NOTE: This is NCEZID's standard outline of most information required. Either a proposal following the outline provided below, or a protocol including information pertaining to all applicable elements is acceptable.

PROJECT TITLE: Enhanced Surveillance of Respiratory Illness Among People Experiencing Homelessness in Anchorage, Alaska

- **Principal Investigator(s):**
  - Jessica Ricaldi, MD, PhD, Health Department Section, COVID-19 STLT Task Force, Co-Principal Investigator
  - Emily Mosites PhD MPH, Office of the Deputy Director for Infectious Diseases, Co-Principal Investigator
  - Scott Santibañez MD, MPHTM, Division of Preparedness and Emerging Infections, CDC, Co-Principal Investigator
  - Mike Bruce MD, MPH, Director, Arctic Investigations Program Division of Preparedness and Emerging Infections CDC Co-Principal Investigator

- **Investigators & Collaborators:**
  - Brenna Simons-Petrusa PhD Laboratory Team Lead, Arctic Investigations Program Division of Preparedness and Emerging Infections CDC
  - Marc Fischer MD, MPH, Epi Team Lead, Arctic Investigations Program Division of Preparedness and Emerging Infections CDC
  - Dana Bruden Team Lead, Biostatistics and Information Management, Arctic Investigations Program Division of Preparedness and Emerging Infections CDC
  - Rieza Soelaeman PhD, MPH, Division of Preparedness and Emerging Infections, CDC
  - Joe McLaughlin, MD, MPH Alaska Department of Health and Social Services, Division of Public Health
  - Louisa Castrodale, DVM MPH Alaska Department of Health and Social Services, Division of Public Health
  - Anchorage Health Department
  - Brother Francis Shelter, Anchorage

- **Project Goals:**

The goal of this project is to inform respiratory infection control and vaccination practices for SARS-CoV-2, influenza, RSV and other respiratory infections in facilities where unhoused people are provided a place to stay in Anchorage, Alaska. The project would also facilitate data sharing between the facilities and the municipal health department. Findings from Anchorage will not be generalizable elsewhere. Anchorage could be considered a pilot site for other locations who choose to conduct similar enhanced surveillance projects in the future.

- **Project Objectives:**

The overall objective of this project is to assess respiratory illness etiology, course of illness, and vaccination status among adults staying in homeless shelters in Anchorage, Alaska. We will:

1. Estimate the 6-month cumulative incidence of respiratory illness and clinical course in ≥2 facilities in Anchorage, Alaska
2. Estimate the 6-month cumulative incidence of pathogen-specific symptomatic infection (RSV, influenza, and SARS-CoV-2) in ≥2 facilities in Anchorage, Alaska
3. Estimate the influenza and COVID-19 vaccination status among people seeking care for respiratory illness in ≥2 facilities in Anchorage, Alaska

- **Projected time frame for the project (clearly *indicate if urgent*):**

The following table outlines the major project milestones, as described in the project work plan.

MAJOR PROJECT MILESTONES	TIMELINE
Human Subjects Review	**September 1, 2022**
Sample collection	**October 2022 – March 2023**

- **Background:**

Residents of congregate living facilities such as homeless shelters are at risk for outbreaks of respiratory diseases, which can spread between facilities. For example, the risk of COVID-19 in homeless shelters has been well described (Bohannon, 2020; Culhane, 2020; Maxmen, 2020; Tsai, 2020). The point prevalence of SARS-CoV-2 in U.S. homeless shelters during outbreaks has been reported as high as 67% (Imbert et al., 2021). In a study assessing complications from COVID-19, persons experiencing homelessness were over twenty times more likely to be admitted to the hospital, over ten times more likely to require intensive care, and over five times more likely to die within twenty-one days of their first positive result (Richard et al., 2021).

However, the extent of understanding of the burden of disease varies widely by pathogen. Despite the availability of data on COVID-19, data are limited on other respiratory pathogens like influenza and respiratory syncytial virus (RSV) in these settings. A study from New York state assessed hospitalization for influenza among persons experiencing homelessness and found that 6.4% of all hospitalizations for influenza from 2007-2012 were among persons experiencing homelessness (Miyawaki et al., 2020). A single case-control study assessed homelessness among people hospitalized for RSV; 50 of the 157 (32%) people positive for RSV were experiencing homelessness (Boonyaratanakornkit et al., 2019).

This surveillance project focuses on congregate and non-congregate facilities in Anchorage, Alaska and will contribute to identifying the needs of people experiencing homelessness in this area. This activity would leverage partnerships between public health, health care and homeless services that have been newly strengthened or developed during the COVID-19 pandemic to understand the risk of other respiratory infections.

The local and state health department will provide situational awareness in the changing situation of services and housing available for people experiencing homelessness in Anchorage. We will leverage existing health department relationships with local partners. Additionally, data collected in this project will be shared with the local and state public health departments, for public health action.

- **Methods:**

A CDC co-PI (J. Ricaldi, MD, PhD) will oversee the project, in coordination with AIP. This will be done remotely, with 1-2 trips to Anchorage. Surveillance staff will consist of CDC FTEs and contractors. CDC DPEI will work through a contractor to hire 2-3 staff for lab support, data management, and coordination in Anchorage. The contractors will be supervised by the term FTE co-PI above, in coordination with AIP. Contract staff will work with site staff to coordinate logistics (e.g., samples, facilities, and incentives).

For the purpose of this activity, respiratory illness will be defined as: a new presentation of symptoms in the last week including one or more of the following: cough, sore or scratchy throat, runny or stuffy nose, increased trouble breathing, and or loss of taste or smell.

Individuals with respiratory illness will be identified through three possible avenues: care-seeking among symptomatic people at facility-based clinics, people who are experiencing respiratory symptoms at the time of COVID-19 screening

testing, or people experiencing symptoms who access a respiratory infection testing kiosk at two or more of the largest congregate and non-congregate shelter sites. This will include people experiencing homelessness who are adults 18 years or older who represent an array of ages, genders, racial/ethnic identities, sexual orientation, family composition (i.e., single individuals, partnered individuals, individuals with children under age 18), and experiences with homelessness (i.e., type and duration).

At the time of recruitment, the project team will request consent for participation. The project team will then collect a nasopharyngeal swab and complete a short symptom questionnaire with the participant.

Data regarding symptoms, course of illness, influenza and COVID-19 vaccination status, and demographics will be collected through interview, and chart reviews will be attempted if contact with healthcare services occurs. Charts may include local databases/logs, local reportable condition databases, electronic medical records (EMR), and/or review of other clinic records, if available. A standardized case report form (Appendix) will be completed using data obtained from the laboratory. All project participants will be assigned a project ID. Raw data obtained through laboratory testing, will be recorded to correspond with the project ID number.

Data Entry and Management

Sites (facility-based clinic, kiosk, or shelter site) will use a REDCap database that follows the case report form. Surveillance staff at each participating site will enter data from the case report form into the database and submit their data, stripped of identifiers, to the reporting database daily to weekly. Data will be collected via-password protected device (i.e., tablet, laptop), and stored on a secure, HIPAA-compliant server through REDCap. Any laboratory samples sent for testing or data sent for statistical analysis will use only the project ID. The link between participant name and project ID will only be accessible to senior staff through password protected files. Electronic data will be monitored regularly by project personnel and checked for data entry mistakes.

Neither the names of individual participants, nor information that could be used to identify participants, will appear on any report or publication resulting from this project. Data will be maintained on a secure server for 6 years after the project is complete. Any identifying information related to this specific protocol will be destroyed when data analysis is complete, manuscripts are written, and the project is closed. Data cannot be released publicly.

Laboratory

Multi-pathogen testing will be performed using a multi-pathogen assay. The CDC AIP lab will perform batched testing on a bi-weekly or monthly basis. Results will not be available in real time to the clinician or onto the medical record (i.e. sites would still need to collect and additional sample for rapid or other clinical testing if needed for immediate decision-making.) Findings would be provided in aggregate (e.g. summary report) to the shelter, municipality, etc. AIP lab will not maintain any identifiers connecting data collected to any particular respondent. Neither will it provide any personal identifiers to others at CDC.

Left over samples will be banked, using the project ID, for the duration of the project and may be used to test for a broader array of pathogens, including Group A Streptococcus, or other respiratory pathogens not included in the initial panel. Left over samples will be destroyed at the end of the project.

Data Analysis Plan

We will calculate incidence of respiratory illness and pathogen-specific infection using monthly census counts of individuals staying in the facilities. Age-specific rates will be calculated using population denominators and facility census counts in the surveillance area. Interim analyses of aggregate data will be conducted periodically throughout the active surveillance to assess data quality. We intend to compare rates and etiologic proportions between certain subgroups, such as those staying in non-congregate shelter compared to those staying in congregate shelter and different age groups. Data abstracted from laboratory testing will be categorized and compared. We will report on the following:

- cumulative incidence of respiratory illness
- pathogen-specific infection
- risk factors for those who developed disease

We anticipate collecting up to 800 swabs, which will provide sufficient power to detect a risk ratio of at least 2 when comparing people within congregate and non-congregate shelters.

Data will be entered into a REDCap database and managed in SAS. Analysis will be performed using SAS, Stata, and excel. No participant identifiers will be included at the data analysis stage.

Ethical considerations:

The risks for this project are minimal. The primary human subjects contact for this surveillance activity is a nasopharyngeal swab, which may cause temporary discomfort, and a short survey. Enhanced surveillance data will be obtained from medical record review only, if available. No treatments, medications, vaccines or interventions will be administered. Staff will specifically inform potential individuals that their choice whether or not to participate will not affect their clinical care or access to other services. There is no direct benefit to people participating. The project results and additional information will not be shared individually with patients. The persons who might benefit from the project participant's experience are other members of the community of people experiencing homelessness in Anchorage. We anticipate that data obtained will benefit people who utilize facilities available to people experiencing homelessness in Anchorage Alaska by identifying information to improve respiratory infection control and vaccination practices. This will occur as aggregated data (from which individuals cannot be identified) and results are made publicly available as quickly as possible, as the circumstances dictate.

Informed Consent

Informed, written consent will be obtained from participants (Appendix.) All project staff will be trained in administering informed consent. The staff will keep a log of eligible participants, but further data collection or procedures would not occur unless the individual signs an informed consent to participate. Before obtaining specimens, staff will inform potential participants of their rights, and that their participation is voluntary. The interviewer will emphasize to participants that they may choose not to participate or leave at any time without retaliation (i.e. losing access to any services offered by the partner site). As part of the consent, participants will be told that the results of the project will not provide any direct benefit to them. Samples will not be obtained for anyone who declines to give consent.

If the participant is interested in participating, staff will have the participant sign and date the consent form and a release of medical information form to allow medical record review. The participants will be asked to consent to a multiplexed nucleic acid test.
The participant will be given a copy of the consent form. All participant forms will be kept in a locked filing cabinet. Only authorized staff will have access to the filing cabinet.

Tokens of Appreciation

Alaska state and local public health officials indicated that the homeless population in Anchorage expects compensation/incentive for participating in public efforts. The officials stated that compensation/incentives are viewed by persons experiencing homelessness as a sign of respect for them and their time. Therefore, all interventions by state and local health officials involving persons experiencing homelessness have involved the provision of incentives to thank them for their time and effort. Based on state and local health officials' strong recommendation that we compensate persons who participate in this activity for their time and the discomfort a nasopharingeal swab may entail, we propose to offer an incentive ($25 value) of in the form of a gift card as a token of appreciation.

Enhanced surveillance will include People Experiencing Homelessness who are adults 18 years or older who represent an array of ages, genders, racial/ethnic identities, sexual orientation, family composition (i.e., single individuals, partnered individuals, individuals with children under age 18), and experiences with homelessness (i.e., type and duration).

Findings will be shared with the facilities to support public health interventions following the surveillance period. The investigators plan to communicate the results of this project at scientific meetings and in publications. All publications related to this project must complete the CDC Clearance process.

This project is part of the public health response to COVID-19 and qualifies for a COVID-19 related OMB review waiver.

We will submit a request for a non-research determination. Findings from Anchorage will not be generalizable elsewhere.

Protection of Privacy and Confidentiality

CDC will receive only coded data/specimens and will not have access to directly identifiable information or biospecimens.

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3. Maxmen A. Coronavirus is spreading under the radar in US homeless shelters. Nature. 2020;581(7807):139-130. https://doi.org/10.1038/d41586-020-01389-3
4. Tsai, J., & Wilson M. COVID-19: A potential public health problem for homeless populations. Lancet, Public Heal. 2020;5(4):186-187. https://doi.org/10.1016/S2468-2667(20)30053-0
5. Imbert et al., 2021
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INFORMED CONSENT

Enhanced Surveillance of Respiratory Illness Among People Experiencing Homelessness in Anchorage, Alaska

INTRODUCTION: This form is to tell you about an activity you can take part in. This public health surveillance project is being done by local partners including XXXX and the Centers for Disease Control and Prevention (CDC). After you finish reading this consent form, we will answer any questions you may have.

PURPOSE OF THIS ACTIVITY:

The goal of this project is to understand what microorganisms (viruses or bacteria) cause respiratory illnesses among people experiencing homelessness in Anchorage, how their living conditions could affect their risk of getting respiratory illnesses, and how these could be prevented.

WHAT THIS ACTIVITY INVOLVES:

Sample and information collection

The project nurse will collect a nasopharyngeal sample (back of your nose) with a swab, to be able to test for multiple microorganisms, including COVID-19, that may be causing the symptoms you currently have. You may have had a similar sample collected if you have been previously tested for the virus that causes COVID-19. The nurse will also ask you about information related to your health and your symptoms.

RISKS AND DISCOMFORTS

We do not expect any serious side effects from the nasopharyngeal sample, only maybe some discomfort while the sample is being collected. Your medical care will not be affected by participating or not participating in this activity. We will use an identification number rather than your name or other personal information on all the information and samples we have related to you in this project. That means that if someone sees the information, they will not know it came from you. When we present the information from this activity, we would never use your name.

Benefits of Participation

This project probably will not benefit you directly. This project will help us learn more about respiratory diseases in people experiencing homelessness in Anchorage and find ways to protect them. You will not get

individual test results. The testing is done many months after your illness. However, data from this project will be shared with medical providers. This project may help providers learn ###.

ACTIVITY DURATION

This project will continue until March of 2023. Signing the consent form for this project does not obligate you in any way for future project procedures. You are able to withdraw from participation at any time.

REIMBURSEMENT FOR TIME:

Reimbursement will be provided for your time and for providing a sample during your visit. You will receive a reimbursement of $25 in a gift card.

CONDITIONS OF THE ACTIVITY:

Taking part in this project is voluntary. You may take yourself out of the project at any time without losing care or services. By signing this consent form and agreeing to be in this project you are not giving up any of your rights. You might be contacted in the future to see if you want to participate in a similar project. If you have any questions about this project or if you are concerned about this project, you may contact the investigators, #### by calling 1-800-699-0767 toll free or 907-729-3400. If you think that you have not been treated fairly, or have been hurt by joining the project, or you have questions about your rights in this project, please contact the Alaska Area IRB Administrator (Terry Powell) at 907-729-3924, (collect calls accepted) or by email: akaalaskaareaIRB@anthc.org of the Alaska Area Institutional Review Board (IRB).

APPROVAL: I have read or was told about this project and all of my questions have been answered to my satisfaction. I have been offered a copy of this consent. I agree to be in the project and to:

☐ Nasopharyngeal sample collection, testing for viral and bacterial pathogens

Name of Participant: _____ Date of Birth: _____

X_____ _____

Signature Date