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

Print Date: 6/1/21

Title: A Longitudinal Examination of Mental and Physical Health among Police Associated with COVID-19

Project Id: 0900f3eb81b7c6f3

Accession #: NIOSH-BB-6/25/20-7c6f3

Project Contact: Erin Mccanlies

Organization: NIOSH/HELD/BB

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 08/01/2020

Estimated Completion Date: 07/31/2022

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Non-Exempt Human Subjects Research when CDC is not engaged *45 CFR 46.102(a) HHS/OHRP 2008 Engagement Guidance at III B(1-11)*	6/29/20	Siegel_Paul D. (pds3) Division HSC
PRA:	**Qualifies for a statutory waiver:** 21st Century Cures Act - Sec. 3087 (Public Health Emergency)	6/30/20	Sawyer Deloney_Tamela (tqs7) OMB /

PRA Applies	*Justification:* Data collection qualifies for PHE waiver (COVID-19 related).		PRA
ICRO: **Returned with No Decision**		6/30/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Urgent

Date Needed: 08/01/2020

Priority Justification: In order to meet the aims of this project, it is imperative we start the project as soon as possible.

Determination Start Date: 06/26/20

Description: The COVID-19 outbreak unmasks the inadequate preparation that society has for dealing with a pandemic, including limited equipment and inadequately trained personnel. For police officers, an already highly stressed population, this quickly changing landscape has likely resulted in even higher levels of mental and physical stress. Addressing police mental and physical health is important for their wellbeing as well as that of the public they serve. Nonetheless, little research has been conducted to evaluate the physical and mental health consequences of the COVID-19 pandemic on police officers. This project will be conducted in collaboration with Dr John Violanti with whom we have previously conducted cross-sectional research projects to evaluate the psychological, physiological, and subclinical measures of mental and physical health in Buffalo, NY police officers as part of the Buffalo Cardio-Metabolic Occupational Police Stress (BCOPS) study. The BCOPs study itself includes a baseline examination and follow-up examinations. Measures include the use of psychosocial stress surveys and stress biomarkers. Health outcomes include changes in blood parameters and components of the metabolic syndrome. We will contract with the University of Buffalo, NY (John Violanti) to recruit police officers for whom they have previously collected mental and physical health data. The contractor will provide NIOSH with deidentified data that can be linked with previously collected data currently being held at NIOSH. This will allow us to compare this mental and physical health data collected prior to the COVID-19 pandemic to data collected during the pandemic and one year later. Given the high rates of mental and physical health issues in the policing population, this study could lead to new knowledge about police specific occupational stressors during a pandemic and identify risk and protective factors that may be used to mitigate these stressors. The objective of this study is to determine the longitudinal effects of the COVID-19 pandemic on the mental and physical health of police officers. The projects specific aims are: 1. To evaluate the impact of COVID 19 on police officers including the longitudinal psychological and biological measures of stress pre-pandemic to those collected during and after the pandemic. 2. To examine personal and organizational resiliency and coping as it modifies stress. 3. To longitudinally examine the impact of stress on cellular aging (telomere length) and stress associated with the COVID-19 pandemic. Frozen blood samples are available prior to COVID-19 and will again be obtained from the same officers during the present proposed study to evaluate longitudinal change in telomere length. 4. Evaluate mental health status one year later, post-COVID-19. 5. To disseminate results in peer reviewed, stakeholder, and various media outlets. To meet the aims of this study, it is imperative that this study begin as soon as possible.

IMS/CIO/Epi-Aid/Chemical Exposure Submission: Yes

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	2019 Novel Corona Virus Response
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	This project is not duplicative. An environmental scan revealed no known projects with similar data collection activities in Erie county, NY. Partners were contacted and no additional data collection activities are planned at this time in Erie county, NY. Literature reviews also indicate that there are no other studies with similar data collection activities.
Objective:	The overarching objective of this proposed project is to determine the longitudinal consequences of the COVID-19 pandemic on the mental and physical health of police officers.
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?:	Not Selected
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Research with Humans
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	novel coronavirus-COVID19 ; police officers
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 employees or agents will obtain or use anonymous or unlinked data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s)
Method Categories:	Prospective Cohort Study
Methods:	The overarching objective of this proposed project is to determine the longitudinal effects of the COVID-19 pandemic on the mental and physical health of police officers. Because this is a longitudinal study, the sample size is set at 240, because that is the number of participants for whom we have previously collected mental and physical health data. We anticipate that approximately 10% of the 240 might not participate in the first round and 10% might not participate in the second round, leaving a sample size of 194. A longitudinal analysis strategy will be used to address or answer the aims of this project. A statistician was consulted to determine if

	we have sufficient power to address the aims of this project. Power calculations showed the minimum detectable effects that would be detected at 80% power given a sample size of n=194, indicating that this is reasonable or sufficient to address the aims of this study.
Collection of Info, Data or Biospecimen:	A sample size of 240 participants with questionnaire, salivary cortisol, and serologic sample collection is required. The questionnaires, salivary cortisol, and serological sample collections will be administered within the first 6 months of the study then one year later the questionnaire data alone will be collected again. We anticipate that approximately 10% of the participants will not present for testing during the first round and another 10% may not respond to the second round of questionnaires. We expect all the participants who complete the questionnaires to provide a blood sample, but it is possible that some of the participants will not return the cortisol collection kit (~1%). The estimated is appropriate. The estimated burden time is: Questionnaire round 1: 216 * 1.0 hours = 216 hours Serological sample collection: 216 * 1.0 = 216 hours Salivary cortisol collection: 216 * 0.5 hours = 108 hours Questionnaire round 2: 194 * 1 = 194 hours Total burden for project: 734 hours The project has sufficiently addressed potential privacy concerns, including a formal agreement to prohibit the release of identifiers.
Expected Use of Findings/Results:	Given the high rates of mental and physical health issues in the policing population this study could lead to new knowledge about police specific occupational stressors during a pandemic and identify risk and protective factors that may be used to mitigate these stressors. Study findings will be disseminated through peer reviewed publications, presentations at scientific conferences, and also directly to police officers through workshops and publications in trade journals.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Funding Intramural	9390EX3		2019	2	

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

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 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 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

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
University at Buffalo - State University of New York	FWA00008824	02/03/25	Select one		

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
Anna Mnatsakanova	12/04/2021	10/21/2021			Co-Investigator	fma8@cdc.gov	304-285-4	BIOANALYTICS BRANCH

Claudia Ma	04/08/2023				Co-Investigator	iia4@cdc.gov	304-285-6280	BIOANALYTICS BRANCH
Desta Fekedulegn	12/10/2021	12/21/2021			Co-Investigator	djf7@cdc.gov	304-285-8	BIOANALYTICS BRANCH
Erin Mccanlies	12/06/2021		12/31/2022		Principal Investigator	eim4@cdc.gov	304-285-6132	BIOANALYTICS BRANCH
John Violanti	12/04/2021	10/21/2021			Principal Investigator	violanti@buffalo.edu	716-829-5481	University at Buffalo, NY
Michael Andrew	12/06/2021	10/31/2021			Co-Investigator	mta6@cdc.gov	304-285-6189	BIOANALYTICS BRANCH
Oliver Wirth	12/21/2021		11/01/2021		Contract Officer Representative	oaw5@cdc.gov	304-285-6323	BIOANALYTICS BRANCH

Data

DMP

Proposed Data Collection Start Date: 8/1/20

Proposed Data Collection End Date: 7/31/22

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact: Dr Erin McCanlies

Public Access Justification: To protect the privacy of the study participants.

How Access Will Be Provided for Data: Individuals interested in using this data must contact the PI, who will determine if the use is for research purposes only. After a data use agreement has been signed, delinked, deidentified data will be provided, or alternatively we will offer to conduct the statistical analysis, so that only aggregate and statistical results are sent rather than raw data.

Plans for Archival and Long Term Preservation: The data will be held in NIOSH/HELD/BB secure LAN file. Only NIOSH study staff will have access to this data. All laws, regulations, and rights regarding the data have been compiled.

Spatiality

Country	State/Province	County/Region
United States	New York	Erie

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...