**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).<br>☒ Yes ☐ No | The Investigation is initiated by CDC, without request from an external partner.<br>☐ 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).<br>☒ Yes ☐ No | The investigation is not urgent in nature.<br>☐ Yes ☒ No |
| The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors.<br>☒ Yes ☐ No | The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge.<br>☐ Yes ☒ No |
| One or more CDC staff (including trainees and fellows) will be deployed to the field.<br>☒ Yes ☐ No | CDC staff (including trainees or fellows) are not deployed to the field.<br>☐ Yes ☒ No |
| Data collection will be completed in 90 days or less.<br>☒ Yes ☐ No | Data collection expected to require greater than 90 days.<br>☐ 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 #** 2016014 - XXX **Date** March 24, 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 risk factors for E.coli O157 among visitors to a goat dairy--Connecticut, 2016

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

| | |
|---|---|
| State: | Connecticut |
| 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: | Connecticut Department of Public Health |
| Name and Position Title: | Matt Cartter, State Epidemiologist & Director of Infectious Diseases |

*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 Connecticut Department of Public Health contacted the CDC Outbreak Response and Prevention Branch Chief, Ian Williams, on March 24, 2016 to request assistance regarding an outbreak of shiga toxin-producing *E. coli* O157 infections among visitors to a goat farm located in Lebanon, CT.

As of March 24, 2016, seven confirmed cases of *E.coli* and two cases of Hemolytic Uremic Syndrome (HUS) have been reported. Patients sickened in this outbreak range in age from 2 to 25 years. The Department of Public Health has confirmed that six of the seven patients recently visited a goat farm in Lebanon, CT which held two public events where there was close contact between goats and the public. As a precaution, the goat farm is currently not permitting the public to visit the animals. Additional case-finding is ongoing.

The Connecticut Department of Public Health has requested assistance with investigating risk

factors for *E. coli* O157 infection at this event, identifying potential environmental exposures, and developing public health recommendations to prevent future transmission. Interviews (Appendix 1) will be conducted among visitors of the dairy farm during recent festival events to determine case status and risk factors for infection.

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): Visitors to the goat dairy farm
- ☐ Healthcare staff (describe):
- ☐ Laboratory staff (describe):
- ☐ Patients (describe):
- ☐ Restaurant staff (describe):
- ☐ Other (describe):

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.*

Respondents will be selected based on ticket sales for events held at the goat dairy

*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):
  - ☐ Cross-sectional Study (describe):
  - ☒ Cohort Study (describe): A cohort study will be conducted among visitors to the goat dairy
  - ☐ Case-Control Study (describe):
  - ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ 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):

A telephone interview will be conducted using a standardized questionnaire to query visitors to the goat dairy about activities and exposures.

☐ 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):

Information will be collected regarding nausea, vomiting, diarrhea, bloody diarrhea, headache, and fatigue

☐ Contact information (describe):

☒ Demographic information (describe):

Name, DOB, age, race/ethnicity, sex and occupation

☐ Environmental factors (describe):

☒ Exposures (describe):
Feeding/holding/petting/kissing/hugging goats

☐ Medical history (describe):

☒ Risk factors (describe):
Hands in mouth/touching railings/eating food in goat area/biting nails/eating at the farm

☐ Specimen/lab information (describe):

☐ Travel history (describe):

☐ Other (describe):

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

**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: | Kelly Gambino Shirley |
| Title: | EIS Officer |
| Affiliation: | Outbreak Response and Prevention Branch |

**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/ORPB |
| Name: | Megin Nichols |
| Title: | Enteric Zoonoses Lead |

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**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: | Megin Nichols |
| Date of Certification: | March 24, 2016 |

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

March 25, 2016

**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
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

For internal use. Do not complete.

| | |
|---|---|
| Date/Time initial GenIC received by ICRL | |
| Date/Time final GenIC received by ICRL | |
| Date/Time submitted to OMB | |
| Date/Time approved | |