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 CLEARANCE 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 <u>can</u> be used. If you select "yes" to any criterion in Column B, the EEI Generic ICR mechanism <u>cannot</u> 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). [**x**] Yes [ ] No	The Investigation is initiated by CDC, without request from an external partner. [ ] Yes [**x**] 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). [**x**] Yes [ ] No	The investigation is not urgent in nature. [ ] Yes [**x**] No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. [**x**] Yes [ ] No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. [ ] Yes [**x**] No
One or more CDC staff (including trainees and fellows) will be deployed to the field. [ ] Yes [**x**] No **Note: CDC role will remain the same irrespective of physical deployment to field. Staff will be deployed to support remote coordination of investigation.**	CDC staff (including trainees or fellows) are not deployed to the field. [ ] Yes [**x**] No **Note: CDC role will remain the same irrespective of physical deployment to field. Staff will be deployed to support remote coordination of investigation.**
Data collection will be completed in 90 days or less. [**x**] Yes [ ] No	Data collection expected to require greater than 90 days. [ ] Yes [**x**] No

Did you select "Yes" to <u>all</u> 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.

TITLE OF INFORMATION COLLECTION: *Increased rates of Cladophialophora bantiana cases across the United States, 2020-present*

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Problem to be Investigated: As of September 21, 2026, CDC has worked with a molecular diagnostic reference laboratory (University of Washington) to identify a 4-fold increase (5/1,000 to 26/1,000 central nervous system cases) of *Cladophialophora bantiana* from 2023-present. Increased testing rates did not account for increase in cases, nor did the laboratory's methodology change. This fungus predominantly causes brain abscesses, has mortality rates of >50%, and typically causes disease in seemingly healthy individuals. The specimens positive for *C. bantiana* have been submitted by laboratories in 21 states and D.C., suggesting a national increase rather than a localized outbreak. There is urgent need for a coordinated CDC response to characterize these infections from a national perspective and to identify commonalities in presentation or exposures and appropriate management, for the purposes of identifying and mitigating any immediate threats to patients associated with *C. bantiana* infections.

2. Characteristics of Outbreak or Event (Check all that Apply):
   [ ] Undetermined agent
   [x] Undetermined source
   [ ] Undetermined mode of transmission
   [x] Undetermined risk factor

3. Location of Investigation:
   State: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, New York City, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, American Samoa, Commonwealth of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Palau, Puerto Rico, US Virgin Islands
   City/County (if applicable):
   Country: US

4. Agency Requesting Epidemiological Assistance/Name and Position Title of Requestor
   Agency: Washington State Department of Health
   Name: Dr. Scott Lindquist
   Position Title: State Epidemiologist

5. **Respondents:**

[ ] General public (describe):

[x] Healthcare staff (describe):

CDC's Mycotic Diseases Branch is working with state and local health departments to investigate an unexplained, national increase of *Cladophialophora bantiana*. To date, a four-fold rate increase has been observed by a large reference laboratory, but no clinical or epidemiological information has been systemically collected to characterize and investigate the increase. A public health investigation is underway to identify and characterize the infections to inform clinical and public health interventions to prevent infections and save lives.

Description: CDC is requesting clinical and epidemiological data from all cases of *Cladophialophora bantiana* throughout the United States. Respondents will report to CDC or state/local health departments cases of *Cladophialophora bantiana* causing clinical infections starting in January 2020.

[ ] Laboratory staff (describe):

[ ] Patients (describe):

[ ] Restaurant staff (describe):

[x] Other (describe): State/local public health departments will receive reports from healthcare providers, and will coordinate with healthcare staff to complete CDC's case report form. Public health departments will submit completed case report forms to CDC's Mycotic Diseases Branch

6. Selection of Respondents: Healthcare facilities will be asked to report cases consistent with call for cases language to state or local health jurisdictions. For reports consistent with the call for cases criteria, public health departments will be asked to complete a case report form by requesting information from reporting healthcare staff or by ensuring completion by the appropriate healthcare staff, to collect epidemiological and clinical information

7. Study Design:

[ ] Epidemiologic Study (indicate which type(s) below)

[x] Descriptive Study (describe): A case series approach will be employed, which will: 1) describe the nature of *C. bantiana* infections and 2) identify risk factors, diagnostic practices, and treatment outcomes

[ ] Cross-sectional Study (describe):

[ ] Cohort Study (describe):

[ ] Case-Control Study (describe):

[ ] Other (describe):

[ ] Environmental Assessment (describe):

[ ] Laboratory Testing (describe):

[ ] Other (describe):

8. Data Collection Mode:
[ ] Survey Mode (indicate which mode(s) below):

[ ] Face-to-face Interview (describe):

[x] Telephone Interview (describe): Patients or family members of the deceased will complete telephone interview administered by health department staff, providers, or CDC staff.

[x] Self-administered Paper-and-Pencil Questionnaire (describe): Health department staff or treating healthcare providers can print out the case report form on paper.

[X] Self-administered Internet Questionnaire (describe): Health department staff or treating provider will use a secure REDCap database to fill out the case report form.

[ ] Other (describe):

[x] Medical Record Abstraction (describe): Case report form completion will necessitate medical record review by treating provider, or health department proxy, to record key clinical information (e.g., past medical history, diagnostics, treatments used, exposures).

[ ] Biological Specimen Sample

[ ] Environmental Sample.

[ ] Other (describe):

9. Type of Information to be Collected:

[ ] Behaviors (describe):

[x] Clinical information/symptoms (describe): Case report form includes fields for: patient demographics, patient underlying conditions and risk factors, patient diagnosis and outcomes, antifungal treatment, antifungal susceptibility testing results, and patient exposure information

[x] Contact information (describe): Case report form includes fields for: contact information for reporting provider the healthcare facilities that administered, treated, or otherwise identified the *C. bantiana* case

[x] Demographic information (describe): Case report form includes fields for: Patient age, sex, race/ethnicity, county of residence

[ ] Environmental factors (describe):

[x] Exposures (describe): Case report form includes fields for: occupation/industry, travel history, recent recollection of trauma, and outdoor activities,

[x] Medical history (describe): Case report form includes field to indicate past medical history with select all the apply option.

[ ] Risk factors (describe):

[ ] Specimen/lab information (describe):

[X] Travel history (describe): international travel within 3 months of *C. bantiana* diagnosis

[ ] Other (describe):

10. Duration of Data Collection (number of weeks): 12 weeks

INVESTIGATION LEAD: *]*
Name: Dallas Smith
Title: Epidemiologist
Affiliation: NCEZID/DFWED/MDB

CDC SPONSORING PROGAM AND PRIMARY CONTACT PERSON:

CIO/Division/Branch: NCEZID/DHQP/PRB (Response Team)
Name of CDC Sponsoring Program Primary Contact Person: Dallas Smith
Title of CDC Sponsoring Program Primary Contact Person: Epidemiologist
Contact Information:
[ ] Office phone:
[ ] Home phone:
[] Cell phone/Blackberry:
[x] E-mail: rhq8@cdc.gov
[ ] Other:

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, Dallas Smith, 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

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measures.

CDC Sponsoring Program Primary Contact Name: Dallas Smith
Date of Certification: 9/24/2026

REQUESTED APPROVAL DATE (MM/DD/YYYY): *10/1/2026*

DATE SUBMITTED TO INFORMATION COLLECTION REQUEST LIAISON
9/24/2026