

## **Centers for Disease Control and Prevention**

National Center for Emerging and Zoonotic Infectious Diseases

**Emerging Infections Program** 

CDC-RFA-CK24-2401

06/20/2023

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#### Part I. Overview

Applicants must go to the synopsis page of this announcement at <a href="www.grants.gov">www.grants.gov</a> and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-CK24-2401. Applicants also must provide an e-mail address to <a href="www.grants.gov">www.grants.gov</a> to receive notifications of changes.

#### A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

#### **B.** Notice of Funding Opportunity (NOFO) Title:

**Emerging Infections Program** 

#### C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at <a href="https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf">https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf</a>. Guidance on how CDC interprets the definition of research in the context of public health can be found at <a href="https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html</a> (See section 45 CFR 46.102(d)).

Please note for this particular NOFO, CDC-RFA-CK24-2401, research activities are allowable and will be subject to all applicable laws, regulations and policy requirements. Note research and human subjects protection requirements inserted throughout this NOFO. All instructions pertaining to research should be addressed and followed as indicated in this NOFO. Please refer to the Strategies and Activities and Attachment 1 for more details.

## D. Agency Notice of Funding Opportunity Number:

CDC-RFA-CK24-2401

## E. Assistance Listings Number:

93.317

#### F. Dates:

#### 1. Due Date for Letter of Intent (LOI):

05/21/2023

#### 2. Due Date for Applications:

06/20/2023

11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

#### 3. Due Date for Informational Conference Call:

## Webinar Info: Public Webinar for 2024 EIP NOFO Applicants

Date: May 1, 2023 from 2:00 - 4:00 PM Eastern Time (US and Canada)

Website: Please click the link below to join the webinar:

https://cdc.zoomgov.com/j/1616323657?pwd=ejB0d3JTMmFtK1NsOUZXQ2pDSzdOQT09

Passcode: x!QAWW^6

Or One tap mobile:

US: +16692545252,,1616323657#,,,,\*43094319# or

+16469641167,,1616323657#,,,,\*43094319#

Audio Call-in: Participant Passcode:

Or Telephone:

Dial (for higher quality, dial a number based on your current location):

US: +1 669 254 5252 or +1 646 964 1167 or +1 646 828 7666 or +1 669 216 1590 or +1 415 449 4000 or +1 551 285 1373

Webinar ID: 161 632 3657

Passcode: 43094319

International numbers available: <a href="https://cdc.zoomgov.com/u/aKLxnpxzU">https://cdc.zoomgov.com/u/aKLxnpxzU</a>

Or an H.323/SIP room system:

H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)

Meeting ID: 161 632 3657

Passcode: 43094319

SIP: 1616323657@sip.zoomgov.com

Passcode: 43094319

# The replay of the recorded EIP NOFO webinar will occur on Tuesday, May $16^{th}$ from 1:00 - 3:00pm ET

When: May 16, 2023 01:00 PM Eastern Time (US and Canada)

Topic: Public Webinar for 2024 EIP NOFO Applicants – Replay Recorded Webinar

Please click the link below to join the webinar:

https://cdc.zoomgov.com/j/1617992179?pwd=bzc5L21Zd1RtRnlWUjV1SnA1cXpnUT09

Passcode: 7h\*sNJPX

Or One tap mobile:

US: +16692545252,,1617992179#,,,,\*17344209# or +16469641167,,1617992179#,,,,\*17344209#

Or Telephone:

Dial(for higher quality, dial a number based on your current location):

US: +1 669 254 5252 or +1 646 964 1167 or +1 646 828 7666 or +1 669 216 1590 or +1 415 449 4000 or +1 551 285 1373

Webinar ID: 161 799 2179

Passcode: 17344209

International numbers available: <a href="https://cdc.zoomgov.com/u/aeuGsPm2f">https://cdc.zoomgov.com/u/aeuGsPm2f</a>

Or an H.323/SIP room system:

H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)

Meeting ID: 161 799 2179

Passcode: 17344209

SIP: 1617992179@sip.zoomgov.com

Passcode: 17344209

#### **G. Executive Summary:**

#### 1. Summary Paragraph

The purpose of this NOFO is to sustain and enhance the multi-site Emerging Infections Program (EIP) network (https://www.cdc.gov/ncezid/dpei/eip/index.html) which provides high quality scientific information to monitor emerging infectious diseases in the United States, evaluate public health interventions, and inform public health policy. Activities of the EIP network include infrastructure and data modernization to support: (1) active surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of pilot prevention/intervention projects; and (4) rapid and flexible response to public health emergencies and newly emerging issues for infectious diseases. The EIP network addresses key public health issues collaboratively, using population-based data, to inform public health policy

recommendations and treatment guidelines for the prevention of disease. Required activities include Infrastructure and Data Modernization and Surveillance and Reporting 1 & 2. Other EIP activities include: Influenza (FluSurv-NET), Respiratory Syncytial Virus (RSV-NET), COVID-19 (COVID-NET), Active Bacterial Core Surveillance (ABCs), Foodborne Diseases Active Surveillance Network (FoodNet), Healthcare-Associated Infections – Community Interface (HAIC), Human Papilloma Virus IMPACT, Lyme and Other Tickborne Diseases (TickNET), Prion Disease, and other infectious-disease related activities. Please refer to Attachment 1 for more details.

#### a. Eligible Applicants:

**Open Competition** 

## **b.** Funding Instrument Type:

CA (Cooperative Agreement)

## c. Approximate Number of Awards

15

Estimated number of awards: 10-15

## d. Total Period of Performance Funding:

\$767,000,000

#### e. Average One Year Award Amount:

\$10,200,000

## f. Total Period of Performance Length:

5 year(s)

#### g. Estimated Award Date:

December 01, 2023

## h. Cost Sharing and / or Matching Requirements:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

#### Part II. Full Text

## A. Funding Opportunity Description

#### 1. Background

#### a. Overview

The Emerging Infections Program (EIP) was initiated in 1995 in response to the growing concern over the emergence and re-emergence of infectious diseases. Following the 1992 Institute of Medicine report "Emerging Infections: Microbial Threats to the United States," CDC developed and published in 1994 a plan for addressing these threats. That plan highlighted the foundational role of public health surveillance and included in its recommendations, the creation of a network of population-based centers of excellence established through state public health departments collaborating with academic institutions, local health departments, public health and clinical laboratories, infection control professionals, healthcare providers, and CDC for special

surveillance and applied public health research, which became the EIP network. See CDC's EIP website at https://www.cdc.gov/ncezid/dpei/eip/index.html and specific activities in Attachment 1.

The EIP network assists with local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases. Activities of the EIP network fall into the following overall categories: (1) active infectious disease surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of pilot prevention/intervention projects; and (4) rapid and flexible response to public health emergencies and newly emerging issues for infectious diseases. The EIP network is particularly suited to address key and emergent public health issues for the U.S. that require a collaborative approach across multiple sites and timely data to inform public health policy and practices and lead directly to the prevention of disease.

The EIP network conducts active, population-based surveillance and special studies for respiratory viral diseases (influenza, COVID-19, RSV), invasive bacterial diseases including antibiotic-resistant infections, foodborne pathogens, healthcare-associated infections (HAIs), and many other infectious diseases. The COVID-19 pandemic has highlighted the importance of having a multi-center surveillance and applied research platform to rapidly respond to public health threats. The EIP network has also played a critical role in responding to emerging infectious diseases by rapidly implementing new collaborative activities, such as the establishment of COVID-NET to rapidly gather public health data for action on COVID-19 hospitalization rates, patient characteristics, and vaccine effectiveness.

For the 2024 NOFO, the EIP network activities will include required components for Infrastructure and Data Modernization (to support core management functions and enhance interoperable data exchange and bioinformatics) and Surveillance and Reporting 1 and 2 for an increase in response efforts for emerging or re-emerging infectious disease(s), outbreak scenarios, or other public health threats. In addition, applicants are encouraged to propose activities for other prioritized areas, described in Attachment 1. Also, enhanced data to understand systemic health and social inequities to advance public health practices and policies that advance health equity, is a new focus for data exchange and across all EIP activities.

#### **b. Statutory Authorities**

This program is authorized under the Public Health Service Act, Sections 301(a) [42 U.S.C. 241(a)], 317(k)(1) [42 U.S.C. 247b(k)(1)], and 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended, and the Patient Protection and Affordable Care Act (PL 111-148), Title IV, Sections 4002 and 4304 (Prevention and Public Health Fund).

#### c. Healthy People 2030

This program addresses the "Healthy People 2030" focus area(s) of Foodborne Illness, Healthcare-Associated Infections, Immunizations and Infectious Diseases, Respiratory Diseases, and Public Health Infrastructure.

#### d. Other National Public Health Priorities and Strategies

This NOFO supports various national public health strategies/priorities for infectious diseases and other conditions including data modernization, public health infrastructure, health equity, social determinants of health, climate and health, respiratory viral diseases and other infectious

diseases, and emerging health threats. See Attachment 1 - EIP 2024 Activities, for specific information regarding national priorities and strategies for each individual EIP activity.

#### e. Relevant Work

EIP network has been in existence and funded by CDC since 1995. There are currently 10 recipients in the EIP that are completing their most recent 5-year EIP period of performance (1/1/2017 - 12/31/2021) plus two extension years (1/1/2022 - 12/31/2023). See https://www.cdc.gov/ncezid/dpei/eip/index.html for details of the relevant work.

## 2. CDC Project Description

## a. Approach

**Bold** indicates period of performance outcome.

CDC-RFA-CK24-2401 Logic Model: Emerging Infections Program

**Bold** indicates period of performance outcome

Strategies and	Short-term	Intermediate	Long-Term
Activities	Outcomes	Outcomes	Outcomes
Enhance	Improved quality	Improved	Improved public
population-	and consistency of	availability and	health system
T I		timeliness of data	surveillance and
to surveillance	efficiency of data	for informing public	response capacity
and public	management	health practices and	
health research		policy	Public health
	Improved timeliness		system better
Provide cross-	of population-based	Increased use of	informed,
cutting	surveillance and	novel and improved	prepared, and
scientific and	data reporting	surveillance	able to identify,
business		methods	control, mitigate,
support	Increased		and prevent
	availability of	Improved outbreak	outbreaks of
Maintain	baseline	monitoring and	infectious
flexibility to	incidence/prevalence	response; trends in	diseases and other
address	of infectious diseases	infectious diseases	conditions
emerging/urgent	and other conditions	and other	including in
issues with a	established	conditions,	disproportionately
population-		including	affected and
based approach	Increased	antimicrobial	historically
	identification of risk	resistance, identified	marginalized
Enhance	factors for infectious		populations
partnerships and	diseases and other	Increased awareness	-
collaborative	conditions identified	of the	Improved
network		incidence/prevalence	treatments and
	Increased	in	guidance to

5			
_	identification of	disproportionately	mitigate the
and workforce	I	affected and	impact of
development	affected and	historically	infectious
	historically	marginalized	diseases and other
Enhance data	marginalized	populations;	health threats
management	populations for	interventions with	
and information	infectious diseases	established	Decreased
dissemination	and other conditions	effectiveness	incidence and
	identified	developed and	severity of
Modernize		publicly accessible	infectious
information			diseases and other
systems for data		Improved disease	conditions and
collection and		treatment guidelines	associated
electronic data		and interventions	disparities
exchange		with established	_
		effectiveness	
Enhance		developed and	
laboratory		shared	
specimen			
collection and			
banking			
Enhance active			
surveillance,			
applied public			
health			
epidemiologic			
and laboratory			
activities and			
public health			
research,			
prevention, and			
evaluation			

#### i. Purpose

The purpose of this program announcement is to sustain and enhance the multi-site Emerging Infections Program (EIP) network which provides high quality scientific information to monitor emerging infectious diseases and other health threats, evaluate public health interventions, and inform public health policy.

Specific purpose and objectives of each EIP activity (listed in Section 2.a.3 – "Strategies and Activities," below) are included in Attachment 1 - EIP 2024 Activities.

#### ii. Outcomes

The overall outcomes will focus on:

• High quality, adequate, and timely data on infectious diseases and other emerging health threats for informing public health policy and practices available

- Novel/improved surveillance methods developed and implemented
- Baseline incidence/prevalence of infectious diseases and other conditions and associated disparities established, and population is monitored for outbreaks
- Risk factors for infectious diseases and other health threats established
- Trends in infectious diseases and other conditions, including antimicrobial resistance, identified and monitored
- Interventions with established effectiveness developed and available
- New/updated disease treatment guidelines and interventions with established effectiveness developed and made accessible for infectious diseases and other health threats
- Disproportionately affected populations for various infectious diseases and other conditions identified and interventions tailored for those populations of focus are developed and publicly accessible

For details regarding the expected outcomes of each EIP activity, refer to Attachment 1 - EIP 2024 Activities. Recipients will be responsible for meeting the period of performance outcomes included in Attachment 1.

#### iii. Strategies and Activities

EIP activities include general crosscutting Infrastructure and Data Modernization (e.g., interoperable data exchange and modernization, training, and workforce development) as well as individual programmatic activities.

Following is a brief overview of each EIP activity. Details for each EIP activity are provided in Attachment 1 - EIP 2024 Activities. Recipients will be responsible for all requirements included in Attachment 1 for each Activity for which they are funded.

EIP Activities – Attachment 1, Sections A – C: All applicants must apply.

- Infrastructure and Data Modernization (required): Attachment 1, Section A
  - O The purpose of this Infrastructure and Data Modernization activity is to provide support to EIP sites to establish and maintain their cross-cutting scientific, programmatic, data modernization, advanced molecular detection (AMD), and business/administrative capacities across all EIP activities. This is intended to include staff, activities, and related costs that are essential to ensuring general EIP infrastructure, and are not supported by the applicant's Indirect Cost Rate Agreement or other cooperative agreement activities. These investments in the basic infrastructure are critical for a comprehensive, efficient, and coordinated approach to general program management from which all EIP activities benefit.
- Surveillance and Reporting 1 (required): Attachment 1, Section B
  - To ensure rapid and flexible response, this potential funding would provide additional epidemiologic, laboratory, and/or health information systems surge capacity necessary for enhanced public health surveillance or applied research activities due to factors such as an increase in response efforts for emerging or reemerging infectious disease(s), outbreak scenarios, or other public health threats.
- Surveillance and Reporting 2 (required): Attachment 1, Section C
  - To ensure rapid and flexible response, this potential funding would provide additional epidemiologic, laboratory, and/or health information systems surge capacity necessary for enhanced public health surveillance or applied research

activities due to factors such as an increase in response efforts for emerging or reemerging infectious disease(s), outbreak scenarios, or other public health threats.

EIP Activities – Attachment 1, Sections D – N: Applicants must apply for at least one (or more) of these activities. Those applicants with relevant experience with these activities are encouraged to apply.

## • Influenza (FluSurv-NET): Attachment 1, Section D

O Population-based surveillance to provide near real-time weekly rates of laboratory-confirmed influenza-associated hospitalizations and data on disparities during each influenza season. Special studies will be conducted to better understand laboratory practices and evaluate prevention strategies in disproportionately affected and historically marginalized populations. Two activity tiers will be offered to sites for FY24. Applicants are required to choose to participate in either Tier 1 or Tier 2 activities. Recipients will be required to complete all activities outlined in their selected tier.

## • Respiratory Syncytial Virus (RSV-NET): Attachment 1, Section E

O Population-based surveillance for laboratory confirmed RSV-associated hospitalizations and associated disparities among children and adults to inform decisions aimed at reducing morbidity and mortality due to RSV. Special studies, such as studies examining testing practices and prevention strategies in disproportionately affected and historically marginalized populations, will be conducted to better understand additional aspects of RSV burden, epidemiology, prevention, and clinical care.

## • COVID-19 (COVID-NET): Attachment 1, Section F

O Population-based surveillance for laboratory confirmed COVID-19-associated hospitalizations and associated disparities among children and adults to inform decisions aimed at reducing morbidity and mortality due to SARS-CoV-2. Special studies, including studies examining testing practices and prevention strategies in disproportionately affected and historically marginalized populations, will be conducted to better understand additional aspects of COVID-19 burden, epidemiology, prevention, and clinical care.

#### • Active Bacterial Core surveillance (ABCs): Attachment 1, Section G

O Active, laboratory, population-based surveillance and conduct special studies for invasive group A Streptococcus, H. influenzae, N.meningitidis, group B Streptococcus and S. pneumoniae to monitor their disease burden, track antimicrobial resistance and evaluate prevention strategies. Enhanced pertussis surveillance and other special studies will be done to better understand rising disease rates and evaluate prevention strategies to reverse these rising trends, including among disproportionately affected populations.

## • Foodborne Diseases Active Surveillance Network (FoodNet): Attachment 1, Section H

 Active, population-based surveillance at EIP sites for laboratory-confirmed infections of 8 bacterial and parasitic pathogens transmitted commonly through food (Campylobacter, Cyclospora, Listeria monocytogenes, Salmonella, Shiga toxin-producing *Escherichia coli* (STEC), *Shigella, Vibrio*, and *Yersinia*). FoodNet also conducts active surveillance for pediatric cases of Hemolytic Uremic Syndrome (HUS) through a network of nephrologists and infection control practitioners and by hospital discharge data review.

- Healthcare-Associated Infections Community Interface (HAIC): Attachment 1, Section I
  - O Population-based surveillance and special projects to inform HAI and AR prevention activities and strategies. The two HAIC Activity categories of work are: 1) population-based surveillance for specific pathogens or infections; and 2) special projects, including HAI and antimicrobial use prevalence surveys. Population-based surveillance monitors the incidence and disparities of infections due to healthcare-associated pathogens at the population level to track changes over time, identify disproportionately affected populations, estimate disease burden, and identify drivers of disparities (i.e., inequities in the social determinants of health). Special projects are limited-duration projects that address specific healthcare safety-related public health questions.
- **HPV-IMPACT:** Attachment 1, Section J
  - Evaluate the impact and effectiveness of the Human Papilloma Virus (HPV)
    vaccination program by monitoring trends and disparities in overall CIN2+ and
    determine HPV type distribution in CIN2+ lesions through a population-based
    surveillance system. Optional projects could also address other HPV-associated
    outcomes.
- Lyme and Other Tickborne Diseases (TickNET): Attachment 1, Section K
  - Better define the public health and societal burden of tickborne diseases in the United States, identify risk factors (e.g., socioeconomic and other determinants of health), and evaluate effectiveness of public health prevention and control strategies to reduce morbidity and mortality due to tickborne diseases and associated disparities.
- **Prion Disease:** Attachment 1, Section L
  - o Implement and maintain an active prion surveillance system in the U.S.
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and ME/CFS like Post-COVID Conditions (PCC): Attachment 1, Section M
  - To advance the understanding of the development and early stages (first 2-5 years) of ME/CFS and ME/CFS-like post-COVID conditions, risk factors, and associated public health burden, and to inform diagnosis and management of these conditions.
- Mpox Vaccine Effectiveness Evaluation: Attachment 1, Section N
  - o To evaluate the effectiveness and durability of JYNNEOS™ vaccine against mpox disease. These data will be critical to informing public health decision—making and vaccine policy for the control and prevention of mpox.

Other emerging or site-specific activities: Applicants may apply

• Applicants may propose individual projects that address emerging issues and/or locally relevant public health issues that meet the objectives of the EIP. These may include activities addressing non-communicable diseases that have the potential to benefit from EIP abilities and approach.

#### 1. Collaborations

#### a. With other CDC projects and CDC-funded organizations:

EIP is a collaborative network between CDC and EIP Recipients, and often strengthened through relationships with recipients' academic and other health partners. Recipients are expected to collaborate with other EIP recipients and collaborate with CDC programs involved in EIP activities as described in the Infrastructure and Data Modernization section, above, and in Application Content and individual program activity sections of Attachment 1. Applicants should include a Letter of Support from each proposed collaborating academic institution or other partner. Letters of Support are to be included as one combined PDF file under "Other Attachment Forms" which should be labeled "Letters of Support". Recipients will be responsible for meeting the collaboration requirements included in Attachment 1 - EIP 2024 Activities.

#### b. With organizations not funded by CDC:

Collaboration with a variety of appropriate partners, including community-based partners and partners from multiple sectors, is strongly encouraged, and the collaboration may be strengthened by including at least one academic institution (if the applicant is not an academic institution). To document these relationships, applicants must include a Letter of Support from each proposed collaborating academic institution or other partner(s). Letters of Support are to be included as one combined PDF file under "Other Attachment Forms" which should be labeled "Letters of Support." If included, the academic partner chosen by the applicant does not need to be within their jurisdiction, it could be any academic institution within the United States. Also, the academic partner can be engaged in select specific activities within the application. Recipients are expected to establish and provide evidence of all local collaborations (e.g., with academic institutions and other partners) to facilitate and enhance their capacity, as described in the Application Content and individual program activity sections of Attachment 1. Recipients will be responsible for meeting the collaboration requirements included in Attachment 1 - EIP 2024 Activities.

#### 2. Target Populations

The population of focus for outcomes from the EIP network is the U.S. population. See individual program activity sections of Attachment 1 for any applicable guidance regarding identifying populations for the individual activities. Overall and as appropriate, surveillance and other activities should consider representativeness of data and ability to assess disparities based on multiple factors, such as geography, rurality/urbanicity, age distribution, race/ethnicity, and socioeconomic status. Recipients will be responsible for meeting any target population requirements included in Attachment 1 - EIP 2024 Activities.

#### a. Health Disparities

Applicants should select a population base/catchment area for their EIP site that includes a diverse population to the extent feasible for the geography/state as well as both traditional and novel data sources to collect and assess health equity indicators. Factors determining diversity of the population and the assessment and reduction of health disparities could include but are not

limited to rurality/urbanicity, race/ethnicity, disability status, socioeconomic status, literacy, health literacy, language, occupation, housing, environment, sexual orientation, gender identity, healthcare access and quality, and other social determinants of health. EIP's ability to source robust population-based data is unique and provides an opportunity to deepening the understanding of health inequities and populations put at increased risk, better enabling targeted prevention and mitigation efforts.

#### iv. Funding Strategy

Applicants will compete for available funds with all other applications submitted in response to this NOFO that are deemed eligible for funding. Successful applicants will be awarded the required Infrastructure and Data Modernization activity and at least one or more optional activities, as applicable, depending on the availability of funds.

## Multiple funding streams are available for EIP awards, including special COVID-19 funding. Estimates of anticipated funding levels:

Infrastructure and Data Modernization (required): \$3,000,000 to \$6,500,000; up to 15 awards

Surveillance and Reporting 1 (required): up to \$30,000,000; up to 15 awards

Surveillance and Reporting 2 (required): up to \$30,000,000; up to 15 awards

FluSurv-NET: \$4,500,000 to \$7,000,000; up to 15 awards

COVID-NET: \$11,000,000 to \$15,000,000; up to 15 awards

RSV-NET: \$3,000,000 to \$5,000,000; up to 15 awards

ABCs: \$11,000,000 to \$13,000,000; 10 awards

FoodNet: \$5,000,000 to \$7,000,000; 10 awards

HAIC: \$29,000,000 to \$30,000,000; 10-15 awards

HPV-IMPACT: \$2,000,000 to \$3,000,000; 5 awards

Lyme and Other Tickborne Diseases (TickNET): \$500,000 to \$2,000,000; up to 4 awards

Prion Disease: \$185,000 to \$300,000; 2 awards

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and ME/CFS-like Post-

COVID Conditions (PCC): \$600,000; 1 award

Mpox Vaccine Effectiveness Evaluation: \$2,000,000 to \$4,000,000; up to 15 awards

Coronavirus Disease 2019 (COVID-19) Funds: A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); and/or the Consolidated Appropriations Act and the Coronavirus Response and Relief Supplement Appropriations Act, 2021 (P.L. 116-260) and/or the American Rescue Plan of 2021 [P.L. 117-2] agrees, as applicable to the award, to: 1) comply with existing and/or future

directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

In addition, to the extent applicable, recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC. HHS laboratory reporting guidance is posted at: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.

Should a public health need (such as a public health emergency or infectious disease outbreak) occur during the life cycle of the award funded under this NOFO, the recipient may have an opportunity to request additional funding. This request may be in response to specific administrative supplemental guidance provided by CDC to conduct additional EIP emergency response support activities within the scope of the funded award and/or a recipient-initiated request for additional resources for existing activities. Any supplemental opportunity is subject to the availability of funds and program priorities.

This award is contingent upon agreement by the recipient to comply with existing and future guidance from the HHS Secretary regarding control of the spread of COVID-19. In addition, recipient is expected to flow down these terms to any subaward, to the extent applicable to activities set out in such subaward.

## **b.** Evaluation and Performance Measurement

#### i. CDC Evaluation and Performance Measurement Strategy

Generally, evaluation and performance measurement for the various EIP activities include quantitative and qualitative measures regarding the following:

- For data modernization
- For surveillance, engagement of applicable partner institutions (clinical institutions, laboratories, etc.)
- For studies, enrollment of subjects/cases
- Completeness of data, including demographic data
- Quality of data
- Timeliness of data submission
- Collection and shipping of isolates and linkage to epidemiological data
- Adherence to study/project protocols

• Staff participation on EIP coordinating group meetings and calls and for individual EIP activity workgroup/committee meetings, calls, trainings, etc.

See each EIP Activity description (Attachment 1) for specifics on measures associated with those specific activities. Each Activity Approach will require its own Evaluation and Performance Measurement plan. See NOFO Section H: Other Information for narrative details that applicants should include for a strong submission.

Specifically, a Data Management Plan (DMP) is required and should include, at a minimum:

- A description of the data to be collected or generated in the proposed project;
- The standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to the data, including a description
  for the provisions for the protection of privacy, confidentiality, security, and intellectual
  property, or other rights;
- Statement of the use of data standards that ensure all documentation that describes the method of collection, what the data represent, and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified; and,
- Other additional requirements based on the program.

Applicants may not be able to provide all of this information when applying but should include a DMP that is as complete as possible.

Under 45 CFR 75.322, CDC is able to obtain a copy of data collected under this award and with CDC funds. CDC recognizes there may be certain legal limitations on the recipients for sharing certain data they may collect, and those legal limitations should be identified in their DMP.

For details regarding each EIP activity's evaluation and performance measurement requirements, refer to each activity section of Attachment 1. Recipients will be responsible for the requirements included in Attachment 1.

#### ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a

description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see <a href="https://www.cdc.gov/grants/additional-requirements/ar-25.html">https://www.cdc.gov/grants/additional-requirements/ar-25.html</a>.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

Applicants are to develop evaluation and performance measurement plans in each of the separate application narratives for the EIP Activities (in Attachment 1) that they are applying for. Detailed application instructions are provided in NOFO Section D, below.

## c. Organizational Capacity of Recipients to Implement the Approach

Competitive applicants must have access to public health data for infectious diseases that are part of the EIP scope (see Attachment 1 – EIP 2024 Activities) including an overall catchment area of one million to eleven million in population. If the applicant is not a state or local public health agency with access and statutory authority to use these data, then applicant must submit a signed letter from public health agency leadership or designee on organizational letterhead. This letter must include the role(s) of the public health agency (e.g., co-lead and participate in which EIP activities throughout the five-year period of performance, etc.) and explicitly state that they agree to provide the applicant access to public health data needed for the proposed EIP activities and have a commitment and pathway to taking public health actions. In addition, applicants are expected to describe an established process for coordination and oversight of data flow and consumption with epidemiology and laboratory agencies, and experience with public health informatics.

Strong applicants will have a demonstrated core organizational capacity to effectively execute the activities outlined by the award. Applicants must describe relevant experience and technical capacity to implement the activities and achieve the project outcomes, experience and capacity to implement the evaluation plan, and a staffing plan and project management structure sufficient to achieve the project outcomes with clearly defined staff roles. This organizational capacity includes skill sets such as program planning and performance management, partnership development, health equity and social and behavioral science, evaluation and program assessment, performance monitoring, financial reporting, budget management and administration, change management, and personnel management (including developing staffing plans and developing and training workforce).

Strong applications will provide evidence of superior organizational capacity to perform as an EIP site, such as:

- Efficient and timely access to public health data for the entire catchment area proposed in this application (from one million to eleven million people) and be able to provide or collaborate on the provision of public health services to that population.
- Experience with program planning, program evaluation, performance monitoring, financial reporting, budget management and administration, personnel management.
- Experience participating in public health emergency response activities.
- Demonstrated relevant experience and capacity (management, administrative, and scientific/technical) to implement the activities and achieve the project outcomes, experience and capacity to implement the evaluation plan, and a staffing plan and project management structure sufficient to achieve the project outcomes and which clearly defines staff roles.
- Existing working relationships with public health entities, academic institutions, and other partners that are critical to successfully implement the EIP.
- Effective relationships with the necessary epidemiology, data science, informatics, public health laboratory, clinical laboratory, and other partners to accomplish the work proposed in the application.
- Skilled and diverse staff and expertise to support activities, including planning, program
  implementation and project management, epidemiology, health equity and social and
  behavioral science, informatics, evaluation, policy, and communications; these capacities
  may reside within the applicant's staff or be formally arranged through contracts and
  other mechanisms of procuring external expertise.
- Demonstrated (or commitment to, if not previously demonstrated) experience with timely data sharing with CDC.
- Demonstrated success at data modernization, with an emphasis on improved interoperability and systems integration.

Health department applicants may describe their current status in applying for public health department accreditation or provide evidence of accreditation as applicable. If providing evidence of accreditation, document should be uploaded as a PDF and labeled "Evidence of Health Department Accreditation." Information on accreditation may be found at http://www.phaboard.org.

Details on what to include in application, and in what order, will be found in this **NOFO Section H: Other Information** and will also be referenced in the evaluation criteria. Applicants are **STRONGLY** encouraged to use the Application Templates that will be made available to ensure they are addressing critical areas to demonstrate capacity.

#### d. Work Plan

In the application narrative, applicants must provide a detailed work plan for each individual activity. Required EIP Activities (Infrastructure and Data Modernization and Surveillance and Reporting 1 and 2) and other activities (FluSurv-NET, COVID-NET, RSV-NET, ABCs, FoodNet, HAIC, etc.) for the first year of the project and a high-level work plan for subsequent years. See application guidance/instructions in Application Content, below, and the individual activity sections of Attachment 1. Applicants are **STRONGLY** encouraged to use the Application Templates that will be made available.

#### e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

Applicants must respond to the performance measures as described for each individual activity: Required activities (Infrastructure and Data Modernization and Surveillance and Reporting 1 and 2) and other activities (FluSurv-NET, COVID-NET, RSV-NET, ABCs, FoodNet, HAIC, etc.) included in Attachment 1 – EIP 2024 Activities. Recipients will also be responsible for meeting recipient reporting (including work plans, performance, and financial reporting). CDC will provide recipient feedback during individual calls and site visits with the recipients. The timing of these feedback activities will be a mutually agreeable timeframe (e.g., at least biannual individual calls with recipients, etc.). CDC will provide aggregated performance feedback for overall NOFO performance to recipients during EIP activity-specific meetings.

## f. CDC Program Support to Recipients

In a cooperative agreement, CDC staff are substantially involved in the program activities, above and beyond routine grant monitoring.

#### **CDC** Activities

- Provide scientific collaboration and subject matter expertise for all EIP sites.
- Provide general coordination for all EIP sites and the overall network.
- Provide coordination specifically for EIP crosscutting activities such as data modernization, quality assurance, epidemiology-laboratory coordination, advanced molecular detection, etc.

- Develop, facilitate, and participate in collaborative multi-site relationships as needed to support the successful completion of projects.
- Provide consultation and scientific and technical assistance as necessary in the operation of the EIP. This may include:
  - o Facilitating the development of protocols and procedure manuals,
  - o Assisting sites with local human subjects requirements,
  - o Assisting with training recipient personnel,
  - o Assisting in the design of projects,
  - o Serotyping isolates,
  - o Performing antimicrobial susceptibility testing,
  - o Assisting with development of detailed Data Management Plans,
  - o Analyzing and interpreting data,
  - o Disseminating results in collaboration with EIP sites,
  - o Coordinating and facilitating communications among EIPs and with other state, tribal, local, and territorial health departments, and
  - Facilitating and coordinating the development and implementation of electronic information exchange. CDC will consult with sites to assist evolution of EIPrelated information systems to conform with applicable (e.g., HHS, CDC) standards.
- Obtain determination of research or non-research from the Associate Director for Science for the respective CIO when CDC scientists are engaged in the research.
- Obtain IRB approval from the CDC Institutional Review Board for research involving human subjects when CDC is engaged.
- Obtain Office of Management and Budget determination and approval per the Paperwork Reduction Act, if necessary.
- Assist recipient principal investigators, as needed, in complying with their responsibilities
  described in the United States Government Policy for Institutional Oversight of Life
  Science Dual Use Research of Concern (DURC)
  <a href="https://www.phe.gov/s3/dualuse/documents/durc-policy.pdf">https://www.phe.gov/s3/dualuse/documents/durc-policy.pdf</a>

#### **B.** Award Information

## 1. Funding Instrument Type:

CA (Cooperative Agreement)

CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

#### 2. Award Mechanism:

U50

Special Cooperative Investigations/Assessment of Control/Prevention Methods

#### 3. Fiscal Year:

2024

#### 4. Approximate Total Fiscal Year Funding:

\$153,400,000

## 5. Total Period of Performance Funding:

\$767,000,000

This amount is subject to the availability of funds.

**Estimated Total Funding:** 

\$767,000,000

#### 6. Total Period of Performance Length:

5 year(s)

year(s)

#### 7. Expected Number of Awards:

15

Estimated number of awards: 10-15

#### 8. Approximate Average Award:

\$10,200,000

Per Budget Period

#### 9. Award Ceiling:

\$0

Per Budget Period

This amount is subject to the availability of funds.

No Award Ceiling

#### 10. Award Floor:

\$0

Per Budget Period

No Award Floor

## 11. Estimated Award Date:

December 01, 2023

#### 12. Budget Period Length:

12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

#### 13. Direct Assistance

Direct Assistance (DA) is available through this NOFO.

## Limited opportunities for Direct Assistance (DA) may be available under this award.

The EIP does not currently have plans for robust DA offerings; however, the program recognizes DA can be a useful tool and therefore chooses to keep the option for DA open throughout this Period-of-Performance. In the event of a DA opportunity, the EIP would communicate details to recipients. For example, EIP Activity partners may find opportunities to offer DA and the EIP could collaborate with existing CDC DA mechanisms (e.g., Career Epidemiology Field Officer Program or Public Health Associate Program) to partially support DA positions. It is likely that any DA support provided would be in lieu of financial assistance (i.e., value of DA support would be subtracted from dollars provided to recipient).

For information on Direct Assistance for Assigning CDC Staff to State, Tribal, Local, and Territorial Health Agencies, refer to:

## https://www.cdc.gov/publichealthgateway/grantsfunding/direct\_assistance.html

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

## C. Eligibility Information

#### 1. Eligible Applicants

Eligibility Category:

00 (State governments)

- 01 (County governments)
- 02 (City or township governments)
- 04 (Special district governments)
- 05 (Independent school districts)
- 06 (Public and State controlled institutions of higher education)
- 07 (Native American tribal governments (Federally recognized))
- 08 (Public housing authorities/Indian housing authorities)
- 11 (Native American tribal organizations (other than Federally recognized tribal governments))
- 12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)
- 13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)
- 20 (Private institutions of higher education)

- 22 (For profit organizations other than small businesses)
- 23 (Small businesses)
- 25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))
- 99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)

Local governments or their bona fide agents

Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau

State controlled institutions of higher education

American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

Non-government Organizations

American Indian or Alaska native tribally designated organizations

Other

Ministries of Health

## 2. Additional Information on Eligibility

The eligibility criteria below will be used to determine whether the applicant has met the program responsiveness criteria for Phase I Review.

#### **Authority**

Eligible applicants must have the public health authority, legislative mandate or otherwise show legal access to the requisite data to conduct population-based infectious disease surveillance and take appropriate public health action based on the data. This authority allows unique and specific access to individual-level identifiable data from multiple data sources that are required to implement the activities outlined in this NOFO and in the individual EIP Programmatic "Approach" sections in Attachment 1 – EIP 2024 Activities. Eligible applicants must document this authority in "Other Attachment Forms" with attachment name "Legal Authority". **CDC will consider any application that does not include this required documentation as non-responsive, and it will receive no further review.** 

For eligible applicants who do **not** explicitly possess the public health authority or legislative mandate but are able to receive access to data (with a commitment and pathway to taking public health action) from their respective public health agency, these applicants must submit a signed letter from public health agency leadership or designee on organizational letterhead. This data

access must allow for unique and specific access to individual-level identifiable data from multiple data sources that are required to implement the activities outlined in this NOFO and in the individual EIP Programmatic "Approach" sections in Attachment 1 – EIP 2024 Activities. In order to be responsive to the Phase I Review, the signed letter by the public health agency leadership or designee must also include the role(s) of the public health agency (e.g., co-lead and participate in which EIP activities throughout the five-year period of performance, etc.) and explicitly state that they agree to provide the applicant access to public health data needed for the proposed EIP activities for the catchment population of [enter catchment population for your jurisdiction] in [enter your jurisdiction] for the duration of the period of performance. Eligible applicants must document this data access in "Other Attachment Forms" with attachment name "Data Access". CDC will consider any application that does not include this required documentation as non-responsive, and it will receive no further review.

## **Letter(s) of Support**

Applicants are required to include a Letter of Support from each of the applicant's proposed collaborating academic and other partners, acknowledging their support and plans to collaborate with the applicant on EIP Activities. Applicants must include at least one academic institution, unless the applicant is an academic institution. The academic partner chosen by the applicant does not need to be within their jurisdiction, it could be any academic institution within the U.S. Also, the academic partner can be engaged in select specific activities within the application. For applicants who do not explicitly possess the public health authority or legislative mandate but are able to receive access to data (with a commitment and pathway to taking public health action) from their respective public health agency, these applicants must submit a signed letter from public health agency leadership or designee on organizational letterhead (see more details above in the Authority section). Letters of Support are to be included in "Other Attachment Forms" with the name "Letter of Support – [Name of supporting institution]." CDC will consider any application that does not include the required letter(s) of support as non-responsive, and it will receive no further review.

#### **Minimum and Maximum Sizes for Catchment Areas**

Due to the goals of national representativeness and feasibility to conduct active population-based surveillance and enhance understanding of health inequities, some proposed catchment areas may be too small to meaningfully contribute to the EIP network, or, alternatively, too large to feasibly conduct these very intensive surveillance activities. While the demographics of catchment areas will be evaluated in these applications, no applicant should propose a catchment area smaller than 1,000,000 people or larger than 11,000,000 people. Of note, this minimum of 1,000,000 people applies to the overall catchment area and not each individual EIP activity (e.g., FluSurv-NET, RSV-NET, COVID-NET, ABCs, etc.). **CDC will consider any application that does not meet this overall catchment area range of 1,000,000 (minimum) to 11,000,000 (maximum) people as non-responsive, and it will receive no further review.** Please refer to *H. Other Information* section of this NOFO (and the provided application template tools – Attachments 2 and 3) for additional information on defining Applicant's catchment area.

#### **Bona Fide Agents**

Bona fide agents for governmental agencies (e.g., state, local, or territorial health departments) are eligible to apply. For more information about bona fide agents, please see the CDC webpage

on Expediting the Federal Grant Process with an Administrative Partner located at <a href="https://www.cdc.gov/publichealthgateway/grantsfunding/expediting.html#Q2">https://www.cdc.gov/publichealthgateway/grantsfunding/expediting.html#Q2</a>.

A bona fide agent is an agency/organization identified by an eligible governmental agency as eligible to submit an application under the agency's eligibility in lieu of the agency itself applying. If applying as a bona fide agent of an eligible governmental agency, documentation is required that establishes the validity of the entity and proves its designation as an authorized representative of the eligible governmental agency. Attach with "Other Attachment Forms" when submitting via www.grants.gov. CDC will consider any application from a bona fide agent that does not include this required documentation as non-responsive, and it will receive no further review.

#### 3. Justification for Less than Maximum Competition

N/A

## 4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

#### 5. Maintenance of Effort

Maintenance of effort is not required for this program.

#### **D.** Application and Submission Information

#### 1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at <a href="www.grants.gov">www.grants.gov</a>.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov- Finding the UEI.

### a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number by registering in SAM.gov prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned to the registering organization.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their UEI numbers before accepting any funds.

## b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number and a Unique Entity Identifier (UEI). All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at <a href="SAM.gov">SAM.gov</a> and the <a href="SAM.gov">SAM.gov</a> Knowledge <a href="Base">Base</a>.

## c. Grants.gov:

The first step in submitting an application online is registering your organization at <a href="www.grants.gov">www.grants.gov</a>, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at <a href="www.grants.gov">www.grants.gov</a>.

All applicant organizations must register at <a href="www.grants.gov">www.grants.gov</a>. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	System for Award Management (SAM)	hefore you can register on	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
2	Grants.gov	Authorized Organization Representative (AOR)  2. Once the account is set up the	It takes one day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI (SAM) which will allow you to register with Grants.gov and apply for federal funding.	Register early! Applicants can register within minutes.

submit applications on behalf of	
the organization	

## 2. Request Application Package

Applicants may access the application package at www.grants.gov.

#### 3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at www.grants.gov.

#### 4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

#### a. Letter of Intent Deadline (must be emailed)

Number Of Days from Publication 30

05/21/2023

## b. Application Deadline

Number Of Days from Publication 60

06/20/2023

11:59 pm U.S. Eastern Time, at <u>www.grants.gov</u>. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

# **Due Date for Information Conference Call Webinar Info: Public Webinar for 2024 EIP NOFO Applicants**

Date: May 1, 2023 from 2:00 - 4:00 PM Eastern Time (US and Canada)

Website: Please click the link below to join the webinar:

https://cdc.zoomgov.com/j/1616323657?pwd=ejB0d3JTMmFtK1NsOUZXQ2pDSzdOQT09

Passcode: x!QAWW^6

Or One tap mobile:

US: +16692545252,,1616323657#,,,,\*43094319# or

+16469641167,,1616323657#,,,,\*43094319#

Audio Call-in: Participant Passcode:

Or Telephone:

Dial (for higher quality, dial a number based on your current location):

US: +1 669 254 5252 or +1 646 964 1167 or +1 646 828 7666 or +1 669 216 1590 or +1 415 449 4000 or +1 551 285 1373

Webinar ID: 161 632 3657

Passcode: 43094319

International numbers available: https://cdc.zoomgov.com/u/aKLxnpxzU

Or an H.323/SIP room system:

H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)

Meeting ID: 161 632 3657

Passcode: 43094319

SIP: 1616323657@sip.zoomgov.com

Passcode: 43094319

## The replay of the recorded EIP NOFO webinar will occur on Tuesday, May 16<sup>th</sup> from 1:00 – 3:00pm ET

When: May 16, 2023 01:00 PM Eastern Time (US and Canada)

Topic: Public Webinar for 2024 EIP NOFO Applicants – Replay Recorded Webinar

Please click the link below to join the webinar:

https://cdc.zoomgov.com/j/1617992179?pwd=bzc5L21Zd1RtRnlWUjV1SnA1cXpnUT09

Passcode: 7h\*sNJPX

Or One tap mobile:

US: +16692545252,,1617992179#,,,,\*17344209# or +16469641167,,1617992179#,,,,\*17344209#

Or Telephone:

Dial(for higher quality, dial a number based on your current location):

US: +1 669 254 5252 or +1 646 964 1167 or +1 646 828 7666 or +1 669 216 1590 or +1 415 449 4000 or +1 551 285 1373

Webinar ID: 161 799 2179

Passcode: 17344209

International numbers available: https://cdc.zoomgov.com/u/aeuGsPm2f

Or an H.323/SIP room system:

H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)

Meeting ID: 161 799 2179

Passcode: 17344209

SIP: 1617992179@sip.zoomgov.com

Passcode: 17344209

#### 5. Pre-Award Assessments

## Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at <a href="https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf">https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf</a>, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at <a href="https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf">https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf</a>, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and UEI.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents \_ Procurement Policy.

## **Duplication of Efforts**

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.

Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

#### 6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at <a href="https://www.grants.gov">www.grants.gov</a>.

#### 7. Letter of Intent

## Due Date for Letter of Intent: 30 days after publication date

Although a letter of intent is not required, it is requested. The purpose of an LOI is to allow CDC program staff to estimate the number of applications and plan for the review of submitted applications.

By the date listed above, prospective applicants are asked to submit a letter of intent that includes the following information:

- Number and title of this funding opportunity
- Name of applicant
- List of EIP Activities for which you intend to apply
- Description of proposed catchment area (provide total population and list of counties included)
- Name, address, email, and telephone number of the Principal Investigator/Project Director
- Names of other key personnel
- Participating academic institution(s), as applicable, and other key partners

The letter of intent should be emailed to:

#### **Programmatic Technical Contact**

Susan Fuller

**Project Officer** 

Division of Preparedness and Emerging Infections

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Email: eipmailbox@cdc.gov

#### 8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at <a href="https://www.grants.gov">www.grants.gov</a>.

#### 9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at <a href="www.grants.gov">www.grants.gov</a>. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at <a href="www.grants.gov">www.grants.gov</a>.

## 10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at <a href="www.grants.gov">www.grants.gov</a>. The Project Narrative must include all of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

#### a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

#### b. Approach

#### i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

#### ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

#### iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

#### 1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

## 2. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

#### c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see <a href="http://www.hhs.gov/ocio/policy/collection/">http://www.hhs.gov/ocio/policy/collection/</a>.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

## d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

#### 11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

## 12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and upload it as a PDF file at <a href="www.grants.gov">www.grants.gov</a>. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at <a href="www.grants.gov">www.grants.gov</a>.

#### **Additional budget instructions:**

As part of your application, provide one single file entitled "Budget Narrative" that includes individual and complete line-item budgets and detailed justification narratives for each EIP activity proposed. Each individual activity budget should be fully detailed for the first 12-Month Budget Period (January 1, 2024 – December 31, 2024).

In addition to the Budget Narrative, applicants must also complete the required EIP budget template provided as Attachment 4. The file should be entitled "EIP Budget Template." The required EIP budget template includes an instruction tab that will detail how budgets should be

broken out. This is the same template that has been used in EIP for current and previous budget periods.

For EIP programmatic activities that have multiple required and/or optional activities, provide one budget that incorporates the costs for all activities under that program with the following exceptions:

- *ABCs* (*Attachment 1 Section G*): If applying to this activity, one single budget should be provided (inclusive of all required and optional ABCs projects you are proposing) with the exception of the Pertussis project. If including a proposal for the pertussis surveillance project, a separate budget should be provided.
- *HAIC* (*Attachment 1 Section I*): If applying to this activity, one single budget should be provided (inclusive of all required and optional HAIC projects you are proposing) with the exception of the Candidemia Surveillance and Mold Surveillance projects. If including a proposal for the candidemia surveillance project and/or mold surveillance project, a separate budget should be provided. See "Budget Note" included in the HAIC section of Attachment 1 EIP 2024 Activities document for additional instructions regarding sub-project budgets.

For the Infrastructure and Data Modernization activity, the budget should include crosscutting scientific, programmatic, and business/administrative staff and related costs (e.g., office rent, utilities, office supplies, travel, etc.) that are not covered by applicant's Indirect Cost Rate Agreement and that are not specific to one or more required or other EIP activities.

Applicants should consider and include requests for travel that may be necessary for proposed activities, including specifically (in the Infrastructure and Data Modernization Activity) travel to the annual EIP coordinating group meeting. Travel that is approved and funded by CDC will be considered a required activity of the cooperative agreement.

## 13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.

- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

## 14. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

## 15. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

#### 16. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.

- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
  - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
  - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See <u>Additional Requirement (AR) 12</u> for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

Please note for this particular NOFO, CDC-RFA-CK24-2401, research activities are allowable and will be subject to all applicable laws, regulations and policy requirements. Note research and human subjects protection requirements inserted throughout this NOFO. All instructions pertaining to research should be addressed and followed as indicated in this NOFO. Please refer to the Strategies and Activities and Attachment 1 for more details.

#### **Additional Funding Restrictions:**

- 1) Applications submitted under this notice of funding opportunity must not include activities that overlap with simultaneously funded research under other awards (no scientific, budgetary or percent effort overlap allowed).
- 2) Please note: Certain grants or recipients are not eligible for expanded authorities. In addition, one or more expanded authority may be overridden by a special term or condition of the award. The Notice of Award (NoA) will indicate the applicability of expanded authorities by reference to the HHS Grants Policy Statement or through specific terms and conditions of the award. Therefore, recipients must review the NoA to determine whether and to what extent they are, or are not, permitted to use expanded authorities.
- 3) Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of

all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions. If multiple collaborating institutions will be involved, please include in the human subjects section of the Project Narrative your single IRB (sIRB) Plan:

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified engaged institutions or participating sites will agree to rely on the proposed sIRB and that any institutions or sites added after award will rely on the sIRB.
- Briefly describe how communication between institutions and the sIRB will be handled.
- Indicate that all engaged institutions or participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- Note: If you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement prior to initiating any multi-site study in the delayed onset study justification.
- 4) Funds relating to the conduct of activities involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols will be required to lift restrictions.
- 5) Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).
- 6) On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC recipient institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at <a href="http://www.phe.gov/s3/dualuse">http://www.phe.gov/s3/dualuse</a>, for a comprehensive listing of those requirements. Non-compliance with this Policy may result in suspension, limitation, or termination of US Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research and may subject the institution to other potential penalties under

applicable laws and regulations.

7) Please note the requirement for inclusion of a Data Management Plan (DMP) in applications described in AR-25 in the Additional Requirements section of this NOFO (<a href="https://www.cdc.gov/grants/additional-requirements/ar-25.html">https://www.cdc.gov/grants/additional-requirements/ar-25.html</a>). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

### 17. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:

https://www.cdc.gov/grants/additional-requirements/ar-25.html.

# 18. Other Submission Requirements

#### a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

- **b. Tracking Number:** Applications submitted through <a href="www.grants.gov">www.grants.gov</a> are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when <a href="www.grants.gov">www.grants.gov</a> receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.
- **c. Validation Process:** Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by <a href="www.grants.gov">www.grants.gov</a>. A second e-mail message to applicants will then be generated by <a href="www.grants.gov">www.grants.gov</a> that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact <a href="https://www.grants.gov">www.grants.gov</a>. For instructions on how to track your application, refer to the e-

mail message generated at the time of application submission or the Grants.gov Online User Guide.

https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get Started%2FGet Started.htm

- **d. Technical Difficulties:** If technical difficulties are encountered at <a href="www.grants.gov">www.grants.gov</a>, applicants should contact Customer Service at <a href="www.grants.gov">www.grants.gov</a>. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at <a href="support@grants.gov">support@grants.gov</a>. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.
- **e. Paper Submission:** If technical difficulties are encountered at <a href="www.grants.gov">www.grants.gov</a>, applicants should call the <a href="www.grants.gov">www.grants.gov</a> Contact Center at 1-800-518-4726 or e-mail them at <a href="support@grants.gov">support@grants.gov</a> for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

- 1. Include the <u>www.grants.gov</u> case number assigned to the inquiry
- 2. Describe the difficulties that prevent electronic submission and the efforts taken with the <a href="https://www.grants.gov">www.grants.gov</a> Contact Center to submit electronically; and
- 3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application via email.

#### E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

#### a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

#### b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

- i. Approach
- ii. Evaluation and Performance Measurement
- iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements

i. Approach Maximum Points: 35

# Overall, across all submitted activity narratives:

- To what extent does the applicant define a proposed **overall** EIP population-base/catchment area that includes a population of at least 1,000,000 and no more than 11,000,000?
- To what extent does the applicant identify and describe appropriate partners for the EIP, including at least one academic institution (not applicable if the applicant is an academic institution)? Has the applicant included Letters of Support from the proposed partnering institution, and are the Letters of Support clear regarding the partner's ability and willingness to fully engage as proposed in the application?
- To what extent does the applicant provide a clear plan on how to implement and conduct each of the activities?
- To what extent does the applicant provide evidence that they can fully accomplish specific activities proposed based on methodology, personnel, and requested budget?
- Are there clear and appropriate timelines for implementation?
- For proposed activities that involve research:

# Specific criteria for any research activities proposed:

- **Significance:** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, clinical practice, and/or health risks, outcomes, and inequities be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and

- members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
- **Investigators:** Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, population of focus, or collaborative arrangements?
- **Protections for Human Subjects:** If the research involves human subjects but does not involve one of the eight categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For research that involves human subjects and meets the criteria for one or more of the eight categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on the review of the Human Subjects section, please refer to <a href="https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general-forms-g.pdf">https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general-forms-g.pdf</a>.
- Inclusion of Women, minorities, and Across the Lifespan: When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children and older adults (>65 years). For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/grants/additional-requirements/ar-2.html) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/grants/additional-requirements/ar-28.html).
- Vertebrate Animals: The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VASchecklist.pdf).

- **Biohazards:** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.
- **Dual Use Research of Concern:** Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed. For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at <a href="http://www.phe.gov/s3/dualuse">http://www.phe.gov/s3/dualuse</a>. Tools and guidance for assessing DURC potential may be found at: <a href="http://www.phe.gov/s3/dualuse/">http://www.phe.gov/s3/dualuse/</a>. Documents/durc-companion-guide.pdf.
- Office of Management and Budget (OMB) under the Paperwork ReductionAct (PRA): Does the applicant adequately describe plans to appropriately manage OMB-PRA requirements/policies? Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the OMB-PRA.
- Per the **Bayh-Dole Act** (the Patent and Trademark Law Amendments Act), businesses (large and small) and nonprofits (including universities) can retain ownership of the inventions made under federally funded research.

Applicants with research activities will not score an advantage over applicants without research activities. Also, applicants proposing only non-research activities will not be negatively scored.

# ii. Evaluation and Performance Measurement Overall, across all submitted activity narratives:

**Maximum Points: 20** 

- To what extent does the applicant demonstrate experience and capacity to implement the evaluation plan?
- To what extent does the applicant describe their plans and ability to collect data and report on the performance measures listed in this NOFO?
- To what extent does the applicant provide measures of effectiveness (performance measures) that will demonstrate accomplishment of the cooperative agreement objectives in each of the activities of this NOFO?
- Are the measures objective and quantitative, and do they adequately measure the intended outcomes of each proposed activity?
- Does the applicant discuss how their program staff will use (e.g., to inform program improvement, identify gaps, program management, etc.) and share performance measurement data collected?
- Does the applicant discuss any barriers or challenges expected for collecting data (i.e., responding to performance measures), and reporting on results? If so, does the applicant describe how these potential barriers would be overcome?

# iii. Applicant's Organizational Capacity to Implement the Approach

**Maximum Points: 45** 

# Overall, across all submitted activity narratives:

- To what extent does the applicant provide adequate descriptions of the catchment areas, including population diversity, for each population-based activity in the EIP that considers sample size or specific population needed to conduct the project?
- Does the applicant's description of its public health authority and legal access to the requisite data to conduct population-based infectious disease surveillance clearly demonstrate that they have direct, comprehensive access to individual-level identifiable data from multiple data sources that are required to implement the activities outlined in this NOFO?
- To what extent does the applicant demonstrate that they have the authority and infrastructure to carry out the proposed activities?
- Do the staff members (applicant and partners) have appropriate experience?
- Are the staff roles clearly defined including particularly the roles of the PI, the partner academic institution, other partners, other EIP site leadership, etc.?
- To what extent does the applicant provide examples of how their EIP has responded (if an existing/prior EIP applicant) or can respond (if a new EIP applicant) in a flexible and timely manner to emerging or critical public health infectious disease threats?
- Does the applicant describe the ability to participate as a working member of the national EIP network and establish local collaborations and partnerships?
- Does the application include opportunities for training for students and public health professionals to expand workforce capacity?
- For eligible applicants who do not explicitly possess the public health authority or legislative mandate but are able to receive access to data (with a commitment and pathway to taking public health action) from their respective public health agency: To what extent does the applicant describe how they will gain and maintain access throughout the period of performance to the various data systems and requisite data (via secure measures) to perform the activities they are applying for in Attachment 1 EIP 2024 Activities? To what extent does the applicant describe any issues that may be encountered as they gain and maintain access to the data systems and requisite data, and how will these issues be resolved in a timely manner?
- For eligible applicants who do not explicitly possess the public health authority or legislative mandate but are able to receive access to data (with a commitment and pathway to taking public health action) from their respective public health agency: To what extent does the applicant describe the level of collaboration with the public health agency? To what extent does the applicant describe the commitment, communication and action plans that the applicant and public health agency will undertake to ensure the data resulting from the proposed EIP Activities will be used for public health action for their jurisdiction, including but not limited to, monitoring emerging infectious diseases, evaluating public health interventions, emergency response activities, and informing public health policy?

Budget Maximum Points: 0 Budget (SF 424A) and Budget Narrative (Reviewed, but not scored). Is the justification and itemized budget for conducting the project reasonable and consistent with stated objectives and planned program activities?

#### c. Phase III Review

Following the Phase II Objective Review (a form of review in which a panel comprised of federal personnel evaluate applications based on stated criteria), a Technical Review comprised of Program staff and CDC Subject Matter Experts will make proposed funding recommendations, considering the following:

- Results of the Phase II Objective Review in light of the NOFO objectives.
- Availability of funds.
- Overall programmatic portfolio balance and need, such as scientific gaps and needs, areas of special interest to EIP, underrepresented scientific areas in EIP's portfolio, and overlap with existing programs.
- Timely data access and commitment to participate in public health emergency response activities
- Geographic distribution to ensure site distribution of funded sites (i.e., selected sites are not all within just a few geographical regions).
- Additional factors to ensure diversity and representativeness of the total U.S. population as it relates to the EIP network, including:
  - o Rural and urban settings
  - Racial/ethnic variation to ensure a population representative of the U.S. and inclusion of sufficient numbers of people from racial/ethnic minority groups to achieve program goals
  - Age distribution
  - Measure of high social vulnerability for socioeconomic status defined as Socioeconomic Status RPL\_THEME1 >= 0.75. The Socioeconomic Status RPL\_THEME1 comprises the following: below 150% poverty, unemployed, housing cost burden, no high school diploma, and no health insurance. Reference:
    - $\underline{https://www.atsdr.cdc.gov/placeandhealth/svi/documentation/SVI\_documentation} \\ zo 2020.html.$
  - Inclusion of populations at increased risk of infectious diseases or at increased risk of poor outcomes of infectious diseases as evidenced by published scientific information and data

Funding recommendations will be decided by the results of the Phase II and Phase III reviews.

Any recommendations for funding out of rank order will be based solely on the criteria listed above.

The review process for non-competitive continuation and supplemental applications will be outlined in future guidance for those proposed activities, consistent with applicable grant

regulations and policies.

# Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- (1) Financial stability;
- (2) Quality of management systems and ability to meet the management standards prescribed in this part;
- (3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
- (4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
- (5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions

restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

# 2. Announcement and Anticipated Award Dates

Awards are expected to be announced no later than January 1, 2024.

#### F. Award Administration Information

#### 1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to annual SAM Registration and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt.

# 2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at <a href="https://www.cdc.gov/grants/additional-requirements/index.html">https://www.cdc.gov/grants/additional-requirements/index.html</a>.

The HHS Grants Policy Statement is available at <a href="http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf">http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf</a>.

- AR-1: Human Subjects Requirements
- AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3: Animal Subjects Requirements
- AR-8: Public Health System Reporting Requirements
- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2030
- AR-12: Lobbying Restrictions
- AR-14: Accounting System Requirements
- AR-15: Proof of Non-Profit Status
- AR-22: Research Integrity
- AR-24: Health Insurance Portability and Accountability Act Requirements

- AR-25: Data Management and Access
- AR-28: Inclusion of Persons Under the Age of 21 in Research
- AR-31: Research Definition
- AR-32: Appropriations Act, General Provisions
- AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
- AR-34: Accessibility Provisions and Non-Discrimination Requirements are incorporated into CDC General Terms and Conditions
- AR-36: Certificates of Confidentiality
- AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

Dual Use Research of Concern Policy: <a href="http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf">http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf</a>

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: <a href="https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75">https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75</a>

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <a href="https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html">https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html</a>.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see <a href="https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html">https://www.lep.gov</a>.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <a href="http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html">http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html</a>.
- HHS funded health and education programs must be administered in an environment free
  of sexual harassment, see <a href="https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html">https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html</a>.

For guidance on administering your project in compliance with applicable federal
religious nondiscrimination laws and applicable federal conscience protection and
associated anti-discrimination laws, see <a href="https://www.hhs.gov/conscience/conscience-protections/index.html">https://www.hhs.gov/conscience/conscience-protections/index.html</a> and <a href="https://www.hhs.gov/conscience/religious-freedom/index.html">https://www.hhs.gov/conscience/religious-freedom/index.html</a>.

## 3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Federal Financial Reporting Forms	90 days after the end of the budget period.	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes

# a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

#### Performance Measurement

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

#### **Evaluation**

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publicly available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

## **b.** Annual Performance Report (APR) (required)

The recipient must submit the APR via <a href="www.Grantsolutions.gov">www.Grantsolutions.gov</a> no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- Evaluation Results: Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- Work Plan: Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- Successes

- Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
- Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
- o Recipients must describe success stories.

## Challenges

- Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
- Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

# • CDC Program Support to Recipients

 Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

## • Administrative Reporting (No page limit)

- o SF-424A Budget Information-Non-Construction Programs.
- Budget Narrative Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- o Indirect Cost Rate Agreement.

The recipients must submit the Annual Performance Report via <u>www.Grantsolutions.gov</u> no later than 120 days prior to the end of the budget period.

#### c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

# d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

# e. Final Performance and Financial Report (required)

The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

# 4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, <a href="http://www.USASpending.gov">http://www.USASpending.gov</a>.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- <a href="https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf">https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf</a>,
- https://www.fsrs.gov/documents/ffata\_legislation\_110\_252.pdf
- <a href="http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA">http://www.hhs.gov/grants/grants/grants/grants-policies-regulations/index.html#FFATA</a>.

# **5.** Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

- B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:
- 1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]
- 2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.
- 3) Terms: For purposes of this clause:
- "Commodity" means any material, article, supplies, goods, or equipment;
- "Foreign government" includes any foreign government entity;
- "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
- 4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
- 5) Contents of Reports: The reports must contain:
- a. recipient name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.
- 6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

#### 6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

- (1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;
- (2) By the HHS awarding agency or pass-through entity for cause;
- (3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- (4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

# **G.** Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

# **Program Office Contact**

# For programmatic technical assistance, contact:

First Name:

Susan

Last Name:

Fuller

Project Officer

Department of Health and Human Services

Centers for Disease Control and Prevention

Address:

National Center for Emerging and Zoonotic Infectious Diseases

Division of Preparedness and Emerging Infections

1600 Clifton Road, MS H24-11

Atlanta, GA 30333

Telephone:

(404) 498-3003

Email:

eipmailbox@cdc.gov

#### **Grants Staff Contact**

# For financial, awards management, or budget assistance, contact:

First Name:

Benita

Last Name:

**Bosier-Ingram** 

Grants Management Specialist

Department of Health and Human Services

Office of Grants Services

Address:

Telephone:

(404) 638-7434

Email:

ula8@cdc.gov

For assistance with **submission difficulties related to** <u>www.grants.gov</u>, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

## **H.** Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at <a href="www.grants.gov">www.grants.gov</a>. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

# For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

Additional Required and Optional Attachments:

- EIP Budget Template (**REQUIRED**)
- Legal Authority or Data Access Documentation (**REQUIRED**)
- Letters of Support (**REQUIRED**)

- Evidence of Health Department Accreditation, as applicable
- Resumes / CVs
- Position descriptions
- Organization Charts
- Indirect Cost Rate, if applicable
- Bona Fide Agent status documentation, if applicable
- Documentation of Relevant Accomplishments: This may include abstracts, publications, bibliographies, number of students trained or training opportunities provided, etc.
- IRB determination/approval letters (for proposed research activities) if available

Appendices submitted via Grants.gov should be uploaded in a PDF file format, and should be clearly titled such as "Curriculum vitaes," "Letters of Support," "Indirect Cost Rate Agreement," "IRBs," etc. Multiple documents of the same type (such as organizational charts, letters of support, CVs, IRBs) should be scanned in as one file. Do not provide a separate attachment for each individual letter or CV.

PROJECT NARRATIVE GENERAL INSTRUCTIONS (Supplemental instructions to Section D. Application Submission Information, Paragraph 10. "Project Narrative," above):

#### FORMAT:

#### PAGE LIMIT:

Disregard page limits stated under first sentence of Paragraph 10 - "Project Narrative" above (but do follow other page and type format instructions).

The EIP application must be written according to the following outline. The entire application should contain a single, overarching 'Background.' Applications must include a separate and distinct *Approach* for each EIP Activity (e.g., Infrastructure and Data Modernization, Surveillance and Reporting 1 and 2, FluSurv-NET, COVID-NET, RSV-NET, ABCs, FoodNet, HAIC, etc.) that is responsive to the supplemental guidance (Attachment 1 - EIP 2024 Activities). Each of these *Approach* sections should include a problem statement, justification and applicant capacity section. These sections must address the activities and outcomes to be conducted over the first budget period and should also address a 'high-level' five-year plan to cover the entire Period of Performance.

Applicants should keep the review criteria (listed in Section E.1. Review and Selection Process, b. Phase II Review, above) in mind while writing the narratives. Be sure to clearly address all applicable review criteria in each narrative.

Applicants are STRONGLY encouraged to use the application template tools provided by EIP for NOFO submission. These tools will capture all required information for each EIP Activity and is being provided to all applicants as Attachments 2 and 3.

Background (a single narrative for entire application) – Applicants are STRONGLY encouraged to use Attachment 2 – EIP Application Template - Background

**Catchment Area and Strategy** 

- 1. Provide information on your jurisdiction's proposed catchment area.
  - o **Identify Catchment Area** [e.g., name state and the counties and census tract identifier(s) (i.e., FIPS codes) of any additional or excluded (whichever is most efficient for describing the catchment area) sub-county areas within the state].

# **Catchment Population**

- 1) Total population associated with catchment area (total number) Use the most recently released 5-year American Community Survey (ACS) dataset available for U.S. Census table DP05 at data.census.gov.
- 2) Urban and rural populations (total number and percentage of catchment population) Use the most recently released data available for U.S. Census table P2 at data.census.gov. Calculate the percentage based on the "Total" from table P2, not the percentage of the total catchment area reported in #1 above.
- i. Please provide data on the following factors that may define the diversity of populations in the catchment area:
- 1. Age distribution (total number and percentage for each age category of the catchment population using 2020 Census data)
- 2. Race/ethnicity (total number and percentage for each race/ethnicity category of the catchment population using 2020 Census data)
  - Describe the rationale for the selection of the applicant's proposed catchment area. If the proposed catchment area does not include the entire jurisdiction, please comment on the feasibility for expansion for specific projects.
  - o Describe the feasibility of conducting comprehensive and active population-based surveillance in the catchment area.
  - Provide an overview of morbidity and mortality related to infectious diseases in this catchment area. Include information on specific infectious diseases being investigated as part of EIP's large programs (FluSurv-NET, COVID-NET, RSV-NET, ABCs, FoodNet, HAIC).
  - Describe the healthcare infrastructure in the applicant's catchment area as it relates to the EIP, focusing on healthcare access and coverage. Explain the applicant's understanding of variations in healthcare and public health infrastructure within the jurisdiction that may impact surveillance activities.

# **Structure and Organization**

- 1. Provide an overview of the applicant's organizational structure (e.g., if a health department, is it centralized, decentralized or hybrid). Provide an organizational chart as an attachment and describe that chart in this section, pointing out key leadership that will be involved in the EIP if the applicant is selected for funding. Briefly summarize the qualifications of these key leaders for implementing and managing the EIP overall. Include their full Curricula Vitae in the application attachments.
- 2. Describe the organization's public health authority, including legislative mandate or otherwise demonstrate legal access to the requisite data to conduct population-based infectious disease surveillance and take appropriate public health action based on the

data. Explain if this authority allows unique and specific access to individual-level identifiable data from multiple data sources that are required to implement the activities outlined in the individual EIP Programmatic "Approach" sections. Also, explain if this authority allows for statutory authority and responsibility for the health of the population the applicant serves, a demonstrated ability to execute public health priorities for the jurisdiction, authority to collect public health data, and infrastructure to carry out the proposed activities. In addition to the description here, document this authority in "Other Attachment Forms" with attachment name "Legal Authority" with a short memo identifying the legal authority within the applicant's jurisdiction. **CDC will consider any application that does not include this required documentation as non-responsive, and it will receive no further review. NOTE:** For applicants who do **not** explicitly possess public health authority or a legislative mandate but are able to receive access to data (as described in the EIP NOFO "Additional Information on Eligibility/Phase I Review" section) from their respective public health agency, refer to #9 in this section and **respond to all the requirements and questions.** 

- 3. i) Describe the organization's experience working as part of a network or multi-partner collaboration to conduct activities or projects related to enhanced surveillance for infectious diseases including active population-based surveillance. ii) Describe the applicant's experience in establishing successful collaborations and partnerships with other organizations in the jurisdiction (e.g., county/city health departments, local non-government organizations or health service providers, etc.).
- 4. i) Provide examples of how the applicant has conducted public health responses/interventions in a flexible and timely manner using early surveillance data to address emerging or critical public health infectious disease threats. ii) Discuss the management controls and processes in place to ensure flexibility and timely public health responses/interventions at the applicant's site.
- 5. i) Describe the applicant's capacity and timeliness to acquire new staff and execute contracts. Explain existing challenges with funded but unfilled staff positions or unawarded contracts related to infectious disease work. ii) If the applicant has received federal funding for the COVID-19 response, describe their ability to spend those funds according to their initial workplan and describe how they overcame, or are overcoming, barriers to implementation.
- 6. i) Identify all proposed partner organizations/institutions, including at least one academic institution, unless applicant is an academic institution. REQUIRED: Provide a "Letter of Support" from the partner as an Attachment to this application (on Attachment titled "Letters of Support" that includes letters of support from all proposed partners). ii) For each proposed partner: Describe the applicant's overall strategy of collaboration with the partner. Include the partner's role(s) in EIP activities and the capabilities expected. Describe how the selected partner will be an asset in conducting the proposed EIP activities. iii) For each proposed partner: Discuss any barriers that may impact this relationship. For example, describe if the applicant has previously contracted with this organization or institution and, if so, have they been able to allocate funds to them efficiently and have those dollars always been expended appropriately?
- 7. i) Describe the applicant's collaborations with other CDC infectious disease-related cooperative agreements (e.g., Epidemiology and Laboratory Capacity for Prevention and

- Control of Emerging Infectious Diseases (ELC) and Public Health Emergency Preparedness (PHEP) Cooperative Agreements). Please describe how capacities supported by those cooperative agreements (and other CDC cooperative agreements) would provide a base on which to build these enhanced EIP activities without duplication. ii) If there are additional federal programs that will have important linkages to the EIP activities that the applicant is applying for, please describe those.
- 8. Describe how the applicant will create and incorporate opportunities for student and other public health professional training to expand public health workforce capacity related to EIP activities.
- 9. For eligible applicants who do **not** explicitly possess the public health authority or legislative mandate but are able to receive access to data (with a commitment and pathway to taking public health action) from their respective public health agency, these applicants must submit a signed letter from public health agency leadership or designee on organizational letterhead. This data access must allow for unique and specific access to individual-level identifiable data from multiple data sources that are required to implement the activities outlined in this NOFO and in the individual EIP Programmatic "Approach" sections in Attachment 1 – EIP 2024 Activities. In order to be responsive to the "Additional Information on Eligibility/Phase I Review" section of this NOFO, the signed letter by the public health agency leadership or designee must also include the role(s) of the public health agency (e.g., co-lead and participate in which EIP activities throughout the five-year period of performance, etc.) and explicitly state that they agree to provide the applicant access to public health data needed for the proposed EIP activities for the catchment population of [enter catchment population for your jurisdiction] in [enter your jurisdiction]. Eligible applicants must document this data access in "Other Attachment Forms" with attachment name "Data Access". CDC will consider any application that does not include this required documentation as nonresponsive, and it will receive no further review.
- For eligible applicants who do **not** explicitly possess the public health authority or legislative mandate but are able to receive access to data (with a commitment and pathway to taking public health action) from their respective public health agency: Describe how the applicant will gain and maintain access throughout the period of performance to the various data systems and requisite data (via secure measures) to perform the activities they are applying for in Attachment 1 EIP 2024 Activities. Describe any issues that may be encountered as the applicant gains and maintains access to the data systems and requisite data, and how these issues will be resolved in a timely manner.
- For eligible applicants who do not explicitly possess the public health authority or legislative mandate but are able to receive access to data (with a commitment and pathway to taking public health action) from their respective public health agency: Describe the level of collaboration with the public health agency. Describe the commitment, communication, and action plans that the applicant and public health agency will undertake to ensure the data resulting from the proposed EIP Activities will be used for public health action for their jurisdiction, including but not limited to, monitoring emerging infectious diseases, evaluating public health interventions, and informing public health policy.

# **Overall Approach**

- 1. i) Describe the overarching goals for the applicant's proposed EIP site (in addition to the CDC defined goals and objectives that appear in this NOFO). ii) If selected, what strengths, skills, or advantages would the applicant's jurisdiction bring to the EIP collaboration?
- 2. Applicant's capacity and experience:
  - Describe the applicant's capacity and demonstrated experience with enhanced surveillance activities for infectious diseases, including active population-based surveillance, and applied public health research.
  - O Discuss how the applicant will optimally leverage the existing healthcare system in their jurisdiction to accomplish EIP objectives. Include electronic data exchange activities and data modernization approaches to improve the efficiency of obtaining data from these healthcare systems.
  - Provide a description of the applicant's previous experience with programs/projects like those appearing in the Attachment 1 for this NOFO.
     Include content specific to each of EIP's major programs for which the applicant is applying: FluSurv-NET, COVID-NET, RSV-NET, ABCs, FoodNet, and HAIC.
  - O Describe the applicant's ability to collect and analyze health record data to supplement standard infectious disease surveillance. Include information on the volume and variables they have been able to collect and analyze for infectious disease surveillance. Provide a description of any work to improve their ability to efficiently access these data. Provide information on current and planned methods for collection of these data (e.g., data entry from faxes, interoperable EHRs, etc.). Describe the data repository for health record data and provide information on interoperability with other surveillance systems.
  - Explain the applicant's overall method(s) for data management and isolate collection including how they would ensure confidentiality. Include tools and information on how the applicant would pilot new methods of surveillance and use data exchange for surveillance and research as local/state information systems modernize.
  - Describe how the applicant would communicate and disseminate findings and lessons learned in the EIP to the local public health community, jurisdictional health departments, and the public as appropriate.

# Project Approach (One Narrative for each EIP Activity) - Applicants are STRONGLY encouraged to use Attachment 3 – EIP Application Template – Project Approach

- 1. **Background:** Applicants must provide relevant background information that includes the context of the problem and describes how this activity relates to EIP program priorities as described in Background section for each EIP Activity.
- 2. **Purpose:** Describe how the applicant's implementation of this activity will address the public health issue(s) identified (See Purpose section for each EIP Activity).
- 3. **Catchment Area (for population-based activities):** State whether the catchment area for this activity is the full area described in Background Catchment Area and Strategy. If not the full area, describe the specific catchment area for this activity. Describe the

- rationale for using the full area or this specific catchment area and how the applicant has taken into account sample size or specific population needed to conduct the activity.
- 4. **Outcomes:** Cleary identify the outcomes expected to be achieved by the end of the first budget period and the five-year period of performance. Refer to outcomes listed in the Outcomes section for the relevant EIP Activity. All outcomes must indicate the intended direction of change (i.e., increase, decrease, maintain, complete, etc.). In addition to outcomes identified by the CDC program, applicants should include any additional outcomes they anticipate.
- 5. **Applicant Capacity:** Describe the current resources, processes and steps planned to implement this activity and achieve expected outcomes.
  - o Current Capacity: For each EIP Activity, describe the applicant's current capacity to successfully implement the proposed strategies and activities.
  - If the applicant was funded for a similar activity in the past, describe capacities attained during that funding period (including staff and other infrastructure already in place).
- 6. **Evaluation Plan for 2024:** If needed, EIP will work with recipients during the first six months of the period of performance to finalize an evaluation and performance measurement plan to monitor the progress of the activities implemented and outcomes achieved. Applicants must provide an overall evaluation and performance measurement plan for each EIP Activity. This plan must address the following points:
  - Propose one or more specific performance measures that can be used to track and demonstrate progress and accomplishment of the activity objectives and proposed outcomes. Measures should be objective, quantitative, and time-bound.
  - Identify key program staff who will participate in collecting and reporting performance measurement data.
  - Describe the applicant's experience and capacity to implement the evaluation plan.
  - Describe the applicant's plans and ability to collect data and report on the performance measures listed in this NOFO.
  - Discuss how the applicant and their program staff will use and share performance measurement data collected (e.g., to inform program improvement, identify gaps, program management, etc.).
  - o If applicable: Discuss any barriers or challenges expected for collecting data (i.e., responding to performance measures, system access), and reporting on results. Describe how these potential barriers would be overcome. In addition, applicants may also describe other measures to be developed or additional data sources and data collection methods that applicants will use to evaluate their activities and outcomes.
- 7. **Work Plan:** Provide an implementation plan for each project within each EIP Activity. Include:
  - o General implementation strategy stating how applicant will approach the activity.
  - o Resources (in place or applied for) for implementation
    - List key staff members (applicant's, academic partner's, other partner's) that will be responsible for implementation and management of this

- activity. Briefly summarize their overall qualifications regarding these activities and include their full Curricula Vitae in the application attachments.
- Describe the specific roles and responsibilities of each listed key staff member.
- o Provide clear and appropriate timelines for implementation of the activity.
- List the planned milestone(s) that will be achieved and tracked to ensure that the activity is completed on time and within budget.
- Describe the expected outcomes resulting from the completion of the activity, and the performance measures/indicators that will be used to assess those outcomes.
- For any proposed activities that are research or include a component that is research, be sure to clearly address the following 9 issues. For 1-9, refer to review criteria details for these issues in Section E.1. Review and Selection Process, b. Phase II Review, in the NOFO:
  - Significance
  - Innovation
  - Approach (including Specific Aims)
  - Investigators
  - Environment
  - Human Subjects and/or Vertebrate Animal Protections: For each proposed activity that involves human subjects and/or vertebrate animal research, describe how adherence to human subjects and/or vertebrate animal protection policies and requirements will be assured.
    - a. For human subjects research, describe the risks to human subjects, the adequacy of protection against risks, potential benefits of the proposed research to human subjects and others and the importance of knowledge gained (see Section 4.1 at: <a href="https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf">https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf</a> #4 1 protection of human subject). If available, indicate the local status of IRB review or determination and provide, in an attachment, copies of the most recent local IRB approvals.
    - b. For human subjects research involving multiple sites, please indicate which IRB is the IRB of record or whether an exception is requested, if known. Exceptions to the single IRB requirement will be considered with adequate justification, as determined by CDC.
    - c. For vertebrate animal research, please address all required components found at <a href="https://grants.nih.gov/grants/olaw/VASchecklist.pdf">https://grants.nih.gov/grants/olaw/VASchecklist.pdf</a>
- Inclusion of Women, Minorities, and Children: For each proposed activity, describe how applicant will ensure inclusion of women, minorities and children in research activities (see Sections 4.2 and 4.4 at:
   <a href="https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4\_1\_protection\_of-human-subject">https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4\_1\_protection\_of-human-subject</a>).

- Biohazards and Dual Use Research of Concern (DURC): a. Describe whether
  biohazardous materials or procedures are proposed and if so, describe whether/how they
  are potentially hazardous to research personnel and/or the environment and describe how
  the applicant will assure adequate protection. b. Describe plans to appropriately manage
  DURC requirements and policies, if applicable. See Dual Use Research of Concern
  Policy at: <a href="http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf">http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf</a>
- Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA)

# I. Glossary

**Activities:** The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see <a href="https://www.cdc.gov/grants/additional-requirements/index.html">https://www.cdc.gov/grants/additional-requirements/index.html</a>. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

**Approved but Unfunded:** Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

**Assistance Listings:** A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

**Assistance Listings Number:** A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

**Award:** Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

**Budget Period or Budget Year:** The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

**Carryover:** Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

**Competing Continuation Award:** A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).

**Continuous Quality Improvement:** A system that seeks to improve the provision of services with an emphasis on future results.

**Contracts:** An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

**Cooperative Agreement:** A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

**Cost Sharing or Matching:** Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

**Direct Assistance:** A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. <a href="https://www.cdc.gov/grants/additional-requirements/index.html">https://www.cdc.gov/grants/additional-requirements/index.html</a>.

**Evaluation (program evaluation):** The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

**Evaluation Plan:** A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

**Federal Funding Accountability and Transparency Act of 2006 (FFATA):** Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at <a href="https://www.USAspending.gov">www.USAspending.gov</a>.

**Fiscal Year:** The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

**Grant:** A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

**Grants.gov:** A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at <a href="www.grants.gov">www.grants.gov</a>.

**Grants Management Officer (GMO):** The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative

agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

**Grants Management Specialist (GMS):** A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

**Health Disparities:** Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

**Health Equity:** Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

**Health Inequities:** Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

**Healthy People 2030:** National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

**Inclusion:** Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

**Indirect Costs:** Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

**Letter of Intent (LOI):** A preliminary, non-binding indication of an organization's intent to submit an application.

**Lobbying:** Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

**Logic Model:** A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

**Maintenance of Effort:** A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

# Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA):

Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

**Nonprofit Organization:** Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

**Notice of Award (NoA):** The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

**Objective Review:** A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

**Outcome:** The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

**Performance Measurement:** The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

**Period of performance –formerly known as the project period - :** The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

**Period of Performance Outcome:** An outcome that will occur by the end of the NOFO's funding period

**Plain Writing Act of 2010:** The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear,

consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

**Program Strategies:** Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

**Program Official:** Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

**Public Health Accreditation Board (PHAB)**: A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation <a href="http://www.phaboard.org">http://www.phaboard.org</a>.

**Social Determinants of Health:** Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

**Statute:** An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

**Statutory Authority:** Authority provided by legal statute that establishes a federal financial assistance program or award.

**System for Award Management (SAM):** The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing <a href="www.grants.gov">www.grants.gov</a> to verify identity and pre-fill organizational information on grant applications.

**Technical Assistance:** Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

**UEI:** The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is free. If an organization does not know its UEI number or needs to register for one, visit <a href="https://www.sam.gov">www.sam.gov</a>.

**Work Plan:** The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

# **NOFO-specific Glossary and Acronyms**