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

Print Date: 5/21/25

Title:	Rural Carveout Survey in Support of Program Evaluation for OT21-2103 COVID-19 Health Disparities Grant
Project Id:	0900f3eb823cf563
Accession #:	PHIC-ODRE-6/24/24-cf563
Project Contact:	Molly M Francis
Organization:	PHIC/OD/ODRE
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	09/02/2024
Estimated Completion Date:	12/31/2025
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-0879

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Program Evaluation	7/25/24	Macaluso_Renita (arp5) CIO HSC
PRA: **PRA Applies**		7/25/24	Macaluso_Renita (arp5) OMB/PRA
ICRO: **PRA Applies**	OMB Approval date: 8/29/23 OMB Expiration date: 8/31/26	8/5/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Priority Justification:

CDC Priority Area for this Project: Other CDC Priority - Strengthening the Public Health Infrastructure

Determination Start Date: 07/03/24

Description: This study will contribute to the evaluation of CDC-RFA-OT21-2103, a funding announcement for an investment of $2.25, of which 19% was allocated as rural carveout funding. This funding sought to address COVID-19 related health differences, including those experienced by people living in rural areas. This grant reflects a novel funding approach as 1) it was the first CDC grant to directly fund 50 local health departments, 2) it provided all funded recipients (state, local, and territorial) with the flexibility to select grant strategies and allocate funds where communities need them most, 3) it included state health department funding set aside for rural communities, and (4) it mandated State Health Departments collaborate with State Offices of Rural Health The purpose of this evaluation is to describe experiences planning for and implementing the rural carveout funding for OT21-2103, describe partnerships, understand the benefits and contributions of the rural carveout, and identify lessons learned to inform future rural carveout readiness and response strategies. This study will use a web-based questionnaire and key informant interviews in a concurrent mixed methods evaluation to assess how the grant was implemented in rural communities and the outcomes associated with this grant. A web-based questionnaire via Qualtrics will be disseminated to all 50 State Office of Rural Health (SORH) directors, managers, or their designees. Concurrently, 47 State Health Departments and SORHs will be invited to participate in semi-structured interviews. Both the questionnaire and the interviews will be voluntary.

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	This evaluation will assess and document the experiences of states with CDC-RFA-OT21-2103#s novel rural funding approach to more directly and flexibly reach rural communities to support readiness and response efforts. The information collection will assess allocation of funds, how funds were used, partnerships, the benefit and contribution of the rural funding approach, and lessons learned to inform possible future rural carveout funding strategies to increase response.
Objective:	Evaluation findings will be used to determine the benefit and contribution of this novel funding opportunity for rural communities and inform improvements to possible future response carveout strategies. CDC and the contracted project team will have access to identifiable data gathered in this information collection.
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other - Rural population
Tags/Keywords:	Capacity Building ; Implementation research ; Evidence-Based Practice ; Rural Health ; Evaluation Studies
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 ; CDC is providing funding
Method Categories:	Individual Interviews (Qualitative); Survey
	Information collected from this concurrent mixed methods study will evaluate the experiences of SORHs and state health departments in planning for and implementing the rural carveout, the benefits and contributions of the rural carveout funding, and lessons learned to inform rural carveout strategies. The study is comprised of two phases. A 60-minute questionnaire will be administered by either the CDC or CDC contractor. Fifty SORH directors, managers, or their designees will receive an invitation to complete the questionnaire in Qualtrics. SORHs will receive an email communication with a unique link that will allow them to save their work. To maximize participation, SORHs who do not respond will receive up to two follow up email communications requesting

Methods:	their participation. Those who do not reply within 30 business days from the initial recruitment email will be considered non-respondents. Once the data collection period is over, data will be downloaded from the web-based platform and stored in a secure environment maintained by CDC or a CDC contractor. Questionnaire data will be cleaned and analyzed using SAS or Stata; content analysis will be conducted with open-ended questionnaire responses using QSR NVivo. To supplement and enhance the questionnaire data, as well as provide an in-depth understanding of each state#s experience with the rural carveout funding; qualitative data will be collected from up to 94 respondents, including 47 SORHs and 47 state health departments via voluntary 60-minute virtual interviews on Zoom or Microsoft Teams. To maximize participation, potential respondents who do not respond will be contacted to determine if they are interested in participating. Those who do not respond within 12 business days from the initial recruitment email will be considered non-responders. Interviews will be led by a CDC contractor. The CDC contractor will record the interviews and take detailed notes. Once the interviews are complete, the CDC contractor will transcribe the interviews. Interviews will then be coded in an iterative process to capture apriori and emergent key themes from the interviews using QSR NVivo software. Results from the questionnaire and interviews will be used to describe experiences planning for and implementing the rural carveout funding for OT21-2103, describe partnerships, understand the benefits and contributions of the rural carveout, and identify lessons learned to inform future rural carveout readiness and response strategies.
Collection of Info, Data or Biospecimen:	The questionnaire will be completed by SORH directors, managers, or their designees. The interview will be conducted by a CDC contractor.
Expected Use of Findings/Results and their impact:	Findings from this evaluation study will be shared internally (e.g., with PHIC leadership, CDC audiences who use data to support cross-agency coordination around public health preparedness and response or rural health initiative) through different products such as summaries and PowerPoint presentations. Findings may also be shared externally (manuscripts, briefs, summaries and reports) as supported by the data. The findings will provide a data-informed lens into the benefits of the rural carveout and inform future rural carveout strategies.
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	Strengthening Public Health Systems and Services through National Partnerships to Improve and Protect the Nations Health	CDC-RFA-PW-24-00800101SUPP24	2025	1	199912.00
CDC Contract	DJS Research, Monitoring, and Program Evaluation Support	75D30124F20126	2025	3	13070000.00

HSC Review

HSC Attributes

Program Evaluation	Yes

Regulation and Policy

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 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

Institution	FWA #	FWA Exp Date	Funding	Funding Restriction Amount
NORC			Strengthening Public Health Systems and Services through National Partnerships to Improve and Protect the Nations Health - CDC-RFA-PW-24-00800101SUPP24	
Westat, Inc.	FWA00005551	07/19/29	DJS Research, Monitoring, and Program Evaluation Support - 75D30124F20126	

Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been Lifted
NORC			
Westat, Inc.			

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
NORC	Designing or Developing Project and/or Data Collection Instrument(s); Other - Studying, Interpreting, or Analyzing Identifiable Data			
Westat, Inc.	Designing or Developing Project and/or Data Collection Instrument(s); Other - Studying, Interpreting, or Analyzing Identifiable Data	DJS Research, Monitoring, and Program Evaluation Support Contract		

Institution	Regulatory Coverage	IRB Review Status
NORC	IRB Review is Not Required	
Westat, Inc.	IRB Review is Not Required	

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
NORC			
Westat, Inc.			

Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB
NORC			
Westat, Inc.			

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
Alana Knudson	n/a	n/a	n/a	n/a	n/a	Co-Investigator	knudson-alana@norc.org		NORC
Alexa Siegfried	n/a	n/a	n/a	n/a	n/a	Co-Investigator	siegfried-alexa@norc.org		NORC
Diane Hall	03/20/2026					Principal Investigator	fqx7@cdc.gov	404-718-1118	OFFICE OF THE DIRECTOR
Diane Ng	08/26/2027					Co-Investigator	DianeNg@westat.com		Westat, Inc.
Hanyu Sun	08/26/2027					Co-Investigator	hanyusun@westat.com		Westat, Inc.
Isabella Hill	08/26/2027					Co-Investigator	isabellahill@westat.com		Westat, Inc.
Kerry Grace Morissey	08/26/2027					Co-Investigator	KerryGraceMorrissey@westat.com		Westat, Inc.
LaShonda Lee	08/26/2027					Co-Investigator	LaShondaLee@westat.com		Westat, Inc.
Michael Meit	08/26/2027					Co-Investigator	meitmb@etsu.edu		NORC
Molly Francis	07/19/2026		06/03/2025			Principal Investigator	tup0@cdc.gov	770-488-1677	CAPACITY BUILDING AND STRATEGIC RESOURCE MANAGEMENT BRANCH
Patricia Spencer	08/26/2027					Co-Investigator	rup9@cdc.gov	512-586-6747	EVALUATION UNIT
Saloni Sapru	08/26/2027					Co-Investigator	SaloniSapru@westat.com		Westat, Inc.
Shaima Bereznitsky	08/26/2027					Co-Investigator	ShaimaBereznitsky@westat.com		Westat, Inc.

Sophia Tsakraklides	08/26/2027					Co-Investigator	SophiaTsakraklides@westat.com		Westat, Inc.
Valentine Polii	08/26/2027					Co-Investigator	valentinepolii@westat.com		Westat, Inc.
Victoria Hallman	08/26/2027					Co-Investigator	hallman-victoria@norc.org		NORC

Data

DMP

Proposed Data Collection Start Date: 7/1/25

Proposed Data Collection End Date: 12/31/25

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - The data sets are restricted due to the temporary nature of the funding.

Public Access Justification: 2103 rural carveout evaluation study data sets will not be made publicly accessible (i.e., are restricted use data sets). This decision protects recipient confidentiality and considers the temporary nature of this initial funding which does not provide resources for long-term management of publicly accessible data sets (see Policy CDC-GA-2005-14).

How Access Will Be Provided for Data: Not applicable

Plans for Archival and Long Term Preservation: The 2103 evaluation team will archive data according to CDC Records Management Policy.?For data sets used in publicly accessible publications, a machine-readable version of data tables shown in the paper will be released at the time of publication.

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
Current	Francis_Molly (tup0) Project Contact	05/20/2025	Data Management Plan for questionnaire data.	Other	Questionnaire DMP_Westat.pdf
Current	Zirger_Jeffrey (wtj5) ICRO Reviewer	08/05/2024	NOA 0920-0879 (2023)	Notice of Action	NOA 0920-0879_2023.pdf