

**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).*

circulation during open heart procedures. Some heater-cooler units have previously been implicated in transmitting NTM through aerosolized particles in cardiothoracic surgical cases in Europe. However, the source, mode of transmission, and risk factors for MAC infection in the current investigation have not been determined. Due to the potential for future cases of NTM among patients undergoing cardiothoracic procedures, PA DOH is requesting CDC assistance with an on-site investigation to determine the source, modes of transmission, and risk factors for NTM infections among hospital A patients in order to prevent further cases.

The objectives of the investigation are listed below:

- 1) Conduct additional case-finding and case confirmation.
- 2) Assess risk factors for NTM infection at hospital A.
- 3) Observe surgical processes to identify potential sources and modes of transmission of NTM to the surgical patient. This could include observation of the preparation, use, and cleaning/disinfection processes of operative equipment, including heater-cooler units.
- 4) Evaluate relevant infection control practices at hospital A.
- 5) Perform environmental evaluation, including the collection of appropriate environmental samples for laboratory testing.
- 6) Make recommendations for control measures to prevent additional illnesses.
- 7) Assist in the development of a patient notification process, if indicated.

This GenIC requests OMB approval for interviews with healthcare staff to assess for risk factors and to evaluate relevant infection control practices at hospital A (Appendix 1).

Federal staff will be conducting the case-finding and investigation abstracting case medical records (Appendix 2); OMB approval is not sought for this investigation component.

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):

All healthcare staff involved in preoperative, intraoperative, and postoperative care of surgical patients undergoing cardiothoracic procedures at hospital A will be interviewed and observed to identify any potential breaches in infection control practices. Additionally, healthcare staff involved in the assembly, use, and cleaning/disinfection of heater-cooler units used in cardiothoracic procedures will also be observed in order to identify any breaches in use as identified by manufacturer's instructions. (Appendix 1)

- 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.*

Healthcare staff will be identified and selected based on their direct involvement with the surgical patient, the operating room, and with intraoperative and postoperative functioning and cleaning/disinfection of devices such as heater-cooler units.

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):

Information included will be obtained by interviewing healthcare workers (Appendix 1), and from patient medical records abstracted by Federal staff (Appendix 2).

- Cross-sectional Study (describe):

- Cohort Study (describe):

- Case-Control Study (describe):

A case-control study could be conducted to assess for risk factors for MAC infection at hospital A. Information included will be obtained by interviewing healthcare workers (Appendix 1), and from patient medical records abstracted by Federal staff (Appendix 2).

- Other (describe):

- Environmental Assessment (describe):

Samples of environment and devices, including water from the facility as well as heater-cooler units, that might serve as potential sources or modes of transmission, and other potential environmental sources of NTM will be collected and submitted to CDC for culture and typing.

- Laboratory Testing (describe):

CDC laboratory will facilitate identification and molecular typing of available, previously-collected clinical isolates for comparison to each other and to environmental isolates. All specimen collection, storage, and transport will be done according to local procedures and protocols.

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):

Healthcare staff will be interviewed regarding preoperative, intraoperative, and postoperative care and management of surgical patients undergoing cardiothoracic procedures at the facility. Interviews will also include an assessment of infection control practices, operation of surgical and ancillary equipment such as heater-cooler units, as well as the cleaning/disinfection of such devices (Appendix 1).

Telephone Interview (describe):

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Federal staff will search for additional cases by reviewing laboratory and medical records. Clinical and patient characteristics of identified cases will be reviewed for case confirmation and be used to document potential risk factors (Appendix 2).

Biological Specimen Sample

Patient isolates already obtained by the facility will be tested at CDC for microbiologic identification and molecular typing. All specimen collection, storage, and transport will be done according to local procedures and protocols.

Environmental Sample:

Environmental samples of air, water, surgical devices of concern such as heater-cooler units, and other appropriate environmental surfaces will be obtained for microbiologic testing and molecular typing at CDC.

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):

Healthcare staff will be observed for preoperative, intraoperative, and postoperative care of surgical patients, handling of surgical equipment including ancillary devices such as heater-cooler units, cleaning/disinfection practices, and standard infection prevention practices (Appendix 1).

Clinical information/symptoms (describe):

Medical chart review and abstraction by Federal staff will be used to obtain

information on clinical and patient characteristics of case patients (Appendix 2). Clinical information such as symptoms, signs, underlying medical conditions such as past medical and surgical history, medications (chronic and administered during surgery and admission), physical exam findings, laboratory testing and results, final diagnoses, and treatments will be collected.

Contact information (describe):

Demographic information (describe):

Medical chart review and abstraction will be used to obtain information on patient demographic information, such as age and sex, of case-patients in order to help identify potential risk factors for infection (Appendix 2)

Environmental factors (describe):

Positioning and use of surgical devices, cleaning/disinfection of operating room environment will be observed.

Exposures (describe):

Potential exposures in the hospital A operating room will be explored by observation and interviews with staff (Appendix 1).

Medical history (describe):

Past medical and surgical history of case-patients will be obtained from medical records. Special attention will be given to medical history that indicates potential immunocompromised conditions (Appendix 2).

Risk factors (describe):

Risk factors including patient characteristics, and environmental factors, and information from healthcare staff interviews will be assessed (Appendices 1 & 2).

Specimen/lab information (describe):

Patient isolates already obtained by the facility will be tested at CDC for microbiologic identification and molecular typing. All specimen collection, storage, and transport will be done according to local procedures and protocols.

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:

Kiran Perkins

Title:

Medical Officer

Affiliation: NCEZID/DHQP/PRB

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/PRB

Name: Kiran Perkins

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: Kiran Perkins

Date of Certification: 7/24/15

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

7/27/15

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