Form Version Date: January, 2019

NCIPC Determination

General Information

Project Title

Drug Overdose Surveillance and Epidemiology (DOSE)

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

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Proposed Project Dates:
Start: 10/01/2019 (Ex: MM/DD/YYYY) **Ending**: 10/01/2022 (Ex: MM/DD/YYYY)

Funding Mechanism

- Cooperative Agreement #: RFA-CE19-1904 Funding FOA#: CDC-RFA-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: Rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses. Fifty-two health departments (all 50 state health departments, the health department of Puerto Rico, and the health department of the District of Columbia) will be funded to share local-collected and aggregate ED data with CDC on at least 75% of ED visits occurring in the jurisdiction on a monthly basis.

Methods: The project will leverage ED syndromic data and hospital discharge data on ED visits already routinely collected by state and territorial health departments. No new data will be systematically collected from EDs, and health departments will be reimbursed by CDC for the burden related to sharing ED data with CDC. Fifty-two funded health departments (50 state health departments, Puerto Rico, and the District of Columbia) will rapidly share existing ED data with CDC on a monthly basis using the *Rapid ED overdose data form* and standard CDC case definitions. Data may come from different local ED data systems, but is expected to cover at least 75% of ED visits in the jurisdiction (e.g., state). Specifically, some health departments conduct rapid overdose surveillance using local ED syndromic systems or hospital discharge data, while others conduct surveillance using CDC's National Syndromic Surveillance Program (NSSP). In order to assess and improve rapid ED data sharing, all 52 participating health departments will also be asked to share counts of ED visits involving suspected drug, opioid, heroin and stimulant overdoses by county, age group, sex, and time (i.e., month and year) from more finalized hospital discharge file using the *ED discharge overdose data form* and standard CDC case definitions.

Outcomes - Receipt, analysis, and dissemination of rates and changes in rates of ED visits involving suspected drug, opioid, heroin, and stimulant overdoses to inform response to emerging outbreaks and provide situational awareness of the progression of the opioid epidemic at the local, regional and national level.

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

CDC will fund 52 health departments (all 50 state health departments, the health department of Puerto Rico, and the health department of the District of Columbia) through a cooperative agreement (Overdose to Action, CDC-RFA-CE19-1904) to share the following data with CDC: 1) ED visits involving suspected drug, opioid, heroin, and stimulant overdoses by county, age group, sex, and time (i.e., month and year) captured from a local rapid ED data system using CDC case definitions and *the Rapid ED overdose data form* on a monthly basis and 2) ED visits involving suspected drug, opioid, heroin and stimulant overdoses by county, age group, sex, and time (i.e., month and year) from more finalized hospital discharge on a quarterly or yearly basis using the *ED discharge overdose data form* and standard CDC case definitions.

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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: 2019.03.27 16:54:31 -04'00'

Branch/Team Official (e.g., Branch chief or Team Lead) — **Date** 03/27/2019

Erin M. Parker -S3 — Digitally signed by Erin M. Parker -S3 Date: 2019.03.28 12:43:17 -04'00'

Division Official (e.g., ADS, Director) — **Date** 03/28/2019

Karen C. Angel -S — Digitally signed by Karen C. Angel -S Date: 2019.03.29 12:08:04 -04'00'

Human Subjects Coordinator — **Date** 03/29/2019

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