



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

Print Date: 12/7/20

Title: Hearing Conservation Program Interviews

Project Id: 0900f3eb81ba41fa

Accession #: NIOSH-NC-7/27/20-a41fa

Project Contact: Azman_Amanda S. (zab9)

Organization: NIOSH/PMRD/WHB/NC

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 02/02/2021

Estimated Completion Date: 07/30/2021

CDC/ATSDR HRPO/IRB Protocol #: 20-NIOSH-22

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Requires HRPO Review	Exempt Human Subjects Research <i>45 CFR 104(D) 1-8</i>	8/26/20	Steiner_Lisa J. (Ins6) Division HSC
PRA: PRA Applies		8/27/20	Sawyer Deloney_Tamela (tqs7) OMB / PRA

HRPO: HRPO/IRB Approves	HRPO/IRB decision date: 9/15/20 IRB Expiration date:	9/15/20	Morris_Diane C. (awu6) HRPO Reviewer
ICRO: Returned with No Decision		8/28/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	12/01/2020
Determination Start Date:	07/27/20
Description:	IRB protocol for collecting and evaluating interview data from miners regarding their workplace hearing conservation practices. OMB clearance is also necessary.
IMS/CIO/Epi-Aid/Chemical Exposure Submission:	No
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:	Not selected
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The goal of this work is to collect data on the opinions of workers and health and safety personnel in the mining industry regarding specific aspects of hearing loss prevention efforts at their worksite. This data set will be used to guide the development of interventions and tools, guidance and other outreach initiatives to reduce the incidence of occupational noise exposure and subsequent hearing loss in the mining industry.
Objective:	Mining continues to demonstrate the highest prevalence of occupational hearing loss. This work is directly aimed at combatting this public health disparity. Based on the data collected, tools and initiatives can be tailored to this population to reduce occupational noise exposure and the incidence of occupational hearing loss.
Activities or Tasks:	Research with Humans
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Noise, Occupational, Hearing Loss, Noise-Induced, Hearing

CDC's Role:	CDC employees or agents will obtain data by intervening or interacting with participants, CDC employees will participate as co-authors in presentation(s) or publication(s), CDC is the sole institution conducting activity
Method Categories:	Individual Interviews (Qualitative)
Methods:	Interviews will take place with willing participants from participating mine sites.
Collection of Info, Data or Biospecimen:	No PII will be collected. Interview data only will be collected.
Expected Use of Findings/Results:	These findings will guide future development of interventions, tools and guidance to reduce occupational hearing loss in mining. This data will provide us with targeted information related to the opinions and beliefs of the targeted worker population. This leads to greater likelihood of adoption and acceptance of guidance.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Funding Intramural	Increasing the Effectiveness of Targeting Mining Hearing Conservation Program Elements	93909QO	2018	4

HSC Review

Suggested level of IRB review

Expedited review is suggested	Yes
1a - Study of drugs not requiring Investigational New Drug exemption from FDA	No Selection
1b - Study of medical devices not requiring Investigational Device Exemption from FDA	No Selection
2a - Collection of blood from healthy, non-pregnant adults; below volume and frequency limits, minimally invasive	No Selection
2b - Collection of blood from other adults and children; below volume and frequency limits, minimally invasive	No Selection

3 - Prospective noninvasive collection of biological specimens for research purposes	No Selection
4 - Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves	No Selection
5 - Research that uses previously collected materials	No Selection
6 - Collection of data from voice, video, digital, or image recordings made for research purposes	Yes
7 - Research that uses interview, program evaluation, human factors, or quality assurance methods	Yes

Controversial or Sensitive Topics

The study addresses a controversial or sensitive topic	No
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HSC Attributes

Other - no PII	Yes
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Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	Yes
Estimated number of study participants	30
Population - Children	N/A
Population - Minors	N/A
Population - Prisoners	N/A
Population - Pregnant Women	N/A
Population - Emancipated Minors	N/A

Suggested level of risk to subjects Minimal Do you anticipate this project will be exempt research or non-exempt research
Exempt

Category 1: Educational Practices	No Selection
Category 2: Educational tests, surveys, interviews, or observation of public behavior	Recorded in such a manner that identity cannot readily be ascertained
Category 3: Benign Behavioral Interventions and Collection of Information	No Selection
Category 4: Secondary Research for Which Consent is not Required	No Selection
Category 5: Research and Demonstration Projects	No Selection
Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies	No Selection
Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required	No Selection
Category 8: Secondary Research for Which Broad Consent is Required	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
Lynn Alcorn	03/23/2023		10/19/2023		Co-Investigator	lyn3@cdc.gov	412-386-6732	NOISE CONTROL
Yousef Elmashae	07/25/2022		08/26/2022		Co-Investigator	opy0@cdc.gov	412-386-5366	NOISE CONTROL

Data

DMP

Proposed Data Collection Start Date:	2/2/21
Proposed Data Collection End Date:	7/23/21
Proposed Public Access Level:	Non-Public

Non-Public Details:

Reason For Not Releasing Data:	Removal of identifiers renders the remaining data of no value
Public Access Justification:	Data is not of use without identifiers
How Access Will Be Provided for Data:	PII will not be collected.
Plans for Archival and Long Term Preservation:	See attached protocol for data management description

Spatiality

Country	State/Province	County/Region
United States	Pennsylvania	Fayette
United States	Virginia	Loudoun
United States	Ohio	Cuyahoga
United States	Pennsylvania	Bedford

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...									



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