

**REQUIREMENT FOR NEGATIVE PRE-DEPARTURE COVID-19 TEST  
RESULT OR DOCUMENTATION OF RECOVERY FROM COVID-19 FOR ALL  
AIRLINE OR OTHER AIRCRAFT PASSENGERS ARRIVING INTO THE  
UNITED STATES FROM ANY FOREIGN COUNTRY  
(OMB Control No. 0920-1318)  
Request for Emergency Clearance**

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**Contact:**

Chip Daymude  
National Center for Emerging and Zoonotic Infectious Diseases  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE  
Atlanta, Georgia 30333  
Phone: 404.718.7103  
Email: [qkh7@cdc.gov](mailto:qkh7@cdc.gov)

## Contents

<b>Contact:</b> .....	1
A. Justification.....	3
1. Circumstances Making the Collection of Information Necessary.....	3
2. Purpose and Use of Information Collection.....	6
3. Use of Improved Information Technology and Burden Reduction.....	10
4. Efforts to Identify Duplication and Use of Similar Information.....	10
5. Impact on Small Businesses or Other Small Entities.....	11
6. Consequences of Collecting the Information Less Frequently.....	11
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	11
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	12
9. Explanation of Any Payment or Gift to Respondents.....	12
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	12
11. Institutional Review Board (IRB) and Justification for Sensitive Questions IRB Approval.....	13
12. Estimates of Annualized Burden Hours and Costs.....	13
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers...	17
14. Annualized Cost to the Government.....	19
15. Explanation of Program Changes or Adjustments.....	20
16. Plans for Tabulation and Publication and Project Time Schedule.....	20
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	20
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	20
Attachments.....	21

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- The goal of this information collection is to ensure that, consistent with the terms of the January 25, 2021 Order Under Section 361 of The Public Health Service Act (42 U.S.C. § 264) and 42 Code Of Federal Regulations §§ 71.20, 71.31(B), & 71.32(B) *Requirement For Negative Pre-Departure Covid-19 Test Result Or Documentation Of Recovery From Covid-19 For All Airline Or Other Aircraft Passengers Arriving Into The United States From Any Foreign Country*, public health authorities in the United States can confirm that individuals have received a negative test result for COVID-19 or, if they tested positive for the virus that causes COVID-19 in the past 3 months to have documentation that they have recovered and been cleared to travel by a licensed health care provider or public health official, prior to departing the foreign country and arriving in the United States.
- The intended use of the information is to enable U.S. public health authorities to ensure that individuals who are coming into the United States via airlines have tested negative for or recently recovered from COVID-19, to prevent further introduction, transmission, and spread of the virus into the United States.
- There are no statistical sampling or research design methods being used.
- There is no subpopulation being studied. The universe of respondents is airline passengers over the age of two years coming to the United States from a foreign country, with certain exemptions as outlined in this information collection request.
- There is no predetermined methodology to analyze the attestations; however there will be random checks of test results upon arrival to inform program improvement. CDC will require that individuals (1) retain proof of their negative viral test or (2) if recovered from COVID-19, retain proof of a positive viral test within the last three months and a signed letter from a licensed healthcare provider or public health official showing they are cleared for travel (Documentation of Recovery), in case inspected upon arrival in the United States and to assist local health authorities in evaluating individuals to determine if further public health measures are needed.

CDC is requesting an emergency clearance for this information collection for 3 years.

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

This information collection accompanies the Notice and Order<sup>1</sup> (Attachment A1) requiring that any airline arriving into the United States from a foreign country submit proof of (1) a negative pre-departure viral test result for COVID-19 (Qualifying Test) or (2) a written (paper or electronic) documentation of recovery from COVID-19 in the form of a positive viral test result within the last three months and a letter from a licensed

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<sup>1</sup> This Order supersedes the previous orders signed by the U.S. Centers for Disease Control and Prevention (CDC) Director on January 12, 2020 requiring a negative pre-departure COVID-19 test result for all airline passengers arriving into the United States from any foreign country.

health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery) for all onboard passengers over the age of 2 years as a condition of controlled free pratique to enter and disembark passengers in the United States. Passengers must provide the Qualifying Test or Documentation of Recovery, which includes a matching identity, and attest to the truthfulness of the Qualifying Test or Documentation of Recovery as instructed by the airline before being allowed to board a flight to the United States as a public health prevention measure to mitigate the potential spread of COVID-19.

The COVID-19 pandemic has spread throughout the world. As of May 11, 2021, there were over 158,000,000 confirmed cases of COVID-19 globally resulting in over 3,000,000 deaths; more than 32,000,000 cases have been confirmed in the United States, with new cases being reported daily, and almost 580,000 U.S. deaths due to the disease.<sup>2</sup> While almost 60% of U.S. adults have received at least one dose of COVID-19 vaccine,<sup>3</sup> the vast majority of the world's population still has not received at least one vaccine dose.<sup>4</sup> Furthermore, many individuals who travel may still be at risk for exposure to SARS-CoV-2, the virus that causes COVID-19, before, during, or after travel. This could result in travelers' further spreading the virus to others during travel, upon arrival in the United States, or at their destinations.

The United Kingdom (UK) faced a rapid increase in COVID-19 cases in South East England at the end of 2020, leading to enhanced epidemiological and virological investigations. On December 14, 2020, Public Health England announced that a new variant of SARS-CoV-2 (B.1.1.7) had been identified across the southeast of England.<sup>5</sup> On December 19, 2020, in response to the emergence of the UK variant, the countries comprising the UK announced stricter measures to be applied from December 20 and over the coming weeks, with affected areas entering a 'Tier 4' level with movement restrictions within and between more and less heavily affected areas. These measures included recommendations for residents of the most affected areas to restrict movements and travel, including international travel, outside of these areas. The government of Scotland announced a travel ban between Scotland and the rest of the UK. In addition, the Netherlands issued a travel ban from the UK effective through January 1, 2021, and Belgium temporarily halted flight and train travel from the UK. Other countries took similar measures to restrict travel from the UK.

A second new variant of SARS-CoV-2 was reported in the Republic of South Africa (RSA) on December 18, 2020, that also appeared to spread more rapidly than earlier variants of the virus. Since then, three more variants were identified, one in Brazil in January 2021, and two more in California in February 2021. These variants seem to spread more easily and quickly than other variants, which may lead to more cases of COVID-19. An increase in the number of cases would put more strain on health care resources, lead to more hospitalizations, and potentially more deaths.<sup>6</sup>

During December 21-26, 2020, several countries implemented restrictions on travel

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<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

<sup>3</sup> <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>

<sup>4</sup> <https://covid19.who.int/> - As of May 6, 2021

<sup>5</sup> <https://www.gov.uk/government/news/phe-investigating-a-novel-variant-of-covid-19>.

<sup>6</sup> <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html>

from South Africa, including China, El Salvador, Germany, Guatemala, Israel, Panama, Sudan, Switzerland, Turkey, and the UK. The Netherlands imposed a ban on travel from RSA on December 21 but lifted the ban for both the UK and RSA on December 23, stating that travelers will instead need to present a negative COVID-19 test result obtained within 72 hours of their scheduled arrival in the Netherlands, followed by 10 days of self-quarantine. On December 28, Japan imposed a ban on entry of all foreign nationals through the end of January 2021. On December 28, the Government of South Africa announced new restrictions on businesses and public movement. As of January 7, 2021, Canada requires air passengers 5 years of age or older to test negative for COVID-19 before arrival. On January 8, 2021 the United Kingdom announced a pre-departure testing requirement for all inbound international travelers with limited exceptions; a 10-day post-arrival quarantine will still be required.

On December 25, 2020, CDC issued an Order requiring proof of a negative Qualifying Test result for all airline passengers arriving from the UK to the United States. Since then, cases of the UK, RSA, and Brazil variants have been discovered in the United States and at least 240 countries.<sup>7</sup>The first case of the B.1.1.7 variant in the United States was found in Colorado on December 29, in an individual with no known travel history. Since then, the B.1.1.7 variant has become the predominant strain in the United States, representing 66% of genetically sequenced viruses during April 11-24, 2021.<sup>8,9</sup> The global spread of these variants highlighted the need for the Order to require proof of a negative COVID-19 test or recovery from COVID-19 for all air passengers arriving in the United States, not just from the UK. An Order extending the testing requirement for all international air passengers to the United States was issued on January 12, 2021. To align with executive orders from President Biden and to further reduce the spread of COVID-19, CDC updated the Order on January 25, 2021 to remove the option for airlines or other aircraft operators with flights from countries that lacked testing capacity for SARS-CoV-2 to apply for two-week waivers from the Order. The Order went into effect on January 26, 2021, and superseded requirements in the December 25, 2020 and January 12, 2020 Orders.

While vaccinations for COVID-19 have become increasingly accessible in the United States and all Americans 12 years and older are now recommended to receive a vaccine,<sup>10</sup> of the vast majority of the world's population still has not received at least one vaccine dose.<sup>11</sup> There is more to be learned about how well vaccines prevent people from spreading the virus that causes COVID-19 to others, even if they do not have symptoms. Scientists are also learning how long COVID-19 vaccines protect people how effective the vaccines are against new variants of the virus that causes COVID-19. Additionally, since it is known and expected that viruses constantly change through mutation leading to the emergence of new variants, new virus variants are likely to emerge as the virus continues to evolve and mutate. Accordingly, further action is needed to help mitigate the importation and spread of these and other new virus variants into the United States.

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<sup>7</sup> <https://covid.cdc.gov/covid-data-tracker/#global-variant-report-map>

<sup>8</sup> <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

<sup>9</sup> <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html>

<sup>10</sup> <https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html>

<sup>11</sup> <https://covid19.who.int/> - As of May 6, 2021

Based on increased transmissibility and spread of variants of SARS-CoV-2, and to reduce introduction and spread of these and future SARS-CoV-2 variants into the United States, testing requirements for U.S.-bound air passengers is warranted. This approach to testing-based risk assessment has been addressed in CDC guidance and the Runway to Recovery guidance jointly issued by the Departments of Transportation, Homeland Security, and Health and Human Services.<sup>12</sup> Testing for SARS-CoV-2 infection is a proactive approach and not dependent on the infecting strain. Approximately 190 countries and territories are now use testing in some form to monitor risk and control introduction and spread.<sup>13</sup> While total case counts and deaths due to COVID-19 have generally decreased in the United States since January 2021, case counts continue to increase in many places around the globe, with cases surging in the Republic of India.<sup>14</sup> Additionally, the high proportion of infected people with asymptomatic or pre-symptomatic infections reinforces the need for the United States to take a dual approach to combatting the virus. This means concurrently mitigating and slowing the introduction and spread of SARS-CoV-2 and controlling transmission within U.S. communities to prevent another surge of infections, hospitalizations, and deaths.

Predeparture testing may detect travelers infected with SARS-CoV-2 before they initiate their travel. CDC's Order aligns with published guidance for travelers and involves viral testing and receipt of results 1-3 days before travel (to include day of testing).<sup>15</sup> This guidance is based on evidence suggesting testing prior to departure for international travelers, particularly those traveling long-distances or passing through transportation hubs such as airports where social distancing may be challenging, may be useful as a means to reduce the risk of SARS-CoV-2 transmission during travel. Testing does not eliminate all risk, but when predeparture testing is combined with other measures such as self-monitoring for symptoms of COVID-19, wearing masks, social distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances and in transportation hubs.

As cases of COVID-19 continue to rise across the globe and travel volume increases, routine pre-departure testing of all U.S.-bound aircraft passengers is needed not only to reduce introduction and spread of known SARS-CoV-2 variants, but also future variants that might be more transmissible and cause more severe illness.

The Order is enforceable through the provisions of 18 U.S.C. §§ 3559, 3571 (Attachment A2); 42 U.S.C. §§ 243, 268, 271 (Attachment A3); and 42 C.F.R. § 71 (Attachment A4).

## **2. Purpose and Use of Information Collection**

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<sup>12</sup> Runway to Recovery 1.1, December 21, 2020, available at <https://www.transportation.gov/briefing-room/runway-recovery-11>

<sup>13</sup> [https://www.iata.org/en/programs/covid-19-resources-guidelines/covid-gov-mitigation/dashboard/?\\_\\_FormGuid=87fd806c-664d-4d7b-9ec3-720aa66c1e31&\\_\\_FormLanguage=en&\\_\\_FormSubmissionId=ef9cb3b8-941d-4f8b-93d5-a60972d94fb5](https://www.iata.org/en/programs/covid-19-resources-guidelines/covid-gov-mitigation/dashboard/?__FormGuid=87fd806c-664d-4d7b-9ec3-720aa66c1e31&__FormLanguage=en&__FormSubmissionId=ef9cb3b8-941d-4f8b-93d5-a60972d94fb5)

<sup>14</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/04/30/a-proclamation-on-the-suspension-of-entry-as-nonimmigrants-of-certain-additional-persons-who-pose-a-risk-of-transmitting-coronavirus-disease-2019/>

<sup>15</sup> <https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html>

Pursuant to 42 C.F.R. § 71.20, the Order prohibits the introduction into the United States of any airline passenger departing from all foreign countries unless the passenger has a negative pre-departure viral test result for COVID-19 or if recovered from COVID-19, required documentation showing they are cleared for travel. The negative test must be a viral test that was conducted on a specimen collected during the 3 days preceding the flight's departure (Qualifying Test). If the passenger wants to show they have recovered from COVID-19, their positive viral test result must have occurred in the 90 days (3 months) before the flight and be accompanied by a signed letter on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery). Passengers must retain written or electronic documentation reflecting the negative Qualifying Test result or Documentation of Recovery presented to the airline and produce such results upon request to any U.S. government official or a cooperating state or local public health authority. Air passengers will also be required to confirm that the information they present is true in the form of an attestation, Attachment A of the Order (Attachment D1 in this information collection). These requirements are independent of the COVID-19 vaccine status of any traveler.

Pursuant to 42 C.F.R. § 71.31(b), the Order constitutes a controlled free pratique to any airline with an aircraft arriving into the United States from all foreign countries. Pursuant to the controlled free pratique, the airline must comply with the following conditions in order to receive permission for the aircraft to enter and disembark passengers in the United States:

- Verify that each passenger has attested to having received either a negative Qualifying Test result or to recovery from COVID-19 after previous SARS-CoV-2 infection and clearance to travel. Airlines or other aircraft operators must retain a copy of each passenger attestation for 2 years. The attestation is attached to this information collection as Attachment D1.
- Confirm that each passenger aged 2 years or older has documentation of a negative Qualifying Test result or Documentation of Recovery from COVID-19.
- Not board any passenger without verifying the attestation and confirming the documentation as set forth in 1.a-b. in the Order.

CDC modeling indicates that predeparture testing is most effective when combined with self-monitoring.<sup>16</sup> Travel should be delayed (i.e., individuals should self-isolate) if symptoms develop or a pre-departure test result is positive and they have not met the requirements to end isolation<sup>17</sup> as documented by a signed letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel. Testing before departure results in the greatest reduction of transmission risk during travel when the specimen is collected close to the time of departure. Earlier testing, i.e., more than 3 days before travel, provides little benefit beyond what self-

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<sup>16</sup> Johansson MA, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: Symptom monitoring, quarantine, and testing. Available at: <https://www.medrxiv.org/content/10.1101/2020.11.23.20237412v1external icon>

<sup>17</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>

monitoring alone can provide for those that do not qualify as having recovered from COVID-19.

If the traveler is submitting negative test results, predeparture testing must be completed and results available to the traveler at maximum 3 days before the traveler attempts to board an aircraft. Travelers who test positive should remain in isolation and delay travel unless they meet criteria for discontinuing isolation and are cleared for travel. Travelers whose test results are not available before departure should delay their travel until results are available and will be denied boarding.

For people previously diagnosed with COVID-19 who remain asymptomatic after recovery, CDC does not recommend retesting within 3 months after the date of symptom onset (or the date of first positive viral diagnostic test if their infection was asymptomatic) for the initial SARS-CoV-2 infection because of the possibility of persistent positive results after they are no longer considered infectious.<sup>18</sup> For this reason, CDC has included the option of presenting documentation of recovery as an alternative to a negative test for people who tested positive in the 3 months before their flight. People who develop any symptoms of COVID-19 during this time period should not travel and should seek care for testing and evaluation. This guidance and CDC's requirement may be updated as additional information about people who have recovered from COVID-19 becomes available.

Air carriers and operators also must ensure that the attestation is submitted by each passenger or an authorized representative before the flight's departure. Boarding processes must incorporate a process by which either a physical signature, an authenticated digital signature, or an electronic system that uses unique identifiers to ensure the person filling out the electronic attestation form is the passenger or an authorized representative.

CDC has provided the language that must be included in Attachment D1. Air carriers and operators may not alter the language of the passenger attestation but may use a third party to provide translations of the attestation. CDC has made some fillable PDF's available on the website, in some languages in Attachments D2-D7 of this information collection request.

CDC is also doing random compliance checks to help ensure documentation, such as test results, meet the requirement of the Order and in the event some public health action is needed at the time of arrival. CDC expects to do random compliance checks for approximately 1.3% of air passengers coming to the United States.

CDC may record some information presented, such as type of test used, whether recovery documentation was presented, vaccination type or status, etc. to evaluate overall program compliance and effectiveness. Collection of name and contact information may occur if a traveler's documentation is deemed non-compliant and possible public health follow up is warranted.

In addition to specific exemptions defined in the Order, a person may receive a time limited exemption for urgent humanitarian reasons. Exemptions may be granted on an

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<sup>18</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

extremely limited basis when emergency travel (like an emergency medical evacuation) must occur to preserve someone's life, health against a serious danger, or physical safety and testing cannot be completed before travel. Additional conditions may be placed on those granted such exemptions, including but not limited to providing consent to testing and/or self-quarantine after arrival in the United States, as may be directed by federal, state, territorial, tribal or local public health authorities to reduce the risk of transmission or spread. The information CDC needs to be able to determine whether an exemption under these terms is appropriate is as follows (Attachment E):

1. Name of passenger and Passport Number and Nationality (or passengers if family unit)
2. Cell phone of Passenger or Guardian if family unit
3. Email of Passenger or Guardian if family unit
4. US destination address
  - a. Is US destination home address?
5. Departure date and flight itinerary, including any connecting flights
  - a. Flight and Departure Date
6. Name of submitting entity if different from passenger
  - a. Name of person submitting on behalf of passenger(s)
7. Name of company submitting on behalf of passenger(s)
8. Purpose of travel to the US (e.g. emergency medical evacuation, preserve health and safety):
9. Justification for Testing Exemption (e.g. no testing available, unable to obtain test/result before required departure, impact on health and safety):
10. Documentation to support justification for test exemption (e.g. medical records or orders for medical evacuation):
11. Information regarding any other solutions that were sought prior to exemption request (e.g. flight changes, assistance for testing):

CDC will work with the Department of State in reviewing this and other information to determine if an exemption to the Order is appropriate. Once CDC makes a determination regarding the exemption, the individual will receive letter from CDC indicating approval or denial. CDC and the Department of State may collaborate on an electronic version of this information collection to facilitate submission by the traveler to the Consular staff at U.S. Consulates and Embassies if the volume of requests increase significantly.

Finally, some outbound air passengers flying to foreign countries may be denied entry to the destination country. This can happen for various reasons, including not having a COVID-19 test for entry to that foreign country, issues with their visas or travel documents, etc. These inadmissible travelers, then have to return to the United States as soon as possible and in most cases will not have time to get a COVID-19 test to board a plane back to the United States. When this occurs, CDC asks airlines to notify them and provide contact and itinerary information to CDC (Attachment F) so that the passenger is

not deemed as non-compliant. CDC may share the contact information of the passenger with state and local health departments in case public health follow up is needed.

### **3. Use of Improved Information Technology and Burden Reduction**

At this time, CDC is not specifying the format of the proof of a negative test, the documentation of clearance to fly from a healthcare provider or health department, or the attestation. Either format is acceptable, as long as the electronic or hard copy contain the information as specified in the Order and detailed on CDC's website.<sup>19</sup> Federal or state and local officials may request the documentation of proof of a Qualifying Test or Documentation of Recovery, such as for compliance checks, so those must be retained by the individual.

Individuals can begin the process for requesting an exemption on urgent humanitarian grounds by contacting the United States Embassy where they are located. Embassy contact information can be found on Department of State's website. If an individual requires medical evacuation, the exemption process can be initiated by the company providing the medical evacuation services.

### **4. Efforts to Identify Duplication and Use of Similar Information**

This Order applies to all air passengers two years and older coming to the United States, including U.S. citizens and legal permanent residents, with the limited noted exceptions as follows:

- Crew members of airlines or other aircraft operators provided that they follow industry standard protocols for the prevention of COVID-19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).<sup>20</sup>
- Airlines or other aircraft operators transporting passengers with COVID-19 pursuant to CDC authorization and in accordance with CDC guidance.<sup>21</sup>
- Federal law enforcement personnel on official orders who are traveling for the purpose of carrying out a law enforcement function, provided they are covered under an occupational health and safety program in accordance with CDC guidance. Those traveling for training or other business purposes remain subject to the requirements of this Order.
- U.S. Department of Defense (DOD) personnel, including military personnel and civilian employees, dependents, contractors (including whole aircraft charter operators), and other U.S. government employees when traveling on DOD assets, provided that such individuals are under competent military or U.S government travel orders and observing DOD precautions to prevent the transmission of COVID-19 as set forth in *Force Protection Guidance Supplement 14* -

<sup>19</sup> <https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-international-air-travelers.html>

<sup>20</sup> [https://www.faa.gov/other\\_visit/aviation\\_industry/airline\\_operators/airline\\_safety/safo/all\\_safos/media/2020/SAFO20009.pdf](https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf). Airlines, aircraft operators, and their crew members may follow even stricter protocols for safety, including testing protocols.

<sup>21</sup> Interim Guidance for Transporting or Arranging Transportation by Air into, from, or within the United States of People with COVID-19 or COVID-19 Exposure available at <https://www.cdc.gov/quarantine/interim-guidance-transporting.html>

*Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic* (December 29, 2020) including its testing guidance.

- Individuals and organizations for which the issuance of a humanitarian exemption is necessary based on both 1) exigent circumstances where emergency travel is required to preserve health and safety (e.g., emergency medical evacuations), and 2) where pre-departure testing cannot be accessed or completed before travel. Additional conditions may be placed on those granted such exemptions, including but not limited to, observing precautions during travel, providing consent to post-arrival testing, and/or self-quarantine after arrival in the United States, as may be directed by federal, state, territorial, tribal or local public health authorities to reduce the risk of transmission or spread.

CDC wants to note that certain classes of individuals traveling from specific countries are already not permitted entry to the United States under travel restrictions named in Presidential Proclamations issued under 8 USC 212(f). The CDC order does not replace these Presidential proclamations. Therefore, providing proof of a negative test result for COVID-19 or documentation of having recovered from COVID-19 to the airline before boarding the flight does not exempt a traveler from any applicable travel restrictions outlined in the Presidential proclamation. The travel restrictions outlined in these Presidential Proclamations do not apply to U.S. citizens, legal permanent residents of the United States, and other limited classes of individuals.

To our knowledge, there is no duplication to CDC's ongoing information collections. No other US federal agencies are requesting this information. Some state and local health departments requested that CDC put in place these requirements so that the travelers would have proof of either a negative COVID-19 test or Documentation of Recovery. We anticipate CDC's order will be complimentary to any state or local health authority requests for this data.

## **5. Impact on Small Businesses or Other Small Entities**

While some aviation, maritime, and other travel companies may be considered small businesses, CDC anticipates that the majority of the burden rests with larger passenger airlines given their volume of travelers. CDC has been judicious in determining the required information collection to those minimally necessary to achieve public health objectives.

## **6. Consequences of Collecting the Information Less Frequently**

Given the scope of the outbreak of COVID-19 identified in international airline travelers, CDC needs to collect this data on a routine basis.

## **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 February 12, 2021, Vol. 86, No. 28, p. 9343-9345 (Attachment B). Two comments were received, and CDC has provided responses to both (Attachment C).

B. CDC communicates frequently with airlines and state and local health departments concerning the latest efforts to address the COVID-19 pandemic. In this case, CDC is aware of several states that have requested federal public health actions to mitigate the risk of entry of this variant of SARS-CoV-2. To attempt to streamline the process and work with airlines' policies and procedures, CDC routinely obliges airlines' requests concerning these kinds of collections. Additionally, CDC is aware that some airlines are already including testing in their business processes, and so this may not represent a significant additional burden in those cases. Finally, CDC's requirements are aligned with a number of other countries who require similar testing documentation from arriving travelers.

CDC anticipates that many travelers will retain copies of their COVID-19 test results or Documentation of Recovery regardless of this information collection, and does not anticipate significant additional burden for this retention requirement as a result of this Order.

## **9. Explanation of Any Payment or Gift to Respondents**

No payment is made to any respondent.

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

This information collection request has been reviewed by the CDC National Center for Emerging and Zoonotic Diseases (NCEZID). NCEZID has determined that the Privacy Act applies to this information collection request. The applicable System of Records Notice (SORN) is 09-20-0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71, HHS/CDC/CCID. Individual's identifiable information will only be shared according to the Routine Uses described in the SORN, which are generally focused on providing public health authorities and cooperating medical providers with this information to assist in dealing with public health threats or for medical follow-up for a traveler.

Collection of name and contact information of traveler may occur if a traveler's documentation is deemed non-compliant and/or possible public health follow up by a state or local health department is warranted. Any information reviewed or collected for this purpose would be treated as described in SORN 09-20-0171.

Further information concerning the protection of privacy can be found in the attached Privacy Impact Assessment (Attachment F).

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

### **IRB Approval**

#### IRB Determination

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required.

#### Justification for Sensitive Questions

The Qualifying Test results and the Documentation of Recovery include results of clinical testing and identifying information to ensure the test results match the bearer of any documents presented to the airlines or public health authorities. Individual exemptions require review by CDC of relevant documents that may include sensitive medical information.

## **12. Estimates of Annualized Burden Hours and Costs**

A.

While the current Order is scheduled to expire on December 31, 2021, CDC estimates the annual burden to be approximately 197,919,950 hours (rounded to nearest hour).

Under the Order, an individual will need to attest to one of the following on Attachment A to the Order:

- That they have received a negative pre-departure test result for SARS-CoV-2. The test was a viral test that was conducted on a specimen collected from that person within 3 days preceding the flight's departure.
- That they have recovered from SARS-CoV-2 infection in the last 3 months (90 days), or the time period specified in current CDC guidance, after having previously tested positive for SARS-CoV-2 and have been cleared for travel by a licensed healthcare provider or public health official.

Unless otherwise permitted by law, a parent or other authorized individual should attest on behalf of a passenger aged 2 to 17 years. An authorized individual may attest on behalf to any passenger who is unable to attest on his or her own behalf (e.g., by reason of physical or mental impairment).

To estimate annual travel volume after the COVID-19 pandemic, CDC first calculated the air travel volume to the United States for the next year if air travel volume remained the same as in the most recent month (3.4 million air passengers for the month of April 2021 x 12 months = 40.8 million air passengers). Recognizing that air travel volume to the United States will likely increase as more people are vaccinated, CDC looked at data from U.S. Customs and Border Protection for travel volume pre-pandemic and took the average between the two calculations. Therefore, the mean of the estimated annual air travel volume at status quo (40.8 million air passengers) with the air travel volume to the United States pre-pandemic (149.4 million in 2019) is estimated to be approximately 95 million air passengers coming to the United States each year. CDC acknowledges that it is possible that an individual may travel to the United States more than once, and in those

cases, that individual would need a negative test or to show their recent positive test result and a doctor's or public health official's note indicating recovery from SARS-CoV-2 infection for each trip.

- Traveler burden for the *Attestation of a negative COVID-19 test/Documentation of Recovery indicating clearance for travel by a licensed healthcare provider or public health official*, is estimated as follows: 95,000,000 respondents x 2 hours per response, for a total of 190,000,000 hours. The 2 hours accounts for the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.
- For airline agent review of the *Attestation of a negative COVID-19 test/Documentation indicating clearance for travel by a licensed healthcare provider or public health official*, burden is estimated as follows: 95,000,000 reviews x 5 minutes (or less) per review, for a total of 7,916,667 hours.

CDC understands that the 95 million traveler volume may still be depressed due to the COVID-19 pandemic but this is the best estimate at this time. If there is a significant increase in volume, CDC will submit a change request to account for that burden.

The order additionally includes an exemption available to individuals for urgent humanitarian reasons. Such exemptions will be time limited, and may include further conditions, as described above. The traveler should present this letter to the airline prior to boarding.

- Based on the number of humanitarian requests to date, CDC estimates that there will be no more than 25 requests from individuals for exemptions per week, or 1,300 (25 requests x 52 weeks) on an annual basis. CDC estimates that each request will require 2 hours to collect documentation to support the need for the waiver, and develop and submit the exemption request. The burden is estimated at 2,600

CDC expects to do compliance checks for approximately 1% of all air passengers flying to the United States. CDC estimates that 0.6% passengers of that 1%, has been shown to have a negative test or documentation of recovery that are non-compliant to date. Based on those proportions, CDC expects approximately 5,700 (95 million x .01 x .006) out of the 95 million travelers will have documentation that does not meet all requirements. CDC estimates it takes 5 minutes or less to collect contact information for public health follow up by state or local health departments. Therefore, the burden estimate for contact information collection for travelers with non-compliant information is approximately 475 hours.

CDC expects that approximately 835 outbound passengers a year will be denied entry to foreign countries and may need to take return flight to the United States before being able to get a COVID-19 test. CDC estimates it will take returned inadmissible travelers approximately 5 minutes to share contact information for the airline to share with CDC in case any public health follow up is required, resulting in approximately 70 burden annual hours for travelers. CDC estimates it will take airlines approximately 10 minutes to gather the contact information and flight itinerary info and send to CDC. This results in approximately 139 annual burden hours for the airlines.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Traveler (3 <sup>rd</sup> Party Disclosure)	Attestation of a negative COVID-19 test/Documentation indicating clearance for travel by a licensed healthcare provider or public health official	95,000,000	1	2	190,000,000
Airline Desk Agent	Attestation of a negative COVID-19 test/Documentation indicating clearance for travel by a licensed healthcare provider or public health official	95,000,000	1	5/60	7,916,667
Traveler	Request Exemption on Urgent Humanitarian Basis – (No form)	1,300	1	2	2,600
Traveler with non-compliant test or documentation of recovery	Contact information collection for public health follow up – (No form)	5,700	1	5/60	475
Returned Inadmissible Traveler	Contact information collection for public health follow up – (No form)	835	1	5/60	70

Airline Representative	Contact information collection for public health follow up – (No form)	835	1	10/60	139
<b>Total</b>					197,919,950

B. The cost to respondents for travelers was calculated using the U.S. Department of Transportation’s Departmental Guidance on Valuation of Travel Time in Economic Analysis (<https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20Travel%20Time%20Guidance.pdf>) Costs to airlines used estimates from the May 2020 National Occupational Employment and Wage Estimates United States data from the Bureau of Labor Statistics ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)) and included adjustments for non-wage benefits and overhead costs by multiplying hourly wage by 2. The total estimated respondent cost is \$9,297,175,735.

- The cost for passengers’ time to provide the additional data was estimated by using recommended hourly value of travel time savings for all type of travel from the U.S. Department of Transportation. This dollar value is \$47.10 per hour.<sup>22</sup>
- 43-4181 Reservation and Transportation Ticket Agents and Travel Clerks job series from the Bureau of Labor Statistics was used to account for Airline Desk Agent who is checking attestations: <https://www.bls.gov/oes/current/oes434181.htm>. CDC used a mean hourly wage rate of \$21.98 x 2 to account for wages, benefits and overhead costs for an estimate of \$43.96.
- 11-1021 General and Operations Managers (<https://www.bls.gov/oes/CURRENT/oes111021.htm>) was used to estimate the costs for Airline Representatives time. The mean hourly wage is \$60.45, and adjusted for non-wage benefits by 2 is \$78.59

Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Traveler (3 <sup>rd</sup> Party Disclosure)	Attestation of a negative COVID-19 test/Documentation indicating clearance for travel by a licensed healthcare provider or public health official (Attachment D1-D7)	190,000,000	\$47.10	\$8,949,000,000

<sup>22</sup> <https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20Travel%20Time%20Guidance.pdf> Page 17

Airline Desk Agent	Attestation of a negative COVID-19 test/Documentation indicating clearance for travel by a licensed healthcare provider or public health official (Attachment D1-D7)	7,916,667	\$43.96	\$348,016,681
Traveler	Request Exemption on Urgent Humanitarian Basis – (No form. Data elements in Attachment E )	2,600	\$47.10	\$122,460
Traveler with non-compliant test or documentation of recovery	Contact information collection for public health follow up – (No form. Data elements in Attachment F)	475	\$47.10	\$22,373
Returned Inadmissible Traveler	Contact information collection for public health follow up – (No form. Data elements in Attachment F)	70	\$47.10	\$3,297
Airline Representative	Contact information collection for public health follow up – (No form. Data elements in Attachment F)	139	\$78.59	\$10,924
<b>Total</b>				\$9,297,175,735

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

CDC anticipates certain additional cost burdens to respondents and record keepers due to the requirements. These costs fall into the following categories:

- Traveler testing and ancillary costs: \$30,789,500,000
- Traveler deferred travel costs: \$116,327,500
- Airline staff costs for digitizing attestations: \$35,783,333
- Airline costs to store attestations: \$3,350 to 2,925,000 a year depending on size of airline and number of travelers.

CDC is assuming that costs for testing and obtaining the Documentation of Recovery will be paid by the traveler. Based on costs available for COVID-19 tests in the United States,

CDC anticipates these tests will cost \$148 and ancillary costs associated with healthcare visits (e.g. specimen collection and the office visit itself) at \$129.<sup>23</sup> CDC also includes an estimate of 1 hour of time to make an appointment, travel to the appointment and submit the specimen. CDC acknowledges this may be an over-estimate of the costs to travelers. Some healthcare systems are publicly funded and individual responsibility to pay may be less than the costs presented here. Health insurance may also reduce out of pocket costs to travelers. The calculations for estimated burden are as follows:

	Test Cost and Ancillary Costs	Time cost	# of Travelers	Total
Traveler Cost	\$277	\$47.10	95,000,000	\$30,789,500,000

There may also be a cost to the travelers for deferred travel in the event they test positive or miss the 3 day window for the validity of the proof of negative test. CDC anticipates that airlines will be flexible in waiving rescheduling fees, but some travelers may endure costs associated with finding accommodations to stay for a limited period of time. CDC cannot predict what percentage of travelers may experience these inconveniences. For the purposes of this collection, CDC is estimating that 1% of travelers will experience deferred travel and a cost of \$122.45 dollars for an overnight hotel stay.<sup>24</sup> With 1% of 95,000,000 travelers experiencing this deferred travel, CDC estimates the additional burden at \$116,327,500.

	1% of total volume	Hotel Cost	Total
Traveler Cost	950,000	\$122.45	\$116,327,500

CDC is requiring that individuals pursuant to 42 CFR 71.20 retain copies of their Qualifying Test or Documentation of Recovery. CDC is including this requirement so that public health authorities in the United States can confirm an individual’s COVID-19 Qualifying Test or Documentation of Recovery is valid, if needed. CDC anticipates this will result in no significant costs or burden in either hard copy or electronic form as most people may want to retain this information for other purposes.

CDC is also requiring that the airlines pursuant to 42 CFR 71.31(b) retain the attestation of negative test provided by the passenger. As long as the attestation conforms to Attachment A of the Order (Attachment D1 to this information collection request), either electronic or hard copy retention is acceptable. CDC anticipates that any hard copy attestation provided by a traveler would be digitized for ease of retrieval and result in some additional storage costs. The cost associated with retention are estimated across the industry using the following methodology:

- Airline staff time to scan or otherwise digitize hard copy passenger attestations:
  1. CDC is using the BLS category 43-4071 File Clerks (<https://www.bls.gov/oes/current/oes434071.htm>), with an average hourly

<sup>23</sup> <https://www.healthsystemtracker.org/brief/covid-19-test-prices-and-payment-policy>

<sup>24</sup> <https://www.statista.com/statistics/245759/average-daily-rate-of-hotels-worldwide-by-region/>

- wage of \$17.38, adjusted to \$34.76 to include non-wage benefits and overhead.<sup>25</sup>
2. CDC is anticipating 1 minute to scan or otherwise digitize each of the 95 million estimated attestations.
    - The estimate for this process is \$55,036,667
  3. CDC assumes airlines have access to common office equipment, such as a document scanner and no new equipment would be needed.
- Airline costs to store the attestations:
    1. Because there are a wide variety of document management systems and process available to airlines, the range of potential costs varies significantly depending on how each airline decides to pursue their retention program, from thousands to millions of dollars a year. Some larger airlines may be able to incorporate this into currently existing document retention programs at low cost, while others may need to purchase a digital solution, or rely on hard copies.
    2. To estimate a range of costs over the airlines, CDC is apportioning the total cost of storing 95 million records over the proportion of travelers carried by each airline, using low and high ranges.
      - The high percentage is calculated by taking the median of the highest percentage in calendar year 2019 (18%) for pre-pandemic estimates, and of the highest percentage (13%) in the last year (May 2020-April 2021), which results in approximately 15%.
      - The low percentage median is less than 1%.
    3. Using this method, the cost for the airline with the highest number of travelers, approximately 15% of all incoming arrivals, ranges from a high of \$ 2,925,000 to \$50,300 a year. The cost for those airlines with less than 1% of arriving travelers may expect a range of costs between \$195,000 to \$3,350 a year. These costs depend on the type of storage system used and the type of file (.gif, .png, .jpg).

#### **14. Annualized Cost to the Government**

CDC estimates the federal government spends approximately \$3,680,193 a year processing requests related to the Order.

In the case of requesting airline attestations, CDC would notify the airline of the request for the documentation, but does not think this would result in a substantial increase in costs to the government.

This collection includes some CDC staff time to review and possibly record information on COVID-19 test results or Documentation of Recovery during compliance checks. CDC staff may also need to spend approximately 5 minutes gathering contact information from travelers with non-compliant test results or Documentation of Recovery in case public health follow up is needed. CDC estimates staff spend approximately 36,000 hours a year doing compliance checks at an average hourly rate for a General Schedule -12 (GS-12), multiplied by 2 to adjust for federal non-wage benefits and overhead which is \$88.66.

<sup>25</sup> <https://www.bls.gov/oes/current/oes434071.htm>

The time it takes for U.S. Department of State to collect and CDC to adjudicate a request for exemption based on an urgent humanitarian basis varies widely depending on the situation. It is estimated that Department of State spends approximately 1 hour per request, at a median hourly wage rate for a Foreign Service Officer Overseas – 3 (FS-3), adjusted for non-wage benefits and overhead (x 2) which is approximately \$100.19. Taking into account that most requests take no more than 2 hours, but others can be more than 5 hours, CDC estimates CDC staff equivalent to a GS-12 spend an average of 3 hours processing each request so approximately 3,900 hours (1,300 x 3) at \$88.66 an hour.

<b>Federal Staff and Contractors</b>	<b>Annual Hours</b>	<b>Hourly Wage</b>	<b>Cost</b>
CDC Quarantine Station staff and contractors doing compliance checks	36,000	\$88.66	\$3,191,760
Collection of Traveler information for Request Exemption on Urgent Humanitarian Basis – FS-3	1,300	\$100.19	\$130,247
Adjudicate Request Exemption on Urgent Humanitarian Basis – GS-12	3,900	\$88.66	\$345,774
Process Returned Inadmissible Traveler	140	\$88.66	\$12,412
<b>Total Costs</b>			<b>\$3,680,193</b>

### **15. Explanation of Program Changes or Adjustments**

CDC has updated this package from the 60-day with information about the current status of the COVID-19 pandemic and updated burden estimates for annual burden. Also, for the purpose of transparency, CDC provided more detail about compliance checks at airports and estimated Annualized Cost to the Government.

### **16. Plans for Tabulation and Publication and Project Time Schedule**

Data are not collected for statistical purposes, but only to meet the regulatory and public health mandate as outlined in 42 CFR part 71.

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

No exemption is requested. The OMB Control Number and expiration date will be displayed on the attestation form.

### **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.



## **Attachments**

Attachment A1: CDC Global Testing Order

Attachment A2 18 U.S.C. §§ 3559, 3571

Attachment A3: Section 361 of the Public Health Service Act (42 USC 264)

Attachment A4: 42 CFR Part 71

Attachment B: 30-day Federal Register Notice

Attachment C: Responses to 60-day

Attachment D1: Attestation

Attachment D2: English

Attachment D3: Russian

Attachment D4: Simplified Chinese

Attachment D5: Arabic

Attachment D6: French

Attachment D7: Spanish

Attachment E: Information requirements for exemption

Attachment F: Contact information collected for compliance checks or returned travelers

Attachment G: QARS Privacy Impact Assessment