



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health
Service**

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 26, 2021

Dominic Mancini
Acting Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C.

Subject: Request for Emergency Clearance

Dear Mr. Mancini:

Pursuant to the Office of Management and Budget (OMB) procedures established at 5 CFR 1320, Controlling Paperwork Burdens on the Public, I request that the following collection of information, *Requirement for Negative Pre-Departure Covid-19 Test Result or Documentation Of Recent Recovery From Covid-19 for all Airline or Other Aircraft Passengers Arriving into the United States From Any Foreign Country*, be processed in accordance with section 1320.13 Emergency Processing.

Over the last few weeks, the United Kingdom (UK) has faced a rapid increase in COVID-19 cases in South East England, leading to enhanced epidemiological and virological investigations. On December 14, 2020, Public Health England announced that a new variant of SARS-CoV-2 had been identified across the southeast of England.¹ Preliminary analysis in the UK suggests that this SARS-CoV-2 variant may be more transmissible than previously circulating variants, with an estimated potential to increase the reproductive number (R0) by 0.4-0.7 or greater with an estimated increased transmissibility of up to 70 percent.²

On December 19, 2020, in response to the emergence of the UK variant, the countries comprising the UK announced stricter measures to be applied from December 20 and over the coming weeks, with affected areas entering a 'Tier 4' level with movement restrictions within and between more and less heavily affected areas. These measures have included recommendations for residents of the most affected areas to restrict movements and travel, including international travel, outside of these areas. The government of Scotland announced a travel ban between Scotland and the rest of the UK. In addition, the Netherlands issued a travel ban from the UK effective through January 1,

¹ <https://www.gov.uk/government/news/phe-investigating-a-novel-variant-of-covid-19>.

² <https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>.

2021, and Belgium temporarily halted flight and train travel from the UK. Other countries took similar measures to restrict travel from the UK.

A second new variant of SARS-CoV-2 was reported in the Republic of South Africa (RSA) on December 18, 2020, that also appears to spread more rapidly than earlier variants of the virus. The RSA variant is distinct from the UK variant but shares a mutation in the spike protein that appears to increase transmissibility. Since being identified, the new variant has spread inland from coastal regions of RSA and has become the predominant variant in some areas of the country.

During December 21-26, 2020, several countries implemented restrictions on travel from South Africa, including China, El Salvador, Germany, Guatemala, Israel, Panama, Sudan, Switzerland, Turkey, and the UK. The Netherlands imposed a ban on travel from RSA on December 21 but lifted the ban for both the UK and RSA on December 23, stating that travelers will instead need to present a negative COVID-19 test result obtained within 72 hours of their scheduled arrival in the Netherlands, followed by 10 days of self-quarantine. On December 28, Japan imposed a ban on entry of all foreign nationals through the end of January 2021. On December 28, the Government of South Africa announced new restrictions on businesses and public movement. As of January 7, 2021, Canada requires air passengers 5 years of age or older to test negative for COVID-19 before arrival. On January 8, the United Kingdom announced a pre-departure testing requirement for all inbound international travelers with limited exceptions; a 10-day post-arrival quarantine will still be required.

On December 25, 2020, CDC issued an Order requiring proof of a negative Qualifying Test result for all airline passengers arriving from the UK to the United States. Since then, cases of the UK and RSA variants have been discovered in four Canadian provinces, including in individuals with no travel history indicating spread in Canada. The UK variant has also been found in at least 50 countries and the RSA variant has also been detected in at least 15 countries. The first case of the UK variant in the United States was found in Colorado on December 29, in an individual with no known travel history. On December 30, a second case was reported in California. Since then, the UK variant strain has accounted for more than 140 cases in more than 20 U.S. states. Another new variant strain of concern initially detected in South America in March 2020 has been detected in at least 19 countries on 5 continents through late December and has mutations in the spike protein that raise concerns of increased infectivity.

While it is known and expected that viruses constantly change through mutation leading to the emergence of new variants, these new variants have emerged at a time when numbers of new cases in the United States have continued to increase at alarming rates. Additional new virus variants are also likely to emerge as the virus continues to evolve and mutate. Accordingly, further action is needed to help mitigate the spread of these and other new virus variants into the United States.

Based on increased transmissibility and spread of these new variants of SARS-CoV-2, and to reduce introduction and spread of these and future SARS-CoV-2 variants into the United States, expanding current UK pre-departure testing requirements to all foreign countries and U.S.-bound passengers is warranted. This approach to testing-based risk assessment has been addressed in CDC guidance and the Runway to Recovery guidance jointly issued by the Departments of Transportation, Homeland Security, and Health and

Human Services.³ Testing for SARS-CoV-2 infection is a proactive approach and not dependent on the infecting strain. Approximately 120 countries now use testing in some form to monitor risk and control introduction and spread. With case counts and deaths due to COVID-19 continuing to increase around the globe and the high proportion of infected people with asymptomatic or pre-symptomatic infections, the United States must take a dual approach to combatting the virus. This means concurrently mitigating and slowing the introduction and spread of SARS-CoV-2 and controlling transmission within U.S. communities that are currently being overwhelmed by a surge in infections, hospitalizations, and deaths.

Pre-departure testing may detect travelers infected with SARS-CoV-2 before they initiate their travel. CDC recommends viral testing and receipt of results 1-3 days⁴ before departure for international travelers, particularly those traveling long distances or passing through transportation hubs such as airports where social distancing may be challenging. CDC modeling indicates that pre-departure testing is most effective when combined with self-monitoring.⁵ Testing before departure results in the greatest reduction of transmission risk during travel when the specimen is collected close to the time of departure. Earlier testing (i.e., more than 3 days before travel) provides little benefit beyond what self-monitoring alone can provide.

For persons previously diagnosed with COVID-19 who remain asymptomatic after recovery, CDC does not recommend retesting within 3 months after the date of symptom onset (or the date of first positive viral diagnostic test if their infection was asymptomatic) for the initial SARS-CoV-2 infection.⁶ For these travelers, the requirement under this order is that they submit their positive test from the last three months and documentation of recovery from COVID-19 and clearance for travel issued by a licensed healthcare provider or health department.

Pre-departure testing does not eliminate all risk. However, when pre-departure testing is combined with other measures such as self-monitoring for symptoms of COVID-19, wearing masks, social distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances, in transportation hubs, and at destinations. For international air travelers and others with higher risk of exposure, CDC additionally recommends a post-arrival test 3-5 days after arrival at destination, combined with self-monitoring and a 7-day period of staying home (or in a comparable location such as a hotel room) to further reduce the risk of translocating the virus into destination communities.⁷

As cases of COVID-19 continue to rise across the globe and travel volume increases, routine pre-departure testing of all U.S.-bound aircraft passengers is needed not only to reduce introduction of the two known SARS-CoV-2 variants from UK and RSA, but also future variants that might be more transmissible and cause more severe illness.

As such, I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential to

³ Runway to Recovery 1.1, December 21, 2020, available at <https://www.transportation.gov/briefing-room/runway-recovery-11>

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html>.

⁵ Johansson MA, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: Symptom monitoring, quarantine, and testing, available at <https://www.medrxiv.org/content/10.1101/2020.11.23.20237412v1>.

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html>

CDC's ability to effectively address this public health emergency. CDC cannot reasonably comply with the normal clearance procedures due to the public harm that could result if routine processing of this request is required. CDC requests emergency clearance to require air travelers from all foreign countries to the US to provide negative COVID-19 tests to airlines prior to boarding and to attest that those tests are truthful and accurate.

The information will not be collected or maintained by CDC and is instead primarily a 3rd party disclosure requirement between travelers and airlines. In limited circumstances, CDC may require that the traveler provide the test results in the course of a specific public health response. However, travelers are expected to retain these materials. Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business Wednesday, January 27, 2021.

Respectfully,

Rima Khabbaz, MD
Director
National Center for Emerging and Zoonotic
Infectious Diseases
Centers for Disease Control and Prevention