U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

*Print Date:* *1/15/26*

| | |
|---|---|
| **Title:** | Distribution of Traceable Opioid Material Kits and Emerging Drug Panel Kits across U.S. and International Laboratories PRA Revision 3 |
| **Project Id:** | 0900f3eb8261a760 |
| **Accession #:** | NCEH-TDAL-8/24/22-b9864 |
| **Project Contact:** | Rebekah Wharton |
| **Organization:** | NCEH/ATSDR/DLS/ERB/TDAL |
| **Status:** | **Pending Clearance : PRA Revision** |
| **Intended Use:** | **Project Determination** |
| **Estimated Start Date:** | 04/21/2020 |
| **Estimated Completion Date:** | 04/10/2026 |
| **CDC/ATSDR HRPO/IRB Protocol #:** | |
| **OMB Control #:** | 0920-1313 |
| **Source System #:** | 2019-0066 |
| **OMB Discontinuation Date:** | |

## Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|---|---|---|
| HSC:<br>**Does NOT Require HRPO Review** | Not Research / Other<br>*45 CFR 46.102(l)*<br>Quality Assurance / Improvement | 8/15/25 | Flores_Sharon (fil4) CIO HSC |
| PRA:<br>**PRA Applies** | | 8/15/25 | Flores_Sharon (fil4) CIO OMB / PRA |
| ICRO:<br>**PRA Applies** | OMB Approval date: 3/28/23<br>OMB Expiration date: 3/31/26 | 8/15/25 | Zirger_Jeffrey (wtj5) ICRO Reviewer |

# Description & Funding

## Description

**Priority:** Standard

**Date Needed:** 04/10/2026

**Priority Justification:**

**CDC Priority Area for this Project:** Not selected

**Determination Start Date:** 12/17/25

**Description:** This project is a continuation and expansion of DLS project 2019-0066. The drug landscape associated with the epidemic is constantly changing. In 2019-2020, fentanyl analogs were driving the epidemic, but recently fewer fentanyl analogs are being found in drug seizures and overdose deaths. Fentanyl is still a major player in the epidemic, but it is often found mixed with other drug substances, including benzodiazepines (examples: clonazolam, etizolam, flualprazolam), other opioids (examples: etodesnitazene, protonitazene, dipyanone), stimulants and hallucinogens (examples: eutylone, alpha-pyrrolidinoisohexanophenone, deschloroketamine), and synthetic cannabinoids (examples: 5F-MDMB-PICA, MDMB-4en-PINACA, 4F-MDMB-BINACA). This project will address the changing drug landscape associated with the opioid epidemic by expanding the types of drugs included in future versions of the TOM kits so laboratories will be equipped to accurately identify novel drug substances in powders, forensic samples, as well as other types of samples.

**IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:** No

**IMS Activation Name:** Not selected

**Submitted through IMS Clearance Matrix:** Not selected

**Primary Scientific Priority:** Not selected

| | |
|---|---|
| **Secondary Scientific Priority (s):** | Not selected |
| **Task Force Responsible:** | Not selected |
| **CIO Emergency Response Name:** | Not selected |
| **Epi-Aid Name:** | Not selected |
| **Lab-Aid Name:** | Not selected |
| **Assessment of Chemical Exposure Name:** | Not selected |
| **Goals/Purpose** | In response to the opioid epidemic, CDC designed and worked with commercial vendors to manufacture and distribute the Traceable Opioid Material (TOM) kits. To date, these kits include more than 200 fentanyl analog and opioid reference materials which have been distributed to domestic laboratories, free of charge, to improve testing efforts associated with the epidemic. |
| **Objective:** | TOM kits will increase 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. |
| **Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:** | Not Selected |
| **Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:** | Not Selected |
| **Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:** | Not Selected |
| **Activities or Tasks:** | New Collection of Information, Data, or Biospecimens |
| **Target Populations to be Included/Represented:** | No Human Population |
| **Tags/Keywords:** | DLS 2019-0066; ; TOM Kit ; Emerging Drug Panel Kit |
| **CDC's Role:** | Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC is provider of materials/services TO an institution ; CDC is providing funding |
| **Method Categories:** | QA/QI; Survey |
| **Methods:** | Reports, such as those released by the Drug Enforcement Administration and the Center for Forensic Science Research and Education, will be monitored on an continuing basis to inform CDC which drugs are currently being found in drug seizures and overdose deaths. This information will be used to guide the contents of future TOM kits, ensuring laboratories are equipped with relevant, quality, and consistent materials for their testing applications. TOM kits use-case metrics will be collected through survey questions posted on contractor website during the application process. Responses will be sent on a regular basis by the contractor. |
| **Collection of Info, Data or Biospecimen:** | Kit distribution and use-case metrics will be collected via survey hosted on the vendor website as part of the kit application process. CDC will use the data collected to evaluate the overall impact of the kits. Personally identifiable information will be collected by the vendor and used solely for shipping and controlled substance license verification purposes. |

| | |
|---|---|
| **Expected Use of Findings/Results and their impact:** | TOM kits will increase laboratories# ability to confirm which drugs 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. |
| **Could Individuals potentially be identified based on Information Collected?** | Yes |
| **Will PII be captured (including coded data)?** | Yes |
| **Does CDC have access to the identifiers (including coded data)?:** | Yes |
| **Is this project covered by an Assurance of Confidentiality?** | No |
| **Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?** | No |
| **Is there a formal written agreement prohibiting the release of identifiers?** | No |

## Funding

| Funding Type | Funding Title | Funding # | Original Budget Yr | # Years Award | Budget Amount |
|---|---|---|---|---|---|
| CDC Contract | Maintenance and evaluation of Fentanyl Analog Screening (FAS) Products for Continued Distribution to Approved Laboratories | 2019-06777 | | | 36000.00 |

# HSC Review

# Regulation and Policy

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|---|---|
| **Do you anticipate this project will require review by a CDC IRB or HRPO?** | No |
| **Estimated number of study participants** | |

| | |
|---|---|
| **Population - Children** | Protocol Page #: |
| **Population - Minors** | Protocol Page #: |
| **Population - Prisoners** | Protocol Page #: |
| **Population - Pregnant Women** | Protocol Page #: |
| **Population - Emancipated Minors** | Protocol Page #: |

**Suggested level of risk to subjects**

**Do you anticipate this project will be exempt research or non-exempt research**

## Requested consent process waviers

| | |
|---|---|
| **Informed consent for adults** | No Selection |
| **Children capable of providing assent** | No Selection |
| **Parental permission** | No Selection |
| **Alteration of authorization under HIPAA Privacy Rule** | No Selection |

## Requested Waivers of Documentation of Informed Consent

| | |
|---|---|
| **Informed consent for adults** | No Selection |
| **Children capable of providing assent** | No Selection |
| **Parental permission** | No Selection |

## Consent process shown in an understandable language

| | |
|---|---|
| **Reading level has been estimated** | No Selection |
| **Comprehension tool is provided** | No Selection |
| **Short form is provided** | No Selection |
| **Translation planned or performed** | No Selection |
| **Certified translation / translator** | No Selection |
| **Translation and back-translation to/from target language(s)** | No Selection |

| | |
|---|---|
| **Other method** | No Selection |

### Clinical Trial

| | |
|---|---|
| **Involves human participants** | No Selection |
| **Assigned to an intervention** | No Selection |
| **Evaluate the effect of the intervention** | No Selection |
| **Evaluation of a health related biomedical or behavioral outcome** | No Selection |
| **Registerable clinical trial** | No Selection |

### Other Considerations

| | |
|---|---|
| **Exception is requested to PHS informing those bested about HIV serostatus** | No Selection |
| **Human genetic testing is planned now or in the future** | No Selection |
| **Involves long-term storage of identfiable biological specimens** | No Selection |
| **Involves a drug, biologic, or device** | No Selection |
| **Conducted under an Investigational New Drug exemption or Investigational Device Exemption** | No Selection |

## Institutions & Staff

### Institutions

Will you be working with an outside Organization or Institution? Yes

| Institution | FWA # | FWA Exp Date | Funding | Funding Restriction Amount |
|---|---|---|---|---|
| United Nations Office of Drugs and Crime | | | | |
| Cayman Chemical | | | 2019-06777 | |
| Centers for Disease Control & Prevention | FWA00001413 | 08/22/30 | | |

| Institution | Funding Restriction Percentage | Funding Restriction Reason | Funding Restriction has been Lifted |
|---|---|---|---|
| United Nations Office of Drugs and Crime | | | |
| Cayman Chemical | | | |
| Centers for Disease Control & Prevention | | | |

| Institution | Institution Role(s) | Institution Project Title | Institution Project Tracking # | Prime Institution |
|---|---|---|---|---|
| United Nations Office of Drugs and Crime | | | | |
| Cayman Chemical | | | | |
| Centers for Disease Control & Prevention | | | | |

| Institution | Regulatory Coverage | IRB Review Status |
|---|---|---|
| United Nations Office of Drugs and Crime | | |
| Cayman Chemical | | |
| Centers for Disease Control & Prevention | | |

| Institution | Registered IRB | IRB Registration Exp. Date | IRB Approval Status |
|---|---|---|---|
| United Nations Office of Drugs and Crime | | | |
| Cayman Chemical | | | |
| Centers for Disease Control & Prevention | | | |

| Institution | IRB Approval Date | IRB Approval Exp. Date | Relying Institution IRB |
|---|---|---|---|
| United Nations Office of Drugs and Crime | | | |
| Cayman Chemical | | | |
| Centers for Disease Control & Prevention | | | |

### Staff

| Staff Member | SIQT Exp. Date | CITI Biomedical Exp. Date | CITI Social & Behavioral Exp. Date | CITI Good Clinical Practice Exp. Date | CITI Good Laboratory Practice Exp. Date | Staff Role | Email | Phone | Organization |
|---|---|---|---|---|---|---|---|---|---|
| Rebekah Wharton | 08/15/2026 | 05/02/2027 | | | | Project Officer | | 770-488-7630 | TOXINS & DRUGS OF ABUSE LABORATORY - TEAM 4 |
| Elizabeth Hamelin | 08/24/2026 | 11/29/2027 | | | | Program Lead | eph3@cdc.gov | 770-488-7082 | DIVISION OF LABORATORY SCIENCES |

## Data

### DMP

**Proposed Data Collection Start Date:** 4/21/20

**Proposed Data Collection End Date:** 4/10/26

**Proposed Public Access Level:** Non-Public

*Non-Public Details:*

**Reason For Not Releasing Data:** Other - QA/QC

**Public Access Justification:** The TOM and EDP kits will be used for QA/QC. The survey questions will be used for CDC to assess the impact of the distributed kits.

**How Access Will Be Provided for Data:** Project data is not public health data

**Plans for Archival and Long Term Preservation:**

## Spatiality

| Country | State/Province | County/Region |
|---|---|---|
| United States | | |

## Dataset

| Dataset Title | Dataset Description | Data Publisher /Owner | Public Access Level | Public Access Justification | Landing Page URL | Direct Download URL | Type of Data Released | Collection Start Date | Collection End Date |
|---|---|---|---|---|---|---|---|---|---|
| Dataset yet to be added... | | | | | | | | | |

## Supporting Info

| Current | CDC Staff Member and Role | Date Added | Description | Supporting Info Type | Supporting Info |
|---|---|---|---|---|---|
| | De Leon Salazar_Alfonsina (wvg4)<br>Division Approver<br>Projects | 01/09/2026 | 0920-1313 TOM Kits 2026 30-D reviewed by DLS ADS team | Other | 0920-1313 TOM Kits 2026 30-D.zip |
| Current | Wharton_Rebekah (flo2)<br>Project Contact | 12/17/2025 | 30 day FRN | Paperwork Reduction Act Form | 30 day package.zip |
| | Zirger_Jeffrey (wtj5)<br>ICRO Reviewer | 08/15/2025 | NOA 0920-1313 (2023) | Notice of Action | NOA 0920-1313_2023.pdf |
| | De Leon Salazar_Alfonsina (wvg4)<br>Division Approver<br>Projects | 08/12/2025 | Zipfile with 60-day package for<br>0920-1313 | Other | 0920-1313 60-day TOM Kits.zip |
| | Wharton_Rebekah (flo2)<br>Project Contact | 08/08/2025 | 60 day FRN package | Paperwork Reduction Act Form | 60 day FRN extension request_eclearance.zip |
| | Wharton_Rebekah (flo2)<br>Project Contact | 08/08/2025 | updated NOA - Feb 2024 | Notice of Action | NOA - 2024-02-06T061107.665.pdf |
| | Wharton_Rebekah (flo2)<br>Project Contact | 02/08/2024 | updated NOA - Feb 2024 | Notice of Action | NOA - 2024-02-06T061107.665.pdf |
| | Zirger_Jeffrey (wtj5)<br>ICRO Reviewer | 01/26/2024 | NOA 0920-1313 (2023). | Notice of Action | NOA 0920-1313_2023.pdf |
| | Wharton_Rebekah (flo2)<br>Project Contact | 01/23/2024 | non-substantive change request to existing PRA | Paperwork Reduction Act Form | Application question change request.zip |
| | Zirger_Jeffrey (wtj5)<br>ICRO Reviewer | 04/14/2023 | NOA 0920-1313 (2023) | Notice of Action | NOA 0920-1313_2023.pdf |
| | Davis_Stephanie I. (sgd8) | 04/13/2023 | 0920-1313 Change Request #1 zipfile | Paperwork Reduction Act Form | 0920-1313 TOM Kits Change Request #1.zip |

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|---|---|---|---|---|---|
| | CIO OMB / PRA | | | | |
| | Wharton_Rebekah (flo2)<br>Project Contact | 04/10/2023 | Change request files | Paperwork Reduction Act Form | Application question change request.zip |
| | Zirger_Jeffrey (wtj5)<br>ICRO Reviewer | 12/09/2022 | NOA 0920-1313 (2020) | Notice of Action | NOA 0920-1313_2020.pdf |
| | Wharton_Rebekah (flo2)<br>Project Contact | 12/07/2022 | TOM kits 30 day package | Paperwork Reduction Act Form | TOM kits 30 day.zip |
| | Zirger_Jeffrey (wtj5)<br>ICRO Reviewer | 09/06/2022 | NOA 0920-1313 (2020). | Notice of Action | NOA 0920-1313_2020.pdf |
| | Wharton_Rebekah (flo2)<br>Project Contact | 08/31/2022 | 60 day package for TOM kits | Paperwork Reduction Act Form | 2022 TOM kit 60 day.zip |