

**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). <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	The Investigation is initiated by CDC, without request from an external partner. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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). <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	The investigation is not urgent in nature. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
One or more CDC staff (including trainees and fellows) will be deployed to the field. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	CDC staff (including trainees or fellows) are not deployed to the field. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Data collection will be completed in 90 days or less. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Data collection expected to require greater than 90 days. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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 # - Date

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]*

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

State:
 City/County (if applicable)
 Country

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

Agency:
 Name and Position Title:

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 Illinois Department of Public Health has identified a cluster of Group A *Streptococcus* cases in a long term care facility in Sangamon county, Illinois. These infections began in February, 2015 and have resulted in 69 group A streptococcal positive individuals since that time. There have been 12 invasive cases in residents with 4 deaths. Despite infection control measures implemented by the facility, screening cultures and implementation of mass treatment, invasive group A streptococcal infections continue to occur. The latest positive culture was on October 26. The Illinois Department of Health is requesting assistance with the following objectives:

1. To evaluate the causes and extent of the ongoing Group A *Streptococcus* outbreak, including risk factors for carriage and infection among residents and staff.
2. To assess current infection control practices and provide recommendations for enhanced control to halt further spread of Group A *Streptococcus* in the facility.
3. To identify other measures and actions to control the outbreak which may include,

performing additional screening for Group A Streptococcal carriage, assessing Group A *Streptococcus* disease incidence in the community, and implementing treatment to protect facility residents and staff.

The planned investigation will involve review of the medical records of residents of the facility (Appendix 1) and administering a questionnaire to the employees of the facility (Appendix 2). If requested by the state, medical records of patients at the local hospitals with invasive Group A streptococcal disease also will be abstracted using the same medical record abstraction form (Appendix 1). Data collection will focus on getting 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. Infection control practices at the facility will be assessed by federal staff directly observing practices in the facility.

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 will complete a questionnaire to assess possibility of being infected with Group A Streptococcus, their infection control practices and possibility of household contacts who are infected with Group A Streptococcus (Appendix 2)

Laboratory staff (describe):

Patients (describe):

Restaurant staff (describe):

Other (describe):

Federal, state, and facility staff will assist with medical record abstraction (Appendix 1)

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 selected for completing a questionnaire (Appendix 2).

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, 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):

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 requested to complete a questionnaire.

Self-administered Internet Questionnaire (describe):

Other (describe):

Infection control practices at the facility will be assessed by federal staff directly observing practices in the facility

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. If requested by the state, medical records of patients at the local hospital with invasive Group A streptococcal disease will be abstracted using the same medical record abstraction form.

Biological Specimen Sample

Group A Streptococcus 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.

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 (Appendix 2)

Clinical information/symptoms (describe):

Description of symptoms and physical signs that will help identify and characterize the risk factors for Group A Streptococcus infection (Appendix 1)

Contact information (describe):

Demographic information (describe):

Age, sex, profession (Appendix 2)

Environmental factors (describe):

Exposures (describe):

Person to person, household contacts with possible Group A Streptococcus infections (Appendix 2)

Medical history (describe):

Group A Streptococcus infections in the recent past (Appendix 2)

Risk factors (describe):

Specimen/lab information (describe):

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:

Title:

Affiliation:

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:

Name:

Title:

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:

Date of Certification:

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

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

EEI Information Collection Request Liaison:

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