

**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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Submission Date: 11/19/2021

Circumstances of Change Request for OMB 0920-0134

The Centers for Disease Control and Prevention (CDC), Division of Global Migration and Quarantine (DGMQ) requests a nonmaterial/non-substantive change of the currently approved Information Collection Request: Foreign Quarantine Regulations (42 CFR 71), OMB Control No. 0920-0134, expiration date: 05/31/2022.

CDC is currently investigating several large outbreaks of respiratory illness among cruise ship crew members and is aware of several rumored outbreaks. CDC recently received approval for the use of a hard copy version of the “Enhanced Data Collection During COVID-19 Pandemic” form (Attachment A). In order to facilitate collection of the data from cruise ships under the revised No Sail Order of April 9, 2020 in the most efficient manner, and in a format that allows for faster analysis in a secure environment, CDC is requesting approval for a web-based version of the form using REDCap (<https://www.project-redcap.org/>) (Attachment B).

Description of the changes

The new, web-based version of the “Enhanced Data Collection During COVID-19 Pandemic” form solicits the same information from the cruise ships concerning acute respiratory illness, influenza-like-illness, and pneumonia. Similarly, it will also ask if any 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.

Burden

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 2,167 hours from 250 respondents. The total burden under 0920-0134 will remain 270,660 hours.

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. The number of cruise ships meeting these criteria is currently unknown at this time, but could be up to 250. Cruise ships should already have the information needed to complete the form in their medical logs; based on the pilot, the form should take around 5-10 minutes to complete. For the purposes of estimating burden hours, the upper limit of this range (i.e., 10 minutes) is used.

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	250	52	10/60	2,167
Total					2,167

Privacy

There is no PII collected as part of this information collection.

Attachments

Attachment A – Enhanced Data Collection During COVID-19 Pandemic

Attachment B – Enhanced Data Collection During COVID-19 Pandemic_REDCap