

**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**

**AND**

**REQUIREMENT FOR PROOF OF COVID-19 VACCINATION FOR  
NONCITIZEN, NONIMMIGRANT AIR PASSENGERS ARRIVING INTO THE  
UNITED STATES FROM A FOREIGN COUNTRY**

**(OMB Control No. 0920-1318)  
Request for Emergency Clearance**

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**Supporting Statement A**

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- **Goal:** The goal of this information collection is two-fold:
  - o To ensure that, consistent with the terms of the December 2, 2021 Amended Order Under Section 361 of The Public Health Service Act (42 U.S.C. § 264) and 42 Code Of Federal Regulations §§ 71.20 and 71.31(b). *Requirement For Negative Pre-Departure Covid-19 Test Result Or Documentation Of Recovery From COVID-19*

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**(OMB Control No. 0920-1318)**

CDC is requesting an emergency clearance for this information collection for 180 days.

**A. Justification**

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

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ) requests an emergency 180-day approval for a revised information collection.

This information collection is necessary to implement requirements for international air passengers to reduce the risk of introduction and spread of COVID-19. These requirements are outlined in the following:

***a) Amended Order: Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 For All Airline or Other Aircraft Passengers Arriving in The United States from Any Foreign Country***

Pursuant to 42 CFR 71.20, 71.31(b) and as set forth in greater detail, CDC issued an Amended Order on December 2, 2021 (“Amended Testing Order”) (Attachment A1) that prohibits the boarding of any passenger – 2 years of age or older - on any aircraft destined to the United States from a foreign country unless the passenger presents:

- (1) Paper or digital documentation of a negative pre-departure viral test result for SARS-CoV-2, the virus that causes COVID-19, that conducted on a specimen collected no more than 1 calendar day before the flight’s departure from a foreign country (*Qualifying Test*).

**Or**

(2) Paper or digital documentation of recovery from COVID-19 in the form of both:

- A positive viral test result conducted on a specimen collected no more than 90 calendar days before the flight; *and*
- A letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel (*Documentation of Recovery*).

**b) *A Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC’s Amended Order Implementing Presidential Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic.***

Pursuant to Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code, on October 25, 2021, the President issued a Proclamation (“the Proclamation”) titled, “*Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic*” (Attachment A2). Pursuant to this Proclamation, the President implemented a global suspension and limitation on entry for noncitizens who are nonimmigrants (“noncitizen nonimmigrants”) seeking to enter the United States by air travel and who are not fully vaccinated against COVID-19. The Proclamation directs, in part, the Secretary of Health and Human Services (HHS), through the Director of the Centers for Disease Control and Prevention (CDC), to implement the Proclamation as it applies to public health in accordance with appropriate public health protocols and consistent with CDC’s independent public health judgment.

To implement this Proclamation, CDC issued the *Order Implementing Presidential Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic* on October 25, 2021, announcing that beginning November 8, 2021, CDC would be requiring noncitizen nonimmigrants to show proof of being fully vaccinated COVID-19 vaccination with one of the approved or authorized for emergency use by the U.S. Food and Drug Administration or a vaccine listed for emergency use by the World Health Organization, or a combination of vaccines as specified in CDC Technical Instructions. Passengers must provide proof of COVID-19 vaccination and attest to the truthfulness of the proof of vaccination. Airlines must also confirm that the proof of vaccination matches the passengers’ identity, 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 Order allows some exceptions to this requirement; however, some categories of exceptions may require the individual to attest to taking certain measures after U.S. arrival such as self-quarantine, getting tested 3-5 days after travel, or if staying more than 60 days, getting fully vaccinated against COVID-19.

CDC issued an amended Order (“Amended Vaccination Order”) (Attachment A3) on October 30, 2021 with minimal changes to clarify that some individuals are not required to attest to having to agree and arrange to self-quarantine after arriving in the United States. The Amended Vaccination Order also includes details about what would be required for noncitizen nonimmigrants who were eligible for an exception related to diplomatic or foreign government travel. The Amended Vaccination Order supersedes the

previous Order signed by the CDC Director on October 25, 2021, implementing the President's direction.

## **2. Background**

Since January 2020, the respiratory disease known as "COVID-19," caused by a novel coronavirus (SARS-CoV-2), has spread globally, including cases reported in all 50 states within the United States, plus the District of Columbia and all U.S. territories. As of December 02, 2021, there have been over 262,000,000 million cases of COVID-19 globally, resulting in over 5,200,000 deaths. In the United States, more than 48,000,000 cases have been identified, and over 775,000 deaths attributed to the disease.

SARS-CoV-2 spreads mainly from person-to-person through respiratory fluids released during exhalation, such as when an infected person coughs, sneezes, or talks. Exposure to these respiratory fluids occurs in three principal ways: (1) inhalation of very fine respiratory droplets and aerosol particles, (2) deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays, and (3) touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them.<sup>20,21</sup> Spread is more likely when people are in close contact with one another (within about 6 feet), especially in crowded or poorly ventilated indoor settings. Persons who are not fully vaccinated, including those with asymptomatic or pre-symptomatic infections, are significant contributors to community SARS-CoV-2 transmission and occurrence of COVID-19.<sup>22,23</sup>

New variants of SARS-CoV-2 have emerged globally, several of which have been broadly classified as "variants of concern." Some variants are more transmissible, even among those who are vaccinated, and some may cause more severe disease, which can lead to more hospitalizations and deaths among infected individuals. Furthermore, recent findings suggest that antibodies generated during previous infection or vaccination may have a reduced ability to neutralize some variants, resulting in reduced effectiveness of treatments or vaccines, or increased diagnostic detection failures. The emergence of variants that substantially decrease the effectiveness of available vaccines against severe or deadly disease is a primary public health concern.

On November 24, 2021, the Republic of South Africa informed the World Health Organization (WHO) of a new variant of SARS-CoV-2, the virus that causes COVID-19, that was detected in that country. On November 26, 2021, WHO designated the variant B.1.1.529 as a variant of concern and named it Omicron.

Some evidence presented noted that Omicron has several mutations that may have an impact on how easily it spreads or the severity of illness it causes. CDC and other federal agencies are working closely with international public health agencies to monitor the situation closely and are taking steps to enhance surveillance for and response to the Omicron variant within the United States. Considering the potential danger to public

health posed by this newly identified variant, CDC has determined that proactive measures must be implemented now to protect the U.S. public health from the importation, transmission and spread of the emergent Omicron variant into the United States.

***a) Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 For All Airline or Other Aircraft Passengers Arriving in The United States from Any Foreign Country***

On January 25, 2021 CDC issued an Order<sup>1</sup> requiring all air passengers 2 years of age and older traveling from any foreign country to show a negative pre-departure COVID-19 test result or documentation of recovery from COVID-19 in the previous 90 days before boarding a flight to the United States.

On October 25, 2021 CDC amended its January 25, 2021 Order to require air passengers who were not fully vaccinated to present a negative result for a pre-departure COVID-19 viral test conducted on a specimen no more than 1 calendar day before travel to the US. Fully vaccinated air passengers still had no more than 3 calendar days for their test and were required to show proof of being fully vaccinated.

In response to the new Omicron variant, the United States Government, including CDC, reexamined its policies on international travel and concluded the proactive 1 calendar day testing measure is necessary to protect the public health and should remain in place until more information becomes available that may alter or improve the public health outlook. Therefore, on December 2, 2021, CDC amended the October 25, 2021 Order<sup>2</sup> to now require all air passengers 2 years or older to present a negative result for a pre-departure COVID-19 viral test conducted on a specimen no more than 1 calendar day before travel to the United States, regardless of vaccination status or citizenship.

All air passengers, regardless of vaccination status, if they tested positive for COVID-19 in the 90 days before the flight's departure, have the option of instead presenting documentation of recovery from COVID-19 in the form of their positive viral test result and a signed letter from a licensed healthcare provider or public health official stating the person was cleared to travel.

Testing for SARS-CoV-2 infection is a proactive, risk-based approach that is not dependent on the infecting variant. This risk-based testing approach 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>3</sup> Most countries now use testing in some form to monitor risk and control

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<sup>1</sup> [Federal Register: 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](#)

<sup>2</sup> [Federal Register: 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](#)

<sup>3</sup> Runway to Recovery 1.1, December 21, 2020, available at <https://www.transportation.gov/briefing-room/runway-recovery-11>.

introduction and spread of SARS-CoV-2.<sup>4</sup> With case counts and deaths due to COVID-19, particularly the Delta variant, continuing to increase around the globe, the high proportion of unvaccinated people in the United States and around the world, and infected people with asymptomatic or pre-symptomatic infections, the United States is taking a multi-layered approach to combatting COVID-19, concurrently preventing and slowing the continued introduction of cases and further spread of the virus within U.S. communities. Vaccination is the most important measure for reducing risk for SARS-CoV-2 transmission during travel and in avoiding severe illness, hospitalization, and death; however, infections in fully vaccinated people indicate that vaccination is a necessary but not sufficient measure; testing of these travelers is still necessary and thus required.

Recent CDC modeling that incorporated the transmission characteristics of the Delta variant shows evidence that for persons not fully vaccinated, getting a viral test one day prior to departure can reduce the risk of traveling with COVID-19 by 40%.<sup>5</sup> When this window is expanded to two days prior to departure, the reduction in risk is 26%, and for three days prior to departure, the risk reduction is only an estimated 14%. This modeling was based on real-world data on virus transmissibility.<sup>6,7,8</sup>

While CDC's previous Amended Order indicated that "decreasing the time window for testing before departure from three days to one day provides minimal additional public health benefit for fully vaccinated travelers," this statement did not account for the Omicron variant, which had not yet been identified. At this time, it is unknown what level of protection current vaccines will provide against this newly emergent mutated Omicron variant.

Pre-departure testing does not eliminate all risk. However, when pre-departure testing is combined with other measures such as self-monitoring for symptoms of COVID-19, wearing masks, physical distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances, in transportation hubs, and at destinations.

***b) Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and Amended Order Implementing Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic.***

Vaccinated individuals are 5 times less likely to be infected and 10 times less likely to experience hospitalization or death due to COVID-19 than unvaccinated individuals. Other mitigation measures are also critical to slowing the spread of COVID-19. While other mitigation measures including testing and mask-wearing, and self-quarantining and

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<sup>4</sup> <https://ourworldindata.org/coronavirus-testing#testing-and-contact-tracing-policy>

<sup>5</sup> Public Health Guidance for Potential COVID-19 Exposure Associated with Travel <https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html>.

<sup>6</sup> He, X., Lau, E.H.Y., Wu, P. et al. Temporal dynamics in viral shedding and transmissibility of COVID-19. *Nat Med* 26, 672–675 (2020). <https://doi.org/10.1038/s41591-020-0869-5>.

<sup>7</sup> Wölfel, R., Corman, V.M., Guggemos, W. et al. Virological assessment of hospitalized patients with COVID-2019. *Nature* 581, 465–469 (2020). <https://doi.org/10.1038/s41586-020-2196-x>.

<sup>8</sup> Rachael Pung, Tze Minn Mak, Adam J Kucharski, Vernon J Lee, Serial intervals in SARS-CoV-2 B.1.617.2 variant cases, *The Lancet*, 2021 ISSN 0140-6736, [https://doi.org/10.1016/S0140-6736\(21\)01697-4](https://doi.org/10.1016/S0140-6736(21)01697-4).



self-isolating are particularly important strategies to limit the spread of COVID-19, vaccination is the most important measure for reducing the risk of COVID-19 transmission and for avoiding severe illness, hospitalization, and death.

On October 25, 2021, President Biden issued a Proclamation “Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic” (Attachment A2). This Proclamation allowed CDC to issue an Order Implementing Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic, and the Amended Vaccination Order on October 30, 2021 (Attachment A3).

This Proclamation and Amended Vaccination Order will only apply to noncitizen, nonimmigrants. It will not apply to anybody who is a U.S. citizen, U.S. national, lawful permanent resident, or immigrants. The Proclamation also does not apply to crew members of airlines or other aircraft operators while they are on official duty status and if they follow industry standard protocols for the prevention of COVID-19.<sup>9</sup> Some noncitizen, nonimmigrants who are not fully vaccinated, as defined by the Amended Vaccination Order, may fall into a category that allows them to be excepted to the requirement if they can present to an airline or aircraft operator that they meet the criteria for that category, such as letters documenting a medical contraindication to receiving a COVID-19 vaccine, documents confirming participation in certain vaccine clinical trials, or U.S. military identification.

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 and the addition of a vaccine requirement for noncitizen, nonimmigrants 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 Amended Order: Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 For All Airline or Other Aircraft Passengers Arriving in The United States from Any Foreign Country* is enforceable through the provisions of 18 United States Code (U.S.C.) §§ 3559, 3571 (Attachment A4); 42 U.S.C. §§ 243, 268, 271 (Attachment A5); and 42 C.F.R. § 71 (Attachment A6). *The Amended Order: Implementing Presidential Proclamation on Safe Resumption of Global Travel During the COVID-19 Pandemic* is enforceable under *A Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic* and sections 1182(f) and 1185(a) of title 8, U.S.C., and section 301 of title 3, U.S.C. (Attachment A2)

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<sup>9</sup> Crew members on official duty assigned by the airline or operator that involves operation of aircraft, or the positioning of crew not operating the aircraft (i.e., on “deadhead” status), are exempt from the requirements of the Amended Vaccination Order provided their assignment is under an air carrier’s or operator’s occupational health and safety program that follows applicable 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), i.e., SAFO 20009, COVID-19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews, available at [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). CDC provides further information in Technical Instructions: <https://www.cdc.gov/quarantine/order-safe-travel/technical-instructions.html> .

## 2. Purpose and Use of Information Collection

### *a) Pre-Air Travel Information Collections*

*Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 For All Airline or Other Aircraft Passengers Arriving in The United States from Any Foreign Country*

#### Qualifying Negative Test or Documentation of Recovery

Pursuant to 42 C.F.R. § 71.20, the Amended Testing Order prohibits the introduction into the United States of any airline passenger 2 years or older, 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 purpose of requiring this information to board a plane, is to minimize the risk of COVID-19 transmission during air travel and importing additional COVID-19 cases and possible variants into the United States. The time window between testing and travel is particularly relevant for those with longer-duration travel, such as traveling long distances or on connecting flights. Decreasing the time window for testing before departure from three days to one day for passengers can provide a significant public health benefit.

The Amended Testing Order updates the requirement for testing by requiring that all passengers two years or older, get a test no more than 1 day before departure to the United States, regardless of vaccination status or citizenship.

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>10</sup> For this reason, CDC has included the option that any passenger who has recently recovered from COVID-19 may present documentation of recovery from COVID-19 in the form of a positive viral test result conducted on a specimen collected no more than 90 calendar days before the flight; and 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).

If somebody is not able to obtain documentation of recovery that fulfills the requirements, they may also show a negative COVID-19 viral test result from a sample taken no more 1 day before their flight to the United States departs. However, if they have recovered from COVID-19, but develop symptoms of COVID-19 they should isolate, not travel, and consult with a healthcare provider for testing recommendations. This guidance and CDC's requirement may be updated as additional information about people who have recovered from COVID-19 becomes available.

Any passenger who tests positive should remain in isolation and delay travel until they

<sup>10</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

meet criteria for discontinuing isolation and are cleared for travel. Passengers whose test results are not available before departure should delay their travel until results are available and will be denied boarding.

#### Exemptions for Negative COVID-19 Test or Documentation of Recovery

The Amended Testing Order has a list of categorical exemptions that would not be subject to this information collection. These include:

- Crew members of airlines or other aircraft operators while on official duty status if 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).
- Airlines or other aircraft operators transporting passengers with COVID-19 pursuant to CDC authorization and in accordance with CDC guidance.
- U.S. 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 that takes measures to ensure personnel are not symptomatic or otherwise at increased risk of spreading COVID-19 during travel. Those traveling for training or other business purposes remain subject to the requirements of the Amended Testing Order.
- U.S. military personnel, including civilian employees, dependents, contractors, and other U.S. government employees when traveling on U.S. military assets (including whole aircraft charter operators), if such individuals are under competent military or U.S. government travel orders and observing U.S. Department of Defense guidance to prevent the transmission of COVID-19 as set forth in Force Protection Guidance Supplement 20 - Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic (April 12, 2021) including its testing guidance.

In addition to specific exemptions defined in the Amended Testing Order, a person may receive a time limited exemption for urgent humanitarian reasons. Exemptions may be granted on an extremely limited basis when emergency travel (like an emergency medical evacuation) must occur to preserve someone's life, protect 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 includes personally identifiable information such as name and age, contact information, vaccination status, and the circumstances for why they need the exemption (Attachment D).

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. CDC will work with the Department of State in reviewing this and other information to determine if an exemption to the Amended Testing Order is appropriate. Once CDC makes a

determination regarding the exemption, the individual will receive a letter from CDC indicating approval or denial. If they are approved, they will be required to present the letter of approval to the airline.

CDC and the Department of State may collaborate on an electronic version of this information collection to facilitate submission by the passenger to the Consular staff at U.S. Consulates and Embassies if the volume of requests increase significantly.

#### Documentation Retention and Attestation

Passengers must retain paper or digital documentation reflecting the negative test or Documentation of Recovery, or any other documentation required to meet the requirements of a humanitarian or emergency testing exemption or vaccination exception 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 provide an attestation that the information they present is true in Section 1 of Attachment A of the Order (Attachment C in this information collection). CDC has updated the attestation to align with the December 2, 2021 Order so that it now only includes three options: 1) For people with a negative COVID-19 test taken no more than 1-day before their flight departed, or 2) people with documentation of recovery, or 3) people with a humanitarian exemption.

Air carriers and operators 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. Digitization of the hard copy form is encouraged if air carriers and operators are able to incorporate a process by which 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. For example, similar methods to those used to verify the identity of a passenger using a pre-boarding kiosk or an air carrier's or operator's website or app to obtain a boarding pass could be used to ensure that the passenger or authorized representative is the individual completing the attestation.

CDC has provided the language that must be included in Attachment C. 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 will make some fillable PDF's available on the website, in some languages and make them available on the CDC's website<sup>11</sup>. Airlines or other aircraft operators must retain a copy of each passenger attestation for 2 years.

*A Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Amended Order Implementing Presidential Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic.*

Pursuant to a Presidential Proclamation issued under Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code, the President issued a

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<sup>11</sup> <https://www.cdc.gov/quarantine/fr-proof-negative-test.html>

Proclamation (“the Proclamation”) and CDC’s *Amended Order Implementing Presidential Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic*, air passengers who are noncitizen nonimmigrants, are required to show proof of COVID-19 vaccination. CDC issued an [Order](#) to implement the President’s direction.

The purpose of this information collection is to confirm that noncitizen nonimmigrants seeking to come to the United States are fully vaccinated, and therefore less likely to import and transmit COVID-19 while in the United States. The Proclamation and CDC’s Amended Vaccination Order do not apply to U.S. citizens, U.S. nationals, U.S. lawful permanent residents, immigrants, or air crew on official duty. Therefore, it will only be noncitizen nonimmigrants who will have to provide proof of being fully vaccinated, matching identity, and attest to the truthfulness of the proof of vaccination 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.

#### Exceptions to Proof of being Fully Vaccinated

There are some noncitizen nonimmigrants who may qualify for an exception to the proof of vaccine requirement and will have to provide additional documentation, as well as attest to taking certain actions after arrival in the United States. These categories include noncitizen nonimmigrants who are:

- **Under 18 years old** must show date of birth on a passport or other travel documents,
- **Traveling for diplomatic and official foreign government travel** must have
  - An approved visa classification<sup>12</sup>; or
  - Traveling with an official letter, such as a letter from the U.S. government or foreign government. If they have been invited by the United Nations, they will need to present a letter of invitation from the United Nations or other documentation showing the purpose of such travel.
- **Participating in certain COVID-19 vaccine clinical trial** must have
  - Documentation they participated in a phase 3 trial of with a qualifying COVID-19 vaccine candidate
  - Documentation they received the full series of an active (non-placebo) qualifying COVID-19 vaccine candidate or an emergency use listed vaccine, with the name of the vaccine product and the date(s) received (showing it has been at least 2 weeks since they completed the series)
- **Have a medical contraindication to an accepted COVID-19 vaccine** must have
  - A signed and dated letter on official letterhead that contains the name, address, and phone number of the licensed physician who signed the letter, and that states that the passenger has a contraindication to receiving a COVID-19 vaccine. The name of the COVID-19 vaccine product and the medical condition must both be listed.
  - Must have sufficient personally identifiable information (at a minimum full name and date of birth) to confirm that the person referenced in the letter matches with the passenger’s passport or other travel documents.
- **Have obtained a humanitarian or emergency exception** must have

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<sup>12</sup> [https://www.cdc.gov/quarantine/order-safe-travel/technical-instructions.html#anchor\\_1635182999610](https://www.cdc.gov/quarantine/order-safe-travel/technical-instructions.html#anchor_1635182999610)

- an official U.S. Government letter (paper or digital) documenting approval of the exception.
- **A citizen of a Foreign Country with limited COVID-19 vaccine availability**
  - A passport issued by a foreign country with limited COVID-19 vaccine availability; **and**
  - A valid nonimmigrant visa that is **not** a B-1 or B-2 visa.
- **A member or a spouse of a member of the U.S. Armed Forces** must have
  - a U.S. military identification document, **such as** a military ID or Common Access Card (CAC) or a DEERS ID Card, or other proof of their status as a member of the U.S. Armed Forces or status as the spouse or child (under 18 years of age) of a member of the U.S. Armed Forces.
- **A sea crew member on a C-1 or D nonimmigrant visa** must have
  - the appropriate nonimmigrant visa and
  - an official letter (paper or digital) from their employer indicating that their entry to the United States is required for the purpose of operating a vessel that will depart from a U.S. seaport.
- **A person whose entry is of national interest to the U.S.** must have
  - an official U.S. Government letter (paper or digital) documenting approval of the exception.<sup>13</sup>

#### Documentation Retention and Attestation

All noncitizen nonimmigrants passengers must retain paper or digital documentation reflecting the proof of vaccination or other documentation required to prove they meet an exception 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. Additionally, all noncitizen nonimmigrant passengers ages 2 years or older, regardless of vaccination status, or have a parent or guardian fill out on their behalf, Section 2 of the attestation of Attachment A of the Order (Attachment C in this information collection), in addition to Section 1 as part of the testing requirement. To ease the burden for airlines and aircraft operators, CDC has provided a combined passenger disclosure and attestation that fulfills the requirements of two CDC Orders on one attestation form: *Requirement for Proof of Negative COVID-19 Test Result or Recovery from COVID-19 for All Airline Passengers Arriving into the United States Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic*.

Noncitizen nonimmigrants who are fully vaccinated will have to attest that they are fully vaccinated. Noncitizen nonimmigrants who are not fully vaccinated and qualify for an exception will be required to attest that they are excepted from the requirement to present proof of being fully vaccinated against COVID-19 based on one of the exceptions listed above. Based on the category of the exception, they may also be required to attest that:

1. They will be tested with a COVID-19 [viral test](#) 3–5 days after arrival in the United States, unless they have documentation of having recovered from COVID-19 in the past 90 days;

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<sup>13</sup> This exception is implemented by the Secretary of State, the Secretary of Transportation, the Secretary of Homeland Security, or their designees.

2. They will [self-quarantine](#) for a full 7 days, even if the test result to the post-arrival viral test is negative, unless they have documentation of having recovered from COVID-19 in the past 90 days;
3. They will [self-isolate](#) if the result of the post-arrival test is positive or if they develop COVID-19 symptoms; or
4. If they intend to stay in the United States for longer than 60 days they agree to be vaccinated against COVID-19; and they have arranged to become fully vaccinated against COVID-19 within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate.

Information about which measures each exception category would have to attest to, can be found in the attestation found in Attachment A of the Orders (Attachment C in this information request).

Given the fluidity of the COVID-19 response and continually emerging science on the best ways to reduce the risk of spreading COVID-19, CDC may have to update requirements for different exception categories. Any changes to the attestation (Attachment C) or *Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order* found here: <https://www.cdc.gov/quarantine/order-safe-travel.html>

Similar to the attestation for the requirement for a negative COVID-19 test or documentation of recovery, air carriers and operators must ensure that the attestation for CDC's *Order Implementing Presidential Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic* 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.

### **(b) Compliance Checks**

CDC Quarantine Station (QS) staff at airports with quarantine stations co-located will conduct compliance checks for testing and vaccination documentation as part of the implementation of the *Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 For All Airline or Other Aircraft Passengers Arriving in The United States from Any Foreign Country* and associated *Notice and Order: Implementing Presidential Proclamation on Safe Resumption of Global Travel During the COVID-19 Pandemic*. These compliance checks will help CDC identify air passengers who may be at higher risk of importing and spread of COVID-19, as well as airlines that may not be implementing the requirements to the Orders correctly. It may also help CDC evaluate the effectiveness of the requirements and areas that may need some adjustment. Depending on the level of compliance seen in the first few months, CDC may phase out compliance checks in 2022 and submit a non-substantive change if they are discontinued.

CDC will do compliance checks for both CDC Orders for approximately 1% percent of people arriving in the United States from a foreign country each year. QS staff will meet a plane arriving from a foreign country after landing and ask approximately 5-10% of the

air passengers on the plane questions about their resident or visa status; proof of vaccination, if applicable; proof of negative COVID-19 test or documentation of recovery; or any other documents they would have needed to provide to meet an exemption or exception (Attachment D). QS staff will also keep tallies of the different categories of air passengers (e.g., documentation of recovery, testing exemption, vaccination status and exceptions, etc.) for all air passengers that go through the compliance checks and create general internal surveillance reports for each flight.

Passengers who have documentation that is non-compliant to the Orders will have to provide additional information, such as name, passport number, and contact information that could be shared with states in case additional public health follow up is needed to reduce risk of spread of COVID-19. Passengers who go through compliance checks and show that they have an exception to the proof of vaccination requirement may also have to provide name, contact, and other personally identifiable information if they fall under an exception that requires attestation for additional public health measures after arrival.

CDC notes that while CDC issued another Order on October 25, 2021 requiring airlines to collect and retain contact information for all passengers arriving into the United States, that data is only provided to CDC upon request, does not include any information regarding the categories of passengers' vaccination or testing requirements, and will not automatically be transmitted to systems used by the quarantine station. The time it would take to match that data with the name and passport number of a person coming off a plane would add significantly more burden time to the air passenger. Therefore, CDC will need to collect the name and contact information, as well as testing and vaccination status for any passenger leaving the gate area of their arriving flight who was deemed noncompliant.

QS staff will use a revised version of the *Air Travel Illness and Death Investigation Form*, currently approved under OMB Control 0920-0134, when collecting information from incoming passengers who are non-compliant. The existing form approved under OMB Control 0920-0134 collects name and contact information, vaccination history, symptoms of illness, and other relevant medical history. The OMB approval for the use of that form will be paused in OMB Control 0920-0134 and moved to this package. The form will be renamed *Air Travel Illness or Traveler Follow Up Form* (Attachment F) and revised to collect information about air passengers whose documentation does not meet the requirements of the Orders. Revisions will include more specifics about vaccination status (e.g., dates of doses, type of vaccine, etc.), COVID-19 testing, whether they meet the vaccination and/or testing public health entry requirements. This information will be entered into CDC's Quarantine Activity Reporting System (QARS) and shared with states on an as needed basis for any public health or medical follow up that may be needed.

The revised *Air Travel Illness or Death Investigation or Traveler Follow up Form* will also be used for routine illness and death investigations, authorized under Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment A5) which authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Statute and the existing regulations governing foreign quarantine activities (42 CFR 71) (Attachment A6) authorize



quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, and shipments of animals and etiologic agents in order to protect the public's health. The burden for routine illness investigations will be included in the burden calculation for this information collect revision to 0920-1318.

***(c ) Returned Passengers***

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, not having proof of vaccination, issues with their visas or travel documents, etc. These inadmissible passengers must return to the United States as soon as possible and in most cases will not have time to become fully vaccinated, get a COVID-19 test to board a plane back to the United States, or in some cases will not be able to get a test to return to the US because they do not have the proper documentation to leave the gate area to get a test. When this occurs, CDC asks airlines to notify them and provide contact and itinerary information to CDC (Attachment G) so that the passenger is not deemed as non-compliant by the QS staff. CDC may share the contact information of the passenger with state and local health departments in case public health follow up is needed.

As always, any personally identifiable information will only be shared according to the Routine Uses described in the 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, 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.

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

***Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 For All Airline or Other Aircraft Passengers Arriving in The United States from Any Foreign Country***

Currently, 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, if the electronic or hard copy contain the information as specified in the Order and detailed on CDC's website.<sup>14</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.

***Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order Implementing Proclamation on Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic***

CDC allows for proof of vaccination records to be paper or digital as long as they meet certain requirements. The types of documentation accepted for proof of COVID-19

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<sup>14</sup> <https://www.cdc.gov/coronavirus/2019-ncov/passengers/testing-international-air-passengers.html>

vaccination, including verifiable (digital or paper), non-verifiable paper records, and non-verifiable digital records.

- A verifiable vaccination record, also known as a verifiable vaccination credential, may be paper or digital and typically includes a QR code (Quick Response code) that links to information confirming the credential was generated from an immunization record in an official database and is protected from tampering. When available, verifiable records are preferred as they indicate that the verifiable credential was generated from an immunization record in an official database and that the credential is valid and legitimate.
- A non-verifiable vaccination record is an official record of vaccination that is not digitally linked to an official database with official immunization records and protected from tampering.
- All forms of proof of COVID-19 vaccination must have personal identifiers (at a minimum, full name and date of birth) that match the personal identifiers on the passenger's passport or other travel documents.
- Airlines and aircraft operators should determine when translation of documentation of vaccination is necessary for review.

All forms of proof of COVID-19 vaccination must have

- Personal identifiers (full name plus at least one other identifier such as date of birth or passport number)) that match the personal identifiers on the passenger's passport or other travel documents
- Name of official source issuing the record (e.g., public health agency, government agency, or other authorized vaccine provider)
- Vaccine manufacturer and date(s) of vaccination

### ***Combined Attestation***

Additionally, to ease the burden for airlines and aircraft operators, CDC added the attestation for the noncitizen nonimmigrants to the attestation for the requirement for Proof of Negative COVID-19 Test Result or Recovery so airlines only had to keep one document.

A digitization of the hard copy form of the attestation is encouraged if air carriers and operators are able to incorporate a process by which 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. For example, similar methods to those used to verify the identity of a passenger using a pre-boarding kiosk or an air carrier's or operator's website or app to obtain a boarding pass could be used to ensure that the passenger or authorized representative is the individual completing the attestation.

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

CDC is the only public health authority authorized by the Secretary of Health and Human Services under Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment A5) to make and enforce regulations necessary to prevent the introduction, transmission or spread of transmission or spread of communicable diseases from foreign countries into the United States. To the best of our knowledge no other US federal agencies are requesting this information for air passengers. However, the U.S.

Department of Homeland Security may develop similar requirements for travelers on the land border. CDC expects that requirements for how to confirm proof of being fully vaccinated would align with CDC's and therefore could be used for air and land travel.

Some foreign governments and some U.S. state and local health departments may have similar COVID-19 travel restrictions. We anticipate CDC's Orders 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 passengers. 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 length and scope of the global outbreak of COVID-19, and evidence of importation and transmission identified following travel, 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. Because this is a request for an emergency clearance of a revision, OIRA has waived the 60-day comment period. However, in the event that this collection exceeds 60 days, CDC is posting a 60-day notice in the Federal Register seeking additional notice and comment (Attachment B 60-day FRN).

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. While the addition of the proof of vaccination requirement increases the burden on airlines, CDC will continue to work with the Federal Aviation Administration and airline partners to address concerns to the best of its ability. Finally, CDC's requirements are aligned with several other countries who

require similar testing documentation and proof of COVID-19 vaccination from arriving passengers.

CDC anticipates that many passengers will already have copies of their proof of vaccination and 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 these Orders.

## **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 an air passenger traveling to the United States.

Collection of name, contact information, and COVID-19 testing or vaccination information of an air passengers may occur if a passenger's documentation is deemed non-compliant, and/or possible public health follow up by a state or local health department is warranted, such as passengers who have attested to getting a COVID-19 test 3-5 days after arrival in the US. 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 H).

## **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 COVID-19 proof of vaccination, test results, documentation of recovery, and other results of clinical testing, and documentation confirming exceptions may include identifying information to ensure the test results match the bearer of any documents presented to the airlines or public health authorities. Individual exemptions or exception requests may also require review of sensitive medical information to ensure that the air passenger meets the exemption or exception to the Orders.

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

A.

CDC estimates the annual burden to be approximately 352,538,030 hours (rounded to nearest hour).

Under the Amended Order, all passengers age 2 years and older will need to provide a test and attest to one of the following in Section 1 of Attachment A to the Order (Attachment C in this information collect request).

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).

The travel restrictions limiting the travel of noncitizens from certain countries will be lifted, allowing significantly more people to travel to the United States than have been since March 2020, if they are fully vaccinated. Therefore, CDC is using the FY2019 air passenger volume of 123,000,000 from the U.S. Department of Transportation's Bureau of Transportation Statistics (DOT BTS), to estimate the number of air passengers that would be required to undergo these requirements because it is more representative of the pre-pandemic air travel volume estimates. These data do not include air crew on official duty, however they do not provide a breakdown for U.S. Citizens and lawful permanent residents (LPRs) versus non-US citizens. For that, CDC is using percentages based off of data from the U.S. Customs and Border Protection (CBP), which estimate that approximately 26% of air passengers coming to the United States are US Citizens or LPRs.

In sum, based on 2019 DOT BTS and CBP data, CDC estimates that approximately 33,000,000 US Citizens, lawful permanent residents, and immigrant air passengers travel by air to the United States each year; and approximately 90,000,000 noncitizen nonimmigrant air passengers travel by air to the United States each year. CDC notes that using these data to calculate number of air passengers is likely an overestimate since it is based on pre-pandemic volume and some noncitizen nonimmigrant air passengers will not meet the requirements or an exception to travel to the United States. However, since this is the first time that travel will resume for a lot of noncitizens coming from countries previously under travel restrictions, this is the best estimate at this time. CDC welcomes public comments on these estimates.

- *Air Passenger burden for the Section 1 of Combined Passenger Disclosure and Attestation to the United States of America*, is estimated as follows: 123,000,000 respondents x 2 hours per response, for a total of **246,000,000 burden 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.
- *Noncitizen nonimmigrant air passengers' burden to fill out Section 2, in addition to Section 2 of the Combined Passenger Disclosure and Attestation to the United States of America* is estimated as follows: 90,000,000 respondents x 1 hour per response for a total of **90,000,000 burden hours**. CDC estimates it will take noncitizen nonimmigrants approximately 1 hour reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information to be able to complete Section 2. CDC acknowledges that this may be an overestimate for noncitizen nonimmigrants who are already considered fully vaccinated or under 18 but is overestimating to account for passengers using exceptions where gathering the necessary documentation may take longer.
- *For airline agent review of Section 1 and Section 2 of the Combined Passenger Disclosure and Attestation to the United States of America*, the burden is estimated as follows: 123,000,000 reviews x 8 minutes (or less) per review, for a total of **16,400,000 hours**.

Since each Order 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 air passenger will have to present a letter from the U.S. government to the airline prior to boarding confirming they have met the requirements for either a humanitarian exemption from the testing or documentation of recovery requirement, or a humanitarian or emergency exception from the proof of vaccination requirement for noncitizen nonimmigrants.

- *Humanitarian Exemption for Requirement for COVID-19 test or documentation of recovery*: CDC currently received approximately 35 requests for a humanitarian exemption to the testing or documentation of recovery requirement each month. Since the Amended Order now requires less time to get a test before travel, CDC estimates these requests may go up slightly, so is rounding up to estimating a total of 500 ( $35 \times 12 = 400$ , rounded to 500) requests for a humanitarian exemption annually. 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 **1,000 burden hours**.
- *Humanitarian or Emergency Exception for Requirement for COVID-19 proof of vaccination*: CDC is extrapolating and using the same estimate for a proof of vaccination humanitarian or emergency exception as the estimate for the testig or documentation of recovery estimate. CDC notes that the population of air passengers who would need to request a humanitarian or emergency exception would only be noncitizen nonimmigrants. As such, CDC a total of 500 ( $35 \times 12 = 400$ , rounded to 500) requests for a humanitarian or emergency exception annually. 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 **1,000 burden hours**.

*Air Passenger Compliance Checks:* CDC expects to do compliance checks for approximately 1% of all air passengers flying to the United States, so an estimated 1,230,000 will undergo compliance checks and spend 3-5 minutes answering questions. CDC has provided the higher estimate of this equaling an estimated **102,500 burden hours** total for everybody undergoing a compliance check.

*Air Passenger, undergoing compliance check with non-compliant documentation:* CDC estimates that 0.6% passengers of that 1%, will have documentation that does not meet the requirements of the Orders. Based on those proportions, CDC expects approximately 7,380 ( $123,000,000 \times .01 \times .006$ ) out of the 95 million passengers will have documentation that does not meet all requirements. CDC estimates it will take 10 minutes to collect name and contact information or other details about why a person's documentation was noncompliance for public health follow up by state or local health departments. CDC notes that information collected in the initial compliance check will just get added to the *Air Travel Illness or Death or Traveler Follow up Form*, so the air passenger will not have to provide it twice. The burden estimate for contact information collection for passengers with non-compliant information is approximately **1,230 burden hours**.

*Noncitizen Nonimmigrant Air Passenger, undergoing compliance check and using humanitarian or emergency exception:* CDC estimates approximately 190,000 noncitizen nonimmigrants may have to provide their name and contact information if they undergo a compliance check and have an exception to the proof of vaccination requirement that requires them to take additional measures (self-quarantine, test, etc.). This number is calculated by multiplying 90,000,000 by the estimated percentage of noncitizen nonimmigrants flying to the United States who are expected to not be vaccinated (~66% according to Our World in Data) by the percentage expected to undergo a compliance check (.01). CDC estimates it will take about 10 minutes to fill this information out for this group, resulting in a total of **31,667 burden hours** ( $[90,000,000 \times .66 \times .01] \times [10/60]$ ).

*Air Traveler, for illness or death investigation:* CDC is adding the estimated burden for using the Air Travel Illness or Death Investigation form from OMB Control 0920-0134 to this package. CDC also estimates filling out the form will take approximately 1700 respondents and 10-15 minutes per response. For the purposes of estimating burden, CDC is using the upper limit of 15 minutes for a total of **425 burden hours**.

*Returned Inadmissible Passenger:* 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 passengers 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 passengers.

*Airline Representative Review of Returned Inadmissible Passenger:* 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)
Air Passenger	Section 1 of Combined Passenger Disclosure and Attestation to the United States of America	123,000,000	1	2	246,000,000
Noncitizen Nonimmigrant Air Passenger	Section 2 of Combined Passenger Disclosure and Attestation to the United States of America	90,000,000	1	1	90,000,000
Airline Desk Agent	Combined Passenger Disclosure and Attestation to the United States of America	123,000,000	1	8/60	16,400,000
Air Passenger	Request Humanitarian Exemption to COVID-19 Test or Documentation of Recovery – (No form)	600	1	2	1,000
Noncitizen Nonimmigrant Air Passenger	Request Humanitarian or Emergency Exception to Proof of Vaccination Requirement – (No form)	600	1	2	1,000



Air Passenger (undergoing compliance check)	Questions Asked to Air Passengers Going Through Compliance Checks (No form)	1,230,000	1	5/60	102,500
Air Passenger (undergoing compliance check with non-compliant documentation)	Air Travel Illness or Death Investigation or Traveler Follow-up Form	7,380	1	10/60	1,230
Noncitizen Nonimmigrant Air Passenger (undergoing compliance check and using humanitarian or emergency exception)	Air Travel Illness or Death Investigation or Traveler Follow-up Form	190,000	1	10/60	31,667
Air Traveler (for illness or death investigation)	Air Travel Illness or Death Investigation or Traveler Follow-up Form	1,700	1	15/60	425
Returned Inadmissible Passenger	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>					352,538,030

B. The cost to passenger respondents 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 \$16,553,049,615.

- 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>15</sup>

<sup>15</sup> <https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20Travel%20Time%20Guidance.pdf> Page 17

- 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

<b>Type of Respondent</b>	<b>Form Name</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Cost</b>
Air Passenger	Section 1 of Combined Passenger Disclosure and Attestation to the United States of America	246,000,000	\$47.10	\$11,586,600,000
Noncitizen Nonimmigrant Air Passenger	Section 2 of Combined Passenger Disclosure and Attestation to the United States of America	90,000,000	\$47.10	\$4,239,000,000
Airline Desk Agent	Combined Passenger Disclosure and Attestation to the United States of America	16,400,000	\$43.96	\$720,944,000
Air Passenger	Request Humanitarian Exemption to COVID-19 Test or Documentation of Recovery – (No form)	1,000	\$47.10	\$47,100
Noncitizen Nonimmigrant Air Passenger	Request Humanitarian or Emergency Exception to Proof of Vaccination Requirement – (No form)	1,000	\$47.10	\$47,100

Air Passenger (undergoing compliance check)	Questions Asked to Air Passengers Going Through Compliance Checks (No form)	102,500	\$47.10	\$4,827,750
Air Passenger (undergoing compliance check with non-compliant documentation)	Air Travel Illness or Death Investigation or Traveler Follow-up Form	1,230	\$47.10	\$57,933
Noncitizen Nonimmigrant Air Passenger (undergoing compliance check and using humanitarian or emergency exception)	Air Travel Illness or Death Investigation or Traveler Follow-up Form	31,667	\$47.10	\$1,491,500
Air Traveler (for illness or death investigation)	Air Travel Illness or Death Investigation or Traveler Follow-up Form	425	\$47.10	\$20,018
Returned Inadmissible Passenger	Contact information collection for public health follow up – (No form)	70	\$47.10	\$3,277
Airline Representative	Contact information collection for public health follow up – (No form)	139	\$78.59	\$10,937
<b>Total</b>		352,538,030		\$16,553,049,615

### 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:

- Passenger testing and ancillary costs: Between \$39,864,300,000-\$44,415,300,000
- Passenger deferred travel costs: \$150,613,500
- 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 passengers.

CDC is assuming that costs for testing, obtaining the documentation of recovery, costs for vaccination, and proof of vaccination will be paid by the passenger. Based on costs available for COVID-19 tests in the United States, CDC anticipates COVID-19 tests will cost approximately \$148 and ancillary costs associated with healthcare visits (e.g.

specimen collection and the office visit itself) at \$129.<sup>16,17</sup> Although COVID-19 vaccine in the United States is free, it may have costs for overseas for some noncitizen nonimmigrants, therefore CDC estimates it could cost anywhere between \$0 and \$37 for a full series of COVID-19 vaccination. 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 passengers. 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 passengers. The calculations for estimated burden are as follows:

	Test, vaccination Cost and Ancillary Costs	Average cost of COVID-19 vaccine	Time cost	# of Passengers	Total
Passenger Cost	\$277	\$0-\$37	\$47.10	123,000,000	\$39,864,300,000 Lower Bound \$44,415,300,000 Upper Bound

There may also be a cost to the passengers for deferred travel in the event they test positive or miss the 1-day or 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 passengers may endure costs associated with finding accommodations to stay for a limited period. CDC cannot predict what percentage of passengers may experience these inconveniences. For the purposes of this collection, CDC is estimating that 1% of passengers will experience deferred travel and a cost of \$122.45 dollars for an overnight hotel stay.<sup>18</sup> With 1% of 123,000,000 passengers experiencing this deferred travel, CDC estimates the additional burden at \$150,613,500.

	1% of total volume	Hotel Cost	Total
Passenger Cost	1,230,000	\$122.45	\$150,613,500

CDC is requiring that individuals pursuant to 42 CFR 71.20 retain copies of their COVID-19 test, documentation of recovery, or proof of vaccination, if applicable. CDC is including this requirement so that public health authorities in the United States can confirm an individual's COVID-19 test, documentation of recovery, or proof of vaccination. 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 combined attestation provided by each passenger. As long as the attestation conforms to Attachment A of both Orders (Attachment C to this information collection request),

<sup>16</sup> <https://www.healthsystemtracker.org/brief/covid-19-test-prices-and-payment-policy>

<sup>17</sup> [https://www.who.int/docs/default-source/coronaviruse/act-accelerator/covax/costs-of-covid-19-vaccine-delivery-in-92amc\\_08.02.21.pdf](https://www.who.int/docs/default-source/coronaviruse/act-accelerator/covax/costs-of-covid-19-vaccine-delivery-in-92amc_08.02.21.pdf)

<sup>18</sup> <https://www.statista.com/statistics/245759/average-daily-rate-of-hotels-worldwide-by-region/>

either electronic or hard copy retention is acceptable. CDC anticipates that any hard copy attestation provided by a passenger 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 wage of \$17.38, adjusted to \$34.76 to include non-wage benefits and overhead.<sup>19</sup>
  2. CDC is anticipating 1.5 minutes to scan or otherwise digitize each of the 123,000,000 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 95,000,000 records over the proportion of passengers carried by each airline, using low and high ranges.
    - The high percentage is calculated by taking the highest percentage in calendar year 2019 (18%)
    - The low percentage median is less than 1%.
  3. Using this method, the cost for the airline with the highest number of passengers, approximately 18% of all incoming arrivals, ranges from a high of \$4,557,000 to \$78,130 a year. The cost for those airlines with less than 1% of arriving passengers may expect a range of costs between \$253,200 to \$4,340 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 \$3,643,488 a year processing requests related to both the Amended Testing Order and the Amended Vaccination 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 record information on COVID-19 tests, documentation of recover, proof of vaccination, or exceptions during compliance checks. CDC staff may also spend approximately 10 minutes gathering name

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<sup>19</sup> <https://www.bls.gov/oes/current/oes434071.htm>

and contact information from passengers with non-compliant documentation, or those with exceptions that require they take additional public health measures like self-quarantine and after travel testing 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.

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. Considering 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 3600 hours ([600 exemption + 600 exception] x 3 hours) 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
Request Humanitarian Exemption to COVID-19 Test or Documentation of Recovery – (No form) – FS-3	600	\$100.19	\$60,144
Request Humanitarian or Emergency Exception to Proof of Vaccination Requirement – (No form)– FS-3	600	\$100.19	\$60,144
Adjudicate Request Exemption on Urgent Humanitarian Basis – GS-12	3,600	\$88.66	\$319,176
Process Returned Inadmissible Passenger	139	\$88.66	\$12,324
<b>Total Costs</b>			<b>\$ 3,643,488</b>

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

CDC has revised the current 0920-1318 package to include the following updates:

*Requirement For Negative Pre-Departure Covid-19 Test Result Or Documentation Of Recovery:*

- A requirement that all air passengers two years or older, regardless of vaccination status or citizenship, have a negative COVID-19 viral test conducted with a specimen taken no more than 1-day before departure

- CDC now requires people who receive a humanitarian exemption to sign the attestation.

*Requirement For Proof Of Covid-19 Vaccination For Noncitizen, Nonimmigrant Air Passengers*

- A new requirement that noncitizen nonimmigrants must show proof of vaccination before boarding a flight to the United States, or show documentation that they are eligible to receive an exception to the requirement.
- CDC has updated the attestation to include a Section 2 for noncitizen nonimmigrant to attest to having proof of vaccination.

*Compliance Checks*

- CDC has also added questions that will be asked to all people undergoing compliance checks.
- CDC will also now use the revised Air Travel Illness or Death or Traveler Follow Up Form to record information about air passengers who are noncompliance as well as air passengers who have received an exception and attested to take additional public health measure such as self-quarantine, an after travel COVID-19 test, or vaccination for COVID-19

*Moving the Air Travel Illness or Death Investigation Form to OMB Control 0920-1318*

- CDC is moving the approval for the Air Travel Illness or Death Investigation Form from OMB Control 0920-0134 to 0920-1318 and renamed it Air Travel Illness or Death Investigation or Traveler Follow up Form

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

No statistics will be performed however descriptive analyses may be performed for programmatic purposes.

**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: *Amended Order: Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 For All Airline or Other Aircraft Passengers Arriving in The United States from Any Foreign Country*
- Attachment A2: *A Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic*
- Attachment A3: *Amended Order: Implementing Presidential Proclamation on Safe Resumption of Global Travel During the COVID-19 Pandemic*
- Attachment A4: 18 U.S.C. §§ 3559, 3571
- Attachment A5: Section 361 of the Public Health Service Act (42 USC 264)
- Attachment A6: 42 CFR Part 71
- Attachment B: 60-Day FRN
- Attachment C: Attachment C - Combined Passenger Attestation-12.2.2021-Clean\_
- Attachment D: Information Needed to Process Humanitarian or Emergency Testing Exception or Vaccination Exemption
- Attachment E: Information Collection for Initial Compliance Check
- Attachment F: Air Travel Illness or Death Investigation or Traveler Follow up Form
- Attachment G: Returned Inadmissible Passenger
- Attachment H: QARS Privacy Impact Assessment