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 # 201601 8 - XXX **Date** 06/13/2016

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 and risk factors for botulism among prisoners at a correctional facility — Mississippi, 2016

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

State:	Mississippi; Oklahoma; Bureau of Prison Facilities
City/County (if applicable)	
Country	United States

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

Agency:	Mississippi State Department of Health
Name and Position Title:	Thomas Dobbs, 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).*

On June 9, 2016, the Mississippi Department of Health notified the CDC botulism consultation service regarding a suspected outbreak of botulism at a single federal correctional institution. Preliminary information suggests that the affected inmates consumed pruno, also known as prison wine. The pruno was distributed among an undetermined number of inmates starting June 5th.

As of June 13th, there are 16 suspected cases in Jackson, MS, and 1 suspected case in Oklahoma City, OK (this patient was transferred to a BOP facility in OK after consuming the pruno). All patients are adult males, and most are severely ill, with 9 patients progressing to respiratory failure and requiring intubation/mechanical ventilation. The correctional institution is screening for additional cases of illness. Overall, this is suspected to be the largest outbreak of botulism potentially associated with pruno in a correctional institution.

The Mississippi Department of Health (MDH) has requested assistance with investigating the scope and identifying the source of the outbreak, determining risk factors for illness, and developing public health recommendations to prevent future outbreaks.

The Epi Aid team members and MDH staff members will interview case patients and inmates at risk for illness using Appendix 1. Interview Questionnaire.

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): Healthcare staff familiar with case patients' medical history
- ☐ Laboratory staff (describe):
- ☒ Patients (describe): Case patients from prison facility
- ☐ Restaurant staff (describe):
- ☒ Other (describe): Prison inmates who are at risk for becoming ill

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 prison inmates who exhibit symptoms consistent with botulism or who are at risk for botulism will be interviewed. For inmates who are too ill to respond, data will be collected via a proxy (e.g., another inmate, a family member, or a clinician who is providing medical care to patient).

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): Case patients and inmates at risk for infection will be interviewed to identify exposures, risk factors for illness, and relevant symptoms.
  - ☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

CDC routinely performs botulism testing on serum and stool for suspected cases of botulism in many states, including Mississippi and Oklahoma. As part of this investigation, CDC will perform testing for the suspected cases in both states when requested by local health authorities.

☐ 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):

The questionnaire will be administered via face-to-face interview

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample

☐ 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):

☒ Clinical information/symptoms (describe):
Interview questions will address exposures, risk factors for illness, and relevant symptoms.

☐ Contact information (describe):

☒ Demographic information (describe):
Data on respondent age, sex, and race/ethnicity will be collected.

☐ Environmental factors (describe):

☒ Exposures (describe):
Data on exposure risk factors, such as source and location of food and beverage, pruno consumption, and prison duties, will be collected.

☒ Medical history (describe):
Data on clinical symptoms will be collected.

☒ Risk factors (describe):
See exposures

☒ Specimen/lab information (describe):
Serum and stool collected as part of routine medical care of suspected botulism cases.

☐ 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:	Kevin Chatham-Stephens
Title:	Medical Officer
Affiliation:	CDC/NCEZID/EDEB

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:	NCEZID/DFWED/EDEB
Name:	Kevin Chatham-Stephens
Title:	Medical Officer

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:	Kevin Chatham-Stephens
Date of Certification:	06/13/2016

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*
6/14/2016

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