

**Request for Nonmaterial/Non-substantive change
Foreign Quarantine Regulations (42 CFR 71)
(OMB Control No. 0920-0134)
Expires 03/31/2022**

Program Contact

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Circumstances of Change Request for OMB 0920-0134

The Centers for Disease Control and Prevention (CDC), Division of Global Migration and Quarantine (DGMQ) requests two nonmaterial/non-substantive changes of the currently approved Information Collection Request: Foreign Quarantine Regulations (42 CFR 71), OMB Control No. 0920-0134, expiration date: 03/31/2022.

Requests

1) Update to Enhanced Data Collection During 2019 Novel Coronavirus (COVID-19) Pandemic REDCap form

CDC continues to manage several outbreaks of COVID-like illness among cruise ship crew. CDC is requesting approval for a set of changes to the “Enhanced Data Collection During COVID-19 Pandemic” REDCap form reporting tool, (Attachment A1(changes), Attachment A2 REDCap screenshot), to facilitate collection of the data from cruise ships under the extended No Sail Order of July 16, 2020 and any future extensions of the No Sail Order. This method remains the most efficient mechanism for collecting information and allows for faster analysis in a secure environment (<https://www.project-redcap.org/>).

CDC is requesting approval for the following changes. These changes are informed by CDC experience with respiratory illness reporting from cruise ships over the last several months, and have benefitted from industry and subject matter expert input. CDC does not anticipate that these changes result in additional reporting burden.

Description of the changes

- Change #1: Added “a” to “CLI” to be listed as “aCLI”
Justification: Clarification in response to confusion with the well-known acronym for COVID-like illness of “CLI”
- Change #2: Additional symptoms added to reporting requirement/surrogate marker for Additional COVID-19-like illness, aCLI.
Justification: The expanded reporting requirement is based on that latest epidemiologic evidence of the clinical manifestations of COVID-19 that has emerged in the scientific literature since the inception of EDC reporting. The additional symptoms/signs align with [CDC guidance](#) and [CSTE clinical definitions for COVID-19](#).
- Change #3: Additional lab reporting option of rapid antibody testing for detecting coronavirus or SARS-CoV-2 for screening or disembarkation and/or repatriation. As a result, adding a minute to the upper time limit estimate so that the estimated time is 5-13 min.
Justification: While this rapid antibody test is *not* [recommended by CDC](#), it is commercially available and at least one cruise line continues to use it for COVID-19 screening purposes. Having this information does provide comprehensive surveillance data.
- Change #4: Added “symptomatic” or “asymptomatic” to questions about testing
Justification: To clarify which questions are about symptomatic persons and which questions are asymptomatic

Change #5 Reordered questions to separate questions about symptomatic persons and asymptomatic persons in two different sections
Justification: To clarify which questions are about symptomatic persons and which questions are asymptomatic

The new, web-based version of the “Enhanced Data Collection During COVID-19 Pandemic” form solicits additional information from the cruise ships concerning acute respiratory illness, influenza-like-illness, pneumonia, and additional symptoms or signs of COVID-like-illness. Similarly, it will also ask if any pre-existing or additional diagnostic testing has been done and whether the cruise ship has implemented isolation procedures according to CDC COVID-19 guidelines. It will also ask for the number of crew on board and the nearest U.S. port.

CDC will be providing guidance on the use of the form via multiple channels to ensure broad distribution to the cruise industry. Those channels include distribution via Cruise Lines International Association (CLIA), which is the world’s largest cruise industry trade association; email correspondence from CDC Maritime Activity to cruise line medical directors; and posting guidance to CDC’s maritime industry website, available here: <https://www.cdc.gov/quarantine/maritime/recommendations-for-ships.html>.

REDCap is a secure internet application for building and managing online surveys and databases. It can be used to collect virtually any type of data, including in environments compliant with electronic records legislation (21 Code of Federal Regulations Part 11), the Federal Information Security Management Act of 2002 (44 US Code §3541), and the Health Insurance Portability and Accountability Act of 1996 (Public Law 104– 191, 110 Stat 1936). The tool is specifically designed to support online or offline data capture for research studies and operations, and is accessible through computers, tablets, and smartphones. CDC believes this process will be easier to integrate into cruise ship operations than using a paper form.

2) Supplemental COVID-19 Questionnaire (Attachment B)

CDC Quarantine Stations continue to respond to reports of ill travelers at U.S. ports of entry to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States or from one State or possession to another State or possession. CDC is requesting the approval of a Supplemental COVID-19 Questionnaire (Attachment B) to assist CDC Quarantine Officers in the evaluation of whether an ill traveler poses a risk of infection of COVID-19. The collection of comprehensive, pertinent relevant health and epidemiologic information during a public health illness response enables Quarantine Officers to make an accurate public health assessment and identify appropriate next steps. CDC currently uses the approved Air Travel Illness or Death Investigation Form (Attachment C), the Land Travel Illness or Death Investigation Form (Attachment D), and the Maritime Conveyance Illness or Death Investigation Form (Attachment E) to capture the collection of relevant health and epidemiologic information about an ill traveler. The emergence of COVID-19 requires certain questions to be asked during the illness investigation ascertain whether a traveler could be infectious for COVID-19. The Supplemental COVID-19 Questionnaire will guide Quarantine Officers through clinical questions appropriate for determining ill travelers’ risk of having COVID-19. The Questionnaire

would be used in addition to the other forms already used for public health illness response and may be updated as new information about COVID-19 becomes available.

Burden

Enhanced Data Collection During 2019 Novel Coronavirus (COVID-19) Pandemic REDCap form. This form would not constitute an additional burden to cruise ship operators, as they would have the option of using the paper or electronic version. The current information collection is approved for 520 hours from 50 respondents.

As the No Sail Order is now in effect, CDC will require that the form be submitted once a week by any cruise ship originating from, stopping in, or anchored off of the U.S., or that is planning to enter waters subject to U.S. jurisdiction during the period of the No Sail Order. The number of cruise ships meeting these criteria is currently unknown at this time, but could be up to 50. Cruise ships should already have the information needed to complete the form in their medical logs; based on the pilot, and the additional question added, CDC estimates the form should now take around 5-13 minutes to complete. For the purposes of estimating burden hours, the upper limit of this range (i.e., 13 minutes) is used, resulting in a new total burden hours of 563 for this form.

Supplemental COVID-19 Questionnaire

This form will be used during public health assessments of ill travelers at air, land, and sea ports of entry. It would be used during illness investigations to supplement health questions from the Air Travel Illness or Death Investigation Form, the Land Travel Illness or Death Investigation Form, or the Maritime Conveyance Illness or Death Investigation Form. Since the burden for each of those forms is 1,700; 100; and 500 respectively, CDC estimates the number of respondents for the Supplemental COVID-19 Questionnaire will be 2,300. CDC estimates answering these questions will take 5 minutes, leaving the total burden hours for these supplemental questions 192 for 2,300 respondents.

These two non-substantive changes result in a total burden under 0920-0134 of 269,248 hours, a 235 hour increase from the previously calculated total burden of 269,013.

Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Cruise ship operator	Enhanced Data Collection During COVID-19 Pandemic	50	52	13/60	563
Traveler or Maritime Vessel Operator	Supplemental COVID-19 Questionnaire	2,300	1	5/60	192
Total					755

Privacy

There is no PII collected as part of the information collection for the Enhanced Data Collection During 2019 Novel Coronavirus (COVID-19) Pandemic REDCap form.

While there is no PII collected for the questions in the Supplemental COVID-19 Questionnaire, PII would be collected in the already approved illness and death investigation forms (Attachments C-E) that would be used in conjunction with the Supplemental COVID-19 Questionnaire.

Attachments

Attachment A1 – Enhanced Data Collection During COVID-19 Pandemic-Changes Highlighted

Attachment A2 – Enhanced Data Collection During COVID-19 Pandemic_REDCap Screenshot

Attachment B – Supplemental COVID-19 Questionnaire

Attachment C – Air Travel Illness or Death Investigation Form

Attachment D – Land Travel Illness or Death Investigation Form

Attachment E – Maritime Conveyance Illness or Death Investigation Form