NCIPC Determination

General Information

Project Title

Overdose Data to Action: CE19-1904

Science Officer(s) Puja Seth and Rita Noonan **Division**: DUIP **Telephone**: (404) 639-6334

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Project Officer(s) Jocelyn Wheaton,Hen Kuoh **Division**: DUIP **Telephone**: (404) 639-1048

E-mail kzw9@cdc.gov; ilq7@cdc.gov **CITI certificate expiration date**: _____

Proposed Project Dates:
Start: 09/01/2019 (Ex: MM/DD/YYYY) **Ending**: 08/31/2022 (Ex: MM/DD/YYYY)

Funding Mechanism

- Cooperative Agreement #: Bulk note — Funding FOA#: CE19-1904
- Grant #: _____ — Funding FOA#: _____
- Contract#: _____
- No funding (Specify): _____

Describe the purpose, methods, and outcomes of the project (Use space provided - Abstract of purpose, methods and outcomes)

Purpose- To support recipients in getting high quality, complete, and timelier data on overdoses, and to use those data to inform prevention and response. There are two required components of this award - a surveillance component and a prevention component.

Methods- Within these two components, recipients will implement required and chosen optional strategies to enhance the quality and timeliness of data on overdose morbidity, and mortality, and then to use these data to inform and target prevention and response efforts at the state and local level.

Outcomes- Recipients are expected to implement activities that will impact relevant short- and intermediate-term outcomes listed in the logic model. All recipients should be positioned and are expected to impact **long-term** outcomes within four to six years or earlier after receiving funding, regardless of the strategies chosen. These long-term outcomes include:
-Decreased drug overdose death rate, including prescription opioid and illicit opioid overdose death rates
-Decreased rate of opioid misuse and opioid use disorder
-Increased provision of evidence-based treatment for opioid use disorder
-Decreased rate of emergency department (ED) visits due to misuse or opioid use disorder.

Describe the roles and responsibilities of CDC and any partner organizations (e.g., grantee, contractor).

CDC will be responsible for conducting monitoring of awards funded through CE19-1904. Monitoring activities included routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Additionally, CDC will provide standardized templates to the funded jurisdictions for collection of fatal and non-fatal surveillance data for program monitoring.

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Applicability of Human Subjects Regulations

Please check appropriate category:

☑ **I. Activity is not research.** Primary intent is public health practice: disease/injury control, surveillance, improvement of programs or services. Objectives focused on a specific population.

- ☐ **A.** Epidemic/endemic **disease/injury control** activity; collected data directly relate to *immediate* disease control needs (e.g., epi-aid).
- ☐ **B.** Routine **disease/injury surveillance** activity; data used for disease control program or policy purposes for a specific health condition/disease in a specific population and setting. (Includes disease reporting)
- ☑ **C. Program evaluation/monitoring** activity; data are used primarily for assessing, monitoring or improving a program, policy, or a communications activity (e.g., message testing) in a specific population/setting.
- ☐ **D.** Purchase orders or contracts for services or equipment.

-OR-

☐ **II. Activity is research but does NOT involve human subjects.** Primary intent is to develop or contribute to generalizable knowledge, but data is obtained solely from non-human sources or not living individuals, or anonymous existing data collected for another purpose are being analyzed:

- ☐ **A.** Activity is research involving collection/analysis of data about health facilities or other organizations or units, which are not individual persons
- ☐ **B.** Activity is research using existing unlinked or anonymous data previously collected for another purpose.
- ☐ **C.** Activity is research involving data and/or specimens from *deceased persons.*

-OR-

☐ **III. Activity is research involving human subjects but CDC is not engaged.** CDC employees including visiting scientists, fellows, and on-site contractors (but not off-site contractors or other collaborators

*Will NOT obtain consent or data by intervening or interacting with participants
*Will NOT have access to identifiable (including coded) private data or biological specimens

***NOTE**: Once local IRB approval has been obtained please forward a copy (electronic preferred) to the NCIPC Human Subjects Coordinator for records keeping purposes.*

-OR-

☐ **IV. Activity is research involving human subjects but exempt according to the categories specified in the regulations 45 CFR 46.101(b).** Educational practices, Educational tests, surveys, interviews, or observation of public behavior. Existing data, documents, records (e.g., not identifiable, publicly available). Demonstration projects.

-OR-

☐ **V. Activity is research involving human subjects, CDC is engaged, and CDC IRB approval will be sought.**

Required Signatures

Puja Seth -S Digitally signed by Puja Seth -S Date: 2019.05.29 14:28:02 -04'00' 05/30/2019

Branch/Team Official (e.g., Branch chief or Team Lead) **Date**

Erin M. Parker -S3 Digitally signed by Erin M. Parker -S3 Date: 2019.05.31 13:15:41 -04'00' 05/31/2019

Division Official (e.g., ADS, Director) **Date**

Karen C. Angel -S Digitally signed by Karen C. Angel -S Date: 2019.06.03 10:45:20 -04'00' 06/03/2019

Human Subjects Coordinator **Date**

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