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

Print Date: 9/5/24

Title:	Antimicrobial Resistance Laboratory Network
Project Id:	0900f3eb82091b38
Accession #:	NCEZID-OAR-1/18/23-91b38
Project Contact:	Masiray Swaray
Organization:	NCEZID/DHQP/OAR
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	01/01/2016
Estimated Completion Date:	01/01/2033
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1310

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	9/5/24	Peterson_James M. (iyr1) CIO HSC
PRA: **PRA Applies**		9/5/24	Vice_Rudith (nhr9) OMB / PRA

ICRO: **PRA Applies**	OMB Approval date: 5/23/23 OMB Expiration date: 5/31/26	9/5/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Priority Justification:	
CDC Priority Area for this Project:	Not selected
Determination Start Date:	01/24/23
Description:	CDC#s AR Lab Network supports nationwide lab capacity to rapidly detect antimicrobial resistance and inform local responses to prevent spread and protect people.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Submitted through IMS Clearance Matrix:	Not selected
Primary Scientific Priority:	Not selected
Secondary Scientific Priority (s):	Not selected
Task Force Responsible:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The AR Lab Network builds capacity to rapidly detect AR in healthcare and the community, inform local responses to prevent spread, and protect people from AR threats. The AR Lab Network includes public health labs in all 50 states and Puerto Rico, including seven regional labs and the National Tuberculosis Molecular Surveillance Center (National TB Center). State and local laboratories will build or sustain capacity to detect and support response to concerning resistance. The Network tracks changes in resistance and helps identify and respond to outbreaks faster. This project determination is intended to serve as an umbrella determination for any sub-project involving only the use of pathogen isolate data. Special projects or other activities with new data collections may need review to ensure they are covered by this determination or if a separate determination is recommended. Implementation of AR Lab Network activities will result in: #Increased state, local, and regional public health laboratory capacity to detect and confirm AR using CDC-recommended methods #Rapid identification and containment of AR threats including novel resistance #Timely and effective response to HAI/AR outbreaks #Improved coordination and information sharing with epidemiology,

Objective:	laboratory, and prevention partners to support outbreak response and prevention efforts #Improved test results and data reporting to partners including public health epidemiologists, laboratorians, healthcare partners, and CDC to inform surveillance efforts and outbreak response #Enhanced molecular surveillance of AR threats #Enhanced capacity for detection of outbreaks and transmission of Mtb
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	Not Selected
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	Not Selected
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Secondary Data or Specimen Analysis ; Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials ; Programmatic Work
Target Populations to be Included/Represented:	Other - State and local health departments
Tags/Keywords:	Laboratories ; Drug Resistance, Bacterial ; Drug Resistance, Multiple, Fungal ; Neisseria gonorrhoeae ; Candida ; Enterobacteriaceae ; Pseudomonas aeruginosa ; Streptococcus pneumoniae ; Mycobacterium tuberculosis ; Clostridium difficile
CDC's Role:	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
Method Categories:	Culture; Pathogen-specific Research; Proficiency Testing; Secondary Data Analysis; Secondary Specimen Analysis; Surveillance Support
Methods:	State and regional labs will perform various testing to improve detection and laboratory diagnostics for rapid detection and faster response to outbreaks and emerging antibiotic resistance related to healthcare-associated infections (i.e, bacterial and fungal pathogens).
Collection of Info, Data or Biospecimen:	Participating laboratories will report all testing results to CDC using a secure online web-portal, REDCap, or Health Level 7 (HL7) transmission. All testing results that indicate immediate threats to patient safety and require rapid public health action will be communicated to CDC and local public health authorities within one day of identification. Participating labs will also submit an annual report describing current testing methods and an annual performance measurement report. Specimen and isolate level testing data from AR Lab Network participants will be shared with CDC via secure FISMA compliant mechanisms such as HL7 or RedCap. Data will be coded using the ARLN ID, with sending laboratory holding the keys to linked PII. In some cases, DOB is sent where age is not available for HL7 transmission. Keys to linking PII are held at the PHL may be shared with public health officials to facilitate public health action (such as an outbreak investigation) but will not be sent to CDC. All specimen level data will be stored in secure access restricted databases at CDC to ensure confidentiality of this data. Prior to sharing aggregated data via reports or publications, procedures will be in place to ensure the granularity of the data is sufficient to protect privacy of individuals and their protected health information. Additional precautions will be taken if reporting rare events that may be linked to individuals. Data collected for public health purposes via the AR Lab Network may be de-identified or aggregated for use in secondary analysis by the recipient program. All secondary analysis should ensure privacy of specimen level data is maintained. The results from laboratory testing will be used to (1) identify and contain new and emerging antibiotic resistant threats, including

Expected Use of Findings/Results and their impact:	carbapenemase-producing organisms that can spread carbapenem-resistance through mobile genetic elements, (2) describe the geographical distribution of antibiotic resistant threats, (3) detect novel resistance phenotypes and genotypes among healthcare-associated organisms, (4) describe and reduce the spread of resistance mechanisms, and (5) provide data for regional, state, and local infection prevention programs to set priorities and mount targeted containment and prevention responses.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)	CK19-1904	2019	5	

HSC Review

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB?	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

Suggested level of risk to subjects

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

Requested consent process waviers

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

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

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection

Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	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	Staff Role	Email	Phone	Organization
Cau Pham	09/23/2025	01/07/2022		04/22/2022	Program Official	whi4@cdc.gov	404-718-5642	STD LABORATORY REFERENCE & RESEARCH BRANCH
Dawn Sievert	04/21/2026				Program Lead	alz1@cdc.gov	404-718-3270	DIVISION OF HEALTHCARE QUALITY PROMOTION
Stephanie Gumbis	08/14/2026				Program Lead	gpf1@cdc.gov	404-639-4778	OFFICE OF ANTIMICROBIAL RESISTANCE

Data

DMP

Proposed Data Collection Start Date:	1/1/16
Proposed Data Collection End Date:	1/1/33
Proposed Public Access Level:	Public
Public Access Justification:	The isolate data generated by testing of pathogens at state health department, regional public health, and CDC labs will have public health importance for the control of antimicrobial resistance such that at least aggregate data should be released. Whole genome sequence data and accompanying metadata will be released on NCBI. Future release of other individual-level isolate data may also be considered after de-identification for secondary research use. All such data releases shall be designed to maintain personal privacy and prevent association of protected health information with any individuals. No personal identifying information will be included.
How Access Will Be Provided for Data:	Aggregated data will be shared via scientific publications, annual reports and other published materials and through CDC maintained dashboards (such as the AR & Patient Safety Portal) to provide this information to the public and the public health community. Whole genome sequencing data from AR Lab Network testing data will be made available to publicly available databases such as NCBI and GISAID. Metadata associated with these results should also ensure privacy with no ability to link to individual patients per the CDC program recommendations.
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	09/05/2024	NOA 0920-1310 (2023)	Notice of Action	NOA 0920-1310_2023.pdf
	Peterson_James M. (iyr1) CIO HSC	09/05/2024	N/A	HS Research Determination Memo	090524MS-NR-signed.pdf
	Swaray_Masiray (sui9) Project Contact	09/04/2024	Final version of project determination	Other	AR Laboratory Network_Umbrella Package Protocol_09042024_final.docx
	Peterson_James M. (iyr1) CIO HSC	09/03/2024	HSC added comments and edits using tracked changes.	Protocol	AR Laboratory Network_Umbrella Package Protocol_08292024_clean with HSC comments.docx
	Swaray_Masiray (sui9) Project Contact	08/30/2024	Project Determination for AR Lab Network	Other	AR Laboratory Network_Umbrella Package Protocol_08292024_clean_for IRB initial review.docx
	Peterson_James M. (iyr1) CIO HSC	04/14/2023	HSC comments added.	Protocol	Antimicrobial Resistance Laboratory Network umbrella determination HSC comments.docx
	Peterson_James M. (iyr1) CIO HSC	02/06/2023	TEMPLATE: PLEASE FOLLOW OUTLINE GUIDANCE FOR COMPLETING	Other	NCEZID Project Determination Request 2021.docx
Current	Swaray_Masiray (sui9) Project Contact	01/24/2023	It is under G2. AR Lab Network in the NOFO.	Notice of Funding Opportunity	ELC_CK19-1904_2022_Continuation_Guidance_BP4 (1).pdf

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