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 # 2015004 - XXX **Date** 12/23/2014

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 source, mode of transmission, and risk factors for mucormycosis among immunocompromised patients — Kansas, 2014

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

State:	Kansas
City/County (if applicable)	Kansas City
Country	USA

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

Agency:	Kansas Department of Health and Environment
Name and Position Title:	Charlie Hunt, 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).*

Mucormycosis is a serious, often fatal infection, caused by a group of angioinvasive molds. These infections most commonly affect the rhinocerebral area and occur typically in persons with marked immunosuppression.

On December 1, 2014, the Centers for Disease Control and Prevention (CDC) was notified by the Kansas Department of Health and Environment (KDHE) of a cluster of rhinocerebral mucormycosis infections among patients in a bone marrow transplant unit (BMT) in Hospital A in Kansas. The hospital reported four rhinocerebral mucormycosis cases which had occurred in the prior two months. A possible source of these infections was thought to be construction on the BMT unit, which occurred from May to October of 2014. However, because several of the cases presented after the construction was completed, Hospital A is concerned that there may be additional relevant exposures in this cluster that might still be unidentified, potentially allowing for continued transmission. Hospital A identifies approximately one case of rhinocerebral mucormycosis in this patient population per year.

Hospital A and KDHE are requesting CDC assistance to:

1) Conduct case-finding;
2) Determine if a significantly higher number of infections has occurred as compared to historical baseline;
3) Characterize epidemiological and clinical aspects of case-patients, including exposures of interest;
4) Conduct an epidemiologic study (case-control) to evaluate potential association between exposures and cases;
5) Provide recommendations for preventive measures and remediation.

To identify cases of mucormycosis, federal (n=4), state (n=3), and hospital (n=3) staff will review existing laboratory records from Hospital A (microbiology and pathology). Additionally, the CDC laboratory will perform testing on previously collected patient clinical isolates or pathology samples to identify which mucormycete species are associated with the outbreak. These samples will have been collected as part of the routine care of patients and have had preliminary identification at the hospital laboratory. Laboratory staff (n=4) will be asked to identify any previously collected clinical isolates or pathology samples on hand at Hospital A and ship them to CDC for species confirmation using standard protocols.

This GenIC seeks approval for two data collections. To identify potential risk factors and exposures of interest, healthcare workers and environmental services staff will be interviewed using Appendix 1. A descriptive study and a case-control study will be conducted using information abstracted from case-patient and control medical records by federal and state staff using Appendix 2.

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):

Staff will be queried about infection control practices in the affected hospital. Staff queried could include physicians, nurses, environmental services, and housekeeping staff. Staff will be asked about infection control practices specific to their jobs. (Appendix 1)

☐ Laboratory staff (describe):

☐ Patients (describe):

☐ Restaurant staff (describe):

☒ Other (describe):

Federal, state, and hospital staff will abstract medical records to obtain clinical information for cases and controls. (Appendix 2)

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 queried about infection control (Appendix 1) will be a convenience sample of staff that worked on the unit during the outbreak period and are available for interview.

Case-patients will be identified through search of hospital laboratory records and will be bone marrow transplant patients diagnosed with mucormycosis. Control-patients will be bone marrow transplant patients without mucormycosis.

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):

A review of case-patient medical records will be performed and demographic, clinical and outcome data on these patients will be extracted. Descriptive statistics to describe the case-patients will be done to better understand commonalities between case-patients for hypothesis generation.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☒ Case-Control Study (describe):

The matched case-control study will examine the association between mucormycosis and a variety of risk factors for invasive fungal disease, including potential exposures identified at Hospital A. Matching criteria will be developed based on findings from the descriptive study and may include age and medical factors.

☐ 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):

Staff will be interviewed about infection control practices in the affected hospital. Staff interviewed could include physicians, nurses, environmental services, and housekeeping staff. Staff will be asked about infection control practices specific to their jobs. (Appendix 1).

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Data will be abstracted from patient charts by federal, state, and hospital staff on the investigation team and recorded on the data collection form (Appendix 2).

☐ 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):

Staff infection control practices (Appendix 1)

☒ Clinical information/symptoms (describe):

Signs and symptoms of mucormycosis patients, procedures performed, medications received (treatment and prophylaxis), patient outcome (Appendix 2)

☐ Contact information (describe):

☒ Demographic information (describe):

Age, sex, race, and city/county of residence will be collected for cases and controls (Appendix

2)

☒ Environmental factors (describe):
Construction practices, air handling during construction, water intrusion events (Appendix 1)

☒ Exposures (describe):
Equipment and supplies used in patients' nose and mouth (Appendix 1). Patient locations in the hospital (e.g., room history, operating rooms where procedures performed) (Appendix 2)

☒ Medical history (describe):
Pre-existing conditions, dates and locations of previous hospitalizations, medical procedures, and medical devices will be collected for cases and controls (Appendix 2)

☐ Risk factors (describe):

☒ Specimen/lab information (describe):
Diagnostic test results listed in the medical record will be collected (Appendix 2)

☐ 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:	Tiffany Walker, MD
Title:	EIS Officer
Affiliation:	CDC, Mycotics Diseases 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/MDB
Name:	Rachel Smith, MD MPH
Title:	Medical Epidemiologist

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:	Rachel Smith, MD MPH
Date of Certification:	12/22/14

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

12/26/15

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	12/19/2014; 9:58AM
Date/Time final GenIC received by ICRL	
Date/Time submitted to OMB	
Date/Time approved	
