# 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**

**Submitted June 10, 2022**

**Supporting Statement A**

**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

Contents

[**Contact:** 1](#_Toc59888394)

[A. Justification 3](#_Toc59888395)

[1. Circumstances Making the Collection of Information Necessary 3](#_Toc59888396)

[2. Purpose and Use of Information Collection 6](#_Toc59888397)

[3. Use of Improved Information Technology and Burden Reduction 10](#_Toc59888398)

[4. Efforts to Identify Duplication and Use of Similar Information 10](#_Toc59888399)

[5. Impact on Small Businesses or Other Small Entities 11](#_Toc59888400)

[6. Consequences of Collecting the Information Less Frequently 11](#_Toc59888401)

[7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5 11](#_Toc59888402)

[8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency 12](#_Toc59888403)

[9. Explanation of Any Payment or Gift to Respondents 12](#_Toc59888404)

[10. Protection of the Privacy and Confidentiality of Information Provided by Respondents 12](#_Toc59888405)

[11. Institutional Review Board (IRB) and Justification for Sensitive Questions](#_Toc59888406)

[IRB Approval 13](#_Toc59888407)

[12. Estimates of Annualized Burden Hours and Costs 13](#_Toc59888408)

[13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers 17](#_Toc59888409)

[14. Annualized Cost to the Government 19](#_Toc59888410)

[15. Explanation of Program Changes or Adjustments 20](#_Toc59888411)

[16. Plans for Tabulation and Publication and Project Time Schedule 20](#_Toc59888412)

[17. Reason(s) Display of OMB Expiration Date is Inappropriate 20](#_Toc59888413)

[18. Exceptions to Certification for Paperwork Reduction Act Submissions 20](#_Toc59888414)

[Attachments 21](#_Toc59888415)

* **Goal:** The goal of this information collection is to ensure that, consistent with the terms of the April 4, 2022 *Amended Order Under* the Presidential Proclamation titled *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,* public health authorities can confirm that non-U.S Citizen, Non-U.S. Immigrant passengers are fully vaccinated against COVID-19 before boarding a plane to the United States.
* **Intended use of the resulting data:** The intended use of the information is to confirm that noncitizen, nonimmigrant passengers are fully vaccinated against COVID-19. This confirmation will help to prevent further introduction, transmission, and spread of the virus into the United States.
* **Methods to be used to collect:** There are no statistical sampling or research design methods being used. Passengers will complete an attestation prior to boarding their flight to the United States from a foreign country. Passengers may also provide information to apply for an exception to the requirement or during compliance checks after the flight.
* **The subpopulation to be studied:** The universe of respondents is noncitizen nonimmigrant air passengers coming to the United States from a foreign country, with certain exemptions as outlined in this information collection request.
* **How data will be analyzed:** There is no predetermined methodology to analyze the attestations; however there will be random checks by CDC staff of vaccine status (if applicable), upon arrival at a U.S. port of entry to inform program improvement. Noncitizen nonimmigrants must retain proof of vaccine status. Random checks will help CDC identify passengers who may need referral to local health authorities for evaluation and further public health measures.

# 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)**

CDC is requesting an emergency clearance for this information collection for 1 year. If requirements related to CDC’s Order associated with this information collection are updated, CDC will update this information collection request accordingly.

# 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 1 year 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 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 A1). 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 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 on October 30, 2021 with minimal changes to clarify post arrival requirements for some categories of exceptions. CDC amended the Order again (“Amended Order”) (Attachment A2) on April 4, 2022, to align with CDC guidance and to align with revised CDC guidance related to isolation and quarantine after travel and make other minor clarifications. The Amended Vaccination Order signed on April 4, 2022 supersedes the previous Order signed by the CDC Director on October 30, 2021, and continues to implement 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 June 4, 2022, there have been over 529,400,000million cases of COVID-19 globally, resulting in over 6,200,000 deaths. In the United States, more than 84,600,000 cases have been identified, and over 1,000,000 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.20,21 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-19.22,23

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. The emergence of variants that substantially decrease the effectiveness of available vaccines against severe or deadly disease is a primary public health concern.

WHO and CDC continue to collaborate with researchers around the world to better understand the Omicron variant and track potential future variants of SARS-CoV-2.

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 amended the Order twice, most recently on April 4, 2022 (Attachment A2) to align with revised CDC guidance for excepted passengers related to isolation and quarantine after travel and to clarify other requirements. Updates to CDC post travel guidance in June 2022, has since removed the requirement for self-quarantine for excepted passengers.

The Proclamation and Amended Order only apply to noncitizen, nonimmigrants. It does not apply to anybody who is a U.S. citizen, U.S. national, lawful permanent resident, or other non-covered individuals. 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.[[1]](#footnote-2) Some noncitizen, nonimmigrants who are not fully vaccinated, as defined by the Amended 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 (including dependent status).

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 A1)

# 2. Purpose and Use of Information Collection

1. ***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 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](https://www.cdc.gov/quarantine/order-safe-travel.html) 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. The Proclamation and CDC’s Amended 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[[2]](#footnote-3); 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 havean 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.[[3]](#footnote-4)

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, or parent or guardian on their behalf, regardless of vaccination status, must fill out the attestation of Attachment A of the Order (Attachment C in this information collection).

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. Depending 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](https://www.cdc.gov/coronavirus/2019-ncov/testing/diagnostic-testing.html) 3–5 days after arrival in the United States, unless they have documentation of having recovered from COVID-19 in the past 90 days;
2. They will self-isolate for a full 5 calendar days and properly wear a well-fitting mask any time they are around others during their isolation period and for an additional 5 days after ending isolation,

• if the result of the post-arrival viral test is positive, or

• if they develop COVID-19 symptoms.;

1. 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 can be* found here: <https://www.cdc.gov/quarantine/order-safe-travel.html>

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 vaccination documentation as part of the implementation of the  *Amended Order: Implementing Presidential Proclamation on Safe Resumption of Global Travel During the COVID-19 Pandemic*. These compliance checks help CDC evaluate the effectiveness of the requirements and areas that may need some adjustment. Depending on the level of compliance, CDC may phase out compliance checks and would submit a non-substantive change if they are discontinued.

CDC will do compliance checks for less than 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; or any other documents they would have needed to provide to meet an exception (Attachment D). QS staff will also keep tallies of the different categories of air passengers (e.g., 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. 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 required to be 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 needs to collect the name and contact information, as well as vaccination status for any passenger leaving the gate area of their arriving flight who was deemed noncompliant.

QS staff use a revised version of the *Air Travel Illness or Death Investigation Form*, which was previously approved under OMB Control 0920-0134, and currently approved under this information collection 0920-1318, when collecting information from incoming passengers who are non-compliant. The form under OMB Control 0920-0134 collected name and contact information, vaccination history, symptoms of illness, and other relevant medical history. The OMB approval for the use of that form is paused in OMB Control 0920-0134 and moved to this package. The form is renamed *Air Travel Illness or Death Investigation or Traveler Follow Up Form (*Attachment F*)* and revised to collect information about air passengers whose documentation does not meet the requirements of the Amended Order. Revisions will include more specifics about vaccination status (e.g., dates of doses, type of vaccine, etc.), and whether they meet the COVID-19 vaccination requirements. This information is 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* is also used for routine illness and death investigations, authorized under Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment A4) 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 A5) 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.

# 3. Use of Improved Information Technology and Burden Reduction

***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 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

***Attestation***

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 A4) 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. 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 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 G).

# 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 for the information collections instruments to be approximately **322,449,761 hours**.

Under the Amended Order, all noncitizen nonimmigrant passengers age 2 years and older will need to fill out an attestation. Those that have proof of vaccination only need to attest that they are fully vaccinated and sign the form. Those that meet an exception will need to attest that they meet one of the exceptions, and attest to taking the post arrival actions associated with their exception. An authorized individual may attest on behalf of any passenger who is unable to attest on his or her own behalf (e.g., by reason of age, or physical or mental impairment).

Based on CBP data from 2019, CDC estimates that approximately 60,000,000 noncitizen nonimmigrant air passengers may travel by air to the United States each year. CDC notes that using these data to calculate the 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, but it is the best estimate at this time. CDC welcomes public comments on these estimates.

*Noncitizen nonimmigrant air passengers’ burden to fill out the attestation* is estimated as follows: 60,000,000 respondents x 1 hour per response for a total of **60,000,000 annual burden hours**. CDC estimates will take noncitizen nonimmigrants approximately 1 hour reviewing instructions, searching existing data sources, gathering and maintaining the data needed.

*For airline agent review of* of attestation*,* the burden is estimated as follows: 60,000,000 reviews x 8 minutes (or less) per review, for a total of **8,000,000 annual burden hours**.

*Humanitarian or Emergency Exception for Requirement for COVID-19 proof of vaccination:* CDC received approximately 1300 requests for an exception to the proof of vaccination requirement between December 2021 – May 2022. Based on this number, CDC is estimating to receive approximately 3,400 requests annually [calculated by 1,300 requests x 2 six-month periods and rounding up by 30% to account for possible increases in travel volume]. 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. Therefore the annual estimated burden is **6,800 burden hours** [calculated by 3400 requests x 2 hours per request].

*Air Passenger undergoing compliance checks*: Based on the number of passengers who received a compliance check in the last six months (135,000 from December 2021-May 2022), CDC is estimating that approximately 270,000 air passengers will undergo compliance checks annually. CDC expects these passengers to spend 3-5 minutes answering questions. CDC notes this is likely an overestimate since the compliance checks the estimate is based on includes U.S. Citizens and Lawful Permanent Residents. Therefore, CDC estimates the annual burden hours associated with compliance checks to be approximately **22,500 annual burden hours** [calculated by 270,000 passengers x 5 minutes].

*Air Passenger, undergoing compliance check with non-compliant documentation:* Based on compliance check data over the last six months,approximately 0.6% of passengers undergoing compliance checks have non-compliant documentation. Based on that percentage, CDC expects approximately 1,620 passengers [calculated by 270,000 passengers x .006] 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 this initial compliance check will just get added to the *Air Travel Illness or Death Investigation or Traveler Follow up Form*, so the air passenger will not have to provide it twice if further investigation is needed. The burden estimate for contact information collection for passengers with non-compliant information is approximately **270 annual burden hours**.

*Noncitizen Nonimmigrant Air Passenger, undergoing compliance check and using humanitarian or emergency exception:* Based on compliance check data over the last six months,approximately 10 noncitizen nonimmigrant air passengers who had an exception to the proof of vaccination requirement underwent a compliance check and provided their name and contact information in addition to the initial compliance check. Therefore, CDC estimates that approximately 30 people using the humanitarian proof of vaccination exception may go through a compliance check and need to provide additional name and contact information. CDC estimates it will take about 10 minutes to fill this information out for this group, resulting in a total of **5 annual burden hours**

*Air Traveler, for illness or death investigation:* CDC also uses the Air Travel Illness or Death Investigation or Traveler Follow Up form (currently paused in OMB Control 0920-0134) for air travel illness or death investigations. Based on current reporting in 2022, CDC estimates there will be approximately 65,000 respondents. CDC is using that as an estimate, however expects that to be an overestimate as the COVID-19 pandemic significantly increased air travel illness investigation reporting temporarily (pre-pandemic estimates were 1700). CDC estimates filling out the form will take approximately10-15 minutes per response. For the purposes of estimating burden, CDC is using the upper limit of 15 minutes for a total of **16,250 annual burden hours**.

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) |
| Noncitizen Nonimmigrant Air Passenger  | Section 2 of Combined Passenger Disclosure and Attestationto the United States of America | 60,000,000 | 1 | 1 | 60,000,000 |
| Airline Desk Agent | Combined Passenger Disclosure and Attestationto the United States of America | 60,000,000 | 1 | 8/60 | 16,400,000 |
| Noncitizen Nonimmigrant Air Passenger   | Request Humanitarian or Emergency Exception to Proof of Vaccination Requirement – (No form) | 3,400 | 1 | 2 | 6,800 |
| Air Passenger*(undergoing compliance check)* | Questions Asked to Air Passengers Going Through Compliance Checks (No form) | 270,000 | 1 | 5/60 | 22,500 |
| Air Passenger (*undergoing compliance check with non-compliant documentation*) | Air Travel Illness or Death Investigation or Traveler Follow-up Form | 1,620 | 1 | 10/60 | 270 |
| Noncitizen Nonimmigrant Air Passenger *(undergoing compliance check and using humanitarian or emergency exception)*  | Air Travel Illness or Death Investigation or Traveler Follow-up Form | 30 | 1 | 10/60 | 5 |
| Air Traveler *(for illness or death investigation)* | Air Travel Illness or Death Investigation or Traveler Follow-up Form | 65,000 | 1 | 15/60 | 16,250 |
| **Total** |  |  |  |  | 68,045,825 |

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>) and included adjustments for non-wage benefits and overhead costs by multiplying hourly wage by 2. The total estimated respondent cost is $3,179,198,358.

* 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.[[4]](#footnote-5)
* 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 $21.94 x 2 to account for wages, benefits and overhead costs for an estimate of $43.88.

Estimated Annualized Burden Costs

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Cost** |
| Noncitizen Nonimmigrant Air Passenger  | Section 2 of Combined Passenger Disclosure and Attestationto the United States of America | 60,000,000 | $47.10 |  $2,826,000,000  |
| Airline Desk Agent | Combined Passenger Disclosure and Attestationto the United States of America | 8,000,000 | $43.88 | $376,800,000  |
| Noncitizen Nonimmigrant Air Passenger   | Request Humanitarian or Emergency Exception to Proof of Vaccination Requirement – (No form) | 6,800 | $47.10 |  $320,280  |
| Air Passenger*(undergoing compliance check)* | Questions Asked to Air Passengers Going Through Compliance Checks (No form) | 22,500 | $47.10 | 1,059,750 |
| Air Passenger (*undergoing compliance check with non-compliant documentation*) | Air Travel Illness or Death Investigation or Traveler Follow-up Form | 270 | $47.10 | $12,717  |
| Noncitizen Nonimmigrant Air Passenger *(undergoing compliance check and using humanitarian or emergency exception)*  | Air Travel Illness or Death Investigation or Traveler Follow-up Form | 5 | $47.10 |  $12,717 |
| Air Traveler *(for illness or death investigation)* | Air Travel Illness or Death Investigation or Traveler Follow-up Form | 16,250 | $47.10 | 765,375 |
| **Total** |  | 322,463,623 |  | $3,179,198,358  |

#

# 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:

* Airline staff costs for digitizing attestations: $51,600,000
* Airline costs to store attestations: $2,117 to $2,223,280 a year depending on size of airline and number of passengers.

CDC is requiring that individuals pursuant to 42 CFR 71.20 retain copies of their proof of vaccination, if applicable. CDC is including this requirement so that public health authorities in the United States can confirm an individual’s 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 the Order (Attachment C in this information collection, 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 $17.70, adjusted to $35.40 to include non-wage benefits and overhead.[[5]](#footnote-6)
	2. CDC is anticipating 1.5 minutes to scan or otherwise digitize each of the 60,000,000 estimated attestations
		+ The estimate for this process is $51,600,000
	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 60,000,000 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 noncitizen nonimmigrants, ranges from a high of $2,223,280 to $38,112 a year. The cost for those airlines with less than 1% of arriving passengers may expect a range of costs between $123,516 to $2,117 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 $4,307,083 a year to process the 3,400 humanitarian or emergency requests [3,400 vaccine exceptions] and do compliance checks related to the Amended Vaccination Order.

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. Total hours is 3,660 burden hours annually [calculated by 3,660 requests x 1 hour].

CDC estimates CDC staff equivalent to a GS-12 spend an average of 2 hours processing each humanitarian or emergency request, therefore a total of 6,800 hours annually [calculated by 3,400 requests x 2 hours]. Average hourly rate for a General Schedule -12 (GS-12) is $45.48, multiplied by 2 to adjust for federal non-wage benefits and overhead which is $90.96.

This collection includes some CDC staff time to review and record information on proof of vaccination, or exceptions during compliance checks. CDC staff may also spend approximately 10 minutes gathering name and contact information from passengers with non-compliant documentation, or those with exceptions that require they take additional public health measures like 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 of $90.96 an hour. This is likely an overestimate since this estimate is based on compliance checks for U.S. citizen and lawful permanent resident air passengers as well, but it is the best that CDC has as at this time.

In the case of requesting passenger attestations from the airline, 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.

|  |  |  |  |
| --- | --- | --- | --- |
| **Federal Staff and Contractors**  | **Annual Hours** | **Hourly Wage** | **Cost** |
| Request Humanitarian Exemption to COVID-19 Test or Documentation of Recovery – (No form)–U.S. Embassy Staff - FS-3 | 3,400 | $100.19 | $340,646 |
| Adjudicate Request Exemption on Urgent Humanitarian Basis – CDC GS-12 | 6,800 | $90.96 | $618,528  |
| CDC Quarantine Station staff and contractors doing compliance checks | 36,000 | $90.96 | $3,274,560  |
| **Total Costs** |  |  | **$4,233,734** |

# 15. Explanation of Program Changes or Adjustments

CDC has made the following updates to OMB 0920-1318:

*Purpose of Collection*

* CDC has removed any requirements related to air passengers needing to provide a negative COVID-19 test or documentation of recovery with the rescission of the testing 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 Into The United States From Any Foreign Country*
* CDC is no longer requiring airlines to report names of returned passengers to CDC, and removed this from Section 2.

*Hour and Cost Burdens*

* The overall estimate of total annualized burden hours associated with the information collection tools has **decreased** from 352,538,050 to 68,045,825 annual burden hours.
	+ CDC has removed burden hours for passengers related to the testing or documentation of recovery requirement, **decreasing** the burden hours by approximately 250,000,000
	+ Estimates for the number of people requesting proof of vaccination exceptions:
		- *Humanitarian or Emergency Exception for Requirement for COVID-19 proof of vaccination:* **Increased** from 500 to 3,400
	+ Estimates related to the compliance checks were updated to reflect compliance check data over the last six months:
		- *Air Passenger undergoing compliance checks:* **Decreased** from1,230,000to 270,000.
		- *Air Passenger, undergoing compliance check with non-compliant documentation:* **Decreased** from 7,380 to 1,620.
		- *Noncitizen Nonimmigrant Air Passenger, undergoing compliance check and using humanitarian or emergency exception:* **Decreased** from 190,000 to 30*.*
	+ *Air Traveler, for illness or death investigation:* **Increased** from1,700 to 65,000. This increase is due to an increase of illness reports based on pre-pandemic levels since this form was also used in OMB Control number 0910-0134 before the COVID-19 pandemic.
	+ *Removing the requirement for airlines to report names of returned travelers* **decreased** the annual burden hours by 209 hours.
* The changes in the number of respondents caused the total cost burden associated with the information collection instruments to **decrease** from $16,553,049,615 to $15,135,228,643. The hourly wage for the Airline Desk Agent also decreased from $43.96 to $43.88 according to the Bureau of Labor Statistics.
* The calculations for the cost to digitize the attestations, decreased from $55,036,667 to $51,600,000 [calculated by 60,000,000\*(.025\*$34.40)].
* CDC updated the estimated annualized cost to the government which **increased** from $3,643,488 to $4,233,734 due to the increase in respondents to humanitarian exception requests.

# 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: *A Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic*

Attachment A2: *Amended Order: Implementing Presidential Proclamation on Safe Resumption of Global Travel During the COVID-19 Pandemic*

Attachment A3: 18 U.S.C. §§ 3559, 3571

Attachment A4: Section 361 of the Public Health Service Act (42 USC 264)

Attachment A5: 42 CFR Part 71

Attachment B: 0920-1318-60-Day FRN

Attachment C: Clean-Proof of COVID-19 Vaccination for Noncitizen Nonimmigrants

Passenger Disclosure and Attestation to the United States of America

Passenger Disclosure and Attestation to the United States of America

Attachment D: Information Needed to Process Humanitarian Exception

Attachment E: Information Collection for Initial Compliance Check

Attachment F: Air Travel Illness or Death Investigation or Traveler Follow up Form

Attachment G: QARS Privacy Impact Assessment

1. 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>. CDC provides further information in Technical Instructions: <https://www.cdc.gov/quarantine/order-safe-travel/technical-instructions.html> . [↑](#footnote-ref-2)
2. <https://www.cdc.gov/quarantine/order-safe-travel/technical-instructions.html#anchor_1635182999610> [↑](#footnote-ref-3)
3. This exception is implemented by the Secretary of State, the Secretary of Transportation, the Secretary of Homeland Security, or their designees. [↑](#footnote-ref-4)
4. <https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20Travel%20Time%20Guidance.pdf> Page 17 [↑](#footnote-ref-5)
5. https://www.bls.gov/oes/current/oes434071.htm [↑](#footnote-ref-6)