Request for Approval Under the Generic Clearance for Emergency Epidemic Investigation Data Collections (0920-1011)

Instruction: This form should be completed by the primary contact person from the CDC CIO that will be sponsoring the investigation.

Determine if your investigation is appropriate for this Generic mechanism: *Instruction: Before completing and submitting this form, determine first if the proposed investigation is appropriate for the EEI Generic ICR mechanism. Complete the checklist below. If you select "yes" to all criteria in Column A, the EEI Generic IR mechanism can be used. If you select "yes" to any criterion in Column B, the EEI Generic ICR mechanism cannot be used.*

Column A	**Column B**
CDC epidemiological assistance is requested by one or more external partners (e.g., local, state, tribal, military, port, other federal agency, or international health authority or other partner organization). ☒ Yes ☐ No	The Investigation is initiated by CDC, without request from an external partner. ☐ Yes ☒ No
The investigation is urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce injury, disease, or death). ☒ Yes ☐ No	The investigation is not urgent in nature. ☐ Yes ☒ No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. ☒ Yes ☐ No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. ☐ Yes ☒ No
One or more CDC staff (including trainees and fellows) will be deployed to the field. ☒ Yes ☐ No	CDC staff (including trainees or fellows) are not deployed to the field. ☐ Yes ☒ No
Data collection will be completed in 90 days or less. ☒ Yes ☐ No	Data collection expected to require greater than 90 days. ☐ Yes ☒ No

Did you select "Yes" to ***all*** criteria in Column A?

If yes, the EEI Generic ICR may be appropriate for your investigation. → You may proceed with this form.

Did you select "Yes" to ***any*** criterion in Column B?

If yes, the EEI Generic ICR is not appropriate for your investigation. → Stop completing this form now.

GenIC # 2020004 - XXX **Date** 05/07/2020

Title of Investigation: *Instruction: Provide the title of the investigation in the following format: [Undetermined agent, undetermined source, undetermined mode of transmission, undetermined risk factor] for [disease/problem] among [subpopulation]—[State], [Year]*

Investigation of SARS-CoV-2 transmission in a jail—Louisiana, 2020

Location of Investigation: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State:	Louisiana
City/County (if applicable)	Franklin Parish
Country	USA

Requesting Agency: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency:	Louisiana Department of Health
Name and Position Title:	Theresa Sokol, Interim State Epidemiologist

Note: Attach the Letter of Invitation requesting support. The letter should include the following information: 1) background on the outbreak or event; 2) steps already taken toward prevention and control, if any; 3) request for CDC assistance, including objectives of the investigation; and 4) how data will be used to inform prevention and control measures. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.

Description of Investigation

1. Problem to be Investigated: *Instruction: Provide a summary of the outbreak or event. The summary should include all the information you know at this time about the outbreak or event and the investigation that is planned. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event, including a justification of the need for an investigation and why this issue requires an urgent response; 2) the objectives of the investigation, including how the information collected will be used to inform prevention and control measures; and 3) a brief overview of the investigation planned, including study design, respondents, mode of data collection. In the description, indicate whether a data collection instrument is attached with the GenIC request (refer to as Appendix 1, etc) and what instruments will be developed in the field. (suggested length: 250-500 words).*

Louisiana Department of Health requested epidemiologic assistance to investigate an outbreak of SARS-CoV-2 at a jail that has ~700 detainees. The first case in a detainee reported April 9. Since the first case was detected, 35 cases have been identified in detainees, and 6 in staff.

During a COVID-19 outbreak investigation in another type of congregate setting (i.e., a skilled nursing facility), over half of cases identified through facility-wide testing were asymptomatic and likely contributed to transmission within the facility; symptom screening alone may be inadequate to promptly identify and isolate case-patients. Findings will inform how the virus is spread, including the extent of pre-symptomatic and asymptomatic infection and potential role in transmission. Findings can inform medical isolation and quarantine policies for congregate settings and the general public, including the role of testing and symptom assessment.

This investigation aims to assess transmission of SARS-CoV-2, the virus that causes COVID-19,

in a correctional facility. Specifically, our current objectives are:

a. To estimate the prevalence of SARS-CoV-2 and/or COVID-19 infection in dorms where a confirmed positive individual had been living.
b. To assess utility of repeat testing to capture additional asymptomatic shedding among contacts from units where a confirmed positive individual had been living.
c. To identify factors associated with transmission.
d. To investigate the extent of transmission during pre-symptomatic and asymptomatic infection.

Public health implications: Implement additional prevention measures where needed and protect populations who may be at increased risk of infection; inform medical isolation and quarantine procedures, including the role of testing and symptom assessment in 1) identifying case-patients who are asymptomatic or with atypical symptoms for medical isolation, and 2) determining when to end quarantine to prevent the early return of case-patients who are asymptomatic or with atypical symptoms while contagious.

We will work with correctional/detention facility staff to identify units (i.e., housing unit or dorm for detained/incarcerated persons) recently placed on quarantine due to identification of a detainee confirmed positive for SARS-CoV-2 (i.e. index patient). Upon identification of a unit being placed under quarantine, the investigation team, in conjunction with the local health departments, and with the assistance of facility health staff and other stakeholders (e.g., Department of Corrections (DOC) Sheriff's Department), will approach all individuals housed on the unit to participate in this investigation. This will occur in addition to ongoing infection control measures and public health response activities already in place at the facility based on recommendations provided by local health departments and according to CDC interim guidance for the management of COVID-19 in correctional and detention facilities (https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/guidance-correctional-detention.html).

This EEI GenIC requests OMB approval for the following forms:

1. Facility assessment (Appendix 1), to assess facility and housing unit-level activities, practices, and layout.
2. Survey Day 0 (Appendix 2). This form assesses symptoms, risk factors for transmission, social distancing practices, use of personal protective equipment, and cleaning processes. It will be completed by consenting participants the same day of testing on investigation day 0.
3. Survey Day 3-4 (Appendix 3). At a second point in time, day 3 or 4, testing for SARS-CoV-2 will be performed again for a cohort of consenting persons who had negative test results (PCR) at enrollment to detect any asymptomatic individuals positive for SARS-CoV-2. Consenting persons will be asked to complete this brief symptom assessment. These individuals who test positive for SARS-CoV-2 will also be isolated and/or re-housed in accordance with current practices at the facility.
4. Survey Day 14 (Appendix 4). At a third point in time, day 14, testing for SARS-CoV-2 will be performed for a cohort of consenting persons who remain in quarantine (asymptomatic, negative PCR test results at day 3 or 4) to detect any asymptomatic individuals positive for SARS-CoV-2. Consenting persons will be asked to complete this brief survey.
5. Louisiana Department of Health Test Request form (Appendix 5). Specimen collection materials will be provided by CDC. The investigation team will collect specimens from each participant at enrollment and at pre-determined intervals following enrollment (e.g., day 3 or 4). We will follow CDC guidance on the recommended sample collection type and approach, which is currently nasopharyngeal (NP) swabs for asymptomatic persons. Viral testing by RT-PCR may be completed at the participating state public health lab,

local healthcare facilities as coordinated by the local health department, or CDC lab, depending on personnel, resources, and current outbreak situation.

Following is the specimen and data collection schema:

Time point	Enrollment (Day 0 or 1)	Day 3 or 4	Interim*	Day 14
Occurrence	ASAP after placement of unit on quarantine	3–4 days following initial swab collection for individuals initially testing negative.	As occurs (contacts with symptoms identified)	At the end of quarantine
Testing*	Collection of specimen (swab) for RT-PCR	Collection of specimen (swab) for RT-PCR	Collection of specimen (swab) for RT-PCR	Collection of specimen (swab) for RT-PCR
Data Collection	Survey for cases and close contacts	Symptom assessment	According to facility health services protocols	Survey for all contacts

* If a detainee develops symptoms during the investigation period, they will be evaluated, tested, and placed in isolation as per facility protocol.

2. Characteristics of Outbreak or Event (Check all that Apply):

- ☐ Undetermined agent
- ☐ Undetermined source
- ☒ Undetermined mode of transmission
- ☒ Undetermined risk factor

3. Respondents: *Instruction: Select all that apply. For each respondent type selected, provide a brief description. Be sure to include a description of control respondents, if applicable. Use as much space as necessary for each description.*

- ☐ General public (describe):
- ☐ Healthcare staff (describe):
- ☐ Laboratory staff (describe):
- ☐ Patients (describe):
- ☐ Restaurant staff (describe):
- ☒ Other (describe): Correctional facility staff; Incarcerated/detained persons

4. Selection of Respondents: *Instruction: Provide a brief description of how respondents will be identified and selected. Use as much space as necessary for the description.*

Appendix 1: We will complete a facility assessment through discussions with facility staff. Appendices 2, 3, 4, & 5: At each facility, we will conduct a point prevalence survey (brief survey and laboratory testing for SARS-CoV-2) among a purposeful sample of contacts (detainees) in a housing unit as soon as a new case(s) is identified in the correctional facility (or unit).

5. Study Design: *Instruction: Select all that apply. For each study design planned, provide a brief description. Use as much space as necessary for the description.*

☒ Epidemiologic Study (indicate which type(s) below)

☒ Descriptive Study (describe):

Descriptive epidemiology of the outbreak at the facility using jail linelist, medical records, and jail records (including movement of facility staff for work shifts and movement of persons who are detained). (Appendix 1, 2, 3, 4)

☐ Cross-sectional Study (describe):

☒ Cohort Study (describe):

Testing (PCR and viral culture for SARS-CoV-2) (Appendix 5) and survey (Appendix 2, 3, & 4) among sample of detainees who stay in selected housing units. Units will be selected based on where new cases have been identified and isolated; the remaining detainees will have been placed under 14 quarantine.

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

CDC team will collect NP swabs from contacts and send to local labs for testing for SARS-CoV-2 (RT-PCT, viral culture) (Appendix 5).

☐ Other (describe):

6. Data Collection Mode: *Instruction: Select all that apply. For each data collection mode planned, provide a brief description. Use as much space as necessary for the description.*

☒ Survey Mode (indicate which mode(s) below):

☒ Face-to-face Interview (describe):

CDC staff will administer a brief interview to detainees and facility staff (Appendix 1, 2, 3, & 4).

☐ Telephone Interview (describe):

☒ Self-administered Paper-and-Pencil Questionnaire (describe):

CDC staff may distribute paper surveys to detainees for completion. CDC staff will then review the paper forms with each detainee and administer to those with low literacy (Appendix 2, 3 &4)

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

PCT lab test results will be sent to the jail (paper record, phone communication for positives) and linked to the survey data using a unique identification number (Appendix 5).

☒ Biological Specimen Sample

We will follow a cohort of cases and high-risk contacts with discrete exposures to cases during pre-symptomatic period and collect nasopharyngeal (NP) swabs for testing (PCR) to detect SARS-CoV-2 at several intervals (minimum: day 0, day 3 or 4, day 14). (Appendix 5)

☐ Environmental Sample:

☐ Other (describe):

7. Type of Information to be Collected: *Instruction: Select all that apply. For each type of information to be collected, provide a brief description. Use as much space as necessary for the description.*

☒ Behaviors (describe):

Handwashing behavior, mask wearing, movement and activities in the facility (for example, using a shared computer, travel in a care, sharing eating utensils), being handcuffed or handcuffing someone (Appendix 1, 2, 4)

☒ Clinical information/symptoms (describe):

Height, weight, symptoms (fever, chills, myalgia, rhinorrhea, nasal congestion, sore throat, cough, shortness of breath, abdominal pain, diarrhea, nausea, vomiting, headache, loss of taste or smell) (Appendix 2, 3, 4)

☒ Contact information (describe):

Jail housing unit (where detained stayed, where staff work) (Appendix 1, 2, 4)

☒ Demographic information (describe):

Age, ethnicity, race, sex; name and date of birth (not included in the electronic database) (Appendix 2, 3, 4)

☒ Environmental factors (describe):

Facility layout such as number of bathrooms per staff or per person detained; number of beds/persons sleeping per unit, ventilation and windows (Appendix 1)

☒ Exposures (describe):

Close contact (< 6 feet) with other people in the facility (Appendix 1, 2, 3, 4)

☒ Medical history (describe):

chronic lung disease, diabetes, cardiovascular, renal disease, liver disease, non-cancer immunosuppressive condition or therapy, cancer chemotherapy, neurologic/neurodevelopmental disorder, other chronic diseases, medication use (Appendix 2)

☒ Risk factors (describe):

Smoking history (Appendix 2)

☒ Specimen/lab information (describe):

Testing history for SARS-CoV-2; nasopharyngeal swab for RT-PCR testing for SARS-CoV-2 and viral culture (Appendix 5)

☐ Travel history (describe):

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
6 weeks

Research Determination: *Instruction: Indicate the research determination decision. If the decision is research, provide the research determination letter and IRB approval, if required.*

☐ Research ☒ Not Research

CDC Investigation Lead: *Instruction: Indicate the name, title, and affiliation of the person who will serve as the CDC lead for this investigation.*

Name:	Katie Curran
Title:	Epidemiologist
Affiliation:	COVID-19 Epidemiology Task Force / Epidemiology Field Studies Team

CDC Sponsoring Program and Primary Contact Person: *Instruction: Indicate the sponsoring CIO/Division/Branch for this investigation. Indicate the name, title, and contact information of the CDC Primary Contact Person for this investigation. Indicate the preferred method of contact during the OMB approval process. Note, contact person or a designee must be available during the OMB approval process in case questions arise.*

CIO/Division/Branch:	NCIRD / COVID Response / Epi Task Force / Epi Field Studies Team
Name:	Katie Curran
Title:	Epidemiologist

Certification: *Please read the certification carefully. Type your name to validate that you are providing certification. Note: If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved. Certification should be signed by the CDC Primary Contact Person for this Investigation.*

I, [insert name of CDC sponsoring program contact], certify the following to be true:
1. The collection is voluntary.
2. Respondents will not be personally identified in any published reports of the study.
3. Information gathered will be primarily used to inform effective prevention and control measures.

CDC Sponsoring Program Primary Contact Name:	Katie Curran
Date of Certification:	5/07/2020

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*
5/07/2020

E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program ICRL designee.