

# **Enhanced Surveillance for Histoplasmosis**

## Request for OMB approval of a New Information Collection

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### **Supporting Statement B**

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## Table of Contents

1. Respondent Universe and Sampling Methods.....	2
2. Procedures for the Collection of Information.....	2
3. Methods to maximize Response Rates and Deal with No Response.....	3
4. Tests of Procedures or Methods to be Undertaken.....	3
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	3

The data collection does not involve statistical methods. The purpose of the collection is not to make statistical generalizations beyond the particular respondents.

### 1. Respondent Universe and Sampling Methods

The project is open to participation from state and local health departments in states where histoplasmosis is reportable. Cases will be identified through routine histoplasmosis surveillance; cases meeting the CSTE definition of a confirmed or probable case are eligible to be interviewed.

Participation from AR, DE, IN, KY, LA, MI, MN, NE, PA, and WI would result in approximately 600 cases reported yearly and eligible to be interviewed. We estimate that approximately half of case-patients will be unable to be contacted, refuse participation, or will not be able to be interviewed for other reasons, resulting in an estimated 300 total interviewed patients. The range in cases reported by state might require different approaches to sampling to reduce the burden of interviews on health departments to which many histoplasmosis cases are routinely reported. For states in which <100 yearly cases are typically reported, attempting to interview every case is preferred. For states in which  $\geq 100$  yearly cases are typically reported, states could consider attempting to interview every other reported case. However, each state may participate to the extent possible, and no minimum proportion of interviewed cases will be established.

### 2. Procedures for the Collection of Information

Interviews will be conducted by state or local health department personnel. All cases reported in the year following the project start date will be contacted by telephone and invited to participate in the voluntary interview.

Ideally, cases should be contacted four to six weeks after they are reported to public health. A total of five attempts should be made for each valid phone number. At least one attempt should be made in the morning (8 am–12 pm) and one in the afternoon (12–5 pm) on weekdays. If there is no response after three attempts during the day, at least one attempt should be made on a weekday evening (5–8 pm).

A standardized case report form (CRF) will be used to collect information on demographics, underlying medical conditions, exposures, symptom type and duration, healthcare seeking behaviors, diagnosis, treatment, outcomes, and awareness of histoplasmosis. Each interview is estimated to take approximately 15 minutes. The last page of the CRF will not be used during the interview but will

collect information about the laboratory method(s) used for histoplasmosis diagnosis based on available information in states' reportable disease databases. No personally identifying information will be recorded on the CRF. Each case will be assigned a unique identifier containing the state postal code followed by a hyphen and sequential numbering (e.g., AR-01, AR-02, etc.). A parent or guardian should be interviewed for cases in persons under 13 years old. For cases in persons aged 13–17 years old, the adolescent can be interviewed if permission from the parent or guardian is obtained. For cases in persons who are deceased or incapacitated, a proxy such as a family member or caregiver can be interviewed on the patient's behalf. Health departments should use their existing processes for gaining voluntary participation from patients/guardians with reportable conditions.

Participating states can share completed CRFs with CDC via email or fax. This information will be stored electronically on secure CDC computers as password-protected files. CDC will enter the data into a password-protected Microsoft Access database and can provide a final copy of the completed database to each state containing only that state's cases. CDC will merge data from all states and import the data to SAS v. 9.4 for analysis.

### **3. Methods to maximize Response Rates and Deal with No Response**

Participation in this surveillance project is voluntary. The case report form has been streamlined to ensure the ease of response and to minimize the public burden. A total of five attempts will be made for each valid phone number. The following script will be used to introduce the project (see Attachment 5):

“Hello, my name is (*name*). I work with (*name of health department*). I'm calling because (*name of health department*) and the CDC are doing a public health investigation about histoplasmosis to better understand how it affects the health of people in (*your state*). I'd like to talk to you because your healthcare provider ordered a histoplasmosis test for you or because you might have histoplasmosis. As you might already know, histoplasmosis is a fungal infection that often affects the lungs and is not contagious. Your participation is voluntary, but I'm hoping you could complete a brief phone interview that will take about 15 minutes. May I ask you a few questions?”

### **4. Tests of Procedures or Methods to be undertaken**

No pre-tests are planned. A similar data collection form was used very successfully for enhanced surveillance of coccidioidomycosis in 2016 (OMB Control Number 0920-1087).

### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Individuals consulted on statistical aspects of the design: not applicable.

The data collection was designed by CDC's Mycotic Diseases Branch in collaboration with state health department personnel in states where histoplasmosis is reportable. State and local health department personnel will collect the data. Data will be analyzed by CDC's Mycotic Diseases Branch.