



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

Print Date: 1/20/23

Title: Airport-based COVID-19 surveillance among international travelers

Project Id: 0900f3eb81d54b5e

Accession #: NCEZID-SET-6/11/21-54b5e

Project Contact: Teresa C Smith

Organization: NCEZID/DGMQ/TH/SET

Status: **Project In Progress : Amendment**

Intended Use: **Project Determination**

Estimated Start Date: 07/01/2021

Estimated Completion Date: 06/30/2022

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>	12/20/22	Peterson_James M. (iyr1) CIO HSC
	Qualifies for a statutory waiver: 21st Century Cures Act - Sec. 3087 (Public Health Emergency)		

<p>PRA: PRA Applies</p>	<p><i>Justification:</i> PRA applies but is waived by the COVID-19 PHE Waiver. Waiver element updates: Burden: For those participating in 2A, the time estimate to participate in this surveillance activity is five minutes per person. With an estimate of 5,000 persons participating per week, it is estimated that 417 person-hours per week will contribute to this activity. Over the course of a year, this results in 21,667 person-hours. Instruments: There is a new, shorter questionnaire that will be moved to a digital format. It is in the protocol appendix.</p>	<p>12/20/22</p>	<p>Daymude_Thomas (qkh7) OMB / PRA</p>
<p>ICRO: PRA Applies</p>	<p>OMB Approval date: 1/4/23 OMB Expiration date: 12/31/99</p>	<p>1/4/23</p>	<p>Zirger_Jeffrey (wtj5) ICRO Reviewer</p>

Description & Funding

Description

Priority:	Urgent
Date Needed:	06/25/2021
Priority Justification:	To respond to risk of spread of the SARS-CoV-2 variant Delta, circulating widely in India, among travelers through enhanced surveillance.
Determination Start Date:	02/10/22
Description:	This project will implement enhanced SARS-CoV-2 surveillance among international travelers at selected ports of entry. Pooled PCR tests will be conducted in at least 5 airports. Through the locations where PCR tests are used, the program will enable the near-real-time (NRT) detection of existing and novel SARS-CoV-2 variants entering the United States through its airports by testing passengers and sequencing all positive cases. This project will leverage a variety of testing technologies, including individual testing, pooled testing, and whole genome sequencing.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	Yes
IMS Activation Name:	2019 Novel Coronavirus Response
Primary Priority of the Project:	COVID-19 disease detection, burden, and impact
Secondary Priority(s) of the Project:	Prevention, mitigation, and intervention strategies
Task Force Associated with the Response:	Global Migration
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	Implement enhanced surveillance via testing of inbound international travelers combined with sequencing of positive samples to inform implementation of appropriate prevention and mitigation measures for arriving international travelers before widespread transmission of new and consequential variants can occur in communities where travelers visit and live.
Objective:	<p>1. Identify COVID cases and rates for populations arriving to US airports, with particular focus on travel routes from geographies with high positivity rates and higher risk for new variants to emerge. Although the initial focus for sequencing will be on flights from India, in light of the current health crisis, it may shift over time based on response priorities. 2. Measure SARS-CoV-2 positivity rates 3-5 days after arrival for vaccinated and unvaccinated passengers arriving into the US from foreign destinations to evaluate current CDC recommendations. 3. Identify variants of interests, concern, and high consequence among the positive cases captured in Point 1. 4. Share the raw data collected with the CDC and public databases. Data include consensus sequences and lineage reports. 5. Combine the raw data from sequencing with travel-related information and publicly available data to prepare epidemiological analyses and reports.</p>
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	No
Project does not incorporate elements of health equity science:	Yes
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Programmatic Work
Target Populations to be Included/Represented:	General US Population ; International
Tags/Keywords:	Genomics ; Travel ; Public Health Surveillance
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
Method Categories:	Genetic Sequencing; Surveillance Support
Methods:	Phase 1A: Pooled tests for flights from India; genomic sequencing of positive pools Phase 1B: Arriving international passengers from India pick up an at-home RT-PCR kit at the airport, take the test 3-5 days later; sequencing for positive cases Phase 1C: Arriving international passengers pick up an at-home Ellume antigen test kit at the airport or have the kit sent to them on arrival day; take test 3-5 days later Phase 2A: Arriving international passengers participate in double collection pooled testing and receive a free

at-home antigen test to take home. Pooled tests use RT-PCR and positives are sequenced for lineage determination Phase 2B: Aircraft wastewater SARS-CoV-2 testing and sequencing.

Collection of Info, Data or Biospecimen:

Phase 1A: self-collected nasal swabs Phase 1B: self-collected saliva samples Phase 1C: self-collected nasal swabs Phase 2A: self-collected nasal swabs Phase 2B: aircraft wastewater collected via device developed by contractor and collection done by airport grounds crew. Demographic information will be collected on paper or electronic form.

Expected Use of Findings/Results and their impact:

This information will help with implementation of appropriate prevention and mitigation measures for arriving international travelers before widespread transmission of new and consequential variants can occur in communities where travelers visit and live.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Contract	Traveler-based SARS-CoV-2 Genomic Surveillance Program	75D30122C14933	2022	1	
CDC Contract	Airport-based COVID-19 Surveillance Among International Travelers	PR57344	2021		

HSC Review

Additional Ethical Considerations

testing under this program is voluntary and will only be performed with consent or parent/guardian permission; this program targets travelers from India because of the high prevalence of the Delta variant in India.

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office 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 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 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

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
XPresCheck					PR57344
Concentric by Gingko					PR57344

Staff

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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
Alida Gertz	03/17/2025		11/30/2025	06/29/2023	Program Lead	qvr9@cdc.gov	470-225-0073	QUARANTINE AND BORDER HEALTH SERVICES BRANCH
Allison Taylor	09/28/2025	03/20/2022			Program Official	eie7@cdc.gov	404-639-6097	TRAVELERS HEALTH BRANCH
Andrew Klevos	07/29/2022				Program Official	hvc4@cdc.gov	305-526-2910	QB ROIC
Anna Shaum	06/14/2025		12/20/2021		Program Official	nla9@cdc.gov	404-375-2812	EPI FIELD TEAM
Cindy Friedman	11/28/2025				Program Official	ccf6@cdc.gov	404-639-1430	DIVISION OF GLOBAL MIGRATION AND QUARANTINE
Clive Brown	12/30/2024				Program Official	cmb8@cdc.gov	404-639-3952	DIVISION OF GLOBAL MIGRATION AND QUARANTINE
Erin Rothney	03/04/2022		02/27/2023	02/28/2023	Program Official	hrp6@cdc.gov	734-502-3191	QB ROIC
Ezra Ernst	04/23/2023				Program Lead	EErnst@hyperpointe.com		XPresCheck
Gabrielle Woronoff	04/23/2023				Program Lead	gworonoff@ginkgobioworks.com		Concentric by Gingko
John Shufeldt	04/23/2023				Program Official	jshufeldt@shufeldtconsulting.com		XPresCheck
Leah Moriarty	12/06/2024	11/26/2024	01/02/2022		Program Lead	wvp4@cdc.gov	404-718-4831	SURVEILLANCE AND EPIDEMIOLOGY TEAM
Marcelo Venegas	04/23/2023				Program Official	gabisa7@gmail.com		
Matthew	02/22				Program		404-	DIVISION OF GLOBAL

Palo	/2023				Official	cle4@cdc.gov	718-5484	MIGRATION AND QUARANTINE
Renee Wegryzn	04/23 /2023				Program Official	rwegryzn@ginkgobioworks.com		Concentric by Gingko
Robert Morfino	04/23 /2023				Program Official	rmorfino@ginkgobioworks.com		Concentric by Gingko
Robin Rinker	11/04 /2025		11/24/2024		Program Official	vqb2@cdc.gov	404-498-1467	TRAVELERS HEALTH BRANCH
Tai-ho Chen	10/06 /2025	12/21/2021		05/03/2022	Program Official	tdc5@cdc.gov	650-272-7452	INACTIVE

Data

DMP

Proposed Data Collection Start Date: 7/1/21

Proposed Data Collection End Date: 6/30/22

Proposed Public Access Level: Public

Public Access Justification: De-identified data from this project will be made accessible to the public to inform public health programs and policies.

How Access Will Be Provided for Data: All data will be de-identified before sharing. Following dissemination of findings, the following data elements will be publicly shared: test results, age range, gender, vaccination status, and state. Sequencing data will be uploaded into public sharing platforms such as GISAIID.

Plans for Archival and Long Term Preservation:

Spatiality

Country	State/Province	County/Region
United States	California	San Francisco County
United States	New York	New York

United States	New Jersey	Essex
United States	California	Los Angeles
United States	Colorado	Denver
United States	Georgia	Fulton
United States	Massachusetts	Suffolk
United States	Virginia	Loudoun
United States	Florida	Miami-Dade County

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	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
	Zirger_Jeffrey (wtj5) ICRO Reviewer	01/04/2023	Amendment to activity approved under the PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval COVID.docx
	Smith_Teresa (pvy2) Project Contact	12/14/2022	CLEAN protocol including appendices with new program documents including consent, questionnaire and recruiting materials	Protocol	TGS_Protocol Amendment_TS_Dec92022_clean.docx

	Smith_Teresa (pvy2) Project Contact	12/14/2022	TRACKED protocol including appendices with new program documents including consent, questionnaire and recruiting materials	Protocol	TGS_Protocol Amendment_TS_Dec92022.docx
	Zirger_Jeffrey (wtj5) ICRO Reviewer	02/16/2022	Amendment to activity previously approved/conducted under PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Appiah_Grace (ydg3) Project Contact	02/10/2022	Tracked changes version of the protocol	Protocol	XPresCheck_Protocol Amendment_Tracked Changes.docx
	Appiah_Grace (ydg3) Project Contact	02/10/2022	Clean version of the updated protocol	Protocol	XPresCheck_Protocol Amendment_Clean.docx
	Zirger_Jeffrey (wtj5) ICRO Reviewer	09/15/2021	Amendment to activity approved under PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Moriarty_Leah F (wvp4) Branch Approver Projects	09/15/2021	Updated version of the 3-5 day data collection tool for at-home testers.	Data Collection Form	Test Taker Data Capture_Sept 14.docx
	Moriarty_Leah F (wvp4) Branch Approver Projects	09/15/2021	PDF of brochure given to participants upon arrival.	Data Collection Form	21-2507 XpresCheck_CDC_TestingBrochure_v15.pdf
	Moriarty_Leah F (wvp4) Project Contact	09/08/2021	Text of the previous formatted brochure for ease of review	Data Collection Form	XpresCheck_CDC_Brochure_v13_TEXT_9.3.21.docx
	Moriarty_Leah F (wvp4) Project Contact	09/08/2021	Questionnaire being given to volunteers participating in the testing 3-5 days after arrival. Questions will be captured on a secure, electronic platform.	Data Collection Form	Test Taker Data Capture_Sept 2.docx
	Moriarty_Leah F (wvp4) Project Contact	09/08/2021	PDF formatted brochure for phase 1A	Data Collection Form	21-2507 XpresCheck_CDC_TestingBrochure_v13.pdf
	Zirger_Jeffrey (wtj5) ICRO Reviewer	07/29/2021	Amendment to activity previously approved under PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx

	Cohen_Nicole J. (hei1) Division ADS	07/20/2021	Screening, consent, initial survey instrument	Consent Form	Initial Survey for Post Arrival Test Project 1c_July 20 2021.docx
	Cohen_Nicole J. (hei1) Division ADS	07/20/2021	Post-test data collection	Data Collection Form	Test Results Reporting Survey for Post Arrival Test Project 1c_July 20 2021.docx
	Cohen_Nicole J. (hei1) Division ADS	07/20/2021	Templates for emails to participants (generated by Redcap)	Other	Emails recieved by user for Post Arrival Test Project 1c_July 20 2021.docx
	Moriarty_Leah F (wvp4) Project Contact	07/12/2021	Data collection form to collect results of the Ellume test kit	Data Collection Form	TestResults_PostArrivalTesting (9).pdf
	Moriarty_Leah F (wvp4) Project Contact	07/12/2021	Initial data collection form for 1C	Data Collection Form	VoluntaryCDCPostArrivalTesting (5).pdf
	Moriarty_Leah F (wvp4) Project Contact	07/12/2021	Email text to participants	Other	Appendices 1c - Emails Text.pdf
	Zirger_Jeffrey (wtj5) ICRO Reviewer	06/23/2021	Activity conducted under the PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Youngblood_Laura L. (zfk9) CIO HSC	06/15/2021	NCEZID non-research determination	HS Research Determination Memo	061521LM-NR-PHS.pdf
	Moriarty_Leah F (wvp4) Project Contact	06/11/2021	Data collection & consent forms for Phase 1C	Consent Form	Post arrival testing project 1-C Appendices.docx
	Moriarty_Leah F (wvp4) Project Contact	06/11/2021	Project protocol	Protocol	XPresCheck_Protocol_V3_Clean.docx
	Moriarty_Leah F (wvp4) Project Contact	06/11/2021	Consent form for sections 1A and 1B	Consent Form	Appendix 1 - 060821_CDC Post Travel Testing Pilot_Consent Draft_v3_Clean.docx
	Moriarty_Leah F (wvp4) Project Contact	06/11/2021	SOP for pooled testing (Phase 1A)	Other-Standard Operating Procedure	Appendix2 - Concentric - Pooled Test SOP.pdf



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