



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

Print Date: 10/1/24

**Title:** FungiSurv Amendment 1  
**Project Id:** 0900f3eb82431a39  
**Accession #:** NCEZID-ET-1/31/23-a62fd  
**Project Contact:** Samantha L Williams  
**Organization:** NCEZID/DFWED/MDB/ET  
**Status:** **Pending Regulatory Clearance : Amendment**  
**Intended Use:** **Project Determination**  
**Estimated Start Date:** 03/01/2023  
**Estimated Completion Date:** 12/31/2024  
**CDC/ATSDR HRPO/IRB Protocol #:**  
**OMB Control #:** 0920-1385

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: <b>Does NOT Require HRPO Review</b>	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	9/24/24	Peterson_James M. (iyr1) CIO HSC
PRA: <b>PRA Applies</b>		9/25/24	Vice_Rudith (nhr9) OMB / PRA
ICRO: <b>PRA Applies</b>	OMB Approval date: 4/18/24 OMB Expiration date: 4/30/27	9/30/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

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### Description

<b>Priority:</b>	Standard
<b>Priority Justification:</b>	
<b>CDC Priority Area for this Project:</b>	Not selected
<b>Determination Start Date:</b>	09/05/24
<b>Description:</b>	A national enhanced surveillance platform for fungal diseases
<b>IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:</b>	No
<b>IMS Activation Name:</b>	Not selected
<b>Submitted through IMS Clearance Matrix:</b>	Not selected
<b>Primary Scientific Priority:</b>	Not selected
<b>Secondary Scientific Priority (s):</b>	Not selected
<b>Task Force Responsible:</b>	Not selected
<b>CIO Emergency Response Name:</b>	Not selected
<b>Epi-Aid Name:</b>	Not selected
<b>Lab-Aid Name:</b>	Not selected
<b>Assessment of Chemical Exposure Name:</b>	Not selected
<b>Goals/Purpose</b>	The goal of FungiSurv, a national enhanced surveillance platform for fungal diseases in the US, is to improve data collection on fungal disease threats to inform public health action.
<b>Objective:</b>	Specific objectives for FungiSurv include collection of data on patient characteristics, healthcare utilization, and outcomes for those affected by certain fungal diseases (e.g., endemic mycoses, molds, Candida). Data might be collected through medical chart reviews and/or in-depth interviews to guide public health action to prevent morbidity and mortality from fungal infections.
<b>Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:</b>	No
<b>Does your project investigate underlying contributors to health inequities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:</b>	No

<b>Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:</b>	No
<b>Activities or Tasks:</b>	New Collection of Information, Data, or Biospecimens ; Secondary Data or Specimen Analysis
<b>Target Populations to be Included/Represented:</b>	General US Population
<b>Tags/Keywords:</b>	Invasive Fungal Infections ; Public Health Surveillance ; Drug Resistance
<b>CDC's Role:</b>	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
<b>Method Categories:</b>	Surveillance Support
<b>Methods:</b>	Cases of fungal diseases will be identified through state, local, and territorial (STLT) reportable disease systems, the Antimicrobial Resistance Lab Network (AR Lab Network), and reporting by local facilities and laboratories to health departments. Chart abstractions and/or patient interviews will be completed by state health departments, local health departments, other federal agencies, or members of the private sector. Data will be submitted into a CDC REDCap project using standardized case-report forms.
<b>Collection of Info, Data or Biospecimen:</b>	Data will be collected through chart abstractions and/or patient interviews by state health department or local health departments, other federal agencies, or members of the private sector. These data will be entered into a CDC REDCap project.
<b>Expected Use of Findings/Results and their impact:</b>	Data from FungiSurv might serve multiple purposes, including identifying at-risk populations, exposures, diagnostic and clinical severity patterns, treatment outcomes, and trends in resistance and geographical spread. These data can help guide public health action to reduce exposures, improve diagnosis and treatment, design novel interventions, drive public and clinician awareness, and prepare for vaccines in the pipeline.
<b>Could Individuals potentially be identified based on Information Collected?</b>	Yes
<b>Will PII be captured (including coded data)?</b>	Yes
<b>Does CDC have access to the identifiers (including coded data)?:</b>	No
<b>Is this project covered by an Assurance of Confidentiality?</b>	No
<b>Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?</b>	No
<b>Is there a formal written agreement prohibiting the release of identifiers?</b>	No

## Funding

Funding yet to be added .....

## **HSC Review**

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### **Regulation and Policy**

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**Do you anticipate this project will require review by a CDC IRB or HRPO?** No

**Estimated number of study participants**

**Population - Children**

Protocol Page #:

**Population - Minors**

Protocol Page #:

**Population - Prisoners**

Protocol Page #:

**Population - Pregnant Women**

Protocol Page #:

**Population - Emancipated Minors**

Protocol Page #:

**Suggested level of risk to subjects**

**Do you anticipate this project will be exempt research or non-exempt research**

### **Requested consent process wavers**

**Informed consent for adults** No Selection

**Children capable of providing assent** No Selection

**Parental permission** No Selection

**Alteration of authorization under HIPAA Privacy Rule** No Selection

### **Requested Waivers of Documentation of Informed Consent**

**Informed consent for adults** No Selection

**Children capable of providing assent** No Selection

**Parental permission** No Selection

## Consent process shown in an understandable language

<b>Reading level has been estimated</b>	No Selection
<b>Comprehension tool is provided</b>	No Selection
<b>Short form is provided</b>	No Selection
<b>Translation planned or performed</b>	No Selection
<b>Certified translation / translator</b>	No Selection
<b>Translation and back-translation to/from target language(s)</b>	No Selection
<b>Other method</b>	No Selection

## Clinical Trial

<b>Involves human participants</b>	No Selection
<b>Assigned to an intervention</b>	No Selection
<b>Evaluate the effect of the intervention</b>	No Selection
<b>Evaluation of a health related biomedical or behavioral outcome</b>	No Selection
<b>Registerable clinical trial</b>	No Selection

## Other Considerations

<b>Exception is requested to PHS informing those bested about HIV serostatus</b>	No Selection
<b>Human genetic testing is planned now or in the future</b>	No Selection
<b>Involves long-term storage of identifiable biological specimens</b>	No Selection
<b>Involves a drug, biologic, or device</b>	No Selection
<b>Conducted under an Investigational New Drug exemption or Investigational Device Exemption</b>	No Selection

## Institutions & Staff

### Institutions

Will you be working with an outside Organization or Institution? Yes

Institutions yet to be added .....

## Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Jeremy Gold	07/28/2025	08/12/2022				Co-Investigator	leo3@cdc.gov	404-718-3650	MYCOTIC DISEASES BRANCH
Kaitlin Benedict	07/29/2025	10/05/2025				Co-Investigator	jsy8@cdc.gov	404-639-0387	Epidemiology Team
Kaitlin Forsberg	09/22/2025	12/04/2020				Co-Investigator	lnv6@cdc.gov	404-718-3474	Epidemiology Team
Meghan Lyman	04/24/2026	08/12/2017		12/17/2021		Co-Investigator	yeo4@cdc.gov	404-639-4241	Epidemiology Team
Mitsuru Toda	06/26/2026	08/19/2021	09/24/2020			Co-Investigator	nrk7@cdc.gov	404-718-6784	Epidemiology Team

## Data

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### DMP

**Proposed Data Collection Start Date:** 3/1/23

**Proposed Data Collection End Date:** 12/31/24

**Proposed Public Access Level:** Public

**Public Access Justification:** Data could be made available upon request. Data are deidentified and do not involve sensitive patient information

**How Access Will Be Provided for Data:** Data will be stored on REDCap on a secure project. Only staff members on this project determination will be given access to these data.

**Plans for Archival and Long Term Preservation:**

## Spatiality

Spatiality (Geographic Locations) yet to be added .....

## Dataset

Dataset Title	Dataset Description	Data Publisher/Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

## Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	09/30/2024	NOA 0920-1385 (2024)	Notice of Action	NOA 0920-1385_2024.pdf
Current	Williams_Samantha (pog3) Project Contact	09/05/2024	Mycetoma CRF	Data Collection Form	Prospective Mycetoma CRF.docx
Current	Williams_Samantha (pog3) Project Contact	09/05/2024	OMB Notice of Action	Notice of Action	NOA - 2024-04-22T060442.883.pdf
Current	Williams_Samantha (pog3) Project Contact	09/05/2024	FungiSurv Pilot Case Report Forms	Data Collection Form	FungiSurv_CRFs.docx
Current	Williams_Samantha (pog3) Project Contact	09/05/2024	Chromoblastomycosis CRF	Data Collection Form	Prospective Chromoblastomycosis CRF.docx
Current	Williams_Samantha (pog3) Project Contact	09/05/2024	Sporotrichosis CRF	Data Collection Form	Prospective Sporotrichosis CRF.docx
Current	Williams_Samantha (pog3) Project Contact	09/05/2024	N/A	HS Research Determination Memo	020623DS-NR-signed.pdf

	Peterson_James M. (iyr1) CIO HSC	02/06/2023	N/A	HS Research Determination Memo	020623DS-NR-signed.pdf
	Smith_Dallas (rhq8) Project Contact	01/31/2023	FungiSurv Pilot Case Report Forms	Data Collection Form	FungiSurv_CRFs.docx



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