

**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 # 0920 - 1011

Date 05/28/2016

Title of Investigation: *Instruction: Provide the title of the investigation in the following format:*Undetermined risk factors for *Exophiala dermatitidis* among oncology patients — New York City, 2016.**Location of Investigation:** *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State:	New York
City/County (if applicable)	New York
Country	USA

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

Agency:	New York City Department of Health and Mental Hygiene (NYCDHMH)
Name and Position Title:	Marci Layton, Associate Commissioner, Bureau of Communicable Disease

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

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).

Exophiala dermatitidis is a neurotropic, dark pigment-forming fungus that is found in soil and is an uncommon cause of human illness.

On May 24, 2016, the Centers for Disease Control and Prevention (CDC) was notified by the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) of a cluster of *E. dermatitidis* bloodstream infections among patients with solid organ malignancies who had received care from an outpatient oncologist at a single outpatient oncology clinic. An initial two cases were reported to DOHMH on May 24, 2016, after the core laboratory facility of a hospital network identified *E. dermatitidis* in blood cultures drawn during May 16–17, 2016. One of the patients had been admitted to Hospital A, where the blood culture was drawn, and then transferred to Hospital B, (part of the same hospital network) and the second patient had been admitted to Hospital B within days of the first patient’s transfer to Hospital B. The network core laboratory reviewed its 2016 records and identified 3 other *E. dermatitidis* bloodstream infections in patients during 2016, including two patients under the care of the same outpatient oncologist who had been hospitalized at Network Hospital B. All four had received port-line flushes with a mixture of vancomycin, ceftazidime, and heparin, prepared at the clinic, refrigerated, and administered to patients over the course of weeks. After DOHMH informed the oncologist about four cases of *E. dermatitidis* bloodstream infections among his patients he began collecting surveillance blood cultures from his patients. A blood culture drawn on May 24, 2016 from another clinic patient yielded an unspciated yeast on May 27, 2016. Initial suspicion is that contaminated medicine due to unsafe medication preparation and compounding practices occurring at the facility are likely contributing factors to the source of infection. To date, one patient has died, and three are currently hospitalized. There is concern that there are many more patients who have been exposed to this mixture used to flush port lines or another contaminated medication and are at risk for this serious blood stream infection.

DOHMH is requesting assistance from CDC to 1) conduct case-finding; 2) characterize epidemiological and clinical aspects of case-patients, including exposures of interest; 3) conduct an epidemiological study to evaluate potential association between exposures and cases; 4) conduct an assessment of the infection control practices at oncology clinic; 5) perform environmental sampling as indicated by findings of the epidemiologic study; and 6) provide recommendations for preventative measures and remediation.

The investigation will require extensive chart reviews of patients seen at this oncology practice, interviews with patients who have had catheters accesses for any reason at this clinic over the last three months to assess exposures and symptoms that could be consistent with a bloodstream infection, a case-control or cohort study to identify common exposures, clinic practices assessment and environmental sampling to find the potential reasons and source of contamination. Healthcare staff working at the outpatient oncology clinic with be interviewed regarding infection control practices in the clinic. The patient and healthcare provider interview form is attached.

1. Characteristics of Outbreak or Event (Check all that Apply):

- Undetermined agent
- Undetermined source
- Undetermined mode of transmission
- Undetermined risk factor

2. 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 providers at the outpatient oncology clinic

Laboratory staff (describe):

Patients (describe):

Patients receiving care at the outpatient oncology clinic

Restaurant staff (describe):

Other (describe):

3. 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.*

A staff roster of the oncology clinic will be requested to identify healthcare staff for interviews

Patient lists will be generated using the clinic's electronic medical record system.

4. 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):

Chart review of case-patients to describe presenting symptoms, hospital course, treatment outcome

Cross-sectional Study (describe):

Cohort Study (describe):

Identify all patients who had central lines accessed at the oncology clinic During March-May, 2016. Assess exposures to IV medications and infusion procedures to identify common risk factors among cases.

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Environmental sampling will be conducted in the clinic targeting sites where medications are prepared and stored. Samples of left over medications at the clinic will also be obtained for culture.

Laboratory Testing (describe):

All patients who had central lines accessed during March-May 2016 will be asked to get blood cultures drawn to assess for presence of infection. These blood cultures will be processed locally. All isolates of *Exophiala* will be sent to the CDC lab for antifungal

susceptibility testing and whole genome sequencing.

Other (describe):

5. 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):

Patient interview form may be administered face- to-face.

Telephone Interview (describe):

Patient interview form may be administered by telephone

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Patient medical records will be abstracted using a standardized CRF.

Biological Specimen Sample

Environmental Sample:

Environmental swabs will be taken in the clinic with a focus on areas where medication are prepared, stored, and administered. All environmental samples will be sent back to CDC for processing.

Other (describe):

6. 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):

Presence of fever, malaise, chills, other constitutional symptoms, new neurologic signs and systems, and a thorough review of systems, and date of onset of any positive symptoms.

Contact information (describe):

Phone number and address if necessary for follow up

Demographic information (describe):

Gender, age, race

Environmental factors (describe):

Exposures (describe):

- Medical history (describe):
 Risk factors (describe):
 Specimen/lab information (describe):
 Travel history (describe):
 Other (describe):

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

3-6 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: Snigdha Vallabhaneni MD, MPH
 Title: Medical Officer
 Affiliation: CDC/NCEZID/DFWED/MDB

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: CDC/CSELS/DSEPD/EWB
 Name: Michael Gronostaj
 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: _____

Date of Certification: _____

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

05/31/2016

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