

Non-Substantive Change Request Memo

Enhanced surveillance of respiratory illness among people experiencing homelessness
in Anchorage, Alaska

(OMB Control No. 0920-1399)

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Program Contact

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The Centers for Disease Control and Prevention (CDC) requests a nonmaterial/non-substantive change of the currently approved Information Collection Request for “Enhanced surveillance of respiratory illness among people experiencing homelessness in Anchorage, Alaska” part of OMB Control No. 0920-1399.

Trained personnel will interview people experiencing homelessness to obtain demographic information, to ascertain their specific symptoms, and vaccination status. Medically trained members will collect a nasopharyngeal (NP) swab from each consenting person. The NP specimen collected will be analyzed using a multiplex viral respiratory panel at CDC/AIP laboratory.

The data collection instrument addresses the uptake of vaccines for respiratory illnesses among people experiencing homelessness. This change request is being made to indicate whether the RSV vaccine, which has just been released, was taken by the participants. The currently approved Data Collection Instrument is designed to include information regarding the uptake of COVID-19 and flu vaccines. With the introduction of the new RSV vaccine, it is important from a public health standpoint to determine whether the participants received the RSV vaccine. Knowing the uptake of RSV vaccine can influence how the RSV vaccine campaign is conducted and what additional steps are needed to improve vaccine uptake. The RSV vaccination question has been added as a subcategory in the flu vaccine question.

Note that two similar versions of this data collection instrument are currently approved: one that is part of the Standard ICR associated with this change request and the other that was later approved under the COVID-19 PHE PRA waiver. The modifications requested in this Change Request would consolidate these two versions. Overall, the changes described are minor and do not constitute more than 10% change to the original package.

The project protocol is being changed to include sequencing of the collected positive respiratory specimens which will be performed by CDC. This is essential to understand the circulating variants of COVID-19, the sequence of respiratory agents in clusters that occur, and sequence of respiratory viruses in co-infections. *The initial laboratory assay that is being used to test the samples in this project is research only, not under CLIA, and individual test results cannot be reported. Additionally, this project is public health surveillance and not diagnostic. The results are reported to the shelters where the samples are being collected; however, participants will not obtain individual test results. In the initial testing we are identifying the infectious agent causing the respiratory illness. Once the infectious agent is known in the positive specimens, CDC is performing pathogen sequencing. That is, CDC is sequencing the virus or bacteria infecting the participant, not sequencing human DNA.*

The changes addressed in this request do not increase the burden hours or affect the participants. Thus, no additional burden or collection from the participants will be incurred from these changes.

1. Update Data Collection Instrument (attached is the clean and redlined collection instrument)

- A. Change: To the question concerning the flu vaccine a subcategory is added to address whether the new RSV vaccine was received.

Rationale: With the introduction of a new RSV vaccine, it is necessary to find out if people experiencing homelessness have obtained the RSV vaccine. The information obtained can help in the RSV vaccine campaign.

Change: To address the concerns of ICRO the following changes were made:

1. After question 5 regarding the participant's race, the question regarding ethnicity is asked (question 6) followed by the question regarding how the participant currently defines their gender (question 7). The order was changed as suggested by ICRO to be in line with type of questions being asked.

2. Question 8 is the new question suggested that asks the participant their sex assigned at birth as requested by ICRO.

3. Question 13 is added to address the location of where the participant usually obtains healthcare as suggested by ICRO.

Rationale: The aforementioned changes were made based on the suggestions made by ICRO .

- B. Change: To the question "Where have you spent at least one night in the last two weeks?", an additional choice was added. The final choice added for the question was "Incarcerated".

Rationale: The participants questioned thus far in this project frequently gave the response such that it should be added as a choice.

2. Update Laboratory Section of the Project Protocol (attached is the clean and redlined versions)

A.

Change: The laboratory section of the project protocol will be changed to include sequencing. In the laboratory section the following statement is added: "Samples will also be used for pathogen sequencing, if specific pathogens are detected or if a cluster of illness occurs."

Rationale: Sequencing will allow the understanding of the prevalent variants of SARS-CoV-2 in circulation, garner insights into disease transmission, virulence, and antimicrobial resistance. The sequencing analysis also helps to track and identify the spread of the disease and forecast disease outbreaks.

- B. Change: The section enumerating the investigators and collaborators has been changed to reflect the roles of the individuals more adequately in the project.

Rationale: The investigators and collaborators are designated separately as their functions are more defined and the current designation is more indicative of their responsibilities.