

2019 Novel Coronavirus Airport Entry Questionnaires

Request for OMB approval of a New Information Collection

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Supporting Statement A

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- **Goal of the study:** The goal of this information collection is to 1) accurately assess risk for infection or exposure to COVID-2019 in travelers coming to the United States from locations experiencing an outbreak of COVID-2019, and 2) assist states in facilitating public health follow-up of contacts in the event of a confirmed case on an aircraft.
- **Intended use of the resulting data:** The information will be used to determine if individuals meet risk thresholds for further medical evaluation, travel restrictions, or public health follow-up according to guidance developed by the CDC, and to assist health departments in facilitating public health follow-up, if needed.
- **Methods to be used to collect:** Travelers will be interviewed by the CDC and state public health departments, using screening and risk assessment tools developed by CDC.
- **The subpopulation to be studied:** The respondent universe for this information collection request is travelers coming to the United States from areas experiencing an outbreak of COVID-2019.
- **How data will be analyzed:** No statistical methods will be used.

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 new information collection.

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A1) 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. Under its delegated authority, DGMQ works to fulfill this responsibility through a variety of activities, including the operation of Quarantine Stations at ports of entry and administration of foreign quarantine regulations; 42 Code of Federal Regulation part 71 (Attachment A2), specifically 42 CFR 71.20 *Public health prevention measures to detect communicable disease*. This information collection concerns CDC's statutory and regulatory authority related to conducting public health screening of travelers upon arrival to the United States and

assessing individual travelers for public health risk following a report of illness from a conveyance.

CDC has been tasked with conducting public health assessments at U.S. airports of travelers coming from areas experiencing an outbreak of a novel (new) coronavirus (named “COVID-2019”). The purpose is to detect ill individuals or individuals at risk of being ill with COVID-2019, which was first detected in Wuhan City, Hubei Province, China. Currently, CDC is conducting these assessments for travelers from Hubei Province, other parts of China, and Iran. As the response evolves, CDC may be tasked with performing this action for additional travelers in the future.

CDC relies on its federal partners in the United States Department of Homeland Security (DHS) to assist in the screening process because of their presence at the ports of entry. DHS will refer travelers that have been to COVID-2019 outbreak areas (e.g. China or Iran) to another location at the airport where DHS contractors or CDC will collect information to help make a public health risk assessment. CDC develops the tools and training to facilitate this screening process and works to ensure that any individual who is identified by DHS as being from the outbreak area is further evaluated. This may involve medical evaluation by CDC followed by transport to a healthcare facility; a location for quarantine at or near that location; and/or communication via phone with CDC or state and local health departments to see if the travelers develop symptoms after arrival.

As part of the entry risk assessment program, CDC is also assisting the Department of State in the repatriation of individuals. These individuals may be assessed for their risk of illness and exposure to COVID-2019 using forms specifically designed for repatriation. These individuals will be subject to a mandatory 14-day quarantine following their arrival to see if they develop any symptoms and require further public health follow-up or medical care. They will not be able to complete their itinerary.

Some of the forms in this information collection may collect the same information as other forms. This overlap is intentional as this information collection is part of an ongoing effort to fill gaps in contact information of travelers who may need public health follow up. The overlap can also help CDC do quality assurance checks to make sure the information collected is accurate, complete, and timely to ensure appropriate public health follow up. CDC aims to require the least amount of burden necessary to protect the public’s health. Some forms may have different formats that will be used depending on the availability of network capabilities and location. For example, if there is unreliable internet connectivity in some screening locations, a screener may fill out the traveler’s information on a fillable PDF and upload to an electronic system later, or on a paper form and enter data manually.

2. Purpose and Use of Information Collection

CDC will require all travelers from a COVID-2019 outbreak area, currently China and Iran, to provide information as part of an initial public health risk assessment. The information collected will be limited to that necessary to identify the person, establish their travel itinerary, and make a public health risk assessment to determine if they should

be released with self-monitoring, receive travel restrictions such as an isolation or quarantine order, or referred directly to a healthcare facility. Collected information includes name, contact information, travel itinerary, and possible exposure and health questions. CDC will ask basic questions about signs or symptoms of illness or exposure as well as observe travelers to determine if the traveler is experiencing any overt signs and symptoms of disease. The information also includes a field for a temperature, which will be taken via a non-contact thermometer. Any traveler who comes from an area determined to be high risk (e.g. currently Hubei Province, China), has signs or symptoms, or exposure to a known case, will be referred for further evaluation. The soliciting of basic symptom information from travelers on commercial flights or after repatriation will provide important information to determine their public health risk.

The primary signs/symptoms of concern for COVID-2019 are fever, cough, and difficulty breathing. COVID-2019 infection has been associated with severe respiratory illness in some patients and, to date, has been limited to specific geographic areas and travelers from those areas. The potential incubation period of concern is two weeks (14 days); this is based on the upper range incubation period seen with coronavirus infections.

The 2019 Novel Coronavirus Entry Risk Assessment Program consists of two types of travelers:

Travelers on commercial flights

CDC's goal is to have a data sharing mechanism that shares accurate, complete, and timely traveler contact information with CDC so travelers can be contacted for any needed public health follow up. Until this process is finalized, CDC will use a Traveler Health Declaration form in an electronic web format (Attachment C) to capture contact and travel itinerary information in addition to checking for signs or symptoms or possible exposure to COVID-2019. If there is an unreliable internet connection available, DHS contractors or CDC staff may fill out information in a fillable PDF computer (Attachment D) to upload later to a data sharing system when internet connectivity has improved. If a computer is not available, screeners may also fill out the information on a paper version (Attachment E).

- I. Any traveler from a high-risk area, currently considered for Hubei Province, China, will be escorted to finish answering questions in the Traveler Health Declaration form (Attachments C, D, or E) and the Supplemental COVID-2019 form (Attachment L) in a different part of the screening area.
 - i. If a traveler from Hubei Province is determined not to have any signs or symptoms, they will be put under travel restrictions, such as quarantine for the 14-day COVID-2019 incubation period and receive a booklet that includes recommendations on what to do after returning from China, including how to properly take a temperature and phone numbers to reach their state health department if they develop signs or symptoms.
 - ii. If a traveler from Hubei Province has signs or symptoms consistent with COVID-2019, they will undergo questions from the COVID-2019 Illness and Death Investigation Form (Attachment M) to determine if they should be referred to a healthcare facility.
- II. Any traveler who was in parts of China outside Hubei Province or Iran in the last 14 days answers all questions that DHS or CDC staff ask them from the

Traveler Health Declaration (Attachments C, D, or E). The traveler will also have their temperature by a screener via a non-contact thermometer.

- i. If a traveler from parts of China or Iran does not have signs or symptoms, and has been determined to not have had contact with a known case, they will be released and given a booklet that includes recommendations on what to do after returning from China, including how to properly take a temperature and phone numbers to reach their state health department if they develop signs or symptoms.
- ii. If a traveler from other parts of China or Iran has any signs or symptoms they will be referred for further evaluation and may get asked questions from the COVID-2019 Illness and Death Investigation Form (Attachment M) to determine if they should be referred to a healthcare facility and Supplemental COVID-2019 form (Attachment L) to understand any possible exposure.
- iii. If a traveler from other parts of China or Iran has been determined to have had contact with a known case, they will also be referred for further evaluation and may get asked questions from the Supplemental COVID-2019 form (Attachment L) to better understand their exposure risk.

If an automatic data sharing mechanism is established so that partners are able to provide CDC with accurate, complete, and timely data on traveler's contact information, then the information collected as part of this screening process could be modified to just collecting the health and exposure information in the COVID-2019 Referral Form (Attachment K). Only those that were coming from a high-risk area (e.g. currently Hubei Province), who had high-risk exposure, or signs and symptoms of COVID-2019 would be referred for further evaluation. Most travelers would only need to answer a few quick questions and have a temperature taken before being released since their contact information for any public health follow up would be shared with CDC and state and local health departments through a separate routine data sharing mechanism.

Travelers on Repatriated Flights, or from Ships

Individuals being repatriated as part of a formal Department of State program may respond to an initial Preboarding Health Screen (Attachment H) and a modified U.S. Traveler Health Declaration for Repatriation (Attachment I) or a modified U.S. Traveler Health Declaration for Repatriation from a Ship (Attachment J). They may undergo information collection from the COVID-2019 Air Travel Illness or Death Investigation (Attachment K) form if the traveler has signs or symptoms. Individuals being repatriated will not respond to the COVID-2019 Supplementary Questionnaire. Individuals being repatriated will be placed under a public health order to restrict their movement for the 14-day incubation period of COVID-2019.

3. Use of Improved Information Technology and Burden Reduction

Because of the rapid implementation required by the development of the outbreak, (Attachments H-L) will be used in hard copy paper forms to assist in assessing traveler

risk for illness and exposure, both at the airport, and during travel of repatriated individuals.

The U.S. Traveler Health Declaration form may be used in one of three formats, depending on network capabilities and where the information is being collected.

1. The electronic web version (Attachment C) will be used at airports that are doing enhanced screening that have computers and available internet connection. The data will be automatically uploaded into a data sharing system.
2. The fillable electronic PDF (Attachment D) can be used if there is a computer, but there is unreliable internet connection because it can be saved and the data uploaded once network capability becomes available.
3. A hard copy paper version of the form (Attachment E) can be used if there is no computer available in the room where the information is being collected. The information can be manually entered into a data sharing system.

Depending on the length of the outbreak, the use of information technology may be considered for other forms if a timely and accurate method of providing information to CDC can be identified and determined to be feasible and cost effective.

The solicitation of basic temperature and symptom information from individuals after repatriation would be done verbally and recorded by CDC or a public health partner on behalf of CDC either on paper or on mobile electronic devices.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has the regulatory authority for performing quarantine-related public health risk assessment and evaluation activities at U.S. ports of entry (42 Part 71). As a result, CDC is the only agency collecting illness or death reports related to the introduction and transmission of communicable diseases at ports of entry. CDC works in collaboration with its international, federal, state, and local partners at ports of entry and through multi-state contact investigations to ensure all illness responses and public health follow-up and travel restrictions are done in a coordinated manner.

5. Impact on Small Businesses or Other Small Entities

Some of the respondents may be considered small businesses. However, data collection variables are kept to an absolute minimum to minimize burden on these entities.

6. Consequences of Collecting the Information Less Frequently

Failure to collect this information for airport public health risk assessments or from individuals under orders could lead to an increased risk of ill travelers coming in contact with the general public.

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

Frequency of data collection is inconsistent with the guidelines, as discussed in Section A6. The frequency of data collection is determined by the frequency of travelers coming from the outbreak areas, and by the frequency of ill travelers identified at the U.S. airports where these travelers enter the United States.

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, CDC asks that the 60-day comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this investigation (Attachment B).

B. CDC is the primary authority with responsibility to prevent the introduction and spread of communicable disease in the U.S. through air, land and sea ports of entry and interstate. No other entity collects the type and quantity of information from ill travelers or from individuals under federal public health orders. While the respondents to this data collection are individual travelers, not industry, CDC does work with the air industries on the information collection process outlined in this Supporting Statement to ensure that these industries are able to operate with the least interference possible, while also maintaining the ability to collect the information needed to protect public health.

9. Explanations of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents.

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

This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases and it has been determined that the Privacy Act does apply to some aspects of this information collection request. The applicable System of Records Notice is 09-20-0171, Quarantine- and Traveler-Related Activities, including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.

Information submitted will be entered into a computer system for analysis and later retrieved if necessary. Data containing personal identifiers and source documents will be retained until the event prompting the collection of data has concluded in accordance with DGMQ's records retention schedule. Data not containing personal identifiers will be retained indefinitely for statistical and historical documentation purposes. Electronic media will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide "need to know" in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. When information is deleted, a special "certified" process will be used to completely overwrite tapes on the mainframe or overwriting (not merely deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

Information collection tools in this request asks for personally identifiable information, to include name, contact information, and travel related information, such as flight number, to ensure accurate identification of travelers. The presence of symptoms and history of exposures to disease is also collected to assist CDC in making a risk assessment and determine if further public health measures are needed. Individuals may make a request for their available information collected through a Privacy Act request. (<https://www.hhs.gov/foia/privacy/how-make-privacy-act-request.html>)

Information is being collected that may have an impact on an individual if the information was disclosed. CDC will only share the information without the consent of the traveler as outlined in System of Records Notice is 09-20-0171, Quarantine- and Traveler-Related Activities, including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71. These purposes are primarily to ensure appropriate follow-up in the event medical care of additional public health response is necessary and recipients of the information will generally be public health departments and medical providers.

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

IRB Determination

CDC's National Center for Emerging and Zoonotic Infectious Diseases has determined that this project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachments L).

Justification for Sensitive Questions

This information collection requests certain personally identifying information of both imports and travelers. Some personally identifying information will be collected during the proposed risk assessments in order to identify ill travelers. Some travelers might find these questions sensitive in nature, but this information is necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.

12. Estimates of Annualized Burden Hours and Costs

Below are the estimates of the Annualized Burden Hours that CDC is requesting for this emergency request.

The total burden requested for this revision is 320,000 respondents, travelers arriving on commercial flights, and repatriated flights or ships, with approximately 136,667 burden hours.

This estimate is based on the following assumptions:

Current travel suspensions limits travel for many foreign nationals coming from China or Iran so travelers coming to the United States from these countries currently are U.S.

Citizens, Legal Permanent Residents (LPR), their families or others that fall into other exempt categories. Between February 3rd and March 3^{rd, 2020}, approximately 38,700 US Citizens, Legal Permanent Residents and their family members who came to the United States from China, a significant drop from January 2020. During that same period, approximately 3,361 US Citizens, LPR, and other admission classes came to the United States from Iran. CDC estimates that this outbreak of COVID-2019 may last another 6 months and that travel will slow even more due to travel advisories and restrictions, and canceled flights. Given the number of U.S. citizens, LPRs, and their families, who came into the United States between February 3rd-March 3rd; and estimating other exempt categories who may travel to the United States; CDC predicts approximately 300,000 travelers will need to be screened over 6 months from China and Iran. CDC is still evaluating the impact of the outbreak on global travel, and has provided the best estimate given the current information.

- An estimated 300,000 travelers from China and Iran may be required to answer the contact, travel history, and symptom questions on the U.S Traveler Health Declaration form (Attachment C, D, or E) which will also be available in English and Mandarin Chinese.
 - CDC anticipates approximately 75,000 hours of respondent burden will be incurred as a result of this portion of the entry risk assessment program
- For repatriation events, individuals on the flights or ships may respond to a brief Pre-Boarding Health Screening questionnaire (Attachment F) prior to boarding a flight back to the United States. Prior to or at arrival at the repatriation center individuals may receive the U.S. Traveler Health Declaration for Repatriation (Attachment G) or the U.S. Traveler Health Declaration for Repatriation from a Ship (Attachment H)
 - CDC estimates approximately 10,000 individuals participating in a repatriation from a country and potentially 10,000 individuals participating in repatriation from a ship in a total of 2,500 burden hours for each form. Since each of these individuals might receive a Preboarding Health Screen, it is estimated there will be approximately 20,000 individuals using the Preboarding Health Screen form for approximately 1,666 burden hours.
- If other mechanisms are developed for CDC to receive traveler's contact information, then CDC may only need to use the Referral Slip (Attachment I) to ask travel itinerary, exposure, or symptom questions to most travelers. An estimated 300,000 travelers from China and Iran may be required to answer questions on the Referral about whether they are from a high-risk area or whether they have symptoms and may be asked additional travel and exposure questions info if they are not immediately referred for further evaluation. A translator or a mandarin version of these questions will be available if needed.
 - CDC anticipates approximately 25,000 hours of respondent burden will be incurred as a result of this portion of the entry risk assessment program
- An estimated 25,000 travelers from China and Iran may be required to answer the exposure and more detailed signs and symptoms questions on the COVID-2019 Supplemental Questionnaire (Attachment J).

- o CDC anticipates approximately 4,167 hours of respondent burden may be incurred as a result of this portion of the entry risk assessment program
- Travelers from China and Iran showing signs or symptoms consistent with COVID-2019 would undergo an illness investigation that uses the COVID-2019 Air Travel Illness or Death Investigation form (Attachment K). CDC estimates approximately 10,000 travelers may have signs or symptoms consistent with COVID-2019. This would result in approximately 2,500 burden hours.
- In the event that CDC needs to monitor individuals after repatriation, CDC anticipates that this would be done verbally and recorded onto a spreadsheet or electronic device. There is no standard form for this process.
 - o The 10,000 estimates repatriated individuals would be contacted a maximum of twice a day for 14 days. Each encounter would be approximately 5 minutes. This totals 23,333 hours.

12 A. Estimates of Annualized Burden Hours

Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Traveler	United States Travel Health Declaration (Web, Fillable PDF, or Paper)	300,000	1	15/60	75,000
Traveler	Preboarding Health Screen	20,000	1	5/60	1,667
Traveler	United States Travel Health Declaration for Repatriation	10,000	1	15/60	2,500
Traveler	United States Travel Health Declaration for Repatriation from Ship	10,000	1	15/60	2,500
Traveler	COVID-2019 Referral Slip	300,000	1	5/60	25,000
Traveler	Supplemental COVID-2019 Questionnaire	25,000	1	10/60	4,167
Traveler	COVID-2019 Air Travel Illness and Death Investigation Form	10,000	1	15/60	2,500
Traveler	COVID-2019	10,000	28	5/60	23,333

	Daily Symptom Check				
Total					136,667

12 B. Estimates of Annualized Cost

There will be no anticipated costs to respondents other than time. Estimates of respondent costs are provided for the six months of requested emergency approval. Wages for travelers were gathered from BLS category 00-0000 “All Occupations” (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). The estimated total cost is \$3,413,933.

Respondent	Form	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Traveler	United States Travel Health Declaration (Web, Fillable PDF, or Paper)	75,000	\$24.98	\$1,873,500
Traveler	Preboarding Health Screen	1,667	\$24.98	\$41,633
Traveler	United States Travel Health Declaration for Repatriation	2,500	\$24.98	\$62,450
Traveler	United States Travel Health Declaration for Repatriation from Ship	2,500	\$24.98	\$62,450
Traveler	COVID-2019 Referral Slip	25,000	\$24.98	\$624,500
Traveler	Supplemental 2019-nCoV Questionnaire	4,167	\$24.98	\$104,083
Traveler	COVID-2019 Air Travel Illness and Death Investigation Form	2,500	\$24.98	\$62,450
Traveler	COVID-2019 Daily Symptom Check	23,333	\$24.98	\$582,867
Total		136,667		\$3,413,933

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

There are no costs to respondents other than the time necessary to respond to the information collection

14. Annualized Cost to the Government

The estimated cost for these activities over the next six months to the federal government is approximately \$17,500,000. This includes costs for staff time, travel and transportation (including shipping), materials, translation services, equipment for the public health risk assessments (e.g., thermometers), and other materials and services needed to conduct these programs. This number may change depending on the volume of travelers, location of CDC public health risk assessments, and volume of contact investigations initiated in response to confirmed cases.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

CDC and CBP may report aggregate totals of number of people screened, number of positives, and number of aircraft contacts publicly, as appropriate. Similarly, aggregate numbers of illness or death investigations may be reported.

Publication of the results of the public health risk assessment, and any lessons learned, may be published to inform future public health interventions and to contribute to the body of knowledge concerning public health interventions at ports of entry. No personally identifiable information will be published.

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

Display of the expiration date is appropriate. No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment A1 - Section 361 of the Public Health Service (PHS) Act (42 USC 264)

Attachment A2 - 42 Code of Federal Regulations part 71

Attachment B - 60-day Federal Register Notice

Attachment C - COVID-2019 Web Format - U.S. Traveler Health Declaration

Attachment D - COVID-2019 Fillable PDF - U.S. Traveler Health Declaration

Attachment E - COVID-2019 Paper Format - U.S. Traveler Health Declaration

Attachment F - COVID-2019 Preboarding Health Screen

Attachment G - COVID-2019 U.S. Traveler Health Declaration for Repatriation

Attachment H- COVID-2019 U.S. Traveler Health Declaration from Ship

Attachment I - COVID-2019 Referral Slip

Attachment J - Supplemental COVID-2019 Questionnaire

Attachment K - COVID-2019 Air Travel Illness or Death Investigation form

Attachment L - Airport Entry Risk Assessment Program IRB