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 # 2016024 - 051 **Date** 09/16/2016

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 *Candida auris* infection — Colombia, 2016

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

State:	
City/County (if applicable)	
Country	Colombia

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

Agency:	Instituto Nacional de Salud, Ministerio de Salud, Colombia (INS)
Name and Position Title:	Dr. Martha Ospina, Director, Instituto Nacional de Salud, Colombia

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).*

Candida auris is an emerging fungus that has caused hospital-associated outbreaks of invasive infections with high mortality. Since May 2016, over 50 cases of *C. auris* infection have been identified in 7 hospitals in 5 cities in Colombia. Because *C. auris* can be difficult to distinguish from other *Candida* species by conventional laboratory methods, some cases were retrospectively identified using more advanced techniques. New cases continue to occur, including seven cases recently reported from a Bogotá hospital in August 2016.

Little is known about risk factors for *C. auris* infection or the organism's environmental reservoirs, modes or transmission, and reason for its recent emergence. Other *Candida* spp. have rarely caused outbreaks, and *Candida* infections are generally thought to result from invasion of a patient's own resident flora, usually from stool. *C. auris*, however, appears to colonize skin and healthcare environments, presenting opportunities for patient-to-patient transmission. Of additional concern, some strains of *C. auris* are resistant to all three of the main classes of antifungal medications used to treat invasive *Candida* infections.

The objectives of this investigation are to:

1. Characterize the burden of *C. auris* infection in Colombia
2. Determine risk factors for infection
3. Identify epidemiologic links between cases
4. Elucidate transmission mechanisms

The investigation team will address these objectives through:

1. Examination of hospital laboratories' microbiology records for additional case finding
2. A case-control study to identify risk factors for *C. auris* transmission and infection (data collection instrument for medical chart review in Appendix 1a [English] and 1b [Spanish])
3. Assessment of the body sites colonized by *C. auris* in patients with active or recent *C. auris* infection to help inform risk of transmission (e.g., colonization of skin sites could imply greater risk)
4. A point prevalence survey for body colonization among patients hospitalized on the same unit as a patient with *C. auris* infection to assess extent of transmission
5. Environmental sampling of hospital rooms
6. Open-ended interviews with healthcare providers (Appendix 2) and patients (Appendix 3)

Findings from this work will help determine the type, degree, and targeting of infection control measures needed to halt the spread of this multidrug-resistant pathogen. Interviews with healthcare workers and medical record reviews may also shed light on its ultimate environmental sources.

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):

Face-to-face open-ended conversational interviews will be conducted with physicians and other healthcare staff at hospitals in which *Candida auris* cases have been reported in order to better understand possible sources and transmission routes of this organism (Appendix 2).

☐ Laboratory staff (describe):

☒ Patients (describe):

Face-to-face open-ended conversational interviews will also be conducted with available patients in order to assess for possible prehospital sources of *C. auris* exposure, including in the natural environment (Appendix 3).

☐ Restaurant staff (describe):

☒ Other (describe):

Public health personnel to perform medical chart reviews for case-patients. (Appendices 1a and 1b)

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.*

Public health personnel will perform medical chart reviews for case-patients and controls at hospitals reporting cases of *C. auris* infection. A case is defined as *C. auris* confirmed by specialized laboratory testing (i.e., MALDI-TOF or sequencing) from a blood culture in a patient in Colombia during 2011–2016. Two controls will be matched to each case based on shared hospital and year of diagnosis. Controls are patients with *Candida* species other than *C. auris* identified on blood culture. Due to diagnostic constraints and misidentification with currently available phenotypic methods, *C. haemulonii*, *C. famata*, and unspeciated (identified as *Candida* spp.) isolates will be excluded.

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 microbiologic and clinical records from hospital patients with *Candida* infections will occur in order to define in greater detail the timeline and characteristics of patients with *C. auris* over the past several years. This activity will help inform the other activities described below.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☒ Case-Control Study (describe):

The objective of the case-case investigation is to better understand risk factors for developing *C. auris* infection compared to infection with other species of *Candida* and compared with non-*Candida* infections. The site or sites of the case-control investigation will depend on the status of *C. auris* infections in Colombia at the time of the investigation and might best include a hospital or hospitals with recent cases. However, cases from earlier in 2016 and before could also be included. The largest cluster of *C. auris* infection occurred in Barranquilla during December 2014–April 2016, and the most recent clusters have occurred in Cartagena and Bogota, both in July 2016.

Medical chart review will be performed using a standardized case report form. All charts will be reviewed for location and duration of hospital stay, date of *Candida* diagnosis, and clinical characteristics such as antimicrobials received, procedures performed, and culture history. Information pertaining to prior contact with the healthcare system, transfer from outside facilities, and individual travel will also be obtained.

☐ Other (describe):

☒ Environmental Assessment (describe):

Healthcare workers, contaminated infusates, and biomedical equipment have previously been implicated as exogenous reservoirs of healthcare-associated candidiasis, but the reservoirs and sources of *C. auris* transmission in this outbreak are unknown. Environmental persistence despite standard cleaning has been reported. Environmental sampling will allow for identification of reservoirs within the facility and assist with infection control measures.
Environmental sampling will be considered for rooms where a *C. auris* case has been identified in the past 3 months. Rooms with more recent cases will be prioritized. Additionally, pre- and post-cleaning sampling will be performed when possible.
The following method developed by CDC's Division of Healthcare Quality and Promotion (DHQP) will be used:

- The room will be divided in three zones, two samples are taken from each zone:
    - Zone 1: Sites close to patient (bedside table, bed rails and mattress)
    - Zone 2: Items located between bed and wall (chair the patient used, IV poles, ventilators of other equipment, ECG monitors, etc)
    - Zone 3: Items located along the wall
    - Extra: sink drain or p-trap

Cleaning products and methods will also be discussed with either infection prevention or environmental services personnel. Additional sampling may be conducted based upon findings during investigation. This will assist in infection control measures and determining if cleaning is being perform in a manner adequate to prevent further transmission from the environment.

☒ Laboratory Testing (describe):

C. auris has been found to colonize patients' skin. This finding suggests a potential

mode of transmission and a challenge for infection control. Sampling to determine colonization in patients and those who have shared common spaces, equipment, and providers will allow for more expeditious implementation of infection control measures.

Sampling Patients with *C. auris* Infection

Patients with active *C. auris* infection will be swabbed at the following sites: nares, oropharynx, external ear canal, axilla, and groin. Information gathered will help inform infection control measures.

Point Prevalence Survey of Colonization

Since colonization has been shown to increase the risk of developing invasive disease but many *Candida*-colonized patients never develop disease, it is important to determine if patients who have had contact with an active *C. auris*-infected patient subsequently become colonized. A point prevalence survey of colonization will be executed in a unit if any of the following are satisfied: (1) there is an active case of *C. auris* infection, (2) a case of *C. auris* infection has been admitted to the unit within the last week, or (3) a patient who had previously been diagnosed with *C. auris* infection is admitted, regardless of the current admission diagnosis. This activity will assist in infection control measures.

Surveillance cultures from the following sites will be collected: nares, oropharynx, external ear canal, axilla, and groin. In the case of a patient in the intensive care unit, specimens will also be collected from stool or rectum, and urine. Detailed epidemiologic data, including location in the unit, duration on the unit, time overlap with case, presence of indwelling lines or catheters, recent surgeries, wounds and dressings, and immunosuppressive and antimicrobial therapy will be collected.

☐ 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):

Face-to-face open-ended conversational interviews will be conducted with physicians and other healthcare staff at hospitals in which *Candida auris* cases have been reported in order to better understand possible sources and transmission routes of this organism (Appendix 2)

Face-to-face open-ended conversational interviews will also be conducted with available patients in order to assess for possible sources of *C. auris* exposure (Appendix 3).

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Medical record reviews will be performed, as described above.

☒ Biological Specimen Sample

As described above, for patients with active *C. auris* infection and those sharing units with such patients, surveillance cultures from the following sites will be collected: nares, oropharynx, external ear canal, axilla, and groin. In the case of a patient in the intensive care unit, specimens will also be collected from stool or rectum, and urine. Specimen collection, storage, and transport will be done according to local procedures and protocols.

☒ Environmental Sample:

Environmental sampling will be performed, as described above. Specimen collection, storage, and transport will be done according to local procedures and protocols.

☐ 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):

Information will be collected about sepsis, radiologic tests, and laboratory values.

☐ Contact information (describe):

☒ Demographic information (describe):

Sex, age, county

☐ Environmental factors (describe):

☒ Exposures (describe):

Data will be collected on institutions where a patient spent time before the hospitalization when *C. auris* infection was diagnosed, as well as on certain medical procedures and time spent in various hospital units that could have led to *C. auris* transmission.

Healthcare workers (Appendix 2) and patients (Appendix 3) will also be interviewed to explore possible sources of exposure.

☒ Medical history (describe):

Information will be collected about case-patient and control underlying conditions, including diabetes, cancer, and renal and liver failure. In addition, data will be collected on procedures (e.g., dialysis, bronchoscopy) and treatment (e.g., chemotherapy, corticosteroid use, antimicrobial use).

☐ Risk factors (describe):

☒ Specimen/lab information (describe):

Microbiologic records will be reviewed.

☐ Travel history (describe):

☐ Other (describe):

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

Most of the data collection will take place in the first two weeks of field investigation, but additional data collection could follow depending on initial findings, up to 90 days (or ~13 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:	Dr. Paige Armstrong
Title:	EIS Officer
Affiliation:	Mycotic 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:	Dr. Brendan R. Jackson
Title:	Lead, MDB Epidemiology Team

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:	Dr. Brendan R. Jackson
Date of Certification:	September 15, 2016

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

09/19/2016

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	