

**Requirements for Negative Pre-Departure COVID-19 Test Result or Documentation
of Recovery from COVID-19 for all Airline or Other Aircraft Passengers Traveling
to the United States from the People's Republic of China**

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

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Supporting Statement A

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- **Goal:** The goal of this information collection request is to ensure that, consistent with the terms of CDC's Order *Requirements for Negative Pre-Departure COVID-19 Test Result or Documentation of Recovery from COVID-19 for all Airline or Other Aircraft Passengers Traveling to the United States from the People's Republic of China*, air passengers from the People's Republic of China (PRC) or those boarding in *Designated Airports* who have been in PRC over the last 10 days show proof of a negative COVID-19 test or documentation of recovery from COVID-19 before boarding a flight to the United States.

Requirements for Negative Pre-Departure Covid-19 Test Result or Documentation of Recovery from Covid-19 for all Airline or Other Aircraft Passengers Traveling to the United States from the People's Republic of China

(OMB Control No. 0920-XXXX)

Request for Emergency Clearance

CDC is requesting clearance for this information collection for 2 years.

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 2-year approval for this information collection.

This information collection is necessary to implement CDC's Order *Requirements for Negative Pre-Departure COVID-19 Test Result or Documentation of Recovery from COVID-19 for all Airline or Other Aircraft Passengers Traveling to the United States from the People's Republic of China*.¹

Pursuant to 42 CFR 71.20 and 71.31(b) and as set forth in greater detail below, this Notice and associated Order will prohibit the boarding of any passenger two years of age or older on an itinerary that includes the United States, on:

- any aircraft departing from the People's Republic of China (PRC)², or
- any aircraft departing from a *Designated Airport*³ if the passenger within the ten (10) days prior to their departure for the United States has been in the People's Republic of China,

unless the passenger presents paper or digital documentation of one of the following requirements or meets a limited exception:

1. A negative pre-departure viral test result for SARS-CoV-2 conducted on a specimen collected no more than 2 calendar days before the flight's departure from the People's Republic of China (*Qualifying Test*)

OR

2. Documentation of having recovered from COVID-19 in the past 90 days in the

¹ <https://www.cdc.gov/quarantine/china-proof-negative-test.html>

² People's Republic of China (PRC), includes the Special Administrative Regions of Hong Kong and Macau

³ *Designated Airports* include Seoul Incheon International Airport in the Republic of Korea, Toronto Pearson International Airport in Canada, or Vancouver International Airport in Canada.

form of one of the following (i.e., *Documentation of Recovery*):

- a. A positive viral test result for SARS-CoV-2 conducted on a specimen collected more than 10 calendar days but fewer than 91 calendar days before the flight's departure; OR
- b. A positive viral test result for SARS-CoV-2 conducted on a specimen collected 10 or fewer calendar days before the flight's departure AND a signed letter from a licensed healthcare provider or public health official stating that the passenger's COVID-19 symptoms began more than 10 calendar days before the flight's departure.

The Order will be enforceable through the provisions of 18 U.S.C. §§ 3559, 3571 (Attachment A1); 42 U.S.C. §§ 243, 268, 271 (Attachment A2); and 42 C.F.R. § 71 (Attachment A3).

2. Purpose and Use of Information Collection

Background and Purpose

COVID-19 is surging in the People's Republic of China because of recent decisions to remove mitigation measures. The population in the People's Republic of China has not had extensive exposure to the virus that causes COVID-19 and therefore has not developed immune protection through prior infection. The recent surge in COVID-19 transmission, particularly in a large population such as the People's Republic of China, increases the potential for new variants to emerge that could be introduced to the United States.

Although COVID-19 variants continue to emerge in countries around the world, the lack of viral genomic sequence data in the People's Republic of China could delay the identification of new variants of concern if they arise. These data are critical to monitor the surge effectively and to allow U.S. public health officials to identify any potential variants of concern.

New COVID-19 variants have the potential to evade the immune protection acquired in the U.S. population through vaccination and prior illness. The emergence of variants that substantially decrease the effectiveness of available vaccines against severe or deadly COVID-19 is a primary public health concern for the United States.

Considering the potential danger to public health posed by emerging new variants in the People's Republic of China, CDC has determined that proactive, preventative measures must be implemented now to protect the U.S. population from potential importation, transmission and spread of new COVID-19 variants into the United States.

Therefore, the purpose of this information collection is to implement CDC's Order by decreasing the number of infected passengers boarding airplanes. These measures provide a safer environment for travelers and protect the health of American, particularly when layered with existing CDC recommendations such as masking during travel, self-monitoring for symptoms, and testing for three days after arrival from international travel.

Implementation and Use of Information

Providing a negative COVID-19 test or documentation of recovery from COVID-19 will determine whether an air passenger for which the Order is applicable should be able to board an aircraft that would be part of an itinerary to the United States.

Airlines must identify which passengers are subject to the requirements of this Order and confirm that each such passenger, prior to boarding the aircraft, has presented paper or digital documentation reflecting a *Qualifying Test* or *Documentation of Recovery* or meets one of the specified exceptions. Air passengers for which the requirement applies will be any passenger two years of age or older on an itinerary that includes the United States, who is boarding:

- any aircraft departing from the PRC, or
- any aircraft departing from a *Designated Airport* if the passenger within the ten (10) days prior to their departure for the United States has been in the People's Republic of China,

The Order will apply to air passengers regardless of citizenship or vaccination status and passengers who have any itinerary with a flight to the U.S. regardless of whether the United States is the final destination or a connection to another country. The Order excludes passengers transiting through an airport in the PRC en route from another country to the United States. The Order also excludes passengers who have been in the People's Republic of China for less than 24 hours.

A parent or other authorized individual may present the required documentation on behalf of a passenger 2-17 years of age. Children under the age of 2 years of age are not subject to the requirements of this Order. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (e.g., by reason of age, or physical or mental impairment).

People previously diagnosed with COVID-19 will have the option to provide documentation of recovery in the form of either:

1. A positive viral test result for SARS-CoV-2 conducted on a specimen collected more than 10 calendar days but fewer than 91 calendar days before the flight's departure; OR
2. A positive viral test result for SARS-CoV-2 conducted on a specimen collected 10 or fewer calendar days before the flight's departure AND a signed letter from a licensed healthcare provider or public health official stating that the passenger's COVID-19 symptoms began more than 10 calendar days before the flight's departure.

CDC may grant a humanitarian exception in very limited circumstances only when an individual must travel to the United States to preserve health (e.g., emergency medical evacuations, life-saving medical treatment) or safety (e.g., violence) and pre-departure testing cannot be accessed or completed before travel because of exigent circumstances. Individuals who fit the exception criteria described in CDC's Order may contact the U.S. embassy or consulate in or nearest the country from which they are departing for the United States. The embassy will then transmit the information to the CDC for adjudication. All information needs to be completed in full and in English for the request to be sent to CDC. Finally, an air passenger may receive a time limited exception for

urgent humanitarian reasons. The information CDC needs to be able to determine whether an exception under these terms is appropriate is indicated in Attachment D.

Passengers must retain paper or digital documentation reflecting the *Qualifying Test* or *Documentation of Recovery*, or any other documentation required to meet the requirements of a humanitarian testing exception presented to the airline and produce such results if they are requested to by any U.S. government official or a cooperating state or local public health authority.

Air passengers will also be required provide an attestation, attesting that the information they present is true. The attestation has three options: 1) For passengers with a negative COVID-19 test taken no more than 2-days before their flight departed, or 2) passengers with documentation of recovery, or 3) passengers 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 of this information collection request. 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. Airlines or other aircraft operators must retain a copy of each passenger attestation for 2 years.

3. Use of Improved Information Technology and Burden Reduction

Qualifying Test or Documentation of Recovery

Currently, CDC is not specifying the format of the proof of the *Qualifying Test* or, the *Documentation of Recovery* to fly, 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.⁴ The documentation should be retained by the individual in the instance that a Federal or state and local officials request the documentation.

Attestation

A digitization of the hard copy form of the attestation (Attachment C of this information collection request) 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

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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 A2) 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.

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, 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 concerning the latest efforts to address the COVID-19 pandemic. 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 negative test or documentation of

recovery 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.

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. Any 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.

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

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 negative testing, documentation of recovery or documentation confirming humanitarian exception may include identifying information to ensure the record or documentation matches the bearer of any documents presented to the airlines or public health authorities. Individual 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 **5,208,373 hours**.

Air passengers' burden: Under the Order, passengers will need to provide a test/documentation of recovery/or proof of receiving a humanitarian exception; AND attest that the information is true. CDC estimates this may take an average of 1-2 hours, including the time it takes to get the test/documentation of recovery or humanitarian exception. For the purposes of estimating burden, CDC is going to use the higher estimate of 2 hours per person. To estimate the number of air passengers who will be required to take a test, CDC took an average of the number of air passengers coming to the United States from PRC in 2022 (both direct and indirect flights and based on volume from October to December 2022) and averaged it with an equivalent estimate for the same time period in 2019. Based on these calculations, , CDC estimates there may be 2,500,000 air passengers coming to the United States annually from PRC. Using the 2019 volume of travel may make the estimate high given current travel volume is low, but it is the best estimate CDC has at this time to account for a possible increase in travel. As a result of the estimates, CDC estimates the annual burden hours to be approximately **5,000,000 annual burden hours**.

For airline agent review: CDC estimates it could take approximately 5 minutes per passenger for airlines to review documentation to board. This may be an overestimate since some processes are electronic, but the preference is to overestimate for the purposes of this information request. Therefore, the burden is estimated as follows: 2,500,000 reviews x 5 minutes (or less) per review, for a total of **208,333 annual burden hours**.

Humanitarian Exception to Requirement: Based on previous requests for testing exceptions from a now rescinded testing requirement for all air passengers, CDC estimates it will receive 20 requests for a humanitarian testing exception annually from PRC. Based on this number, and that it's estimated submitting a request takes about 2 hours, CDC estimates it the humanitarian exception requirement will result in approximately **40 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)
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Air Passenger	<i>Attestation</i> -Proof of Negative Covid-19 Test Result or Documentation of Recovery for Air Passengers from the People's Republic of China	2,500,000	1	2	5,000,000
Airline Desk Agent	<i>Attestation</i> -Proof of Negative Covid-19 Test Result or Documentation of Recovery for Air Passengers from the People's Republic of China	2,500,000	1	8/60	208,333
Air Passenger	Request Humanitarian Exception – (No form)	20	1	2	40
Total					5,208,373

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 2021 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 \$244,643,551.

- 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.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
Air Passenger	Attestation - Proof of Negative Covid-19 Test Result or Documentation of Recovery for Air Passengers from the People's Republic of China	5,000,000	\$47.10	\$235,500,000
Airline Desk Agent	Attestation - Proof of Negative Covid-19 Test Result or Documentation of Recovery for Air Passengers from the People's Republic of China	208,333	\$43.88	\$9,141,667

⁵ <https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20Travel%20Time%20Guidance.pdf> Page 17

Air Passenger	Request Humanitarian Exception – (No form)	40	\$47.10	\$1,884
Total				\$244,643,551

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: \$2,212,500
Airline costs to store attestations: \$88 to \$92,637 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 test or documentation of recovery, or exception, if applicable.

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, if all airlines digitize hard copies:
 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.⁶
 2. CDC is anticipating 1.5 minutes to scan or otherwise digitize each of the 2,500,000 estimated attestations
 - The estimate for this process is \$2,212,500
 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.

⁶ <https://www.bls.gov/oes/current/oes434071.htm>

2. To estimate a range of costs over the airlines, CDC is apportioning the total cost of storing 2,500,000 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 \$92,637 to \$1,588 year. The cost for those airlines with less than 1% of arriving passengers may expect a range of costs between \$5,146 to \$88 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 will spend approximately \$5,642 a year to process the 20 humanitarian requests.

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 20 burden hours annually [calculated by 20 requests x 1 hour]. This results in an estimate of \$2,004 annually for U.S. Embassy Staff to help the adjudication process.

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 40 hours annually [calculated by 20 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 results in an estimate of \$3,638 annually to adjudicate humanitarian exceptions.

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	20	\$100.19	\$2,004
Adjudicate Request Exemption on Urgent Humanitarian Basis – CDC GS-12	40	\$90.96	\$3,638
Total Costs			\$5,642

15. Explanation of Program Changes or Adjustments

This is a new collection.

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

The OMB Control Number will be displayed on the attestation form, but the expiration date will not be displayed. The purpose of this is to decrease the burden to airlines to have to update the attestation expiration date on printed attestation forms or digital forms integrated into digital air travel check-in systems.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment A1: 18 U.S.C. §§ 3559, 3571

Attachment A2: Section 361 of the Public Health Service Act (42 USC 264)

Attachment A3: 42 CFR Part 71

Attachment A4: *Order: Requirements for Negative Pre-Departure COVID-19 Test Result or Documentation of Recovery from Covid-19 for All Airline or Other Aircraft Passengers Traveling to the United States from the People's Republic of China*⁷

Attachment B: 0920-XXXX - 60-Day Federal Register Notice

Attachment C: Passenger Disclosure and Attestation to the United States of America

Attachment D: Information Needed to Apply for Humanitarian Exception to Testing Requirement-PRC

Attachment E: QARS Privacy Impact Assessment

⁷ Will be posted at: <https://www.cdc.gov/quarantine/china-proof-negative-test.html> and can be sent as follow up after it is signed.