

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

We intend to amend one question on our list of potential additional questions to support data collection for a winter 2023/2024 pilot project. This list of additional questions can be found in ‘Attachment 4C’ of the TGS PRA package. Because we will continue to have no more than four of the additional questions added to the primary instrument at any given time, there is no additional burden to the participant. The responses to these questions will be collected using the same digital questionnaire as the primary instrument.

Statement about additional questions in the 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.’

The currently approved pilot is expanding testing within the TGS platform to other pathogens beyond SARS-CoV-2, including respiratory syncytial virus (RSV), influenza, and other respiratory viruses. We are amending our list of potential additional questions to modify our previously approved symptom question. The amended question will obtain information on whether the participant is experiencing respiratory or flu-like symptoms and if so what type of symptoms (see updated attachment 4C).

The PRA-approved supporting statement A (SSA) and consent form both indicate the potential for testing for additional pathogens, and the data collected from this additional question is necessary for the interpretation of test results from the pathogens for which we are now testing.