

Traveler-based Genomic Surveillance

Request for OMB approval of a New Information Collection

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Supporting Statement A

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- **Goal of the study:** To monitor importation of SARS-CoV-2 variants among arriving international air travelers at select U.S. airports.
- **Intended use of the resulting data:** To inform early detection of imported SARS-COV-2 variants into the U.S. and for program management purposes.

Methods to be used to collect: We collect two lower nasal dry self-swabs from participants in airports that are pooled in batches of 5-10 samples. One sample will be pooled with samples from other travelers from the same flight origin country. Pooled samples undergo SARS-CoV-2 reverse transcription polymerase chain reaction (RT-PCR) testing and whole genome sequencing on positive samples to determine viral lineage. The second will be kept if there is a need to look more closely at a positive pool. Some samples may be sent to CDC for further testing. Surveillance may be expanded to test for other pathogens such as influenza.

Demographic, clinical, and travel information: All participants complete a questionnaire with their demographic, clinical, and travel history information. Participants will be given a free antigen test kit as a thank you for their time.

- **The subpopulation to be studied:** Arriving international air travelers that opt to participate in pooled or individual SARS-CoV-2 testing.
- **How data will be analyzed:** To assess variant detection and differences in positivity rate, for pooled and individual participants, across distinct collection periods, by clinic-demographic and travel characteristics, and by flight country of origin.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Travelers' Health Branch (THB) requests 3-year approval for information collection from international air travelers that participate in the Traveler-based Genomic Surveillance project.

Genetic variants of SARS-CoV-2 have been emerging and circulating around the world throughout the COVID-19 pandemic. Of particular concern are variants for which there is evidence of an increase in transmissibility, more severe disease (for example, increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures.

CDC recommends that all arriving international travelers get tested before departing and 3–5 days after travel. However, this testing is not mandatory for all travelers. Furthermore, there are currently few systems that conduct disease surveillance in the population of arriving international travelers.

Moreover, as testing and sequencing for SARS-CoV-2 continue to decline worldwide, detecting emerging variants of concern in a timely manner is becoming more and more difficult.

To address this gap, in September 2021, the Travelers' Health Branch, in collaboration with private partners, implemented a voluntary SARS-CoV-2 genomic surveillance program with the goal of early

detection of novel variants of concern (VOCs). Surveillance for new and emerging variant strains among travelers can provide researchers and public health officials critical time to collect information about the transmissibility, virulence, and effectiveness of existing vaccines, diagnostics, and therapeutics. The project is conducted with external partners and groups within DGMQ and across CDC, including the Office of Advanced Molecular Detection. The program began at New York's John F. Kennedy International Airport in September 2021 and later expanded to include Newark Liberty, San Francisco, and Hartsfield-Jackson Atlanta international airports. Since November 2022 the program has expanded to Los Angeles, Seattle, and Washington Dulles international airports. Information collection for this project is currently approved under a Public Health Emergency PRA Waiver.

The information collection for which approval is sought is in accordance with CDC DGMQ's mission to reduce morbidity and mortality among travelers and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. This mission is supported by Section 361 of the Public Health Service Act regulations found in 42 Code of Federal Regulations part 70 and 71. Also supported under general authorities provided by Sections 301 and 311 in the Public Health Service Act regulations (Attachments 1A-1D).

2. Purpose and Use of Information Collection

Project data is collected as follows: a volunteer sample of travelers, 18 years and older, from selected international flights are invited to participate in the program. A trained staff member uses language from a script to try to encourage travelers passing by to participate (Attachment 4B). Travelers interested in participating complete an informed consent form (Attachment 4A) and fill-out a questionnaire on enrollment in the airport. The questionnaire (Attachment 3) includes demographic, travel, and clinical information. After completing the questionnaire, two nasal swabs are self-collected by the traveler with instructions as needed by project staff. This should take under two minutes in most cases. The voluntary surveillance project also includes laboratory data collection from nasal samples from arriving travelers.

There are 19 questions on the questionnaire (digital or paper). Some will not be asked to every participant based on skip patterns. The questions are mostly multiple choice/drop down boxes. Drop down boxes are only available for the digital platform. Only a few travel questions related to the traveler's origin are required, the rest can be skipped. If this is information they do not want to provide, they can decline to participate at any time.

Travel information is collected for the purposes of knowing where the person who contributed a sample came from. This is important for decisions on grouping pools together because we try our best to group pools together based on country of origin. Additionally, this allows us to track SARS-CoV-2 test positivity across different origin countries, and act as an early warning system for where SARS-CoV-2 rates may be growing.

Demographic information collected includes age category, sex, race and ethnicity, and whether the participant is a US resident or not. All demographic questions are optional. These questions are collected to monitor the population that volunteers to participate in the program to understand the biases in our

sample and understand the limitations that must be considered and mentioned when drawing conclusions about our results. For this same reason we also ask why the individual participated in the program.

COVID-19 data collected is all optional. Questions include asking whether the participant took a pre-departure test, if they have ever tested positive for COVID-19, and the most recent positive test date. We also ask if the participant has ever received a vaccination dose for COVID-19 and the date of their most recent vaccination date. This data will be used to provide context to any interesting findings that may come up related to the person's COVID-19 history.

Additional questions: The TGS program may ask additional questions as interests and research questions evolve. For example, a pre-departure test question was added when the pre-departure test requirement for passengers coming from China was enacted. The question will likely be removed shortly after the policy is removed. We may also ask questions about mass gathering attendance to be able to do analyses on whether a particular event is linked to increased COVID-19 prevalence and/or a particular variant of interest. Potential additional questions have been drafted (Attachment 4C). No more than four additional questions will be added at any given time.

The laboratory may also expand the breadth of pathogens under surveillance with multiplex testing. This is described in the consent form and does not impose any additional burden on the participant.

3. Use of Improved Information Technology and Burden Reduction

The questionnaire operates on a digital platform that can be operated from either the participant's own phone via scanning a QR code, but iPads will be available as well for participants to borrow if they do not have their own device with internet access. There will be paper pamphlets available in the case of power/wifi outages at the airport or if a participant prefers this modality. The digital platform also makes it easy to make clear which questions are optional with a 'skip question' button that appears at the bottom of every applicable screen. The digital platform also has drop down boxes in certain questions that are free response for those who use the paper pamphlet. This improves data quality and makes it quicker for the participant filling out the form. The entire process should take less than five minutes of the participant's time. We anticipate that most participants will use the digital modality as it is streamlined, poses little burden and requires less time for recruiters to transcribe responses later. A paper will be available in case any participant prefers paper.

All lab results are automated as well and electronically linked to the participant's questionnaire data. These data are stored in a secure internal dashboard.

4. Efforts to Identify Duplication and Use of Similar Information

Because DGMQ's agency mission is dedicated to limiting the spread of infectious disease into and within the United States from travelers and migrating populations, it is not expected that the majority of the information collected under this project is available through other systems maintained by the federal government. The traveler-based genomic surveillance program collects information on demographic, clinical, and travel characteristics of arriving international travelers, in addition to SARS-CoV-2 PCR testing and sequencing results. These data are not available through any existing CDC system. The

collection of data is being conducted by project partners and directed and managed by CDC DGMQ staff.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Information will only be collected when a traveler volunteers to participate in surveillance. Further reduction of required reporting would prevent CDC from meeting its regulatory mandate, thereby endangering the public's health.

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

This request fully complies with the regulation 5 CFR 1320.5.

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 May 6, 2022, Vol. 87, No. 88, page 27155 (Attachment 2). CDC received one public comment related to this notice (Attachment 7).

B. There has been some consultations with groups outside the agency including the companies with which there is a contract agreement (Ginkgo and XpresCheck), and academic collaborators at Yale University, Johns Hopkins University, and Emory.

9. Explanation of Any Payment or Gift to Respondents

Participants will receive an antigen test kit to take home as a thank you. They will not be receiving results related to the nasal samples they voluntarily donated to the program. This gift allows them to receive a result from a COVID-19 test if desired. These tests are inexpensive and given out to the public for free through other programs.

There is potential to make the incentive an option between the antigen test kit and a \$5 gift card to expand participation.

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

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply and a privacy impact assessment is not required (attachment 5).

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

Institutional Review Board (IRB)

NCEZID’s Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required (Attachment 6).

Justification for Sensitive Questions

Some medical and vaccination history is asked in order to provide additional context for any unusual variant findings. These questions are optional for the participants.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Arriving traveler	TGS questionnaire and swabs	555,000	1	5/60	46,250
Total					46,250

*This is likely an overestimate because it includes optional CLINs for potential surges and optional expansions.

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Arriving traveler	TGS questionnaire and swabs	46,250	22.00*	\$1,017,500
Total				\$1,017,500

* 22.00 hour rate based on BLS May 2021 Wage Estimates for ‘All Occupations’ (00-0000)

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Contract cost	Up to \$20,000,000

Miscellaneous (eg. travel and translations)	\$10,000
6 staff at GS13 step 5 Atlanta (estimate)	\$677,244
Total	\$20,687,244

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Data collection	January 2023 - January 2026
Publications of first year of data (descriptive)	March 2023
Pre-departure test publication – Uses fixed/random effects model to estimate efficacy of the pre-departure test	February 2023
Publications of second year of data (descriptive)	March 2024
Publications of third year of data (descriptive)	March 2025
Publications of fourth year of data (descriptive)	March 2026
Comparing TGS data to community reported SARS-COV-2 case data – using Spearman’s correlation	May 2023
Sample size calculator and simulations	April 2023

There are many other research questions that may be publication worthy concerning the TGS data set and those papers will be written on an appropriate time scale as well.

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

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Authorizing Legislation
 - a. 42 CFR 70
 - b. 42 CFR 71
 - c. Section 301
 - d. Section 311
2. 60-Day FRN
3. Information Collection instrument
4. Additional attachments (IRB, scripts, consent forms, etc.)
 - a. Consent

- b. Recruitment Script
 - c. Potential Additional Questions
- 5. Privacy Impact Assessment
- 6. Human Subjects Determination
- 7. 60 Day FRN Comment and Response