

Non-substantive Change Request – Traveler-based Genomic Surveillance
OMB Number: 0920-1406

We intend to add two questions to our list of potential additional questions to support data collection for a fall 2023 pilot project. This list of additional questions can be found in 'Attachment 4C' in the approved PRA package. Because we intend to continue to have no more than four of the additional questions added to the questionnaire at any given time, there is no additional burden to the participant. The responses to these questions will be collected in the same digital questionnaire as the primary instrument.

Statement about additional questions in the TGS approved SSA:

Additional questions: The TGS program may ask additional questions as interests and research questions evolve. For example, a pre-departure test question was added when the pre-departure test requirement for passengers coming from China was enacted. The question will likely be removed shortly after the policy is removed. We may also ask questions about mass gathering attendance to be able to do analyses on whether a particular event is linked to increased COVID-19 prevalence and/or a particular variant of interest. Potential additional questions have been drafted (Attachment 4C). No more than four additional questions will be added at any given time.

This project will expand testing within the TGS platform to other pathogens beyond SARS-CoV-2, including respiratory syncytial virus (RSV). We are amending our list of potential additional questions to include questions regarding prior RSV vaccination.

Both the PRA-approved supporting statement A (SSA) and consent form indicate the potential for testing for additional pathogens, and the data collected from these additional questions are necessary for interpretation of test results for RSV. Questions regarding RSV vaccination will initially only be used during the pilot project while samples are being tested for RSV. The questions will be added to the list of potential additional questions for potential future use pending the outcome of the pilot.