

**Generic Clearance for CDC/ATSDR**

**Formative Research and Tool Development**

**Title: Formative Research to Inform an Intervention to Improve the Early Detection and Surveillance of Pneumoconiosis in U.S. Coal Miners**

Supporting Statement B

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### 1. Respondent Universe and Sampling Methods

The proposed study will involve collecting data from two samples—coal miners and mining stakeholders. Coal miners will be recruited to participate in the elicitation interviews. In 2018, U.S. coal mines employed 53,515 workers [1]. According to the U.S. Energy Information Administration, there were 671 active coal mines in 2017 [2]. Most coal mines are in the Appalachian and Illinois Basins [2].

Current, retired, former, and contracted coal miners will be invited to participate in the study interviews. To meet the study inclusion criteria, miners will need to be at least 18 years of age, proficient in reading and speaking English, and have experience working as a coal miner within the last 10 years (i.e., current, retired, former, or contracted). Both surface and underground coal mineworkers will be included in the study.

Researchers will also recruit mining stakeholders. While this population may also include coal miners, it encompasses individuals in a variety of job positions. Further, the mining stakeholder population includes individuals who work in or support the mining sector. These individuals may be employed by mining companies, industry associations, regulatory agencies, labor unions, suppliers, manufacturers, or academic institutions [3].

### 2. Procedures for the Collection of Information

Data will be collected using elicitation interviews and focus groups. Elicitation interviews involve asking a series of open-ended questions to individuals in the target audience to understand the population’s attitudes, beliefs, behaviors and experiences regarding the behavior of interest (i.e., pneumoconiosis screenings) [4]. Elicitation interviews provide researchers with four types of information: (1) experiential attitude or affect, (2) behavioral beliefs, (3) normative referents, and (4) control beliefs and self-efficacy [4]. These information types are summarized in Table 1.

**Table 1. Information Collected During Elicitation Interviews**

Information Type	Example
<b>Experiential Attitude or Affect</b>	Attitudes or feelings about engaging in black lung screenings
<b>Behavioral Beliefs</b>	Perceived outcomes of engaging in black lung screenings
<b>Normative Referents</b>	Perceptions of how others feel about their engagement/lack of engagement in black lung screenings
<b>Control Beliefs and Self-Efficacy</b>	Factors that facilitate or impede their engagement in black lung screenings

Data collected from the elicitation interviews will be used to address Research Question 1: What are mineworkers’ attitudes, beliefs, and behaviors relative to black lung screenings? The following outlines the specific steps used to recruit participants and collect and manage data.

- (1) **Recruiting Coal Miners.** Researchers will recruit coal miners at mining events such as mine health and safety conferences and mine rescue competitions. Researchers will attend the event and recruit during interactions at these events. The interview recruitment script will guide the conversation (see Attachment F). Individuals who volunteer to participate will select an interview time and location from the interview sign-up sheet (see Attachment G).

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- (2) ***Gaining Informed Consent.*** Prior to the interview, informed consent will be verbally obtained from all participants. Since the study presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, a waiver of documentation of informed consent was approved by the NIOSH IRB, HSRB exempt determination pending (exempt determination pending, see Attachment I).
- (3) ***Demographic Survey.*** Participants will be asked to complete a demographic survey. The survey is expected to take no more than 5 minutes to complete (see Attachment C).
- (4) ***Conducting the Interviews.*** Face-to-face interviews will be conducted. With the permission of the participant, the interview will be audio recorded. Interviews will last a maximum of 45 minutes depending on the depth of the participant's responses. The interaction will be guided by the interview protocol and probes for clarification and additional information. The interview facilitator will take notes during the interaction. The interview includes questions about the participants' experiences and perceptions relative to black lung screenings. For example, mineworkers will be asked to discuss the advantages and disadvantages of participating in black lung screenings. The protocol will include open-ended elicitation questions like those presented by Montano & Kasprzyk [4]. The interview protocol is included as Attachment B. Personally identifiable information will not be collected.
- (5) ***Managing the Data.*** Following an interview, the facilitator will place the demographic survey, interview notes, and audio recording (if applicable) in a secure location. Any information that could potentially identify the participant or their employer will be removed from the data.

Researchers will also conduct focus groups with stakeholders to help establish priorities and generate ideas for an intervention to improve mineworkers' participation in early detection and medical surveillance programs. Researchers will use the nominal group technique to engage stakeholders in a collaborative and interactive process. The nominal group technique (NGT) was introduced by Delbecq and Van de Ven in the late 60s and is based on social-psychology research [5]. NGT has been identified as an effective tool to help groups establish priorities or identify and resolve problems [6, 7]. The highly-structured, qualitative technique helps to eliminate group behaviors and dynamics that may impede individual creativity and group decision making [5, 6].

Prior to each focus group, a researcher will provide a presentation on factors that may negatively influence mineworkers' participation in medical surveillance and early detection programs. Information about the presentation will be included in the event program. Figure X provides an example of a presentation abstract drafted for the Training Resources Applied to Mining conference.

**Figure 1. Example of Presentation Abstract**

***Factors that Keep Mineworkers from Getting Black Lung Screenings***

Coal workers pneumoconiosis (CWP), commonly known as "black lung", is a progressive occupational lung disease that can lead to disability and premature death. Recent reports show that the number of miners with advanced forms of the disease have increased over the last 10 years. According to David Blackley, DrPH, epidemiologist, and colleagues (2018), approximately one in every 10 long-tenured miners in the U.S. has CWP. Additionally, one in every 20 long-tenured miners in central Appalachia has a progressive form of the disease. Even with this increased health risk, less than 50% of miners voluntarily participate in the NIOSH Coal Workers' Health Surveillance Program. What prevents miners from participating in early detection programs? This presentation will review potential barriers and challenges identified in previous studies and reports. In addition, session attendees will have the opportunity to share their thoughts and concerns on black lung screenings in a guided group discussion.

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Attendees will have the option to participate in a focus group following the presentation. During the focus group, researchers will address Research Question 2: What challenges should be addressed to improve miners' participation in black lung screenings? The focus group protocol and procedures are provided in Appendix D. In addition, the following outlines the specific steps used to recruit participants and collect and manage data.

- (1) **Recruiting Stakeholders.** Researchers will recruit stakeholders at mining events such as mine health and safety conferences and mine rescue competitions. Researchers will provide a 20- to 30-minute presentation on factors that influence mineworkers' participation in black lung screenings at the event. Following the presentation, the researcher will use the focus group recruitment script to invite stakeholder participation (see Attachment H).
- (2) **Gaining Informed Consent.** Prior to the focus group, informed consent will be verbally obtained from all participants. The researcher will read the consent form and ask the participant to verbally consent if he or she would like to participate. Since the study presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, a waiver of documentation of informed consent was approved by the NIOSH IRB, HSRB determination pending.
- (3) **Demographic Survey.** Participants will be asked to complete a demographic survey (see Attachment E). The survey is expected to take no more than 5 minutes to complete.
- (4) **Structuring the Focus Groups.** The researcher will serve as the facilitator if the number of participants is less than five. If the number of participants exceeds five in any one session, the researcher may divide the participants into multiple groups and select an individual to serve as the facilitator to ensure the efficiency and manageability of the process. This approach has been recommended and used in other nominal group technique studies [5, 6] The researcher will rotate between the group to address questions and offer direction.
- (5) **Conducting the Focus Groups.** In-person focus groups will be conducted. With the permission of all participants in the group, the focus group will be recorded. Focus groups will last a maximum of 40 minutes depending on the depth of participants' responses. The interaction will be guided by the focus group protocol. The facilitator will take notes during the interaction. During the focus groups, participants will individually generate a list of priorities, create a collective list of priorities, and discuss and then individually rate the collective list (see Attachment D). The facilitator will lead a brief discussion on the results. Personally identifiable information will not be collected.
- (6) **Managing the Data.** Following a focus group, the facilitator will place the demographic surveys, focus group notes, and audio recording (if applicable) in a secure location. Any information that could potentially identify the participants or their employers will be removed the data.

### 3. Methods to Maximize Response Rates and Deal with No Response

Since the study addresses a recent stakeholder concern, it is anticipated that any data collected will offer valuable information. However, the quality of the data collected will significantly influence future intervention work. For example, a low response rate may limit the number of perspectives represented in the data. As a result, researchers may not have adequate data to tailor the future intervention to meet the needs of various audiences.

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Based on the consent rate from previous studies involving a similar sample, an 80% response rate is expected. For example, the response rate for a safety culture assessment conducted by NIOSH Office of Mine Safety and Health Research (OMSHR) was between 80% and 90% (see Peters & Kosmoski, 2014).

Unfortunately, due to the nature of field research, it will be difficult to ensure participation. In an effort to maximize the response rate, NIOSH researchers will work to (1) clearly communicate expectations with mineworkers and stakeholders, (2) offer convenient times and locations for mineworkers to participate in interviews during mining events, (3) ensure the interviews and focus groups do not exceed the allotted amount of time to minimize disruptions to the mining event.

#### 4. Tests of Procedures or Methods to be Undertaken

A version of the protocol for elicitation interviews has been validated and used in previous studies (see Montano & Kasprzyk [4]). The nominal group technique that will guide the focus group discussions has also been applied in previous research (see Rahman, Otim, Almarzouqi, & Rahman [6]). In addition, the interview and focus group protocols were reviewed internally by CDC/NIOSH behavioral research scientists to ensure readability and relevance.

#### 5. Individuals Consulted on Statistical Aspects/Individuals Collecting and/or Analyzing Data

The research task leader has experience and training in quantitative and qualitative analysis. However, the proposed study does not require in-depth statistical analysis. Descriptive statistics will be used to summarize the data including frequencies and means. Researchers will apply the constructs from the integrated model for behavioral prediction [8] to qualitative analysis. Qualitative data will be coded and themes will be identified.

The following individuals will assist with leading study design, data collection, and/or data analysis. If additional assistance or guidance is required regarding data collection, analysis, or management, other internal resources are available through teams within the project staff's branch.

**Table 2. Study Personnel**

Personnel	Title	Organization	Email
Emily Haas, PhD	Senior Research Behavioral Scientist	NIOSH/PMRD	wcq3@cdc.gov
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#### References

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