

Non-substantive Change Request - Traveler-Based Genomic Surveillance (TGS) - Nasal Swab Participant Questionnaire
OMB Number: 0920-1406

SUMMARY: From its beginning, the TGS participant questionnaire has:

- provided voluntary, anonymous metadata to compliment the nasal swab component of the program,
- enhanced the information available for public health decision-making, and
- supported the underlying program priorities of
 - o 1) early detection and
 - o 2) determining importation and domestic circulation risk for infectious disease targets of public health concern.

The proposed changes to the TGS participant questionnaire are the result of a multi-month, systematic review process consisting of:

- quantitative and qualitative analysis of current questions,
- feedback from frontline ground staff responsible for administering the questionnaire to program participants, and
- a thorough review of the match between current questions and programmatic needs.

As a result, we propose changes that:

- reduce the questionnaire by ~6 questions through combining and/or dropping questions,
- standardize response choices,
- limit areas of confusion and conversation with frontline ground staff, and
- prioritize collection of the highest value information with the most important use-cases aligned with TGS program goals and objectives.

Specifics of the proposed changes are detailed below, including the:

- introduction of two confirmation screens (travel itinerary and consent),
- combination of 2 questions,
- relocation of 1 question,
- standardizing of the option “Prefer not to answer” across all questions, and
- refinement of answer choice categories to increase information value.

All proposed changes align with and enhance survey objectives and programmatic goals.

DETAILED PROPOSAL AND JUSTIFICATIONS

Overall:

- We propose decoupling “Don’t know” and “Prefer not to answer” as an answer choice where it currently appears as a single choice. These are qualitatively different responses, and it is not best practice to combine them, particularly as it limits analytical usefulness.
- We propose offering the answer choice ‘Prefer not to answer” to all applicable questions (we have not repeated at each appearance this in the table). The “Sex” question is an example of an exception because the question and answer choices are dictated by Executive Order #14168.
- Five permanent questions about vaccine and COVID-19 history were **removed**.
 - We also are removing the potential questions designed to be rotated in and out of the questionnaire. One was modified and added to the permanent questionnaire

Impact on Annualized Burden

	Number of total possible questions	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden per year (in hrs.)
Original Form	17 permanent + 2 spots for temporary rotating questions	555,000*	1	0.083 (5 minutes)	46,250
Proposed Form	13 +2 potential confirmation screens	555,000*	1	0.067 (4 minutes)	37,000
Difference between Original & Proposed	Reduced by 4	No change	No change	Reduced by 0.016	Reduced by 9,250

*550,000 is a large annual overestimate, for the first two program years since PRA approval (6/9/2023), the program has had ~322,000 responses annually.

Existing questions (and answer choices) and proposed questions (and answer choices), along with change proposal justifications are presented in the table below. Questions and answer choices for which no changes are proposed are not represented.

Current Question & Answer Choices	Proposed Question & Answer Choices	Justification
Did you travel on any connecting flights in order to get to the United States? Yes No	Did you travel on any connecting flights in order to get to the United States? Drop down list to select all connections	Updating the questionnaire instructions and answer choices to capture <i>all</i> connecting flights the participant took to reach the United States will allow the program to capture more accurate travel information.

	No	
What country did your travel itinerary to the United States originate from? Drop down options for countries, excluding United States	What country did your air travel itinerary to the United States originate from? Drop down options for countries, excluding United States	Updating the questionnaire instructions to clarify the point of air travel origin will provide more specificity to the data field.
	We propose to add a flight confirmation screen visually illustrating the itinerary reported by the participant in questions 1-3: Does this correctly reflect your travel? [If YES] moves to question 4 [IF NO] returns to flight information questions	By confirming the itinerary with a visual check, we will increase data quality and minimize potential misunderstandings regarding the sequence of connecting travel legs.
From this point forward, participants can choose a discrete “Skip to swab” button (upper right corner of screen; replaces “Skip to end”), which allows them to provide a nasal swab without completing the rest of the questionnaire.		The proposed option maximizes recruitment efforts, prioritizes highest value participant metadata, and improves data completeness and quality.
What state(s) are you traveling to in the United States? Select a state N/A. Layover in the U.S. I don’t know/Prefer not to answer	<i>Question moved to the end of the questionnaire</i>	<p>We propose to relocate, combine, and reword the question asking participants where they are traveling to in the United States.</p> <p>Relocation: We propose moving this question to the end of the survey so that it is the last question asked. Based on a quit-rate analysis, this question, as currently asked, in its current location, is the single most common point for participants to drop out of the survey.</p> <p>Combine: We propose combining one of the answer choice categories of the current question with an existing question (also reworded) to capture the participant’s type of trip. (See next question.)</p> <p>Rewording: We propose rewording this question to: “What is your final destination?” (see new question on</p>

		<p>page 6)</p> <p>The proposed language is expected to be more acceptable to participants.</p>
<p>Do you live in the United States? (<i>Single select</i>)</p> <p>Yes</p> <p>No</p> <p>I don't know/Prefer not to answer</p>	<p>Which best describes your reason for travel to the United States on this trip?</p> <p>I live in the United States</p> <p>I have a layover in the United States</p> <p>I am visiting the United States</p> <p>Prefer not to answer</p>	<p>We propose combining one answer choice from the reworded and relocated "What state(s) are you traveling to in the United States?" with the question "Do you live in the United States?" We believe the proposed question (Which best describes your reason for travel to the United States on this trip?") and the proposed answer choices will be better received by volunteering participants while also capturing the information required to meet program goals.</p>
<p>[IF YES] to "I live in the United States"] How long have you been outside the country on this trip?</p> <p>1-3 days</p> <p>4-7 days</p> <p>8-14 days</p> <p>15-30 days</p> <p>1-6 months</p> <p>7-12 months</p> <p>More than 12 months</p> <p>I don't know/Prefer not to answer</p>	<p>[IF YES] to "I live in the United States"] How long have you been outside the country on this trip?</p> <p>1-3 days</p> <p>4-7 days</p> <p>8-14 days</p> <p>15-30 days</p> <p>More than 30 days</p> <p>Prefer not to answer</p>	<p>We propose reducing the number of response categories for this question based on a frequency analysis of existing TGS data and utility for public health decision making.</p>
<p>What is or was the main reason for your trip?</p> <p>Tourism/vacation</p> <p>Business/occupational</p> <p>Visiting friends/relatives</p> <p>Migration</p> <p>Student</p> <p>Other (please specify)</p> <p>I don't know/Prefer not to answer</p>	<p>What is or was the main reason for your trip?</p> <p>Tourism/vacation</p> <p>Business/occupational</p> <p>Military service</p> <p>Visiting friends/relatives (including weddings and funerals)</p> <p>Migration</p> <p>Study/Education</p> <p>Other (please specify)</p> <p>Prefer not to answer</p>	<p>We propose 3 changes to the answer choices for this question based on an analysis of the "Other" free text responses, feedback from frontline ground staff, and to maximize partnership opportunities to meet TGS program goals:</p> <ol style="list-style-type: none"> 1. We propose adding a dedicated category for military service 2. We propose adding text "(including weddings and funerals)" to the "Visiting friends/relatives" answer choice to clarify its scope, reduce questionnaire administration time, and prevent

		<p>the need to recode participant free-text responses, which will improve data quality.</p> <p>3. We propose harmonizing answer choice type across all choices; specifically, we propose changing “Student” to “Study/Education” to align with the other choices.</p>
<p>Why are you interested in participating today? Select as many as you like.</p> <p>I want a free at-home test to take later</p> <p>It was recommended to me at the airport by testing staff</p> <p>I want to help the CDC monitor disease entering the United States</p> <p>I want to support public health work</p> <p>I thought this was required</p> <p>Other (Please specify)</p>	<p>Why are you interested in participating today? Select as many as you like.</p> <p>It was recommended to me by airport staff</p> <p>I want to support public health work monitoring disease entering the United States</p> <p>I thought this was required</p> <p>Other (Please specify)</p> <p>Prefer not to answer</p> <p>[IF “I thought this was required”, a confirmation screen will appear with the text of the original consent page and 2 button options for the participant:</p> <p>Confirm consent (continues survey)</p> <p>Withdraw consent (exits survey)</p>	<p>We propose 4 changes to the answer choices for this question.</p> <p>1. We must drop the answer choice “I want a free at-home test to take later” because take-home tests to give to participants will no longer be available for program use.</p> <p>a. We propose revising the language for the answer choice referencing airport staff for clarity.</p> <p>2. We propose combining 2 answer choices that seem redundant in order to streamline the options and improve data quality.</p> <p>3. We propose adding a pop-up screen if a participant selects “I thought this was required” that includes the text of the original consent page and provides the option for the participant to confirm or withdraw their consent. This modification will help improve data quality and help reduce the possibility of misunderstandings regarding the voluntary nature of the TGS program.</p>
<p>What is your age?</p> <p>18-49 years old</p> <p>50-64 years old</p> <p>65+ years old</p> <p>I don’t know/Prefer not to answer</p>	<p>What is your age group?</p> <p>18-24 years old</p> <p>25-44 years old</p> <p>45-64 years old</p> <p>65 years or older</p> <p>Prefer not to answer</p>	<p>We propose adding the word “group” to this question to match the question format.</p> <p>We also propose narrower and more standard age groups which better characterize TGS participants and are more useful and comparable for data analyses.</p>
<p>What sex were you assigned at birth, on your original birth certificate?</p> <p>Male</p> <p>Female</p> <p>I don’t know</p>	<p>Sex</p> <p>Male</p> <p>Female</p> <p>Skip question</p>	<p>As of 2/5/25, this question changed per Executive Order (EO) #14168.</p> <p>Per further direction, a visually distinct colour choice for the “Skip question” answer choice went live in the field 2/18/25.</p>

Prefer not to answer		STARS protocol amendment reflecting compliance with EO #14168 was submitted 2/11/25; approval confirmed 2/13/25.
<p>Please check any symptoms you have experienced in the past 2 days. Check all that apply, or check "none of the above" if you have not experienced any of the symptoms listed (multi select)</p> <p>Cough, shortness of breath, or difficulty breathing Congestion or sore throat Fever or chills Nausea, vomiting, or diarrhea New loss of taste or smell None of the above I don't know/prefer not to answer</p>	<p>In the past 48 hours, have you experienced any of the symptoms listed below? Do not include symptoms from a chronic condition. Select all that apply.</p> <p>Fever or chills Cough Shortness of breath or difficulty breathing Fatigue Muscle or body aches Headache Loss of taste or smell Sore throat Congestion or runny nose Nausea or vomiting Diarrhea None of the above Prefer not to answer</p>	<p>We propose changing the recall period from "2 days" to "48 hours," which has more relevance for a traveling population, especially those crossing the international date line. The proposed changes to the answer choices aligns them with more standard and commonly used symptom lists, including those used by CDC in other settings, and solicits symptoms across a wider range of pathogens, which enhances responsiveness to TGS program goals and objectives.</p>
	<p>If the response to proposed question "Which best describes your reason for travel to the United States on this trip?" is either [I live in the United States] or [I am visiting the United States], we propose the reworded question: What is your final destination? Drop down list of states—Select all that apply</p>	<p>Justification provided above on pages 3-4.</p>