Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 0923-0047)

TITLE OF INFORMATION COLLECTION:
Distribution of Traceable Opioid Material[§] Kits across U.S. Laboratories

PURPOSE:
The Centers for Disease Control and Prevention (CDC) developed the Traceable Opioid Material[§] Kits, which provide over 150 opioid samples, including over 100 fentanyl types. These kits will dramatically increase the laboratories' ability 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.

When CDC first made the kits publicly available online on 2/1/2019 (**Attachment 1**), the kits were distributed on a first come/first served basis, but the demand for the kits was greater than anticipated, and requests vastly exceeded supply. Currently, the limited information that CDC receives when laboratories request kits does not allow CDC to prioritize by geography, capacity or expertise, which labs receive kits nor to allocate kits to best address the opioid epidemic. Thus, CDC proposes additional questions to requesting laboratories (**Attachment 2**). The questions will allow CDC to: (1) distribute the test kits across U.S. laboratories; (2) decide on the number of kits to send to a selected laboratory; (3) provide information in GAO audits; and (4) modify future kits in volume and content.

Responses to these additional questions are currently collected by CDC under a Public Health Emergency Paperwork Reduction Act (PHE PRA) Waiver (**Attachment 3**), and are necessary to allow CDC to distribute the kits for maximize impact. The purpose of this GenIC request is to obtain PRA clearance to continue this collection for future test kit distribution and after the PHE PRA Waiver expires. The Research Determination Form for this project is also included (**Attachment 4**).

DESCRIPTION OF RESPONDENTS:
Respondents will include public, private, clinical, law enforcement, research, and public health laboratories that will request Traceable Opioid Material[§] Kits.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form	[ ] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software)	[ ] Small Discussion Group
[ ] Focus Group	[x] Other: Service Delivery

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

CERTIFICATION:
I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Stephanie I. Davis -S Digitally signed by Stephanie I. Davis -S Date: 2019.04.29 09:02:14 -04'00'

Stephanie Davis, NCEH/ATSDR OMB PRA Coordinator

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [x] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [x] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No

Gifts or Payments:
Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [x] No

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time Per Response (in hours)	Burden (in hours)
Private Sector Laboratory	1000	6/60	100
State or Local Laboratory	500	6/60	50
Federal Government Laboratory	500	6/60	50
Totals	**2000**	6/60	**200**

FEDERAL COST: The estimated annual cost to the Federal government is $20,000 which was calculated as 20% of the FTE salary maintaining, reviewing, and summarizing the Service Delivery question contents and answers.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[x] Yes[ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Any laboratory requesting Traceable Opioid Material§ Kits will be the respondents for the application questions. Of these, only laboratories with scheduled registration through the U.S. Drug Enforcement Administration (DEA) will be able to receive the kits; there are roughly 1,550 of these registered laboratories. The CDC works closely with its federal partners at the DEA so that they can announce newly available products using their registered laboratories mailing list.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   - [x] Web-based or other forms of Social Media
   - [ ] Telephone
   - [ ] In-person
   - [ ] Mail
   - [ ] Other, Explain

2. Will interviewers or facilitators be used? [ ] Yes [x] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

List of Attachments

Attachment 1 – Traceable Opioid Material§ Kits Fact Sheet
Attachment 2 – Traceable Opioid Material§ Kits Questions
Attachment 3 – PHE PRA Waiver Memo 20190329
Attachment 4 –RDF – CDC NCEH DLS Traceable Opioid Material§ Kits crrctd

Instructions for completing Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback"

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request. (e.g. Comment card for soliciting feedback on xxxx)

PURPOSE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Provide a brief description of the targeted group or groups for this collection of information. These groups must have experience with the program.

TYPE OF COLLECTION: Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:
Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households;(2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.
No. of Respondents: Provide an estimate of the Number of respondents.
Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group)
Burden: Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Provide an estimate of the annual cost to the Federal government.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.

Please make sure that all instruments, instructions, and scripts are submitted with the request.