Distribution of Traceable Opioid Material Kits across U.S. Laboratories

OMB Control No. 0920-xxxx

NEW

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Respondent laboratories can be from any sector (academic, public, or private), must be located in the U.S., must have a verifiable business address, must have a current DEA registration, must comply with respective state and local regulations, and must submit requests directly to the respective vendor (**Attachment 3**).

CDC is currently distributing a product line of Traceable Opioid Material* Kits (TOM Kits*). Examples of the products in this line are the: (1) Opioid Certified Reference Material Kit (Opioid CRM Kit); and (2) Fentanyl Analog Screening Kit (FAS Kit) (**Attachment 3**).

To receive TOM Kits*, the requestor must provide answers to the survey of choice (**Attachment 6**). Questions on the survey involve the volume of samples processed by the requesting lab and other questions involving how many lab samples, including those provided by the TOM Kit*, will be prepared and analyzed. The attributes of the lab and the analysis method of the TOM Kits* may change; therefore, future requests will require filling the survey out again to ensure the most up-to-date information is used to prioritize kit distribution.

No statistical methods or sampling is necessary. The respondent laboratories will be a convenience sample of those interested in receiving the TOM Kits* at no cost from the CDC.

B.2. Procedures for the Collection of Information

Information collection will be performed on the TOM Kits* manufacturers' websites (**Attachments 3 and 6**). This information collection form is 100% electronic. There is no special software that will be used and the survey uses common internet interfaces to fill out, thereby minimizing any training time and cost to fill out the form. Upon completion, a submission button is used to submit electronically and instantaneously.

B.3. Methods to Maximize Response Rates and Deal with No Response

To receive any TOM Kit*, the requestor must provide answers to the survey. Therefore, response rates will be 100 percent.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

B.4. Test of Procedures or Methods to be Undertaken

In 2019, the CDC conducted an emergency information collection, titled "Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. Laboratories," under the Health and Human Services (HHS) Secretary's Public Health Emergency Paperwork Reduction Act (PHE PRA) Waiver mechanism for the period from 03/20/2019 to 05/10/2019 (**Attachment 4**). From 05/10/2019, CDC continued distributing kits using a generic information collection (GenIC) under "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" (OMB Control No. 0923-0047; expiration date 01/31/2022) (**Attachment 5**).

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The individuals working on this information collection, including development, data collection, and data analysis are members of the CDC Emergency Response Branch (in the CDC National Center for Environmental Health – Division of Laboratory Sciences).

Table 1. Personnel Responsible for Collection and Analysis of Information

Name	Title	Affiliation	Phone	Email
Melissa D. Carter, PhD, MBA	Senior Service Fellow	CDC	*(770) 488-7263*	vsm8@cdc.gov

References

https://www.cdc.gov/nceh/dls/erb_opioid_kits.html

https://www.cdc.gov/nceh/dls/pdf/Opiod_Factsheet-508.pdf

http://www.cerilliant.com/ShopOnline/CDC.aspx

https://www.caymanchem.com/forensics/faskit/?q=*%3A*

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