



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

*Print Date: 1/7/22*

**Title:** National Initiative to Address COVID-19 Health Disparities among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities

**Project Id:** 0900f3eb81cc6920

**Accession #:** CSTLTS-NPB-3/11/21-c6920

**Project Contact:** Christine Graaf

**Organization:** CSTLTS/DPPS/NPB

**Status:** **Project In Progress**

**Intended Use:** **Project Determination**

**Estimated Start Date:** 03/15/2021

**Estimated Completion Date:** 06/15/2023

**CDC/ATSDR HRPO/IRB Protocol #:**

**OMB Control #:**

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other  <i>45 CFR 46.102(l)</i>  Other - Workplan template	3/14/21	Colman_Laura (mwu4) CIO HSC

PRA: PRA Applies	<p><b>Qualifies for a statutory waiver:</b> 21st Century Cures Act - Sec. 3087 (Public Health Emergency)</p> <p><i>Justification:</i> As a result of the declared public health emergency, COVID-19, CDC's COVID-19 related data collections currently fall under a PHE PRA Waiver as part of the 21st Century Cures Act. Recipients will be funded to plan and implement activities specifically related to mitigating COVID-19 in communities. If information collection activities continue beyond the period of the declared public health emergency or beyond the termination PHE PRA Waiver, all collections will become subject to requirements of the PRA and CSTLTS will work with the program to obtain necessary approvals prior to the expiration of the PHE waiver.</p>	3/15/21	Wigington_Corinne J. (jgi2) OMB / PRA
ICRO: Returned with No Decision		3/15/21	Zirger_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

### Description

<b>Priority:</b>	Urgent
<b>Date Needed:</b>	03/15/2021
<b>Priority Justification:</b>	This item is associated with the publication of an emergency grant for state, local, US territorial, and freely associated state health departments (or their bona fide agents) to address COVID-19.
<b>Determination Start Date:</b>	03/11/21
<b>Description:</b>	Included for PRA clearance is the work plan template associated with the NOFO for OT21-2103: National Initiative to Address COVID-19 Health Disparities among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities. The work plan template will be completed by applicants between March 16, 2021 and April 30, 2021.
<b>IMS/CIO/Epi-Aid/Chemical Exposure Submission:</b>	Yes
<b>IMS Activation Name:</b>	2019 Novel Coronavirus Response
<b>Primary Priority of the Project:</b>	Prevention, mitigation, and intervention strategies
<b>Secondary Priority(s) of the Project:</b>	Other Science Topic - Healthy Equity
<b>Task Force Associated with the Response:</b>	Not selected

<b>CIO Emergency Response Name:</b>	Not selected
<b>Epi-Aid Name:</b>	Not selected
<b>Assessment of Chemical Exposure Name:</b>	Not selected
<b>Goals/Purpose</b>	<p>The purpose of the work plan template is to gather information from applicants regarding proposed grant activities. This information will be used to conduct the technical review process and to pre-populate the performance and fiscal monitoring forms recipients will complete quarterly throughout the period of performance. No other data of this kind are being collected as this is a novel grant being administered. Thus we are confident there is no duplication of effort.</p>
<b>Objective:</b>	<p>Applicants must develop and submit a high-level work plan for the 2-year period of performance. The work plan must align with the strategies and activities outlined in the NOFO. Specifically, activities must align to one or more of the following strategies: Strategy 1: Expand existing and/or develop new mitigation and prevention resources and services to reduce COVID-19 related disparities among populations at higher risk and that are underserved Strategy 2: Increase/improve data collection and reporting for populations experiencing a disproportionate burden of COVID-19 infection, severe illness, and death to guide the response to the COVID-19 pandemic Strategy 3: Build, leverage, and expand infrastructure support for COVID-19 prevention and control among populations that are at higher risk and underserved Strategy 4: Mobilize partners and collaborators to advance health equity and address social determinants of health as they relate to COVID-19 health disparities among populations at higher risk and that are underserved Applicants are not required to implement all four strategies, but rather they should select the strategies and activities that best address their jurisdiction's respective priorities and needs. Strategies should engage representatives of populations and communities to be served by this NOFO. CDC will also allow applicants to propose additional strategies and activities beyond those included in the NOFO to best achieve local outcomes. Any proposed new strategy or activity should include the rationale for the approach or a brief justification with evidence showing why it should be included. Applicants must use the template provided as Attachment B: CDC-RFA-OT21-2103 Work Plan. Applicant must name this file #[Name of Jurisdiction] Work Plan# and upload it as an attachment to <a href="http://www.grants.gov">www.grants.gov</a>.</p>
<b>Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and/or decreasing disparities?:</b>	Yes
<b>Project does not incorporate elements of health equity science:</b>	Not Selected
<b>Measuring Disparities:</b>	Not Selected
<b>Studying Social Determinants of Health (SDOH):</b>	Not Selected
<b>Assessing Impact:</b>	Yes
<b>Methods to Improve Health Equity Research and Practice:</b>	Not Selected
<b>Other:</b>	Not Selected
<b>Activities or Tasks:</b>	Programmatic Work
<b>Target Populations to be Included/Represented:</b>	Other - Applicants of the OT21-2103 NOFO
<b>Tags/Keywords:</b>	Health Equity

**CDC's Role:** CDC is providing funding

**Method Categories:** Other - Excel Work Plan Template

**Methods:** Information will be collected from applicants via the Excel work plan template submitted to CDC in Grants.gov as a part of their grant application. The proposed template ensures maximum quality while ensuring minimum burden to recipients. Descriptive statistics (i.e., frequencies) may be generated from work plan reports.

**Collection of Info, Data or Biospecimen:** Information will be collected from applicants via the Excel work plan template submitted to CDC in Grants.gov as a part of their grant application. We estimate 108 respondents and 2 hours per respondent = 216 burden hours total for completion.

**Expected Use of Findings/Results and their impact:** Information collected will be used to conduct the technical review process and to pre-populate the performance and fiscal monitoring forms recipients will complete quarterly throughout the period of performance.

**Could Individuals potentially be identified based on Information Collected?** No

## Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Grant	National Initiative to Address COVID-19 Health Disparities among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities	OT21-2103	2021	2	

## HSC Review

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### HSC Attributes

Other - Workplan template Yes

## Regulation and Policy

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Do you anticipate this project will be submitted to No

the IRB office

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 HIPPA 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 identifiable 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

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
Christine					Project	khx2@cdc.	404-498-	NATIONAL PARTNERSHIP





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