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 # 2016006 - XXX **Date** 12/9/2015

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 ocular syphilis — North Carolina, 2015

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

State:	North Carolina
City/County (if applicable)	Raleigh
Country	United States

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

Agency:	North Carolina Division of Public Health
Name and Position Title:	Megan Davies, 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 North Carolina Division of Public Health (NC DPH) reports a nearly two-fold increase in cases of syphilis with ocular manifestations. Thirty-two cases of ocular syphilis have been reported so far in 2015, compared to 18 cases in 2014. Ocular syphilis can be a clinical manifestation of neurosyphilis, and can occur during any stage of syphilis. Ocular syphilis may lead to decreased visual acuity including permanent blindness. In North Carolina, two cases of blindness attributed to ocular syphilis have occurred in the last several months. To address this unexplained rise in cases, an investigation is urgently needed. NC DPH requests CDC assistance with this investigation to describe the cases and clinical course of ocular syphilis and identify factors influencing risk for ocular syphilis and blindness. The primary purpose of this investigation is to identify prevention and control measures.

Data will be collected via chart review (Appendix 1) and interviews with cases (Appendix 2).

This request seeks OMB approval for the new data collections: chart abstraction (Appendix 1) and case patient interviews (Appendix 2). Only federal staff will conduct chart reviews.

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):

  Interviews (Appendix 2): Respondents are patients identified with syphilis and 'ocular manifestations'.

- ☐ Restaurant staff (describe):
- ☐ Other (describe):

  Chart Abstraction (Appendix 1): Respondents are federal staff who will abstract medical and NC public health records for case patients identified with syphilis and ‘ocular manifestations’.

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 persons identified as having ocular manifestations and syphilis will be included.

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):

    Risk factors and the clinical course of those diagnosed with ocular syphilis will be described using abstraction both from the health department syphilis case investigation records and from medical records (Appendix 1) and follow-up

interviews with the case patients (Appendix 2).

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ 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):

Case patients will be contacted by phone and invited to complete a brief questionnaire via interview (Appendix 2). This interview seeks to collect information that will complement the data collected during medical record abstraction.

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Data will be abstracted from the medical records of case and control patients (Appendix 1). Abstractions will be completed by federal staff.

☐ 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):
See risk factors.

☒ Clinical information/symptoms (describe):
Clinical information will be collected via medical chart abstraction (Appendix 1) and interview (Appendix 2). Information abstracted will include: previous medical conditions affecting the eye, diagnosis of visual problem, eye exam findings, and other relevant clinical findings.

☐ Contact information (describe):

☒ Demographic information (describe):
Demographic information such as sex, age and race/ethnicity (Appendix 1).

☐ Environmental factors (describe):

☐ Exposures (describe):

☒ Medical history (describe):
Medical history, including medications, previous medical conditions and previous eye conditions (Appendices 1 and 2).

☒ Risk factors (describe):
Risk factors for a sexually transmitted infection, including sex of sex partners, number of sex partners, previous diagnosis of a sexually transmitted infection, and drug use will be abstracted from the health department syphilis case investigation records and from medical records (Appendix 1).

☐ Specimen/lab information (describe):

☐ Travel history (describe):

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
3 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:	Sara Oliver, MD, MSPH
Title:	Epidemic Intelligence Service Officer
Affiliation:	NCHHSTP, DSTDP, ESB

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:	NCHHSTP, DSTDP, ESB
Name:	Lauri Markowitz, MD
Title:	Medical Epidemiologist, Epidemiology Team Lead

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:	Sara Oliver, MD, MSPH
Date of Certification:	

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

December 12, 2015

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