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 # 2014017 - XXX **Date** 09/12/2014

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 and mode of transmission for bloodstream infections among hemodialysis patients – California, 2014

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

State:	California
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:	California Department of Public Health
Name and Position Title:	Gilberto F. Chávez, M.D., M.P.H., 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).*

Bloodstream infections (BSI) are a potentially preventable cause of deaths and an increasing number of hospitalizations among hemodialysis patients in the United States. On May 9, 2014, the California Dept. of Public Health (CDPH) notified CDC of 6 cases of *Burholderia cepacia* BSIs among hemodialysis patients in a single outpatient dialysis center in 2014. Additional case finding conducted by CDPH revealed 2 cases of *Stenotrophomonas maltophilia* BSIs among patients at the center in late 2013. CDC was subsequently notified of 2 cases of *S. maltophilia* and 1 case of *B. cepacia* BSIs during June and July, 2014 at another dialysis center belonging to the same company. All 11 cases appeared to be in patients whose dialyzers were reused and reprocessed. Environmental cultures performed in the facility with the index cluster identified *B. cepacia* from a dialyzer preprocessing machine. At the second facility, *S. maltophilia* was recovered from a culture taken from a connector attached to the

sink used to rinse dialyzers prior to reprocessing. In response, the facilities temporarily halted dialyzer reuse, adjusted their reprocessing practices, and then resumed reuse. A complete assessment of risk factors, reprocessing practices, and other opportunities for introduction of waterborne organisms is needed to determine if additional prevention and control measures are necessary.

A broader search of BSIs caused by similar waterborne organisms that could be introduced during dialyzer reprocessing (*B. cepacia*, Pseudomonas, Stenotrophomonas, Proteus, Morganella, Serratia) during January through July 2014 revealed 18 potential cases across multiple facilities within the same company (Company A), with most recent occurrences identified in late July. A search for similar BSIs in facilities belonging to other companies was not conducted; this investigation will be conducted among facilities of Company A.

Because of the scope of the outbreak, potential for ongoing cases at these facilities, and CDC's expertise in infection prevention in the dialysis setting, CDPH is requesting CDC assistance with an urgent public health investigation.

The objectives and data collection plans are listed below:
1) Conduct case-finding and case confirmation
Additional cases will be identified by reviewing microbiology records and medical records from dialysis centers and hospitals (Chart Abstraction Form, Appendix 1). Clinical characteristics of identified cases will be reviewed for case confirmation and to document potential risk factors.

2) Assess dialyzer reuse and reprocessing practices
The investigation team will conduct observations of dialyzer reprocessing and interview key staff members about the facility's reuse and reprocessing practices to identify modes of transmission. A draft of the Reprocessing Observation Checklist is included (Appendix 2); this form will be modified in the field based on the needs of the investigation. An example interview form (Outpatient Dialysis Center Practice Survey, Appendix 3) is included and is based on an OMB-approved form under OMB Control No. 0920-0666, expiration: 10/31/2016; this form will be modified in the field based on the needs of the investigation.

3) Assess risk factors
A case-control study will be conducted to assess risk factors. Risk factor information will be abstracted from medical records for cases and controls (Chart Abstraction Form, Appendix 1).

4) Perform environmental evaluation
A review of existing facility records of routine water testing will be conducted. Additional water samples will be collected from 2 facilities and will be submitted to CDC for culture.

5) Make recommendations for control measures
Recommendations will be made on the basis of the investigation findings.

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 at the affected facilities who perform dialyzer reprocessing

☐ Laboratory staff (describe):

☒ Patients (describe):
Will abstract information from dialysis patient medical records

☐ 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.*

Medical records for all case-patients will be reviewed. Controls will be selected among patients treated at the same facilities who did not develop a bloodstream infection caused by a waterborne bacteria. Interviews will be conducted with key staff involved in dialyzer reuse and reprocessing practices in each facility; these staff members will be identified by the facility. The environmental evaluation will be conducted in the two facilities where the initial 11 cases were identified.

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):
Characteristics of cases may be described. Reuse and reprocessing practices may also be described.

☐ Cross-sectional Study (describe):

☒ Cohort Study (describe):
A retrospective cohort study of all patients at the 2 facilities where the initial 11 cases were identified may be conducted

☒ Case-Control Study (describe):
A case-control study of cases and selected controls may be performed if electronic medical records are available at a centralized location. Controls will be selected among patients treated at the same facilities as cases.

☐ Other (describe):

☒ Environmental Assessment (describe):

We plan to collect water samples in dialysis treatment and dialyzer reprocessing areas. The specifics of this will be determined in the field.

☒ Laboratory Testing (describe):

Cultures of the environmental specimens may be performed

☐ 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):

Interviews (Appendix 3) with facility staff will be conducted face-to-face or by telephone, depending on their location and availability. An Internet questionnaire might be developed if interviews cannot be scheduled. The best mode of questionnaire administration will be determined in the field.

☒ Telephone Interview (describe):

Interviews (Appendix 3) with facility staff will be conducted face-to-face or by telephone, depending on their location and availability. An Internet questionnaire might be developed if interviews cannot be scheduled. The best mode of questionnaire administration will be determined in the field.

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

☒ Self-administered Internet Questionnaire (describe):

Interviews (Appendix 3) with facility staff will be conducted face-to-face or by telephone, depending on their location and availability. An Internet questionnaire might be developed if interviews cannot be scheduled. The best mode of questionnaire administration will be determined in the field.

☒ Other (describe):

Direct Observation: The investigation team will conduct observations of dialyzer reprocessing about the facility's reuse and reprocessing practices to identify modes of transmission (Appendix 2).

☒ Medical Record Abstraction (describe):

Clinical and risk factor information will be abstracted from existing patient medical records using a chart abstraction form (Appendix 1) that will be modified in the field based on the needs of the investigation.

☐ Biological Specimen Sample

☒ Environmental Sample:

Samples may be taken from environmental sources (e.g., water used for rinsing dialyzers)

☒ 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):
Timing of symptoms consistent with bloodstream infection relative to dialysis treatment, and clinical outcomes such as hospitalization or death

☐ Contact information (describe):

☒ Demographic information (describe):
Age, race, gender

☐ Environmental factors (describe):

☐ Exposures (describe):

☒ Medical history (describe):
Relevant comorbidities such as immunosuppressive conditions and duration of dialysis

☒ Risk factors (describe):
Dialyzer reuse, use number, vascular access type, heparin use
Facility reprocessing practices

☒ Specimen/lab information (describe):
Blood samples will not be collected. However, if case-patient isolates are identified from specimens previously collected for diagnostic purposes, these will be sent to CDC for further testing.

☐ Travel history (describe):

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
3-4 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 Edens, PhD
Title:	EIS Officer
Affiliation:	Prevention and Response Branch, DHQP/Epidemiology Workforce Branch, DSEPD

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/DHQP
Name:	Priti Patel
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:	Priti Patel
Date of Certification:	9/10/14

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

09/12/2014

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	9/11/2014; 5:32AM
Date/Time final GenIC received by ICRL	9/12/2014; 10:15AM
Date/Time submitted to OMB	9/12/2014; 10:30AM
Date/Time approved	
