



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

Print Date: 9/25/23

Title: The Assessment and Implementation of Sewage Surveillance to Inform COVID-19 in the United States

Project Id: 0900f3eb81b8a666

Accession #: NCEZID-DWASHEPI-7/8/20-8a666

Project Contact: Jeffrey W Mercante

Organization: NCEZID/DFWED/WDPB/DWASHEPI

Status: **Project In Progress : PRA Revision**

Intended Use: **Project Determination**

Estimated Start Date: 07/15/2020

Estimated Completion Date: 12/31/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: No OMB Control Number issued

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	9/7/23	Harris_DeMoncheri (yfj7) CIO HSC
	Qualifies for a statutory waiver: 21st Century Cures Act - Sec. 3087 (Public Health Emergency) <i>Justification:</i> PRA applies but is waived by		

PRA:
PRA Applies

the PHE waiver. This purpose of this amendment is to include the collection of sewershed boundary data, which, when overlaid with SARS-CoV-2 case data, provides information on the number of cases that may contribute to results from a given sample. This amendment also adds the collection of SARS-CoV-2 sequencing data to allow for early tracking and surveillance of variants to help inform public health policy and decision makers. How it relates to COVID-19: The goal of the project is to collect and test sewage data for the presence of SARS-CoV-2 and to characterize SARS-CoV-2 variants. These sewage data will be used to inform estimates of COVID-19 infections and track SARS-CoV-2 variants in the community. Sewage data will be compared to existing COVID-19 response case-based and syndromic-based data to assess whether sewage data serve as a leading indicator for other health indicators, such as cases and hospitalizations. Statistical methods review (if any): Wastewater data on SARS-CoV-2 will be normalized by flow and/or presence of controls, and trends estimated using linear regression of the most recent three and five wastewater samples. Additionally, wastewater data will be binned into quintiles for the sewershed, and percent change of pathogen or target concentrations for the past 15 days will be calculated. For settings where incidence is very low, the detection proportion (i.e., the proportion of samples with any target detection over a defined lookback period of days to weeks) will be used. To contextualize the wastewater data, normalized wastewater data and case data will be visualized on a timeseries plot by sewershed. Samples that have been sequenced may be analyzed to monitor for genetic variants or targets of concern. Efforts to reduce duplication of collection: An environmental scan revealed no known projects with similar data collection in the United States. Estimated burden (X respondents x Y minutes per response = Z total hours): Therefore, the anticipated burden per wastewater utility is in the range: (52 weeks * 1 sample * 2 hours * 43 jurisdictions)=4,472 hours; (52 weeks * 7 samples * 2 hours * 43 jurisdictions) =

9/7/23

Vice_Rudith (nhr9) OMB / PRA

	31,304 Collection instruments themselves (can be drafts): There are no additional data collection instruments for this amendment. Previously approved instruments are attached.		
ICRO: PRA Applies	OMB Approval date: 9/8/23 OMB Expiration date: 12/31/99	9/8/23	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Urgent

Date Needed: 09/12/2023

Priority Justification: Sewage Surveillance is an urgent priority that supports respiratory virus detection and surveillance activities prioritized for the upcoming respiratory virus season in Fall and Winter, 2023-2024.

Determination Start Date: 10/05/21

Description: The project aims to establish a sewage surveillance system to inform the COVID-19 response in the United States. CDC will work with local wastewater utilities and state and local health departments to evaluate sewage for the presence of SARS-CoV-2 and to detect SARS-CoV-2 variants to inform public health partners and policymakers actions during the COVID-19 response.

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

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: 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 An environmental scan revealed no known projects with similar data collection in the United States. The goal of the project is to collect and test sewage data for the presence of SARS-CoV-2 and to characterize SARS-CoV-2 variants. These sewage data will be used to inform estimates of COVID-19 infections and track SARS-CoV-2 variants in the community. Sewage data will be compared to existing COVID-19 response case-based and syndromic-based data to assess whether sewage data serve as a leading indicator for other health indicators, such as cases and hospitalizations.

Objective: The objective of this project is to develop a surveillance system to identify an early indicator for increasing COVID-19 infections in a community. Earlier information on COVID-19 infections in a community will allow public health and other policymakers to implement more effective prevention and control measures to limit COVID-19 spread within the community.

Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?: No

Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?: No

Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?: No

Activities or Tasks: New Collection of Information, Data, or Biospecimens ; Secondary Data or Specimen Analysis

Target Populations to be Included/Represented: General US Population

Tags/Keywords: Sewage ; Sentinel Surveillance ; Biosurveillance

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 employees or agents will obtain or use anonymous or unlinked data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight ; CDC is recipient of private data/specimens FROM an institution

Method Categories: Biomonitoring; Outbreak Investigation; Secondary Data Analysis; Surveillance Support

Methods: All methods proposed in this project have been reviewed extensively by CDC environmental microbiologists and engineers. Data collection activities will obtain sufficient information to inform standardization and normalization of samples across the country. Sewage data collection and testing: Wastewater utilities will collect routine grab or composite sewage samples from their respective sewershed. Samples collected by the utilities will be sent to academic, industry, or public health laboratories for processing and testing, and in some cases for sequencing of SARS-CoV-2, if the utility does not possess testing capabilities. A standard set of collection and testing data elements in addition to the sample testing results will be collected by the wastewater utilities and testing partners to ensure comparability of sewage data across sampling sites and testing laboratories. Participants: Wastewater utilities will collect and provide sewage samples to testing laboratories, and will also collect and provide sewershed boundary data to the CDC. State and local health departments will interview cases and identify cases residing or admitted to hospitals within sewershed boundaries. Participation in the data collection activities is voluntary. Recruitment: Interested wastewater utilities will be identified and invited to participate by CDC. Officials at the state and local public health departments within the communities served by participating wastewater utilities will contact COVID-19 cases to conduct the interviews. Sewage Data: The sewage data contain questions in the following content areas that would allow for comparison of sewage data across sampling sites and testing laboratories. This includes: 1) wastewater utility details, including sewershed boundary data, 2) wastewater utility sampling details, 3) wastewater utility collection details, 4) sample processing, 5) sample quantification and/or characterization methods, 6) sample normalization, 7) sample testing conditions, and 8) sample results, including PCR or sequencing results. The sewage data do not include any personally identifiable information (PII). Sampling: Sewage samples will be collected on a regular interval. Officials in state and local public health departments contact all COVID-19 cases for interviews. However, only cases residing in participating

sewersheds or who were hospitalized at a hospital in a participating sewershed will be included in data provided to CDC for this project. Incentives: No incentives will be provided to wastewater utilities or state and local health departments submitting data to CDC for this project.

Collection of Info, Data or Biospecimen:

Data collection: Wastewater utilities will oversee and perform sewage sample collection and sewershed boundary data collection. Results of this data collection will be provided to CDC for analyses. No sewage data collection activities will place a burden on the American public. Existing case data will be obtained from DCIPHER and HHS Protect. These data were voluntarily collected from all COVID-19 cases by state and local health departments. There are no research questions addressed through this data collection activity. Standardized data will be compiled on recent health outcomes related to COVID-19 in the context of the national response. Data will be used to evaluate model estimate validity and to assess whether sewage data provide an early indication of future case data. Specimen collection: Wastewater utilities will collect routine grab or composite sewage samples from a representative sample of their sewershed. Samples will be processed and tested at the wastewater utility, if they have the testing capacity, or will be provided to an academic, industry, or public health laboratory for testing, and in some cases, SARS-CoV-2 sequencing. We anticipate sewage data collection will occur at least weekly but likely more often than once sample per week per wastewater utility. Therefore, the anticipated burden per wastewater utility is in the range: 52 weeks * 1 sample * 2 hours = 104 hours 52 weeks * 7 samples * 2 hours = 728 hours

Expected Use of Findings/Results and their impact:

Aggregated summaries of findings to describe the utility of sewage data as a predictor of case outcomes and the ability of the sewage model to estimate COVID-19 prevalence will be shared as part of COVID-19 response communications, including calls with non-CDC public health agencies, wastewater utilities, and academic partners and at internal CDC meetings. Additionally, aggregated summaries of findings may be shared externally through conference presentations and peer-reviewed journal articles to describe the ability of COVID-19 sewage data to inform COVID-19 response and prevention efforts.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding yet to be added

HSC Review

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB? 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 wavers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA 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 No Selection

language(s)

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 identifiable 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

Institutions yet to be added

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Amy Kirby	01/21	08/25/2026			Program	agk1@cdc.	404-718-	Environmental Microbiology and

Dataset yet to be added...

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	09/08/2023	Amendment to activity approved under PHE (COVID) PRA Waiver	Notice of Action	PHE PRA Waiver Approval COVID.docx
	Mercante_Jeffrey (wyh5) Project Contact	09/07/2023	Determination memo of non-research public health surveillance.	HS Research Determination Memo	071320ZM-NR-signed.pdf
	Mercante_Jeffrey (wyh5) Project Contact	09/07/2023	PDF version of email documenting review and approval of amended Sewage Surveillance Project Determination by Nicole Fehrenbach, Branch Chief of the Rapid Response, Research and Surveillance Branch (R3SB).	Other	R3SB Approval of NWSS Amended Project Determination.pdf
	Mercante_Jeffrey (wyh5) Project Contact	09/07/2023	Activity will be conducted under the PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Mercante_Jeffrey (wyh5) Project Contact	09/07/2023	PDF version of email documenting review and approval of amended Sewage Surveillance Project Determination by Amy Kirby, NWSS Team Lead, in the Rapid Response, Research and Surveillance Branch (R3SB).	Other	Kirby_NWSS Approval of NWSS Amended Project Determination.pdf
	Mercante_Jeffrey (wyh5) Project Contact	09/07/2023	Sewage Surveillance to Inform COVID-19 amended project with track changes for reference comparison to original document.	Other	Sewage Surveillance to Inform COVID-19_Amended_Track_Changes_Final.docx
			PDF version of email documenting review and approval of amended		

Current	Mercante_Jeffrey (wyh5) Project Contact	09/07/2023	Sewage Surveillance Project Determination by Amy Kirby, NWSS Team Lead, in the Rapid Response, Research and Surveillance Branch (R3SB).	Other	Kirby_NWSS Approval of NWSS Amended Project Determination.pdf
	Mercante_Jeffrey (wyh5) Project Contact	08/28/2023	Determination memo of non-research public health surveillance.	HS Research Determination Memo	071320ZM-NR-signed.pdf
	Mercante_Jeffrey (wyh5) Project Contact	08/28/2023	PDF version of email documenting review and approval of amended Sewage Surveillance Project Determination by Nicole Fehrenbach, Branch Chief of the Rapid Response, Research and Surveillance Branch (R3SB).	Other	R3SB Approval of NWSS Amended Project Determination.pdf
	Mercante_Jeffrey (wyh5) Project Contact	08/28/2023	Activity will be conducted under the PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Mercante_Jeffrey (wyh5) Project Contact	08/28/2023	Sewage Surveillance to Inform COVID-19 amended project with track changes for reference comparison to original document.	Other	Sewage Surveillance to Inform COVID-19_Amended_Track_Changes_Final.docx
	Mercante_Jeffrey (wyh5) Project Contact	08/28/2023	Sewage Surveillance to Inform COVID-19 amended project with track changes for reference comparison to original document.	Other	Sewage Surveillance to Inform COVID-19_Amended_Track_Changes_Final.docx
	Mercante_Jeffrey (wyh5) Project Contact	08/28/2023	PDF version of email documenting review and approval of amended Sewage Surveillance Project Determination by Nicole Fehrenbach, Branch Chief of the Rapid Response, Research and Surveillance Branch (R3SB).	Other	R3SB Approval of NWSS Amended Project Determination.pdf
	Mercante_Jeffrey (wyh5) Project Contact	08/25/2023	Sewage Surveillance to Inform COVID-19 amended project with track changes for reference comparison to original document.	Other	Sewage Surveillance to Inform COVID-19_Amended_Track_Changes.docx
	Mercante_Jeffrey (wyh5) Project Contact	08/25/2023	Wastewater Surveillance amended project with track changes for reference comparison to original document.	Other	Project Determination_NWSS_Track_Changes.docx
	Zirger_Jeffrey		Activity will be conducted under		

	(wtj5) ICRO Reviewer	10/06/2021	the PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Marsh_Zachary (ksf6) Project Contact	10/04/2021	Survey of states for NWSS	Data Collection Form	Wastewater Surveillance Data Landscape Survey Questions.docx
	Daymude_Thomas (qkh7) Project Contact	09/29/2021	Survey of states for NWSS	Data Collection Form	Wastewater Surveillance Data Landscape Survey Questions.docx
	Daymude_Thomas (qkh7) Project Contact	09/29/2021	Survey of states for NWSS	Data Collection Form	Wastewater Surveillance Data Landscape Survey Questions.docx
	Peterson_James M. (jyr1) CIO HSC	07/13/2020	Determination memo of non-research public health surveillance.	HS Research Determination Memo	071320ZM-NR-signed.pdf
	Marsh_Zachary (ksf6) Project Contact	07/09/2020	This is a data schematic describing the anticipated minimum data elements the sewage surveillance project will need to collect.	Other-Enter new type	SewageSurveillanceDiagram.pdf



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