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

OMB Control No. 0920-xxxx

NEW

Supporting Statement Part A –

Justification

Project Officer: Melissa D. Carter, PhD, MBA
Title: Senior Service Fellow
Phone: 770-488-7263
Email: vsm8@cdc.gov
Fax: 770-488-7518

Date: 05/04/2020

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

Table of Contents

Part A. Justification

Goal of the study: The purpose of this information collection (IC) is for the CDC to assure that the Traceable Opioid Material* Kits (TOM Kits*) product line is being distributed to different types of laboratories in public, private, and non-profit sectors.

Intended use of the resulting data: 1) To gather information on the types of laboratories requesting the kits, and 2) To determine the types of instrumentation, matrices, and sample size for those requesting kits.

Methods to be used to collect: CDC vendors will distribute the 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). TOM Kits* products will use the same online survey on their respective websites.

Subpopulation to be studied: The subpopulation for this information collection will be laboratories located in the U.S. They must have a verifiable business address, must have a current DEA registration, must comply with respective state and local regulations, and must submit requests for TOM Kits directly to the respective vendor.

How data will be analyzed: General purpose statistics such as aggregation of similar responses to compare quantities with different responses.

A.1. Circumstances Making the Collection of Information Necessary

For the first time in U.S. history, a drug class has been declared a national public health emergency (Hargan, et al); each day more than 140 Americans die from drug overdoses, 91 specifically because of opioids. Since 2013, there have been significant increases in overdose deaths involving synthetic opioids – particularly those involving illicitly-manufactured fentanyl. The U.S. Drug Enforcement Administration (DEA) estimates that 75% of all opioid identifications are illicit fentanyls (DEA, 2018 Emerging Threat Report). Laboratories are routinely asked to confirm which fentanyl or other opioids are involved in an overdose or encountered by first responders, as it is critical to identify and classify the types of drugs involved in an overdose, how often they are involved, and how that involvement may change over time. By understanding which drugs are present, appropriate prevention and response activities can be implemented.

The illegal manufacture of a variety of fentanyl analogs presents one of the more difficult problems for laboratory analyses of forensic and post-mortem cases. In 2015, members of the

scientific community called for more specificity in opioid analyses, and up until 2016, national epidemiological data was sparse on the specific illicit fentanyl analogs entering the market or causing death.

Laboratory testing does exist for opioids that are available clinically or are widely recognized. However, there has been a rapid expansion in new types of illicit opioids, particularly fentanyl analogues. Health care providers, public health surveillance officials, and law enforcement officers need to know which opioids are in use to treat, monitor, and investigate fatal and non-fatal overdoses. For laboratories to test them, they need samples of the new illicitly manufactured fentanyls of concern. Laboratories will use small amounts of these deadly fentanyl types to develop and maintain the critical ability to identify them.

To fill this need, the Centers for Disease Control and Prevention (CDC) has developed the Traceable Opioid Material* Kits (TOM Kits*), which provide over 200 opioid reference standards, including over 190 fentanyl analogs.[1] These kits were designed to dramatically increase laboratory capability to confirm which opioids are on the streets and causing deaths. The kits are free to laboratories in the public, private, clinical, law enforcement, research, and public health domains (**Attachment 3**).

To equitably distribute the TOM Kits*, 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**).

To continue this collection, the CDC is requesting approval for a three-year Paperwork Reduction Act (PRA) clearance for this new information collection request (ICR) also titled "Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. Laboratories."

CDC is authorized to carry out this activity under the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241) (**Attachment 1**). The 60-day Federal Register Notice was published on 02/28/2020 (**Attachment 2**) and is further discussed in Section A.8.

A.2. Purpose and Use of the Information Collection

[1] See CDC TOM Kits website at https://www.cdc.gov/nceh/dls/erb_opioid_kits.html

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

The purpose of this information collection is for an application for benefits and general purpose statistics.

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

- Example 1 - Opioid CRM Kit
    - Manufactured and distributed by Cerilliant Corporation [2]
    - Includes 1 milligram each of 22 opioids and their matched, stable isotopes (carbon-13; nitrogen-15)
    - Addresses 99.5% of DEA fentanyl/fentanyl-related cases in the DEA 2018 Q1 Report
    - Improves confirmation of mass spectrometry methods analysis
    - Includes unprecedented isotopically-labeled internal standards
    - Opioid CRM Kit Request (**Attachment 6**) available online at http://www.cerilliant.com/ShopOnline/CDCRequest.aspx
- Example 2 – FAS Kit
    - Manufactured and distributed by Cayman Chemical [3]
    - Includes 200 micrograms each of 200+ fentanyl analog analytical reference materials
    - Provides largest collection of available fentanyl analog reference materials
    - Improves immunoassay and mass spectrometry screening methods
    - Includes structural variability for fentanyl analog
    - FAS Kit Application (**Attachment 6**) available online at https://www.caymanchem.com/forensics/faskit/?q=*%3A*

Respondent laboratories requesting one of the kits 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 Drug Enforcement Administration (DEA) registration, must comply with respective state and local regulations, and must submit requests directly to the respective vendor.

As the number of laboratories requesting TOM Kits* exceeds the supply, this information collection will be used to prioritize which laboratories will receive the limited quantities of kits. The brief six-minute web-based surveys will allow the CDC to (1) determine what service the recipient laboratory performs and the volume of samples the laboratory processes and (2) equitably distribute TOM Kits* based on the analysis techniques, matrix, and sample size used by the recipient laboratory.

---

[2] Cerilliant Corporation - http://www.cerilliant.com/default.aspx
[3] Cayman Chemical - https://www.caymanchem.com/

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

The information collection will serve to gather information on the types of laboratories requesting the kits and to determine the types of instrumentation, matrices, and sample size that those requesting kits will use them for. Since the demand for the kits has shown to be greater than the supply of kits, questions about the laboratory function will aid in assuring that labs that serve a variety of different functions will have access to kits. Collecting information about the volume of samples that the lab typically processes assures that the labs with the biggest volume do not get all the kits, thereby allowing smaller labs access to the kits. Questions pertaining to the matrix, sample size, and method of analysis is information that can be used to tailor future kits to the needs of the labs that are using the kits. This information will be gathered upon request for TOM Kits* and compiled by the vendors of the TOM Kits*.

If no information about lab function is collected, there may be a disproportionate distribution of kits to labs that serve similar or identical functions, thereby leaving a paucity of kits for laboratories that perform other functions. Additionally, no information to assist in improving the program, or how to optimize the way the sample material is provided would be possible.

The program is funded in the upcoming year, and is anticipated to be funded over the next three years.

A.3. Use of Improved Information Technology and Burden Reduction

Information collection will be on the TOM Kits* manufacturers' websites (**Attachments 3 and 6**). The information collection is 100% electronic. There is no special software that will be used and the surveys use common internet interfaces to complete, thereby minimizing any training time and cost to fill out the form. Upon completion, a submission button is used to submit electronically and instantaneously. By adopting a common internet interface, and one that can be accessed with any major web browser, errors are minimized, costs and burden time are reduced, and ease of submission is maximized.

A.4. Efforts to Identify Duplication and Use of Similar Information

It is possible that a laboratory may submit more than one request for TOM Kits*. The CDC website, "Traceable Opioid Material* Kits to Improve Laboratory Detection of Synthetic Opioids in the U.S." states that although laboratories may request multiple kits, supplies are limited and requests will be filled based on product availability. If requesting multiple kits over time, the

attributes of a laboratory and the analysis method of the TOM Kits* materials may change. Therefore, future requests will require filling the survey out again to ensure the most up-to-date information is being used to prioritize kit distribution.

There is no information elsewhere about the types of labs, quantity of samples analyzed by the labs, or matrix types used by labs performing opioid analysis so it is critical that the program ask these questions for prioritizing kit distribution.

A.5. Impact on Small Businesses or Other Small Entities

Because this information collection involves laboratories as respondents, a large proportion will affect small businesses or other small entities. Nevertheless, the TOM Kits* survey (**Attachment 6**) is designed to collect the absolute minimum amount of information needed (six-minute surveys) to distribute materials, and the recipient laboratories will benefit by receiving free TOM Kits*.

Based on our respondent estimates (**Section A.12**), we assume that 67 percent of the respondents will be small businesses or other small entities (e.g., 400 state/local/tribal government laboratories + 400 private/not-for-profit institutions ÷ 1200 = 67%). The remaining 33 percent of the respondents are estimated to come from the federal government.

A.6. Consequences of Collecting the Information Less Frequently

The respondents will be able to follow the links from the CDC TOM Kits* Factsheet (**Attachment 3**) and website [1] to the vendor websites[2,3] to fill out the appropriate TOM Kits* online survey (**Attachment 6**). This information collection is itself used as a voluntary but formal request for the TOM Kits*. The respondents must complete their online requests to be considered to receive the requested TOM Kits*.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

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

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on 02/28/2020, Vol. 85, No. 40, pp. 11991 (**Attachment 2**). CDC/ATSDR received three comments in support of this information collection and a fourth comment that did not address the posted project (**Attachment 2a**). Because three comments were supportive of the work and a fourth was not a comment on the posted project, no further revision to the information collection was required.

B. The data collection surveys were designed collaboratively by CDC personnel. Consultation will continue throughout the implementation process. There were no external consultations.

Name	Title	Affiliation	Phone	Email
Melissa Carter, PhD, MBA	Senior Service Fellow	Emergency Response Branch	*(770) 488-7263*	VSM8@cdc.gov
Rudolph, Johnson, PhD	Supervisory Research Chemist	Emergency Response Branch	*(770) 488-3543*	RMJ6@cdc.gov
Mike Mojica, PhD	Associate Service Fellow	Emergency Response Branch	*(404) 498-1404*	lta4@CDC.gov
Samantha Isenberg, PhD	Associate Service Fellow	Emergency Response Branch	*(770) 488-3435*	yhx1@cdc.gov

A.9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments for providing information. Selected recipient laboratories will receive the TOM Kits* at no cost as described in **Section A.2**.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC Chief Privacy Officer has reviewed this submission and determined that the Privacy Act does not apply (**Attachment 8**).

Any business information provided to a TOM Kits* manufacturer is for distribution mailing purposes only and will not be used by CDC.

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

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The NCEH/ATSDR Human Subjects Advisor has determined that this information collection is not research involving human subjects and that IRB approval is not required (**Attachment 7**).

CDC collects information about laboratories and does not collect personally sensitive information (**Attachment 6**). Laboratories may view information collections pertaining to organizational policies, performance data, or other practices as sensitive; however, the information that CDC is requesting is not anticipated to result in liability or competitive disadvantage if a breach should occur.

A.12. Estimates of Annualized Burden Hours and Costs

The following burden hours and number of annualized responses were estimated from CDC's 2019 experience with the information collected under the PHE PRA Waiver (03/20/2019 to 05/10/2019) and the GenIC approved on 05/10/2019 and conducted under "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" (OMB Control No. 0923-0047; expiration date 01/31/2022).

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Federal Laboratories	TOM Kits* Questions	400	1	6/60	40
State, Local, and Tribal Government Laboratories	TOM Kits* Questions	400	1	6/60	40
Private or Not-for-Profit Institutions	TOM Kits* Questions	400	1	6/60	40
Total					120

Estimates of the annualized cost to respondents were based on the Department of Labor "May 2018 National Occupational Employment and Wage Estimates, United States" mean hourly wages. (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

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

NCEH used the following occupation codes and hourly wage estimates to represent each respondent type in the burden table.

Mean Hourly Wages for Respondent Types

Respondent Type	Occupation Code	Occupation Title	Mean Hourly Wage
Laboratorians and laboratory directors	19-0000	Life, Physical, and Social Science Occupations	$36.62

Estimated Annualized Burden Costs (Based on 2019 requests)

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Federal Laboratories	TOM Kits* Questions	400	1	6/60	40	$36.62	$1,464.80
State, Local, and Tribal Government Laboratories	TOM Kits* Questions	400	1	6/60	40	$36.62	$1,464.80
Private or Not-for-Profit Institutions	TOM Kits* Questions	400	1	6/60	40	$36.62	$1,464.80
Total							$4,394.40

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

The information system is designed to use existing hardware within funded sites. No capital or maintenance costs are expected. Additionally, there are no start-up, hardware or software costs.

A.14. Annualized Cost to the Federal Government

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

Average annualized cost is $5,000,000 or less. This estimate was based on the following table:

Staff	GS Level	Salary (2018)	% FTE	$ Cost
Project Officer, Senior Service Fellow	13	$97,740	10%	$9,774.00
Associate Service Fellow	12	$79,626	10%	$7,962.60
Salary Sub-total				$17,736.60
Other Annualized Costs				$ Cost
Travel				$20,000.00
Contracts				
Procurement of Traceable Opioid Material* Kit Materials and Recipient Laboratory Support, 75D301-19-D-06776				$4,700,000.00
Total				$4,737,736.60

A.15. Explanation for Program Changes or Adjustments

This is a new ICR.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Information collected will be used to prioritize requests received by the CDC. If this prioritization is discussed within a manuscript describing kit distribution, then it may be published with other data.

Table A.16.1

Project Time Schedule	
Activity	Time Schedule
Collection begins when GenIC expires	May 2020
Analyses	As needed
Publication	TBD if applicable

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

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

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

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*

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