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 # 2016012 - XXX **Date** 03/18/2016

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]*

Undetermined source, mode of transmission, and risk factors for an outbreak of group A *Streptococcus* among residents of a long term care facility — Chicago, Illinois, 2016

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

State:	Illinois
City/County (if applicable)	Chicago
Country	United States

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

Agency:	Illinois Department of Public Health
Name and Position Title:	Connie Austin, 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).*

The Chicago Department of Public Health has identified a cluster of group A streptococcal infections in a long term care facility in Chicago, IL. These infections were first identified in August, 2015 and have resulted in confirmed disease in nine residents (five residents with invasive and four with non-invasive infections). The latest positive cultures were obtained on March 6 and 9, 2016. Screening cultures were taken from staff (n=354) and residents (n=158) in December 2015 and January 2016; three staff were identified to have asymptomatic throat colonization. Isolates recovered from the residents had the same *emm* type (*emm* 87) which differed from employee isolates. Despite improved infection control measures and antibiotic prophylaxis provided to the facility's wound care team, cases continue to occur at the facility. The Chicago Department of Public Health and Illinois Department of Health have requested assistance to determine ongoing sources of infection, risk factors for disease, and recommendations to stop transmission. To evaluate the causes and extent of the ongoing group A *Streptococcus* outbreak,

including risk factors for carriage and infection among residents and staff the following investigation is planned:

1. To evaluate the causes and extent of the ongoing group A *Streptococcus* outbreak, including risk factors for carriage and disease among residents.
2. To assess current infection control practices and provide recommendations for enhanced control to halt further spread of group A *Streptococcus* in the facility. Infection control practices at the facility will be assessed by Federal staff directly observing practices in the facility; OMB approval not requested for this component.
3. To identify other measures for disease control which may include performing additional screening for group A streptococcal carriage and implementation of antibiotic treatment to protect facility residents and staff.

The planned investigation will involve review of the medical records of residents of the facility (Appendix 2) and administering a questionnaire to the employees of the facility (Appendix 1) and wound care team staff (Appendix 3). Data collection will focus on obtaining information on a) epidemiology of those who have tested positive, b) finding additional infected individuals who might be acting as sources of infection, c) characterizing when and where transmission might have occurred.

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):
  Employees and wound care team staff will complete a questionnaire to assess risk factors for infection with group A *Streptococcus*, their infection control practices, and possibility of household contacts who are infected with group A *Streptococcus* (Appendices 1 and 3).
- ☐ Laboratory staff (describe):
- ☒ Patients (describe):
  The investigation team will perform medical chart abstraction for select residents for case-control study. Some residents might also have further laboratory testing done with results recorded on Appendix 2.
- ☐ Restaurant staff (describe):
- ☒ Other (describe):
  Federal, state, and facility staff will assist with medical record abstraction (Appendix 2)

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.*

All staff of the facility who come in contact with the patients or could be potential sources of group A *Streptococcus* transmission at the facility will be asked to complete a questionnaire (Appendices 1 and 3).

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):

To describe the epidemiology of the outbreak, risk factors for infection, and assess the infection control practices at the facility to provide recommendations leading to the control of the outbreak.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☒ Case-Control Study (describe):

Perform a case-control study to determine various risk factors for group A streptococcal disease among the residents of the facility

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

Isolates of group A *Streptococcus* from the facility residents and staff will be forwarded to CDC Streptococcus Laboratory for molecular typing following local procedures. Clinical specimens will be collected and processed by the facility itself as part of routine clinical care and infection control practices.

☐ 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):

☐ Telephone Interview (describe):

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

Staff of the facility who come in contact with the patients or could be potential sources of group A *Streptococcus* transmission at the facility will be asked to complete a questionnaire (Appendices 1 and 3)

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Medical records of residents will be abstracted to characterize the epidemiology of the outbreak and determining the risk factors and possible sources transmission (Appendix 2).

☒ Biological Specimen Sample

Group A streptococcal isolates from either residents or staff of the facility will be forwarded by the Illinois Department of Public Health to the Streptococcus Laboratory at CDC for molecular typing following local procedures for collection and transport (results to be listed on Appendix 2).

☐ 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):

Questions regarding work practices in the context of risk of spreading group A *Streptococcus* infections (Appendices 1 and 3)

☒ Clinical information/symptoms (describe):

Description of symptoms and signs that will help identify and characterize the risk factors for group A *Streptococcus* infection (Appendix 2)

☐ Contact information (describe):

☒ Demographic information (describe):

Age, sex, profession (Appendices 1 and 3)

☒ Environmental factors (describe):

Description of rooms and wards that residents resided or employees worked in will characterize locations of cases and possible contacts (Appendix 2)

☒ Exposures (describe):

Assess routes of transmission from persons with possible group A *Streptococcus* infections (Appendices 1 and 3)

☒ Medical history (describe):

Group A *Streptococcus* infections in the recent past (Appendix 1)

☒ Risk factors (describe):

Health care staff and wound care team at the facility were asked about their work practices, policies, and wound management (Appendices 1 and 3).

☒ Specimen/lab information (describe):

Previous throat and wound culture results will be obtained from medical charts (Appendix 2)

☐ Travel history (describe):

☐ Other (describe):

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

2 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:	Chris Van Beneden
Title:	Medical Epidemiologist
Affiliation:	CDC/NCIRD/DBD/RDB

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:	CDC/NCIRD/DBD/RDB
Name:	Chris Van Beneden
Title:	Medical 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, Chris Van Beneden, 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:	Chris Van Beneden
Date of Certification:	3/18/16

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

3/21/16

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

EEI Information Collection Request Liaison:
Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
EWB/DSEPD/CDC
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