, vaccine choice, geographic scope of SIAs, and age group targeted for SIAs. Modeling is one approach that can be used to inform outbreak responses.

CDC seeks to identify effective strategies to hasten the end of poliovirus transmission in cVDPV2 outbreak-affected countries. Key to this will be the development of an infectious disease model that can

serve as the testing environment for different response strategies. Evaluation will include the identification of strategies that result in 1) no breakthrough cases (i.e., no cases occur after the standard operating procedure recommended initial number of outbreak response SIAs); 2) interrupt virus transmission with the fewest number of vaccination campaigns; 3) interrupt virus transmission in the least amount of time; and 4) lead to the fewest overall number of cases of paralysis.

Topic 2. Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness (CPR)

2.1 Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness

Public trust in science is of heightened importance during a public health emergency, which is further compounded by the need for clear, correct, and targeted messages to effectively garner public health trust. Johns Hopkins University surveyed 1,468 adults in the US and found that about half (54%) trusted science "a lot" with 46% split across other response categories ("some", "not much", and "not at all"). Public trust in science is essential when the risks and benefits of new policies and practices are not well understood because the public must rely on the decision-makers to make informed judgments, as demonstrated during the COVID-19 pandemic. For example, the public may not adhere to mitigation strategies if they do not know, understand, or trust the evidence supporting the strategy. There are a number of plausible explanations for the decline in the trust of science including the politicization of scientific issues. CDC and other key stakeholders, including the public, would benefit from the development of evidence-based knowledge about the state of the public's current knowledge of and attitudes towards public health emergency preparedness and response (PHEPR) science. This evidence-based knowledge will allow us to develop effective strategies to establish and maintain public confidence and trust in PHEPR science.

Communication approaches have been effectively used to change public perceptions standard marketing for products such as food or automobiles as well as health messages related to smoking, exercise, preventive care, and medication adherence. Effective communication approaches that promote public health preparedness and response awareness, dialogue, trust-building, and knowledge, while also combating misperceptions and complacency, particularly about the scientific underpinnings of public health recommendations and how science evolves are urgently needed.

With a focus on risk communication, white papers should describe communication approaches or interventions that use an existing (e.g., mass media, small media, social media, application) or innovative channel and are supported by formative research (either completed prior to or as part of the contract), process evaluation, and outcome evaluation. Formative research can identify and prioritize needs, desires, and values of the target audience and test message frames. Determining the theoretical conceptual foundation and examining the prospective target audience's their behavior(s) and the factors which influence their behavior(s) are also key to successful messaging. Overall, white papers should include a description of the problem, market research, a defined market strategy, newly developed communication approaches, and evaluation of the communication approaches.

The objectives are to:

- Develop, implement, and evaluate communication approaches to increase trust in PHEPR science in subpopulations, jurisdictions, or the entire United States and its territories
- Build public health trust around PHEPR and various types of emergencies, hazards, and public health crises
- Increase the evidence-base, skills, and capacities of the state, tribal, local, and territory (STLT) health departments and communities

Priority will be given to offerors who:

- Have a successful track record of development, implementation, and evaluation of similar intervention activities

- Have the capacity to enroll and maintain large cohorts that include diversity in sociodemographic characteristics while minimizing selection and participation biases
- Experience in PHEPR research and evaluation
- Experience in conducting inclusive and population appropriate research
- Capacity to collect and manage the data required by this effort
- Can initiate and implement the study in a timely manner
- Are or work in partnership with an academic institution
- Are or work in partnership with STLT health departments
- Provide a plan to scale the approach as well as a sustainability plan (if the studied communication approach is effective)
- Be designed to increase trust in people who are traditionally underserved and underrepresented in the US
- Not focus on single issues, but more broadly on science or the scientific process (e.g., COVID-19, vaccines)
- Include measurement outcomes that address general awareness and knowledge about PHEPR; increased understanding of how to prepare for various types of emergencies; an overall increase in public trust, particularly during a public health crisis; and an increase in intentions to follow future public health guidance during public health emergencies
- Include knowledge, translation, and dissemination into practice products (for example, how to implement an approach determined to be effective) or messages (for example, translating the results into a webinar for practitioners) to share information to large audiences.

Topic 3. Address critical gaps in knowledge regarding personal protective equipment (PPE) standards in a laboratory setting (CPR)

CDC seeks to investigate the performance of personal protective equipment (PPE) manufactured domestically and globally (and met certain local and global standards) for impact penetration, tensile strength, tear resistance, and viral penetration with a simulated laboratory environment and the effects of chemical decontamination and reuse on PPE efficacy. PPE serves a critical function in protecting laboratory workers from biohazards with enhanced PPE providing an increasingly important line of defense for poliovirus post-eradication. Although new research has become available since the COVID-19 pandemic, most information is focused on healthcare settings and may not have comparable characteristics to poliovirus, a 20-30 nm non-enveloped virus resistant to many disinfectants, and common laboratory matrices that may impact surface tension properties important in PPE testing standards. This effort will: 1) evaluate national and international standards that assess performance requirements for PPE manufactured domestically and globally such as: impact penetration, tensile strength, tear resistance, viral penetration analyzed with and without the introduction of a chemical disinfectant (i.e. sodium hypochlorite or alcohol) and/or reuse in a simulated laboratory environment, 2) conduct standard test methods for PPE based on PPE commonly used in a laboratory setting using a poliovirus or surrogate virus, common laboratory matrices, with and without chemical decontamination and/or reuse for articles of PPE (e.g., gloves, gowns, coveralls), 3) develop evidence-based guidance on selection of PPE for biohazardous agents in a laboratory setting that consider chemical decontamination and reuse of articles of PPE, and 4) investigation of leakage through glove and protective clothing interface and the impact of mitigation methods (e.g. taping).

3.1. Comparison of PPE used in the United States and globally in terms of physical and barrier resistance using standardized performance tests (e.g., water resistance, viral penetration tests)
3.2. Effects of chemical decontamination on the durability and reliability of PPE in standardized performance tests (e.g., water resistance, viral penetration tests)
3.3. Effects of reuse of PPE in standardized performance tests (e.g., viral penetration tests)

Priority will be given to offerors who:

- Have a successful track record in conducting standardized testing methods for PPE
- Have demonstrated experience and capacity to perform virological studies

- Are interested and motivated to collaborate with CDC on testing projects and timely dissemination of the scientific data; and
- Are interested and motivated to use these data to inform public health and laboratory biosafety practice

Topic 4. Address Critical Knowledge Gaps related to Emerging and Re-emerging Infectious Diseases During Pregnancy and the Risks, Benefits and Acceptance of Prevention and Treatment Strategies (NCBDDD)

Current research about infectious diseases during pregnancy and their impact on pregnant individuals and infants is limited for several reasons. First, pregnancy status is not routinely captured in electronic health records and there are no standard data linkages in clinical or administrative datasets to capture the mother-infant dyad. Second, pregnant people are often excluded from randomized clinical trials of preventive therapies or treatment for infectious diseases leaving pregnant people and their health care providers to rely on small non-comparative cohort studies to make clinical decisions about these therapies. Finally, many studies do not capture a diverse group of pregnant people and infants. As part of this BAA focused on data modernization and health equity, CDC is seeking white papers to address research questions related to the primary objectives below, around the pregnancy, birth, and early childhood outcomes associated with emerging and reemerging infectious diseases in pregnancy and the risks and benefits of preventive and treatment strategies for these infectious diseases and their sequelae.

Given the period of performance for the contracts developed under this BAA mechanism, the most competitive applicants are those with existing cohorts in which data about the pregnant person and the infant are already linked (i.e., mother-baby linked longitudinal cohort). These data can include linked clinical data, administrative data, or other sources. Cohorts with existing protocols, procedures and institutional review board (IRB) approvals with existing infrastructure to address research questions may be most competitive, and able to accomplish the objectives within the period of performance of the contract. Using the pregnancy and infant cohort along with the appropriate comparison group(s), the research should assess the impact of infectious disease on mothers, infants and young children, as well as the acceptance of and use of applicable preventive strategies (e.g., masking, social distancing, routine testing, vaccination, mosquito repellent use, hand washing and other infection control practices, prophylactic medications) and treatments (e.g. antivirals, antimicrobials, novel therapeutics, intensive care). Existing protocols, including linked electronic datasets are encouraged to include the appropriate comparison cohort(s) (e.g., pregnant and/or non-pregnant; unexposed pregnancies and infants). Proposed target subpopulations of interest are also encouraged to include pregnant people from diverse racial/ethnic minority groups and sociodemographic backgrounds.

4.1. Mother-baby linked longitudinal cohort studies to examine the impact of emerging and re-emerging infectious diseases and prevention and treatment strategies on pregnancy, birth, and early childhood outcomes

Objectives of analyses of the electronic mother-baby linked longitudinal cohort may include the following:

- Examine susceptibility to the infectious disease by comparing the incidence of selected emerging and reemerging infectious diseases among pregnant and non-pregnant people.
- Compare the clinical severity of infection during pregnancy to the clinical severity of infection among non-pregnant people and describe risk factors and characteristics that increase the risk of severe disease.
- Estimate the risk of adverse outcomes associated with emerging and reemerging infectious disease during pregnancy, including, but not limited to early pregnancy loss, stillbirth, preterm delivery, preeclampsia, fetal distress perinatal transmission of infection, congenital infection, birth defects, and neonatal and post-neonatal morbidity and mortality. To understand the risks of these outcomes with untreated infection requires an appropriate comparison group of uninfected pregnant people matched for potential confounding characteristics.
- Estimate the risks and benefits of prevention and treatment strategies by comparing maternal, fetal, neonatal, and infant outcomes and other clinical parameters between pregnant people receiving and not receiving timely and appropriate prevention and/or treatment for the disease.

To address secondary objectives, ancillary quantitative or qualitative data collection (e.g., focus groups and surveys) of subpopulations within the cohort are encouraged to assess the uptake and acceptance of prevention (e.g., vaccine) and treatment (e.g., antivirals) strategies during pregnancy, and any barriers and challenges to acceptance among healthcare providers and patients. For the ancillary quantitative and qualitative data collection, proposed target subpopulations of interest would include pregnant people from diverse racial/ethnic minority groups and sociodemographic backgrounds as well as diversity in the healthcare provider population caring for pregnant people and infants in the main cohort and in the comparison groups. Assessment of uptake and acceptance of prevention and treatment strategies are encouraged to include but healthcare providers of various racial and ethnic backgrounds, those in private and academic clinical practice, and those with different medical specialties (e.g., obstetrics and gynecology, midwifery, family medicine, infectious disease, pediatrics, neonatology).

Objectives of ancillary data collections (e.g., focus groups and surveys) include:

- Compare acceptance of preventive and treatment strategies by pregnancy status using a cohort of pregnant and similar-aged non-pregnant people.
- Compare acceptance of preventive and treatment strategies for pregnant people based on racial/ethnic diversity and other sociodemographic characteristics and clinical factors such as prior pregnancy status and prior acceptance of preventive strategies (e.g., vaccines and prophylactic medications) and treatments (e.g., antivirals and antimicrobials).
- Assess acceptance of preventive and treatment strategies by provider type, provider characteristics, practice type, provider age and other factors and monitor over time.
- Elicit barriers and challenges to acceptance of preventive and treatment during pregnancy (e.g., availability of medications/vaccines, accessibility, and the role of myths and misinformation).

This announcement is not restricted to any specific infectious diseases; however, the emerging and re-emerging infectious diseases in pregnancy monitored and tracked by the Centers for Disease Control and Prevention, and specifically those included in the Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET) are of particular interest https://www.cdc.gov/ncbddd/aboutus/pregnancy/emerging-threats.html.

Priority will be given to applicants who

- Have an established history of successful implementation of similar activities with cohorts of pregnant people, infants, and appropriate comparators;
- Demonstrate experience designing and implementing electronic cohorts with defined, appropriate analytic questions;
- Demonstrate capacity to collect, manage, analyze, and publish the data required by this effort with a focus on data modernization and health equity;
- Are most likely to initiate and implement the study in a timely manner using innovative methodology;
- Are interested and motivated to collaborate with CDC on analytic projects and timely dissemination of the scientific data; and
- Are interested and motivated to use these data to inform public health and clinical practice.

Topic 5: Expand the portfolio of effective interventions to prevent or delay type 2 diabetes and manage diabetes among populations who are underserved (NCCDPHP)

CDC currently has one evidence-based intervention [the National Diabetes Prevention Program (DPP)'s lifestyle change program (LCP)] that has been shown to reduce or delay the onset of type 2 diabetes and a limited number of evidence-based interventions (i.e., diabetes self-management education and support services, clinical efforts to improve detection of chronic kidney disease (CKD), screening for diabetic retinopathy) that have been shown to improve outcomes for those living with diabetes. CDC seeks to expand this portfolio to support other evidence-based interventions, strategies, programs, or policies to achieve these goals. CDC is particularly interested in white papers that reduce health inequities through interventions, strategies, programs, or policies that are targeted to populations who are historically underserved by these interventions (Black or African

American persons, Hispanic or Latino persons, Asian and Pacific Islander persons, persons with disabilities, men, young adults, and others).

5.1. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in type 2 diabetes prevention.
Issues to consider:

- Scalability: CDC seeks to support interventions, strategies, programs, or policies that can demonstrate a feasible path to scaling beyond the context in which they are tested, but interventions should still be tailored to reach populations who are underserved.
- Sustainability: To expand access interventions, strategies, programs, or policies need to be easy to access for the population being served. Interventions, strategies, programs, or policies should not place a consider burden on the recipient/participant.
- All interventions, strategies, programs, or policies for type 2 diabetes prevention should be targeted to persons living with prediabetes [as determined by the CDC risk test (https://www.cdc.gov/prediabetes/takethetest/) or a HbA1c of 5.7-6.4].
- Outcomes for type 2 diabetes prevention interventions could include one of the following: reduction of weight by 5%-7%, or reduction of HbA1c by 0.2% coupled with weight loss of 4%.
- CDC is also interested in intermediate implementation improvement strategies (e.g., acceptability, adoption, length, cost, etc.).

Use of the National DPP LCP curriculum is not required, but not disallowed. Alternative versions of the LCP (e.g., difference in length, unique tailoring to specific audiences, other delivery mode or implementation modifications) are eligible for consideration but not required. Two alternate versions that are already developed but not required include the Road to Health (https://www.cdc.gov/diabetes/professional-info/toolkits/road-to-health.html) and On Your Way (https://www.cdc.gov/diabetes/prevent-type-2/guide-prevent-type2-diabetes.html).

Place-based or venue-based (e.g., Federally Qualified Health Center, faith-based institutions, employers, community-based organizations) interventions, strategies, programs, or policies are encouraged.

5.2. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in diabetes management.

Issues to consider:

- Scalability: CDC seeks to support interventions, strategies, programs, or policies that can demonstrate a feasible path to scaling beyond the context in which they are tested, but interventions should be tailored to reach populations who are underserved.
- Sustainability: To expand access interventions, strategies, programs, or policies need to be easy to access for the population being served. Interventions, strategies, programs, or policies should not place a consider burden on the recipient/participant.
- All interventions, strategies, programs, or policies for diabetes management should be targeted to persons living with diabetes
- Outcomes for diabetes management interventions can include clinical changes (e.g., HbA1c, blood pressure, cholesterol, weight), behavioral changes (e.g., self-care behaviors, physical activity), awareness of **diabetes** self-management education and support (**DSMES**) and when to go, or others.

5.3. Study the effectiveness of various approaches/supports currently used by recognized organizations in the National Diabetes Prevention Program (National DPP) to eliminate or reduce barriers to enrollment and retention in the National DPP lifestyle change program related to the social determinants of health (e.g., food insecurity/limited access to healthy foods, lack of reliable transportation or internet access, lack of safe places to get physical activity, others). Determine which approaches are effective in addressing these barriers for populations currently underrepresented in the program.

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 National DPP 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 by eating healthier, increasing physical activity, managing stress, and maintaining these healthier behaviors over time to lose weight and ultimately reduce risk for type 2 diabetes.

Priority will be given to offerors who establish:
• A track record of successful implementation of similar research or evaluation activities with populations who are underserved, including established partnerships with organizations/institutions serving populations who are undeserved.
• Capacity to conduct rigorous scientific studies to determine effectiveness based on selected outcomes;
• Capacity to collect, manage, and analyze the data required by this effort;
• The overall likelihood that they can initiate and implement the study in a timely manner.

Topic 6. Wastewater Surveillance (NCEZID)
6.1. Detection and typing of disease targets from wastewater

Wastewater testing can provide a complimentary and independent surveillance system to traditional disease-based pathogen surveillance. Most disease surveillance programs are linked to clinical care, but clinical surveillance is impacted by healthcare-seeking behaviors and can be biased towards symptomatic and severe infections. Wastewater surveillance can provide systematic data to mitigate such biases, reflecting the total infection burden at the community level. It can also be used to help address health equity issues by providing infection data where clinical testing is limited or absent. However, the sample matrix, the laboratory methods, and bioinformatics approaches can impact detection and molecular typing of pathogen and antibiotic resistance (AR) targets from wastewater.

CDC seeks projects that evaluate multiple methods with respect to the ability to recover spiked controls and mock communities under various concentration and background nucleic acid scenarios for liquid wastewater and sludge. The well-characterized spiked control material should include clinically relevant viral, bacterial, fungal, and antibiotic resistance targets (e.g. norovirus, foodborne bacteria, *Candida auris*, *Cryptosporidium*, and carbapenem and colistin-resistance genes and other high consequence AR threats described in the CDC 2019 AR Threats Report). CDC is specifically interested in quantitative detection and subtyping of pathogens from wastewater and characterization of sequencing performance for quantitative detection of multiple health targets from liquid wastewater and primary sludge. Innovative methods will also be considered. Methods that can provide information on multiple targets in a single run are preferred.

6.2. Fecal shedding of SARS-CoV-2 RNA

Understanding fecal shedding of SARS-CoV-2 RNA is important for interpreting COVID-19 wastewater surveillance data. Quantitative measurements in stool over the full time-course of infection, from individuals representing a range of demographic profiles, and illness severities, could help map wastewater measurements to community infection burden and help understand the potential for wastewater measurements to lead other COVID-19 surveillance indicators, like reported cases and syndromic surveillance. However, few quantitative fecal shedding data are published, and capturing fecal shedding dynamics over the full course of infection is challenging. CDC seeks a study that provides quantitative data on SARS-CoV-2 RNA levels in human stool over the full time-course of infection, including stool from individuals representing a range of demographic profiles, vaccination status, and illness severities. A study that measures RNA quantities per unit stool using molecular tools is preferred. Quantitative sample and laboratory controls, including matrix recovery controls and

endogenous fecal microbial controls, are encouraged. In particular, data between the period of infection and illness onset, and data from asymptomatic individuals, are desired, as well as viral variant data. Projects that characterize the stool composition, including solids content, and that use archived samples will be prioritized.

Topic 7. Genomic sequencing of SARS-CoV-2 to investigate viral evolution, and emergence and spread of variants in communities and populations. (NCEZID)

7.1. Incorporate viral genomic data, clinical and demographic data to better predict poor outcomes of SARS-

CoV-2 infection, increased likelihood of reinfection and risk factors for vaccine breakthrough.
The clinical picture of SARS-CoV-2 infection is often complicated by a range of viral, host and environmental factors. White papers for this subtopic, might include studies of SARS-CoV-2 infection that include both viral genomic and detailed host profiling (e.g., host genetic, immunologic, clinical data) to identify biomarkers that predict poor outcomes of SARS-CoV-2 infection, vaccine or therapeutic failure (e.g., clinically severe disease, multi-system inflammatory disease, breakthrough infection).

7.2. 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 proceed with 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 roll-out are also strongly encouraged. Additional consideration will be given to white papers that plan to engage state or local public health departments, to better apply new data and insights to public health decision-making.

7.3. Adapt and optimize sequencing instrumentation, reagents and workflows for the specific needs of public health infectious disease laboratories and field activities.

Over the course of the past several years, many laboratories have developed specific workflows to support SARS-CoV-2 sequencing efforts in different scales and contexts. This topic area is intended to help translate these new and optimized sequencing strategies and package them for routine public health use. Interested respondents may propose projects related to: 1) the miniturization of sequencing reactions and workflows; 2) efforts to streamline automation, decrease workflow complexity and limit overall consumable requirements of sequencing; 3) strategies to improve overall sequencing throughput, while reducing per-sample cost; 4) tools to simplify CLIA-compliant microbial sequencing in regulated laboratory settings; 5) the development and optimization of laboratory and bioinformatic methods for the analysis and deconvolution of complex surveillance samples, such as pooled testing, wastewater and environmental; and 6) the development and standardization of robust, field-deployable systems for surveillance support and outbreak response. While this white paper topic is meant to encourage innovation in laboratory protocols and technology, proposed solutions could include open-source software (e.g., for use with mobile devices) or mobile sequencing tools that provide rapid turn-around with high quality data.

7.4. Develop or enhance open source bioinformatic tools, databases and visualization software that improve the availability, utility, integration and interpretation of genomic data from SARS-CoV-2 and other pathogens of public health concern.

With the advent of rapid, open sequence data sharing for SARS-CoV-2 and other pathogens, there is a growing wealth of data available to help guide state and local infectious disease surveillance and public health response. CDC is soliciting white papers for 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. 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 across public repositories, enable linkage to other surveillance data sources (e.g., case reports, wastewater surveillance data, etc.) or simplify standardized analysis and electronic laboratory reporting or improve linkage to medical records systems.

Priority will be given to projects that facilitate and enable the use of molecular epidemiologic data for state and local investigations and response activities. As such, projects for this subtopic could also include tools that may be used by public health departments for field applications (e.g., contact investigation), with an emphasis on field-deployable open solutions for use by front-line public health workers.

Topic 8. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness (NCEZID)

8.1. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness by distributing assays 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 emerging infectious disease (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.
Solutions should include a framework for data reporting and analytics necessary for determination of public health action. In addition, the white paper should provide plans associated with analytical verification and deployment.

Topic 9. Address gaps in direct detection diagnostic assays for Lyme borreliosis (NCEZID)
Human infection by the tick-borne spirochete, *Borrelia burgdorferi* results in Lyme borreliosis, a disease that often initially presents with a skin lesion termed erythema migrans accompanied by viral-like symptoms e.g., malaise, fatigue, headache, arthralgias, myalgias, fever and regional lymphadenopathy. The infection can progress to more severe manifestations (arthritis, carditis, neurologic) if not accurately diagnosed and treated properly with antibiotics.

B. burgdorferi exists in an enzootic life cycle of obligate symbiosis consisting of reservoir hosts, primarily rodents and birds, and *Ixodes* spp. ticks that serve as vectors to transmit the pathogen to other hosts including humans. In vertebrate hosts, *B. burgdorferi* disseminates to tissues and organs but does not produce sustained, high density spirochetemia thereby rendering direct detection (e.g. culture isolation) of the organism difficult if not impossible. Therefore, laboratory diagnosis currently is dependent mainly upon serological testing which has limitations, particularly for detection of early infection. In addition, there are not laboratory tests to indicate cleared infections or for the possibility of latent infection in patients with Post-treatment Lyme disease syndrome (PTLDS) or antibiotic-refractory arthritis. These examples represent gaps in diagnostic testing for

Lyme borreliosis that could be alleviated by development of new direct detection assays for *B. burgdorferi* in infected patients.

B. burgdorferi is highly motile by virtue of a structure of bundled periplasmic flagella and chemotaxis proteins that are recognized as virulence factors essential for infection. Motility and chemotaxis are important factors enabling *B. burgdorferi* to i) move from tick midgut to salivary glands in preparation for deposition into the host, ii) disseminate within the host to distal organs and tissues, and iii) migrate from within the host to a newly feeding tick.

The acquisition of *B. burgdorferi* by ticks feeding on infected individuals is the principle behind xenodiagnosis, a sensitive approach to determine the infection status of a host suspected of harboring an organism. Xenodiagnosis has been used as a method to detect *B. burgdorferi* in animals and has been modeled as a potential direct detection tool to determine latent or active *B. burgdorferi* infections in humans. The mechanisms responsible for signaling borreliae from disseminated tissues to an attached tick are largely unknown although undoubtedly involves the chemotactic and motility machinery of the spirochete responding to substances from tick saliva.

9.1. Development of a xenodiagnostic-like assay for direct detection of the Lyme spirochete in infected individuals.
CDC seeks creative investigations for direct detection assays based on chemoattractant capabilities of tick saliva components that act as signals for *B. burgdorferi* to migrate to the tick attachment site. The objectives are to:

i. Create a mouse model of infection to assess *B. burgdorferi* migration from tissues to chemoattractant inoculation site
ii. Identify components of tick saliva with chemoattractant properties (jointly with SME laboratory)
iii. Develop technical process for chemoattractant inoculation
iv. Generate successful endpoint to determine *B. burgdorferi* migration to chemoattractant inoculation site

Topic 10. Address critical gaps in human tick bite prevention (NCEZID)

10.1. Development and evaluation of human tick bite prevention methods
10.2. Killing of ticks that go undetected while biting humans

Personal protection measures aiming to prevent human tick encounters from resulting in bites are widely recommended as the first line of defense against health impacts associated with ticks (tick-borne diseases, tick paralysis, and Alpha-gal syndrome/red meat allergy). Despite well-documented use by the public of personal protection measures to prevent tick bites, there are major knowledge gaps for the effectiveness of these measures to prevent tick bites and tick-borne infections when they are used by the public in their daily lives. Additionally, as evidenced by Lyme disease patients often not being aware of a tick bite prior to symptom onset, some proportion of tick bites go undetected. Novel methods to kill ticks that go undetected while biting humans therefore would be of value to public health.

The objectives consequently are to:
1) Develop novel methods to prevent human tick bites and evaluate the effectiveness of existing tick bite prevention methods to reduce human tick bites and tick-borne infections
2) Develop novel methods capable of killing biting ticks that go undetected while feeding on humans

Topic 11. Novel prevention methods to reduce transmission of *Rickettsia rickettsii* by brown dog ticks(NCEZID)

11.1 Development of a canine vaccine against *Rickettsia rickettsii*

Rocky Mountain spotted fever (RMSF) is a severe disease caused by the tick-borne pathogen, *Rickettsia rickettsii*. Over the last 20 years, epidemic levels of RMSF have been observed in Northern Mexico and among tribal communities in the Southwestern U.S., with the incidence of spotted fever in some tribal communities being 150 times the national average. In these settings, *R. rickettsii* is transmitted by the brown dog tick, which is maintained by the local dog populations. Prevention of RMSF in these areas has been shown to be possible by application of tick preventives to dogs, acaricide application to homes, spay/neuter campaigns, and community education. A potential new prevention tool would be a vaccine given to dogs that prevents the acquisition of *Rickettsia rickettsii* by ticks. This broad agency announcement solicits white papers for the production and initial evaluation of a prototype vaccine aimed at the immunization of dogs to reduce the human risk for Rocky Mountain spotted fever. The prototype vaccine should elicit broad immunity to *Rickettsia rickettsii* in canines and be able to prevent acquisition of rickettsia from immunized dogs by feeding ticks.

The specific objectives are:
1) Create a prototype vaccine that could be a whole cell vaccine, a subunit recombinant DNA vaccine, an mRNA vaccine, or other novel vaccine.
2) Test the vaccine in canines to demonstrate safety and the production of an immune response against *Rickettsia rickettsii.* Data on both humoral and cellular immunity are desired.
3) Demonstrate the effect of canine vaccination on acquisition of *Rickettsia rickettsii* by brown dog ticks.
4) Demonstrate the effect of canine vaccination on disease in dogs infected with *Rickettsia rickettsii* post-vaccination.

Topic 12. Evaluation of novel Aedes aegypti control tools (NCEZID)
12.1 Evaluate effectiveness of dried attractive bait stations to control *Aedes aegypti*, the main vector of dengue viruses
Aedes aegypti is the primary vector of dengue virus and other *Aede*s mosquito transmitted arboviruses including chikungunya and Zika. Approximately 95% of locally acquired dengue cases in the U.S. occur in Puerto Rico, causing a high burden of disease in the population. The threat of arbovirus transmission in Puerto Rico is exacerbated by the rapid evolution of insecticide resistance in *Ae. aegypti* and the loss of an effective control measures. New, effective, and sustainable mosquito control strategies are needed to reduce the morbidity and mortality caused by these diseases. Attractive Toxic Sugar Baits (ATSBs) control mosquito populations by exploiting nectar-seeking behaviors. ATSBs attract female and male mosquitoes to aromatic natural sugar sources, which are comprised of an attractant, and a toxicant like boric acid. ATSBs are delivered to mosquitoes by foliar spraying methods or bait-stations. Dried attractive toxic sugar bait stations (DABs) are an innovative modification of ATSBs and differ in that they use both visual and olfactory cues to attract mosquitoes and can be used inside of homes where *Ae. aegypti* are most often found. Because of these characteristics, DABs minimize exposure to non-target insects (e.g., pollinators) and maximizes potential exposure to *Ae. aegypti*. DABs are a low-cost and noninvasive intervention that can be scaled in low resource settings and do not require a strong and expensive infrastructure or trained personnel, supplies, and logistics. Current research has shown the DABs are effective in semi-field environments and the next step would be to optimize the intervention in full field studies with entomological endpoints. If successful, a much needed new intervention to control Ae. aegypti will be added to our toolbox of vector control strategies.

CDC seeks to support research projects that implement and evaluate the effectiveness of DABs at the community level to control *Ae. aegypti* in Puerto Rico by (1) monitoring entomological endpoints in intervention and non-intervention communities, (2) determining the optimal number and locations of DABS needed at each house to successfully reduce mosquito abundance in intervention communities and (3) understand the acceptability of DABs from residents that have them deployed in their homes.

Topic 13. Novel Assays for Dengue Vaccine Evaluation (NCEZID)
Dengue is a growing public health threat, with increasing numbers globally and regular outbreaks in dengue-endemic areas in the United States. One of the most important risk factors for severe dengue is second infection with a different dengue virus serotype, as antibody-dependent enhancement can lead to increased viral uptake, higher levels of viremia, and poor outcomes after a secondary dengue infection. Achieving balanced, protective immunity for the four dengue virus serotypes has been challenging for the development of effective tetravalent

dengue vaccines, as there are no reliable correlates of protection against dengue. The only FDA approved dengue vaccine and other vaccines in the pipeline show uneven serotype-specific protection. In addition, these vaccines show enhanced protection in pre-exposed individuals. Therefore, it is critical to assess the level of protective immunity to the four dengue virus serotypes through laboratory testing of individuals and communities in endemic areas to determine previous infection, balanced protection against future dengue infection after vaccination, and potential risks for post-vaccination infections.

Quantification of total neutralizing antibody titers through tissue culture-based methodologies, such as plaque reduction neutralization tests currently used to measure vaccine immunogenicity, are not accurate correlates of protection and are impractical and difficult to standardize. Additionally, they do not contribute to our understanding of the specificity, strength, and duration of subsets of serotype-specific protective antibodies. Infection with other flaviviruses like Zika virus create an additional challenge in detecting serotype-specific antibodies, which may cause false positive results in current dengue serological tests.

This announcement addresses the compelling need to identify reliable immune correlates of protection after dengue infection or vaccination by encouraging research to detect serotype-specific antibody responses. The proposed research should have the following objectives: (1) Demonstrate serotype specificity of antibody binding for relevant, serotype-specific antigenic virus epitopes, assessments of natural or vaccine-induced monotypic antibody responses, or depletion of cross-reactive antibodies to improve specificity of immunoassays; (2) Establish sample-sparing, high-throughput tissue culture-free methods for the detection of dengue serotype-specific antibody binding to selected virus epitopes; (3) Thought should be given to implementation of testing for serotype-specific immunity in existing cohorts or populations following implementation of dengue vaccines with the aim of documenting acquired immunity over time. (4) Assembling panels of sera from participants with confirmed monotypic and multitypic immunity should assist stakeholders in evaluating and implementing these or similar assays. Tests developed for detection of dengue serotype-specific antibodies that correlate with protective immunity should show minimal or no cross-reactivity with ZIKV antibodies. The availability of these methods could help determine pre- and post-vaccination serostatus and balanced immunity against all dengue serotypes after vaccination. This work can guide vaccine developers to achieve balanced protection with next generation vaccines or facilitate implementing vaccines that may not require natural pre-exposure and therefore benefit children in endemic countries who are mostly DENV naïve. Thus, the work will support novel discoveries to drive innovation and positively influence the development and efficacy of dengue vaccine strategies.

13.1. Correlates of protective immunity against dengue
13.2. Measurement of dengue type-specific antibody binding
13.3. Assessments of dengue vaccine immunogenicity
13.4. Dengue immunoassay development or optimization
13.5. Sample collections for test development or validation

Topic 14. Implementation of Wolbachia-based strategies for dengue control in Central America (NCEZID)

As climate change increases the geographic spread of competent arboviral disease vectors, globally and in the continental United States, there is a need to develop an evidence base around novel vector control strategies. Developing the evidence base in international settings will help reduce risk of importation to the US, and rapidly eliminate disease spread when importation does occur to minimize the impact of tropical arboviral diseases in the US. Central America is a region endemic for dengue, with abundant populations of *Aedes aegypti*, and similar ecology to the U.S. territories and U.S. Southern States. Working in Central America where there is a high dengue incidence and transmission is endemic will provide opportunities to evaluate the implementation of vaccination and vector control and establish model surveillance approaches. It will also create an opportunity for meaningful collaboration with international partners and reducing current disease burden in parts of the world and populations disproportionately affected by both arboviral diseases and the impact of climate change. One of the most promising new methods for arboviral disease reduction is introduction of *Wolbachia*-infected mosquitoes. *Wolbachia* is a naturally occurring bacteria present in 60% of insect species, and have been shown to pose no risk to humans or the environment. When *Aedes* mosquitoes are infected with *Wolbachia*, it reduces

their ability to transmit arboviruses, including dengue, chikungunya, and Zika viruses. *Wolbachia* replacement is a strategy where *Wolbachia*-infected mosquitoes are introduced into wild mosquito populations. Because the bacteria are passed on when mosquitoes mate, the wild mosquito population is slowly replaced by *Wolbachia*-infected mosquitoes with a limited ability to transmit viruses. *Wolbachia* replacement has been studied in at least 11 countries globally and was shown to significantly reduce dengue incidence by 77% in a large randomized controlled trial in Indonesia.

CDC seeks to support research projects that implement *Wolbachia*-replacement in one or two countries in Central America, including the following activities: 1) Evaluate the viability of Wolbachia-infected mosquitoes in the local mosquito population;2) Release *Wolbachia*-infected mosquitoes in controlled sites in Central America; 3) Monitor the presence and spread of *Wolbachia*-infected mosquitoes; 4) Work with public health officials to evaluate the impact of *Wolbachia* replacement on arboviral incidence in treated areas; 5) Document the evidence base and lessons learned to support regulatory approval and implementation of *Wolbachia* replacement in US territories where dengue is endemic.

14.1 Establish surveillance systems to track climate-sensitive mosquito-borne diseases and monitor if they are increasing or shifting over time**.**
14.2 Evaluate the implementation and sustainability of *Wolbachia* replacement intervention in Central America
14.3 Develop the evidence base for *Wolbachia* replacement implementation in international settings to support implementation of effective strategies in the United States and help reduce risk of importation of vector borne diseases to the U.S.

Topic 15. Towards dengue elimination: enhanced vector control and surveillance in Puerto Rico (NCEZID)

Puerto Rico faces endemic and epidemic cycles of dengue and other *Aedes* mosquito transmitted diseases, causing significant morbidity and mortality. The burden of dengue among Americans falls disproportionately on residents of Puerto Rico and other U.S. territories, further exacerbating disparities in health linked to socioeconomic status, environmental factors, healthcare spending and access to care, and natural disasters. With recent approval of a dengue vaccine for children, promising mosquito control technologies, and advancements in field-based data systems, there is an opportunity to eliminate dengue from Puerto Rico in the next decade. A key component of dengue elimination is the ability suppress dengue transmission in hotspots and enhance mosquito-based dengue surveillance to detect new introductions of dengue and complement human-based disease surveillance. However, there are no evidence-based methods for how to stop re-introduction or further spread of dengue in areas at risk for outbreaks by responding to focal hotspots.

CDC seeks to support research projects that develop, implement, and evaluate the effectiveness of vector control techniques and enhanced mosquito surveillance in known and emerging dengue hotspots in Puerto Rico. Hotspots are urban areas where: A) an introduced case could lead to an epidemic of an emerging or re-emerging arbovirus, B) historical records show high incidence and persistence of cases, or C) concentrations of people can act as arbovirus “super-spreaders”, such as schools. This effort will support research in 1) developing and implementing mosquito surveillance programs with geographic representativeness across areas of known dengue transmission, 2) modernizing data systems and mapping to measure mosquito surveillance activities in real-time, 3) implementing evidence-based, comprehensive vector control strategies in known and emerging dengue hotspots, 4) supplementing vector control strategies with community-based education to ensure community buy-in and encourage prevention activities, 5) measuring and evaluating activities 1-4 to determine their impact on mosquito populations, human dengue incidence, and timeliness in responding to dengue hotspots and suppressing mosquito populations, and lastly 6) developing cross-cutting communication channels among a range of stakeholders to facilitate situational awareness, project sustainability, and capacity development.

In addition to the objectives described above, projects are encouraged to place a special emphasis on maximizing the impact of the proposed research on reducing health disparities within Puerto Rico associated with socioeconomic status and environmental/housing factors that put certain communities at greater risk of dengue transmission and morbidity.

15.1. Develop and implement methods for enhanced surveillance and response to dengue hotspots in Puerto Rico

15.2. Evaluate the effectiveness of hotspot responses in preventing additional disease spread

Topic 16. Research to inform optimal approaches to environmental sampling and understanding of the prevalence and distribution of pathogenic fungi in healthcare settings (NCEZID)
Healthcare-associated invasive fungal infections (HA-IFIs), including invasive aspergillosis, mucormycosis, and candidiasis, cause devastating morbidity and mortality. The utility of environmental sampling to prevent and respond to fungal infections and outbreaks is limited by the lack of established threshold values or regulatory levels for these pathogens in the healthcare setting and the lack of widely accepted industry qualification or practice standards for assessment and remediation of healthcare sources of fungal diseases. This effort would close key knowledge gaps regarding expected mold and other fungi concentrations in healthcare settings. Further, this effort would help determine optimal approaches to performing environmental sampling for both mold and yeasts with the ultimate goal of preventing HA-IFIs.

16.1. Develop innovative methods for detection and surveillance of pathogenic fungi in healthcare environments

16.2. Quantify baseline levels of pathogenic fungi within healthcare environments

16.3. Correlate fungal quantitative data with episodes of fungal infections or transmission in patients.

16.4. Pilot early detection and surveillance methods for invasive mold and other fungi in patients and in the environment to guide public health efforts.

16.5. Evaluate the feasibility and utility of different environmental sampling approaches for pathogenic fungi in healthcare environments.

Topic 17. Understanding the impact of climate change and other predictors on the distribution and severity of fungal diseases (NCEZID)
Climate change is an urgent public health threat. The environmental disturbances created by climate change will change the impact of fungal pathogens on human health, especially for fungi with environmental habitats. Several tools, including environmental sampling techniques, complex modeling (e. g. machine learning) may help researchers understand how climate change will impact the abundance and pathogenicity of fungi found in the environment. This topic is aimed at soliciting white papers that will help us to prepare for and mitigate climate change-induced fungal disease threats, whether by examining changes in geographic distribution of previously geographic-restricted fungi, evaluating disease risk from fungal spores, like those abundant in wildfire smoke (which is becoming more common with climate change), or better understanding the influence of specific environmental factors on pathogens in the environment.
17.1. Evaluate the influence of climate on diversity and abundance of human-pathogenic fungi in the environment –

17.2. Model geographic spread of fungal diseases based on predicted and observed climate changes

17.3. Understand the effect of severe weather events on the incidence of fungal infections

17.4. Assess role of social factors (e.g., health disparities) in determining severity of fungal diseases.

17.5. Assess role of host factors on determining severity of fungal diseases.

Topic 18. Development of rapid point-of-care (POC) syphilis diagnostic tests (NCHHSTP)
The resurgence of syphilis, an infection caused by the bacterium **Treponema pallidum subspecies** pallidum (*T. pallidum*), in the last two decades is a major public health concern in the United States (US). In 2019, US health

departments reported 129,813 cases of syphilis, an increase of more than 70% since 2015. Congenital syphilis has increased a staggering 279 percent since 2015. In 2019 alone, there were nearly 2,000 cases of congenital syphilis reported, including 128 deaths.

Serological tests that detect treponemal and nontreponemal antibodies remain the mainstay for routine laboratory diagnosis of active syphilis infection. A treponemal test is specific for detection of *T. pallidum* antibodies. They usually remain detectable for life, even after successful treatment. Therefore, such tests cannot distinguish between active or past infection. The nontreponemal antibody test detects antibodies against lipoidal antigens released as a consequence of cell damage from the infection. The nontreponemal titer, in conjunction with clinical signs and symptoms, can help identify acute infection and a reduction in the titer relative to baseline post-treatment usually signals response to therapy. Two current FDA-cleared rapid POC serological tests for syphilis, based on the detection of only total treponemal antibodies, cannot distinguish between active and past/treated syphilis. The WHO convened a panel of diagnostics experts to develop and publish target product profiles of point-of-care serological syphilis tests with potential to advance the field. Minimal and optimal criteria were developed. Results of the consult are publicly available TPPs_STIPOCT_MAY2021_draft (who.int).

However, Serology tests are not ideal because up to 46% of patients with primary syphilis do not have detectable antibodies and because in later stages of syphilis, titers may be low. In addition, persons with treated syphilis also have antibodies, making detection of active infection difficult. For a more targeted approach, polymerase chain reaction (PCR) and other nucleic acid amplification tests (NAATs) have been developed to directly detect *T. pallidum*. However, the sensitivity of NAATs decreases among individuals in later syphilis stages and in specimen sources other than lesion exudate because the lesions resolve. FDA-cleared molecular tests are still not available. Commercial molecular laboratory developed tests (LDTs) for *T. pallidum* are used in the US but not widely available. These assays require specialized laboratory equipment, highly trained staff and have a long turnaround time.

Innovative assays, be it serological or based on direct detection of genetic materials or antigens, that can rapidly and accurately detect active syphilis infection at the point-of-care are urgently needed.

18.1 Development of a rapid point-of-care combo treponemal/ nontreponemal antibody test for active syphilis diagnosis

Objective: CDC seeks white papers to develop a rapid combo treponemal/nontreponemal antibodies test for active syphilis diagnosis. The objectives are to:

1. Develop a rapid combo treponemal/nontreponemal antibodies diagnostic test: The developed POC test will simultaneously screen for the presence and quantitation (optional) of nontreponemal antibodies and confirm syphilis by the detection of antibodies to *T. pallidum*. This configuration of the test must allow for differentiation between current and historic (or treated) infections.
2. Design and perform clinical studies to validate the sensitivity and specificity of the developed dual rapid test using clinical syphilis reactive and nonreactive specimens. The initiation of clinical studies and data collection should proceed in accordance with FDA requirements for Premarket Approval (PMA) application.

18.2 Development of a direct detection test for *T. pallidum,* ideally for all stages of syphilis

Objective: CDC seeks to support the development and evaluation of a diagnostic assay for direct detection of *T. pallidum,* ideally for all stages of syphilis. Such an assay could be very useful for early diagnosis of syphilis to allow timely treatment and prevent horizontal and vertical (mother to infant) syphilis transmission. The expectation is that applicants will develop a POC NAAT or antigen assay for the direct detection of *T. pallidum* in mucocutaneous lesions and non-lesion samples from anatomical sites where lesions may not be apparent (anorectal, mouth) in primary and secondary syphilis, or whole blood specimens from different stages of

syphilis, or other accessible specimens, validate the sensitivity and specificity of the assay for diagnosing syphilis infection, and optimize assay performance for different specimen types and clinical stages.

Topic 19. Decreasing disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, other sexually transmitted infections (STIs), tuberculosis and adolescent health (NCHHSTP)

19.1 Develop, implement, and/or evaluate innovative evidence-based interventions to reduce population-level disparities in the incidence, morbidity and mortality associated with HIV, viral hepatitis, STIs, or tuberculosis.

There are stark disparities in the incidence, morbidity and mortality associated with HIV, viral hepatitis, other STIs, tuberculosis and adolescent health in the United States. CDC seeks to eliminate disparities in health and in all of its determinants through public health programs and policies that address the social and structural factors contributing to population-level disparities in HIV, viral hepatitis, STIs, and tuberculosis among adults and adolescents. Social and structural factors encompass the conditions in which people are born, grow, live, work, and age, as well as the complex interrelated social structures and economic systems that shape these conditions, including aspects of the social environment (e.g., discrimination, income, education level, and marital status), the physical environment (e.g., place of residence, crowding conditions, buildings, spaces, transportation systems, and products that are created or modified by people), and health services (e.g., access to care, quality of care, and insurance status).

The evidence to promote health equity is robust. However, there is a dearth of evidence-based interventions and strategies that are specifically designed to reduce population-level disparities in the incidence, morbidity, and mortality associated with the infections and diseases addressed by our Center. The goal of this announcement is to address that gap. Specifically, CDC seeks to develop, implement, and/or evaluate evidence-based interventions that can reduce population-level disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, STIs, tuberculosis, and adolescent health in the United States. We define evaluation as the systematic method for collecting, analyzing, and using data to examine the effectiveness and efficiency of public health interventions, and to contribute to continuous intervention improvement to address public health actions.
Priority will be given to:

- Offerors who intend to use both absolute and relative health disparity measures to measure reductions in disparities.
- Offerors with experience in screening, prevention, treatment, and care of HIV, viral hepatitis, STIs, or tuberculosis in disproportionately affected populations.
- Interventions that include multi-sector involvement (i.e., health, housing, labor, correctional, and other non-health sectors).
- Interventions that can be scaled up and sustained to achieve significant public health impact.
- Interventions that are focused on reducing disparities in screening, prevention, treatment, and care of HIV, viral hepatitis, STDs, or tuberculosis in large areas of the country with a disproportionate burden of one or more of the indicated diseases and infections.
- Interventions that are focused on addressing the social and structural factors (i.e., changing the conditions in which people are born, grow, live, work and age as described above) that contribute to population-level disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, STIs, tuberculosis, and adolescent health.

Topic 20. Influenza and Other Acute Respiratory Infections (NCIRD)

Influenza (flu) is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and lungs. Some people, such as older people, young children, and people with certain health conditions, are at higher risk of serious flu complications. There are two main types of influenza (flu) viruses: Types A and B. The influenza A and B viruses that routinely spread in people (human influenza viruses) are responsible for

seasonal flu epidemics each year. The best way to reduce the risk of flu and its potentially serious complications is by getting vaccinated each year.

This area of interest involves two (2) focus areas.
1. Diagnostics
2. Prevention

The current gold-standard tool for detection and surveillance of pathogens is real time reverse transcription polymerase chain reaction (rRT-PCR) due to its high level of accuracy and sensitivity. However, there are sometimes limitations in using rRT-PCR as the primary tool for detection and further characterization of pathogens. For example, while rRT-PCR assays can be multiplexed to allow for detection of multiple pathogens simultaneously, the scalability of this multiplexed approach is limited by the filter options on the real time instruments, and typically only four to five targets can be detected within one multiplex design. Furthermore, scenarios can arise in which there is a genomic aberration of interest in a pathogen genome but in a region of the pathogen genome in which an rRT-PCR design is not feasible due to the surrounding sequence. There can also be situations in which it is difficult to design a single rRT-PCR design that can capture and detect the diversity within a specific pathogen (e.g., H5 influenza). Finally, in situations in which a pathogen is evolving rapidly during an outbreak, it would be beneficial to have access to additional diagnostic platforms beyond rRT-PCR that have the ability for a modular approach for design and approval, which could lead to quick implementation of widespread testing if needed. Clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated endonuclease (Cas) systems function in nature as an immune mechanism in prokaryotes to detect and degrade foreign genetic material. This biological system has been recently leveraged to create CRISPR-based diagnostics due to its ability for rapid, sensitive nucleic acid detection with single-base specificity.

20.1. CRISPR-Based Diagnostic Assays for Multi-Pathogen and Multi-Analyte Detection

NCIRD's Influenza Division (ID) seeks to enhance its diagnostic repertoire towards respiratory pathogens, beyond rRT-PCR, through development of CRISPR-based diagnostics to allow for multi-pathogen and multi-analyte detection:

1) Implement a panel of CRISPR-based diagnostic assays that target common respiratory pathogens, which can be used for identification and surveillance purposes during outbreaks of respiratory disease.:
    - Create CRISPR-based diagnostic assays that target a variety of respiratory pathogens.
    - Demonstrate specificity of CRISPR-based diagnostics through inclusivity and exclusivity experiments.
    - Demonstrate relative sensitivity of CRISPR-based diagnostics to rRT-PCR in single infection and co-infection scenarios.
2) Establish a CRISPR-based diagnostic assays that can be used in a reflexive manner once a pathogen has been detected to gain more granular details around subtype or substitutions of interest within the identified pathogen. Establish CRISPR-based diagnostic assays that can be used in a reflexive manner once a pathogen has been detected to gain more granular details around subtype or substitutions of interest within the identified pathogen, and create a subpanel of CRISPR-based diagnostic assays that can:
    - Distinguish influenza virus subtypes of interest.
    - Detect substitutions relating to treatment-resistance within influenza viruses.
    - Detect substitutions within the SARS-CoV-2 genome predicted to affect transmission, diagnostics, therapeutics, or immune escape.
3) Evolve the CRISPR-based diagnostics into a portable version that can be used directly in-field at points of outbreak. Objectives include developing a method for testing CRISPR-based diagnostics in field with minimal equipment/reagent requirements.

Priority will be given to offerors who establish:

1) Experience in CRISPR-based diagnostic design and data analysis.
2) Access to viral materials necessary to evaluate and verify designs.
3) Skill in evolving laboratory-based testing into portable versions that can be implemented in the field.

The COVID-19 pandemic and the response have changed the landscape of influenza. Global circulation of influenza viruses has been universally disrupted and virus transmission has been at historic lows. Although surveillance systems for respiratory illness were severely disrupted in many places, there are now enough data to indicate these decreases in influenza were real and not an artifact of surveillance disruptions. This situation is likely time limited, and influenza is expected to return as measures are lifted and the population returns to pre-COVID behavioral patterns. Indeed, in some tropical countries we have already observed influenza epidemics. This short window of substantial change offers a unique opportunity to better understand the role of non-pharmaceutical interventions (NPIs, including school closures, workplace closures, cancelling public events, restrictions on gatherings, closing public transportation, stay at home requirements, restrictions on internal movements, international travel controls, physical distancing when gathered, hand washing, case isolation, contact tracing, improvements to ventilation, public information campaigns, and mask mandates) on influenza circulation.

NPIs are most effective when they are used in a layered approach, so it can be difficult to tease out which NPIs have or will work best to interrupt influenza circulation. However, knowing this could help us understand what is the least disruptive collection of NPIs that could effectively decrease influenza transmission among a diverse set of sociodemographic groups. Various global data sources exist to explore these questions. For instance, the Oxford School of Government developed the Oxford Stringency Index, which collected systematic data on measures taken by countries to address the threat of COVID-19. In addition, there is a global source for influenza data from routine surveillance systems. Countries report weekly influenza data (specimens tested and specimens testing positive for influenza viruses) to WHO through FluNet. Other, more granular country-specific data (including for the United States) exist on these and other variables of interest that could help explore NPI impact and factors that confound or modify that impact. Creative approaches are needed to explore the separate contribution of various NPIs and their adherence) on influenza circulation, both retrospectively and prospectively as NPI policies are modified. Comparisons to other infections or conditions may be necessary to ensure associations identified with influenza are robust.

20.2. Assessing the role of non-pharmaceutical interventions (NPI) in preventing influenza

NCIRD's Influenza Division (ID) seeks to estimate the separate and joint impact of COVID-19 NPI's and their adherence on influenza circulation to identify which measures were most effective in decreasing influenza transmission through creative and innovative methods to:

1) Estimate the separate and joint effects of layered NPIs on the timing and impact (e.g., reductions in cases, hospitalizations, and deaths) of influenza circulation, both domestically and/or internationally
2) Assess the equitability of NPI impact across a diverse set of sociodemographic groups

The period of interest to CDC is June 2022 to August 2025. Each year, an assessment by CDC will be made as to the utility to move forward, taking several factors into account, including the current level of influenza virus circulation.

Priority will be given to offerors who establish:

1) Track record of similar evaluation activities for COVID-19 or seasonal and pandemic influenza;
2) Track record of using multiple diverse data sources, including those not routinely used in PHh;
3) Experience with or knowledge of surveillance systems to identify acute illness and influenza;
4) Capacity to collect, manage, and analyze the data required by this effort, including data that measure observed or reported behaviors related to NPI policies (e.g., measures of adherence);

5) Estimate NPI effects among diverse sociodemographic groups to assess drivers of inequity;
6) Ability to quantify the preventive value of alternative non-pharmaceutical interventions;
7) Assessments conducted in multiple countries, including the United States.

Topic 21. SARS-CoV-2 (COVID-19) and Children (NCIRD)
School-aged children are exposed to significant respiratory virus transmission in schools, after-school programs, and other community settings. SARS-CoV-2 causes a significant burden of mild disease in children, but the extent of asymptomatic infection and transmission in educational settings remains under studied.

As children and adolescents return to in-person learning mitigation measures to prevent the spread of SARS-CoV-2 are critical. Mitigation measures such as frequent testing, distancing, and mask use have been shown to decrease school-associated SARS-CoV-2 infection; however, COVID-19 vaccination for children is another crucial measure necessary to preventing SARS-CoV-2 transmission.

In December 2020, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the use of COVID-19 Pfizer BioNTech mRNA vaccines in adolescents 16 years and older and expanded this to children 12 years and older in May 2021. Approvals for this same vaccine in children aged 5-11 years occurred in October and other COVID-19 vaccines for children will likely follow. This area of interest involves three (3) focus areas.
1. Transmission
2. Vaccine Effectiveness (VE)
3. Impact

CDC is hoping to leverage existing SARS-CoV-2 school-based testing programs to learn more about SARS-CoV-2 and other respiratory virus transmission in school settings, and to evaluate the effectiveness of COVID-19 vaccines among children and adolescents at varying levels of transmission intensity within schools. Further study of the transmission dynamics of other respiratory pathogens including influenza, and RSV, could also be prioritized from this collaboration to further inform mitigation strategies and improve understanding of best practices for transmission reduction in educational settings.

21.1. Describing respiratory virus transmission in educational settings

NCIRD's Division of Viral Diseases (DVD) seeks to expand the current knowledge base of respiratory virus transmission in schools.

Objectives include:
1) Documenting the proportion of children infected with priority viral respiratory pathogens including SARS-CoV-2, influenza, RSV and others such as parainfluenza, seasonal coronaviruses, human metapneumovirus annually through regular multi-pathogen testing of both symptomatic and asymptomatic children;
2) Estimating the proportion of respiratory virus infections that are symptomatic;
3) Estimating the duration of test positivity for different respiratory viruses;
4) Evaluating the impact of mitigation strategies on the proportion of children infection with priority viral respiratory pathogens;
5) Based on testing results and additional epidemiologic information, determining and/or describing likelihood of in-school transmission.

Priority will be given to offerors who establish:

1) Track record of collaboration with large or multiple school districts (ideally >10,000 children);

2) Capacity to enroll and maintain participation of children aged 5-11 years and adolescents aged 12-17 years in regular (preferably weekly) PCR-based testing of both vaccinated and unvaccinated children while minimizing selection and participation biases;
3) Capacity to document prior history of SARS-CoV-2 infection in enrolled children;
4) Capacity to document the presence or absence of symptoms at the time of testing;
5) Capacity to document the date and product of all COVID-19 doses and influenza vaccines received on or since 12/2020;
6) Capacity to collect and manage data required for this effort.

21.2. Evaluating COVID-19 vaccine effectiveness in schools

NCIRD's Division of Viral Diseases (DVD) seeks to expand the current knowledge base of COVID-19 vaccine effectiveness in educational settings.

Objectives include:

1) Estimating COVID-19 vaccine effectiveness against symptomatic SARS-CoV-2 infection in children aged 5-11 years and adolescents aged 12-17 years;
2) Estimating COVID-19 vaccine effectiveness against asymptomatic SARS-CoV-2 infection in children aged 5-11 years and adolescents aged 12-17 years;
3) Evaluating product-specific COVID-19 vaccine effectiveness by age group, time since second dose, and intensity of transmission within the school setting.

The implementation of SARS-CoV-2 vaccines in the United States has greatly reduced SARS-CoV-2 transmission but with the emergence of highly transmissible variants of concern, such as delta, and the reopening of schools and early care and educations programs, estimating vaccine effectiveness (VE) of COVID-19 among children is vital. While there are several existing pediatric study platforms that estimate VE against hospitalization, VE against asymptomatic infection, and VE against symptomatic infection from urgent care and emergency department settings, these platforms cannot assess VE in the ambulatory care setting and concurrently assess correlates of protection along with long-term follow-up.

A large scale platform is needed to concurrently 1) estimate VE against symptomatic infection among children 0-17 years attending the full range of ambulatory healthcare settings, including pediatrician offices, and identify factors that may modify VE 2) have capacity to collect and test respiratory specimens to report VE by variant and blood specimens to assess correlates of protection, and 3) conduct long-term follow-up to assess persistent symptoms and disruption of education. In addition to estimating VE, collecting this type of data, including genetic sequencing of the viruses, will provide early indicators for the next SARS-CoV-2 surge, emergence of new variants of concern, or different respiratory viruses of pandemic potential. With anticipated expansion of pediatric COVID vaccines to younger age groups, CDC seeks to estimate SARS-CoV-2 VE among children in ambulatory healthcare settings at multiple sites representative of the pediatric population in the US.

21.3. Children 5-17 years: Evaluating the duration of immune protection following COVID-19 vaccination

NCIRD's Division of Viral Diseases (DVD) seeks to evaluate the duration of immune protection in children 5-17 years old following COVID-19 vaccination.

Objectives include:

1) Estimating immune protection following vaccination for 5-11 years and adolescents aged 12-17 years using serologic testing/presence of antibodies;
2) Estimating immune protection following vaccination for 5-11 years and adolescents aged 12-17 years using epidemiologic outcomes, i.e. describing duration of protection from time of vaccination without incident infection at the individual level;
3) Conducting ecological analysis at the age-group (5-11 years or 12-17 years), classroom, and/or school level that quantifies the relationship between vaccine coverage and numbers of incident infections.

21.4. Children 0-17 years: Estimating COVID-19 vaccine effectiveness in ambulatory healthcare settings

NCIRD's Division of Viral Diseases (DVD) seeks to estimate SARS-CoV-2 vaccine effectiveness among children 0-17 years in ambulatory healthcare settings at multiple sites that are representative of the pediatric population in the US, including geographic regions with diverse racial/ethnic and socioeconomic groups.

Objectives include:

1) Determining vaccine effectiveness against symptomatic laboratory-confirmed SARS-Cov-2 among children 0-17 years in ambulatory healthcare settings
2) Determining duration of overall vaccine effectiveness and by variant among children 5-17 years in ambulatory healthcare settings
3) Estimating vaccine effectiveness against persistent symptoms and disruption of education among children 0-17 years attending ambulatory healthcare settings
4) Determining vaccine effectiveness of booster doses or heterologous vaccine schedules among children 0-17 years attending ambulatory healthcare settings
5) Genetically characterize SARS-CoV-2 viruses causing infection in children 0-17 years in ambulatory healthcare settings
6) Assessing correlates of protection against symptomatic SARS-CoV-2 infection among children 0-17 years in ambulatory healthcare settings
7) Identifying demographic and clinical factors that modify the effectiveness of COVID-19 vaccines in preventing SARS-CoV-2 infection among children 0-17 years
8) Estimating incidence of symptomatic laboratory-confirmed SARS-Cov-2 and other respiratory viruses of pandemic potential among children 0-17 years in ambulatory healthcare settings
9) Estimating the incidence of co-infection with SARS-CoV-2 virus and other respiratory viruses of pandemic potential in children 0-17 years
10) Estimating incidence of SARS-CoV-2 reinfection based on self-report history of a positive test and/or access to testing results

Priority will be given to offerors who establish:

1) Track record of successful implementation of similar evaluation activities among pediatric populations;
2) Experience designing and implementing surveillance systems in ambulatory healthcare settings;
3) Capacity to collect respiratory specimens and sera from participants and conduct all steps of specimen processing, management, testing, and sequencing;
4) Capacity to collect, manage, and analyze the data required by this effort.

21.5. COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C)
Multisystem inflammatory syndrome in children (MIS-C) is a rare but severe condition in children and adolescents infected with SARS-CoV-2. The mechanisms of MIS-C are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. The risk of recurrence of the same hyperinflammatory response following reinfection of SARS-CoV-2 or in response to COVID-19 vaccination among people with a history of MIS-C is unknown. Interim clinical considerations on the CDC website have suggested that people with a history of MIS-C should consider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-C, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection. Data are needed in inform vaccination recommendations for persons who have had MIS-C. Because of the concern of a robust hyperimmune response in children with a history of MIS-C when they receive COVID-19 vaccination, evaluation of the immune response and data regarding safety and timing of COVID-19 vaccination after MIS-C are critically important for recommendations and decision-making about the use of COVID-19 vaccines in this population.

NCIRD's Division of Viral Diseases (DVD) aims to evaluate clinical and immune responses among children receiving COVID-19 vaccination after multisystem inflammatory syndrome in children (MIS-C).

Objectives include:

1) Conducting a systematic and prospective evaluation of the immunologic response to COVID-19 vaccination in children <21 years with a history of hospitalization for MIS-C and children in comparator groups, including humoral, T-cell, and innate immunity before and after COVID-19 vaccination.
2) Documenting adverse events by product and dose among children with a history of MIS-C who then receive COVID-19 vaccines.
3) Comparing clinical and immune responses after COVID-19 vaccination among children with a history of MIS-C to those of children in comparator groups. Comparator groups may include children with a history of other inflammatory syndromes (e.g., acute COVID-19, Kawasaki Disease, and Toxic Shock Syndrome) and previously healthy control children without history of an inflammatory/infectious syndrome, as feasible.
4) Identifying potential genetic polymorphisms associated with unique or aberrant immune response to COVID-19 vaccination among children with MIS-C and among children in the comparator groups.
5) Determining if the immune response to COVID-19 vaccination among children who have had MIS-C differs according to MIS-C treatment received (e.g., IVIG + corticosteroids, IVIG alone, corticosteroids alone, tocilizumab, etc.).
6) Describing clinical signs and symptoms associated with SARS-CoV-2 re-infection in persons with a history of MIS-C and COVID-19 vaccination.

Priority will be given to offerors who establish:

1) Past experience designing and implementing longitudinal surveillance of children who have had COVID-19 infection or MIS-C, and capacity to enroll adequate sample size for analysis by age stratification (e.g., ages 16-20, ages 12-15, ages 5-11, and younger as vaccination is authorized).
2) Capacity to perform laboratory testing including inflammatory markers and to collect prospective sera and whole blood samples for peripheral blood mononuclear cells from participants and conduct all steps of specimen processing and management, to include a pre-vaccination draw ideally within 2 weeks prior to COVID-19 vaccination and post-vaccination draws at time points after vaccination (e.g., at 1-2 weeks, 1 month, and every 1-2 months thereafter for 6-12 months.
3) Capacity to collect standardized questionnaires at the time of blood draws to record clinical signs and symptoms and any specific adverse reactions to COVID-19 vaccination (to include recurrence of an MIS-C-like illness, myocarditis, and other events), as well as to assess frequency and clinical manifestations associated with SARS-CoV-2 reinfections.
4) Capacity to perform chart abstraction for initial MIS-C hospitalization and subsequent acute care visits (e.g., clinic, urgent care, emergency department) and hospitalizations, as well as all SARS-CoV-2 laboratory testing to document potential SARS-CoV-2 reinfection through 12 months post-vaccination, as feasible.
5) Capacity to collect specimens and perform similar laboratory testing and questionnaire administration from enrolled comparison groups, including children who have had COVID-19 (or Kawasaki Disease or Toxic Shock Syndrome) and receive COVID-19 vaccination, and children without a history of inflammatory or infectious illness who receive COVID-19 vaccination.
6) Capacity to perform whole genome sequencing for a subset of children in the MIS-C and control groups.
7) Capacity to collect and manage the data required by this effort.
8) The overall likelihood that they can initiate and implement the study in a timely manner.

9) Offerors should describe the outcomes they propose will best evaluate the immunologic response to COVID-19 vaccination in children with a history of MIS-C, including evaluation in comparator group(s).

21.6. 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. 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. 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.

NCIRD's Division of Bacterial Diseases (DBD) Respiratory Diseases Branch (RDB) seeks white papers to assess the prevalence of nasopharyngeal carriage of Streptococcus pneumoniae in children and etiology of AOM during the COVID-19 pandemic in populations that have been disproportionately affected by pneumococcal disease.

Topic 22. Bacterial Respiratory and Vaccine-Preventable Diseases (NCIRD)

CDC aims to improve detection, prevention, and control of respiratory and related invasive bacterial pathogens and accelerate development, introduction, and monitoring of bacterial vaccines domestically and globally.

This area of interest involves two (2) focus areas.
1. Group A Streptococcus (GAS)
2. Pertussis Disease

Group A Streptococcus (GAS) is a persistent public health problem worldwide. GAS causes infections such as strep throat and impetigo. These bacteria also cause approximately 11,000–24,000 cases of severe (invasive) GAS disease, such as necrotizing fasciitis, in the United States each year. Each year, about 1,200–1,900 people die due to invasive GAS disease. The disease burden in developing countries, especially due to rheumatic heart disease, is much greater.

22.1. Assessing the molecular epidemiology of group A Streptococcus (GAS) isolates among children.

NCIRD's Division of Bacterial Diseases (DBD) Respiratory Diseases Branch (RDB) is seeking Offeror's to assess the molecular epidemiology of group A Streptococcus (GAS) isolates among children with pharyngitis and asymptomatic GAS carriage in geographically diverse sites and assess the relationship of these non-invasive GAS isolates to invasive GAS isolates from the Active Bacterial Core surveillance program.

Pertussis, also known as whooping cough, is a highly contagious respiratory disease. It is caused by the bacterium Bordetella pertussis. Pertussis is known for uncontrollable, violent coughing which often makes it hard to breathe. After cough fits, someone with pertussis often needs to take deep breaths, which result in a "whooping" sound. Pertussis can affect people of all ages, but can be very serious, even deadly, for babies less than a year old. Pertussis is a persistent public health problem in the United States despite sustained high vaccination rates, partly because vaccine-induced immunity wanes as demonstrated in numerous studies. Failure of current acellular pertussis vaccines to reduce disease transmission as suggested by animal studies and

differences in the immune response to acellular vs. whole-cell pertussis vaccines may also be drivers of the inability to bring pertussis under better control. The reasons that long-term immunity is not acquired after natural infection or vaccination remains unclear however, due to longstanding gaps in knowledge of the pathogenesis, infectivity, and the immune response to pertussis.

Controlled Human Infection Model (CHIM) studies have emerged as an important tool in the development of a variety of new drugs and vaccines and are suitable for study of pertussis given the infection can be eradicated when antibiotics are administered early in the course of infection. The PERtussIS Correlates Of Protection Europe (PERISCOPE) Consortium has developed a human pertussis colonization model in the United Kingdom and demonstrated that experimental infection with B. pertussis is safe. Because the type of pertussis vaccine used for the primary series has been shown to influence on the subsequent immune profile, pertussis CHIM studies in populations that received acellular vaccines for the childhood series are needed to better understand the immune response to early clinical disease for developing next-generation vaccines in the United States. Additionally, identifying biomarkers that correlate with clinical endpoints is a priority to accelerate FDA licensure of next-generation pertussis vaccines. This topic focuses on the use of a Controlled Human Infection Model platform to accelerate development and licensure of next-generation pertussis vaccines in the United States.

22.2. Understanding the spectrum of clinical pertussis.

NCIRD's Division of Bacterial Diseases (DBD) Meningitis and Vaccine Preventable Diseases Branch (MVPDB) seeks to expand understanding of the spectrum of clinical pertussis disease (through the catarrhal stage), influence of pre-existing vaccine-induced cellular immunity on disease progression, and predictors of symptomatic disease using a controlled human challenge model.

22.3. Understanding immune response to pertussis infection.

NCIRD's Division of Bacterial Diseases (DBD) Meningitis and Vaccine Preventable Diseases Branch (MVPDB) seeks to gain mechanistic insight into the innate and adaptive human immune response to pertussis infection and to identify immune biomarkers of protection using a systems immunology approach with samples from participants in a pertussis colonization trial.

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.

1. **Format**
   - Font size: 12-point, unreduced
   - Single-spaced and Printed only on one side
   - Paper size: 8.5 by 11 inches
   - Page Margin Size: One inch
   - Descriptive Title of the Proposed Project
   - BAA Number

2. **Inclusions:**
   - FORM 1: White Paper Cover Page and Checklist
   - Administrative point of contact and Subject Matter point of contact
   - Project Description addressing in sufficient detail the characteristics identified in Part II
   - Estimated Timeline to complete the project
   - Rough Order of Magnitude (ROM) /high level estimate of what the project will cost

   As applicable:
   - Select Agent Approvals for projects involving hazardous materials or select agents.
   - Public Health Service (PHS) Assurance number and expiration date along with AAALAC accreditation number and renewal date, and United States Department of Agriculture registration number (if applicable) for projects involving live vertebrate animals.
   - Institutional Review Board (IRB) number for projects involving human subjects or data collection.
   - Description of any proposed IT or IT systems development, including whether or not:
     - Investment uses cloud-based solution or modern technology to meet the defined business need
     - Investment provides re-usable functionality and/or data
     - Investment leverages existing solutions, services, or data available at CDC
     - Investment results in data or system modernization (e.g., improves sustainability, mitigates the risk/cost of inaction, uses modern technology and processes)
     -

- 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.

WHITE PAPER SUBMISSION

This BAA is open and in effect for 39 days from the date of release **(December 6, 2021 through January 14, 2022). 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 14, 2022** 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.

****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****

To ensure your submission is received and processed in a timely manner, the subject line of your email must include the **BAA number**, **topic number** and the name of your **Organization**.

Once white papers are submitted technical dialogue STOPS!

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. Timothy Barnes	1	krz3@cdc.gov
Mr. Tray Burch	5, 6	vwa8@cdc.gov
Elizabeth Cole Greenblatt William O'Bryan	3	qst7@cdc.gov rvq0@cdc.gov
Ms. Latoya Hill	7, 8, 9	mdx7@cdc.gov
Mr. Kristopher Lemaster	10	ene3@cdc.gov
Ms. Marva D. Lewis	2	knn5@cdc.gov
Mr. Marty Nemec	18, 19	oga2@cdc.gov
Ms. Jasmine Powell	11, 12, 13	qes1@cdc.gov
Ms. Denedra Threatt	4	qfa5@cdc.gov
Mr. Ronnie Williams	14, 15, 16, 17	oga3@cdc.gov
Mr. Tim Williams	20, 21, 22	tpw8@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: 2022
- Approximate Total Funding: $75,000,000.00 (This amount is an estimate, it is not intended to be a ceiling, and is subject to availability of funds.)
- Anticipated Award Date: July/August, 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 – *Issuance of GFP shall be determined by the CDC Contracting Officer Representative (COR). Access to CDC IT systems and facilities is not anticipated. If it is determined that GFP or access is required, it will be controlled through use of CDC-issued HSPD-12 compliant ID badge.*

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. A sample of the tabs that should be included in the deliverable table are included below.*
NOTE: Deliverables included in Deliverables table must correspond to the tasks outlined under "Technical Requirements"

Task/Subtask	**Purpose**	**Deliverable Description**	**Quantity / Frequency**	**Deliverable Due Date**	**Deliver To Whom**

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 - FORMS & ATTACHMENTS

(See Attached Document)