Supporting Statement

Field Evaluation of Prototype Kneel-Assist Devices in Low-Seam Mining

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Part A

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List of Attachments

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This Information Collection Request (ICR) is classified as "New".

According to the Mining Safety and Health Administration (MSHA) injury database, 227 knee injuries were reported in underground coal mining in 2007. The median days lost due to a knee injury in underground coal operations was 41 days. Low-seam coal mines are those with an extremely low working height (~42"). National Institute for Occupational Safety and Health (NIOSH) researchers have found that the average cost per knee injury in low-seam coal operations was $13,121.29. Thus, it can be estimated that the financial burden of knee injuries was nearly three million dollars in 2007. Typically, mine workers utilize kneepads to better distribute the pressures at the knee.

The effectiveness of these kneepads was only recently investigated in a study by NIOSH that has not yet been published. The results of this study demonstrated that kneepads do decrease the maximum stress applied to the knee albeit not drastically. Additionally, the average pressure across the knee remains similar to the case where subjects wore no kneepads at all. Thus, the injury data and the results of this study suggest the need for the improved design of kneel-assist devices such as kneepads. NIOSH is currently undertaking the task of designing more effective kneel-assist devices such as a kneepad and a padded support worn at the ankle where mine workers can comfortably rest their body weight.

Designing and testing prototype kneel-assist devices in the laboratory environment to quantitatively demonstrate superior performance to similar products currently available is only the first step in designing more effective devices. These devices must also be field tested to verify they do not result in body discomfort or inadvertent accidents. It is also important to determine how usable and durable these devices are in the harsh mining environment. In order to quantitatively demonstrate that these prototype devices have a positive effect on their users and are of improved quality to their predecessors, it is important to obtain feedback from mine workers that are performing their tasks while wearing the prototype devices. Their feedback will identify any necessary changes to the design of the devices such that NIOSH can ensure the prototypes will be well-accepted by the mining community.

The laws and regulations authorizing or mandating the data collection are Section 20(a)(1) of the Occupational Safety and Health Act (29 U.S.C 669). A copy of this section of the legislation can be found in Attachment 1.

Privacy Impact Assessment

Overview of the Data Collection System

Phase I

Data collection will be conducted using a series of questionnaires. The entire study will take approximately 24 months (this includes Phase I testing, Phase II testing, and time to analyze the data). A mine will be identified to test the prototype kneel-assist devices prior to commencing Phase II of the study. The data collected at this mine will be Phase I and it will ensure that the prototype kneel-assist devices are likely to be successful. At the Phase I mine site, a questionnaire will be administered to the section foreman via a conference call. This questionnaire will be used to determine the environmental conditions at the mine such as the type of surrounding rock, type of roof bolts being utilized, and the amount of wetness. Once these data are collected, those mine workers willing to participate in the study will be interviewed by NIOSH researchers to obtain baseline data such as their age, sex, handedness, years in mining, and job type. At this time, the mine workers will be given the prototype kneel-assist devices. One month later, the NIOSH researchers will return to the mine and interview the mine workers a second time both individually and as a group (i.e. focus group). This time, the interviewers will use a questionnaire designed to determine such things as the usability and durability of the prototypes. In addition to the individual interviews, a series of focus group questions will also be asked. For these questions, all participating mine workers will be in one room with a moderator and a tape recorder. The focus group questions are designed to determine the level of acceptance of the prototype kneel-assist devices and to highlight any useful modifications made to the prototypes. If the prototype kneel-assist devices do not appear to be successful, the data collected will be used to adequately redesign them and the above described process will begin again. If the prototype kneel-assist devices appear to be successful, Phase II of the study will commence.

Phase II

Once Phase II is ready to commence, cooperating mines will be identified. Every month, the section foreman at the cooperating mines will be asked to supply some information regarding the current mine environment (e.g. wet, dry, roof control plan). At each cooperating mine, a group of mine workers willing to participate in the study will be identified. These mine workers will be asked to answer questions regarding the prototype kneel-assist devices at several time points.

Initially, the mine workers will be given a control kneel-assist device. Currently, mine workers only utilize kneepads as a kneel-assist device. Therefore, only a control kneepad will be provided. No other controls will be necessary. Once they receive the control kneepad, they will be asked some basic demographics information such as their age, time in the mining industry, sex, and job type. Once this baseline data is collected, additional data will be collected at 1, 3, and 6 months after the study commences. At each time point, the mine workers will be asked to provide their feedback regarding factors such as body part discomfort, usability, durability, and ease of movement. After using the control kneepad for 6 months, participating mine workers will then be given the prototype kneel-assist device.

They will use this for a total of 6 months and will be asked to provide their feedback at 1, 3, and 6 months after beginning its use. Thus, Phase II of the study will last a total of 12 months (6 months with control; 6 months with prototype) and the mine workers will be asked questions a total of 7 times (baseline; 1, 3, and 6 months after control and after prototype usage begins). Additionally, after the mine workers have been using the prototype kneel-assist devices for the full 6 months, they will be asked a series of focus group questions. Again, these questions are designed to determine the level of acceptance of the prototype kneel-assist devices and to identify any useful modifications made to the devices.

Thus, information will be collected via conference calls and in-person interviews. Only NIOSH researchers will be involved in data collection. Since control kneepads will be used, it is important to link the data collection to the same person at each interview. Therefore, a sheet will be maintained that lists the participants' names and their assigned subject number. This list will be maintained until data collection has ended at which time the list will be destroyed. The collection data will then only consist of an unidentifiable subject number. These data will be permanently maintained.

Items of Information to be Collected

Several pieces of Information in Identifiable Form will be necessary for this study. It will be necessary to link each subject's responses between interviews. The mine management will be asked to assign each participating subject a unique identifier. NIOSH will never see this list. At the beginning of each interview, the subject will provide NIOSH with this number. Thus, it is a form of Information in Identifiable Form.

Additionally, subjects will need to consent to the study and photo release form. These forms (Attachments 3 and 4) were approved by the NIOSH Human Subject Review Board (Attachment 5). Required on these forms are the subject's names, age, address, and signature. These forms will be locked in the Principle Investigator's office at all times.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No web-based data collection methods will be used in this study.

2. Purpose and Use of Information Collection

Information will be collected at several time points. For Phase I of the study, a mine site will be identified where data is collected at baseline and again at one month (individual interviews and a focus group) following baseline data collection. The prototype kneel-assist devices will continue to be evaluated in this way until it appears that they will likely be successful in Phase II. Once Phase II begins, a control device will be given to the participants and baseline data will be collected. Data will then be collected at 1, 3, and 6 months following. The mine workers will then be given the prototype kneel-assist devices and data will again be collected at 1, 3, and 6 months following. In order to link the data collected at each time point, it will be necessary to have a unique identifier that the subject provides researchers with at the beginning of each interview. Mine management will create

a list of all participants and assign them a number. At the beginning of each interview, the subjects will only give this number. Thus, NIOSH will not be able to link the data to a specific person. All of the data will be collected by NIOSH researchers who are members of the Pittsburgh Research Laboratory's Mining Injury Prevention Branch.

The data collected will be used to have a positive effect on the design of the prototype kneel-assist devices. These data will ensure such things as acceptance, usability, and durability. Through this method, it becomes far more likely that these devices, when put into production, will be utilized by members of the mining community. In addition to field investigations, laboratory experiments will also be conducted to demonstrate that these kneel-assist devices decrease the stresses, forces, and moments at the knee far more than that which is currently available to mine workers. The laboratory component of this study does not require asking questions to the subjects and is, therefore, not included in this application. As a whole, this project should result in two kneel-assist devices (kneepad, body weight support at the ankle) that can withstand the harsh mining environment and decrease the stresses, forces, and moments at the knee. Therefore, these kneel-assist devices are likely to decrease the number of knee injuries observed in low-seam mining.

The negative consequences of not having this information is that factors such as body part discomfort, usability, and durability would be unknown for the prototype kneel-assist devices. Therefore, while the devices may prove to be superior in laboratory testing, the mining community still may reject them as a form of personal protective equipment due to problems in these areas. If the mining community rejects these devices, the risk of developing a knee injury in low-seam mining will go unaffected.

If the Information in Identifiable Form (name, address, age, signature, and unique identifier) is not collected, NIOSH will be unable to conduct the study as the subjects would not have consented. Conducting the study and publishing the findings is an avenue of communication with the mining industry to inform them as to the availability and success of these devices.

Privacy Impact Assessment Information

The information described above is being collected to obtain useful feedback regarding the design of the kneel-assist prototypes allowing necessary improvements to be identified and made.

The intended use of each subject's name, address, age, and signature is only for the purpose of consent to participate in the study and allow NIOSH researchers to take photographs. Only a subject number will appear on the information collection documents (i.e. questionnaires). The mine managers will keep a list with the subjects' names and assigned number. NIOSH researchers will not have access to this list.

The intended use of the feedback regarding the kneel-assist devices will be to improve the design of these devices. Due to time constraints and the fact that the primary form of personal protective equipment investigated in this study is a kneepad, the questionnaire asks more in depth questions about kneepads. A separate, shorter, section that is devoted to the body weight support device at the ankle is included at the end of the questionnaire. The

feedback for the kneepad will be obtained for the control and prototype kneepads and is divided into several different sections: 1) demographics; 2) body part discomfort; 3) usability; 4) ease of movement; 5) durability; 6) cleaning; and 7) changes to the kneepad. Many of these same areas are addressed by the shorter section for the body weight support device at the ankle.

The demographics information about the subject will be collected (e.g. job type, sex, handedness, time in mining) in case their responses to the questionnaire place them as an outlier. In this case, these demographics data may be used to determine a possible reason for their being an outlier. Additionally, there may be similar responses amongst people with similar demographics. For example, there may be a large number of section foreman that report problems with ease of movement. However, roof bolter operators may report no problems with ease of movement. This difference is likely due to the different tasks performed by these job types. Results such as these may suggest that multiple designs of the prototypes may be necessary for all job types to accept them as usable.

Body part discomfort information will also be collected. This information will be used to determine if the kneepad is causing any unanticipated discomfort. Other negative effects can also be identified from the questions in this section (e.g. restricted blood flow, causing a knee injury). Lastly, questions in the body part discomfort section are also designed to determine if there are any body positions or mining conditions that are uncomfortable due to the design of the kneepad.

The questions pertaining to usability are designed to determine how effective specific design features are such as the straps. The effects of the materials selected on biological conditions such as the amount of sweat are also determined. How much water is held by the kneepad is also of concern and is addressed in this section. Lastly, it is important to determine if using the kneepad has resulted in any unanticipated events such as inadvertently hitting a lever.

Ease of movement is another area of concern. This section of the questionnaire is designed to determine if there are any body positions that are made more difficult by the use of the kneepad. Additionally, the ability of the prototype kneepad to stay in place is also of concern since it likely will not be selected over the control kneepad if the user must continuously adjust it.

Durability is also a concern and is addressed by one section of the questionnaire. This section of the question asked questions that address what features of the kneepad failed and how durable the user felt these features were. It was also important to ask questions regarding the number of kneepads the subjects use on a regular basis. If they rotate between kneepads, it is likely that their kneepads will appear more durable than what is reported by subjects that do not rotate between pairs.

The frequency and method by which subjects choose to clean their kneepads is also of concern. The type of solution used may effect the durability of the kneepads since it may breakdown the materials earlier than if a subject did not use any form of cleaning solution.

The last section pertaining to the kneepad asks questions regarding changes the subjects made to the kneepad to make it more usable, comfortable, durable, etc. These changes offer a unique opportunity to determine various ways to address the shortcomings of the prototype kneepad. These questions not only ask what changes the subjects made but also what features they disliked and liked which allows some understanding of what features must be reconsidered.

As indicated above, all of these issues are also addressed for the body weight support device at the ankle. However, due to time constraints only select questions are asked of the subject.

Finally, the section foreman will be asked questions regarding the mining conditions on a monthly basis via a telephone call. The purpose of this information is to identify any changes to the mining environment that may impact the results of the field study. For example, if the subjects are working in wet, muddy conditions different responses to the questionnaire may be experienced. Since mine conditions routinely change, it is not sufficient to gather this information only at the time of the interviews.

3. Use of Improved Information Technology and Burden Reduction

Only in-person interviews and phone calls will be used in this study. General literacy is a problem in the mining community. For those that can read, the average reading level is only at the eighth grade level. Computer literacy is an additional problem. Therefore, any computer based data collection methods would be undesirable. Furthermore, due to the general literacy problem, in-person interviews were believed to be the most effective way to obtain the information. Since the information to be collected from the section foreman is not very complicated, an in-person interview is not necessary. Instead, monthly telephone calls should be sufficient.

4. Efforts to Identify Duplication and Use of Similar Information

The history of trying to reduce knee injuries in low-seam coal mining dates back some thirty-five years. The following are brief descriptions of work performed by the Bureau of Mines and NIOSH to address ways to better protect the knees of low-seam miners.

In March 1974 the report titled Testing of Prototype Knee Protective Devices published findings from a field study on a kneepad prototype. A qualitative review of nine kneepads ranked the prototype kneepad second. Even with prototype modifications, the resulting conclusion of this study was that kneepads of the user's preference should be issued to all those who work in low-seam coal.

In 1978, the U.S. Bureau of Mines released a report titled, Use of Personal Equipment in Low Coal: A Review of the Personal Equipment Literature. This document encompassed many different types of personal protective equipment one of which being kneepads. The resulting general recommendations from this report proposed that a kneepad should be designed specifically for use in low-seam mines.

A study conducted by Sanders in 1982 revealed eight characteristics preferable for a kneepad designed for low-seam mining. A prototype kneepad containing all eight design elements was field tested for a limited period of time, but testing ended prematurely due to the lack of durability of the prototype. The eight design features were: "V" shaped foam pads, durable hard outer shell, high side walls, cut-out for accommodating thigh, single strap design, wide soft strap, belt-buckle single prong strap and air cushion. From subjective data collected from miners, it was determined that three of the design features were preferable. The three features were the "V" shaped foam pad; high side walls; and single strap construction.

In March of 1986, the Bureau of Mines published a report titled, Personal Equipment for Low Seam Coal Miners: Improved Knee Pads, a Modified Design. This report completed the second phase of the Sanders 1982 work. The attempt was made to use the Sanders prototype as a starting point, but from there develop a more durable kneepad that would withstand the harsh environment of a mine. The work was unsuccessful in developing a kneepad given the design elements and readily available materials.

In addition to literature searches, the principal investigator of this study has attended numerous cross-sector meetings within NIOSH that focus on reducing musculoskeletal disorders in the workplace. The principal investigator had personal discussion with the attendees and also presented their research at one of the meetings. At these meetings only one relevant research project was identified. Within NIOSH, a kneel-assist device was designed to aid ship yard workers. However, upon receiving the drawings and prototypes of this device, it was clear that the design would not function in the mining environment due to the existence of mud and wetness.

At this time, there exists no kneel-assist device that is superior to the kneepads commonly used in the mining industry today. Therefore, there exists a need to design new kneel-assist devices. Since this study will investigate a novel design for kneel-assist devices, no data currently exists that may be used to demonstrate their usability, durability, etc. in the mining environment. However, lessons learned from the previous work will be incorporated into the new prototype designs. It is believed that significant advances in materials science and manufacturing techniques will allow for the successful design of new kneel-assist devices despite the failed attempts in the past.

5. Impact on Small Businesses or Other Small Entities

The questionnaires (phone call and in-person interviews) will be administered to individuals not to businesses. However, these individuals will be working for mining companies that must be willing to cooperate with their workers' participation. These mining companies have not yet been identified but may fall into the realm of small businesses or small entities. One set of questions will be asked of the section foreman at the mine. These questions will be in regards to the current mining environment. It is not possible to reduce these questions for small entities since a full understanding as to the mining environment is important to the study. The other questions will be asked of individuals regarding their personal opinion of the kneel-assist devices (control kneepad, prototype kneepad, prototype body weight support worn at the ankle). Thus, it is not possible to reduce the number of questions for those employees working at smaller businesses/entities since it would make comparison of the data

across subjects much more limited. There are no redundant questions; therefore, it is important to understand every subject's opinion regarding every aspect of the kneel-assist devices.

6. Consequences of Collecting the Information Less Frequently

Initially, data will be collected for at a mine site for Phase I of the study. For this mine, data will be collected at the commencement of the study and one month following. The baseline data is collected to mark the start of the study and to determine some basic demographics about the subjects. The data collected at the one month mark consists of the mine workers' opinions regarding the prototype kneel-assist devices based on personal interviews and a focus group. From these data, it will be determined whether or not the prototypes are ready for Phase II of the study. It is not possible to collect these data less frequently and still draw such conclusions.

Once Phase II commences, the section foreman at the cooperating mines will be asked a series of questions regarding the mining environment on a monthly basis via a phone call. The mining environment is extremely dynamic and can actually change on a weekly or even daily basis. Collecting these data on a monthly basis allows us to have a general understanding as to how the mining environment is changing throughout the study. If these data were collected less frequently, the data obtained from the section foreman would likely omit conditions that were only experienced temporarily (for one week perhaps). However, these conditions are likely to impact the kneel-assist devices. These data will help determine if there are specific environmental conditions where the kneel-assist devices do not function well.

In addition to collecting data from the section foreman, data will also be collected from the participating mine workers. Initially, some baseline data will be collected which will mark the start of Phase II of the study. These data will consist of demographics information about the subject which may be used to group similar responses of individuals. For example, we may find that roof bolter operators have no difficulty with ease of movement since their job does not require constant movement. However, the section foreman may find have great difficulty in this area since he/she is constantly moving. Thus, these baseline data must be collected.

Once the baseline data is collected, the subjects will be given a control kneepad. They will then be asked their opinion about the kneepad at 1, 3, and 6 months following. They will then be given the prototype kneel-assist devices and will again be asked their opinion at 1, 3, and 6 months following. Previous attempts to design kneel-assist devices for the mining environment fell short in the area of durability. Current kneepads are usable for 1 to 3 months depending on the user. It is important to demonstrate that the prototype kneel-assist devices can match or improve upon this level of durability. Otherwise, they will not be accepted in the industry. In order to ensure that all subjects use at least two of each prototypes, data must be collected for at least 6 months. Data will be collected at 1, 3, and 6 months in an attempt to assign a level of durability to the prototype kneel-assist devices. These data must also be collected for the control kneepad so that a direct comparison of durability may be made.

There are no legal obstacles to address the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Explain and special circumstances that would cause an information collection to be in a manner:

- Requiring respondents to report information to the agency more often than quarterly;

    - The entire study, including Phase I, should take approximately 24 months to conduct. Data from Phase I will be recorded at the commencement of the study (baseline data) and at one month following. It should only take about one month for the subjects to ascertain whether or not the prototype kneel-assist devices are likely to be successful in Phase II of the study. Therefore, there is no advantage to waiting until a quarter of the year has passed. Additionally, the section foreman will have to answer questions regarding the mining environment one time.

    - During Phase II, the section foreman will need to report on the mining environment on a monthly basis via a telephone call. This is so that changes in the mining environment may be linked to problems found with the kneel-assist devices. Since the mining environment can change weekly or even daily, reducing the frequency to less than a month would greatly reduce the section foreman's ability to recall the conditions since his last phone interview.

    - For the control kneepads and the prototype kneel-assist devices (kneepad, and body weight support worn at the ankle), information will be collected from the study subjects at 1, 3, and 6 months following their initial use. These time points were selected based upon the known durability of kneepads currently used in the mining industry which ranges from 1 to 3 months. These time points ensure that each subject would use at least two of each device throughout the duration of the study. In this way, a measure of durability may be obtained.

- Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

    - A written response by the respondents/subjects is not required by this study. Instead, they will be interviewed via the phone or in person for all data collection efforts.

- Requiring respondents to submit more than one original and two copies of any document;

    - The respondents/subjects will not be required to submit any documents for this study. All data will be collected via phone and in person interviews.

- Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years

    - The respondents/subjects will not be required to retain any records for this study.

- Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

    - No statistical data classification not approved by OMB will be used in this study.

- Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

    - Information in Identifiable Form will be obtained from the respondents/subjects when they consent to the study and to their photograph being taken. This information includes name, address, and age and is considered confidential. This information will be kept in a locked cabinet in the principle investigator's office and will be destroyed at the completion of the study.

Also explain if information collection:

- Is in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;

    - The results from this statistical survey can be generalized to other industries/sectors beyond mining. However, the kneel-assist devices and the associated questionnaires are designed for use within the mining industry. Therefore, these other industries may benefit from conducting their own investigation where all of their concerns may be addressed.

- Includes a pledge of confidentiality that is not supported by authority established in statue or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use.

    - This study will follow all confidentiality regulations as stipulated by the Human Subjects Review Board at NIOSH.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Federal Register notice was published in the *Federal Register* on March 23, 2009, vol. 74, No. 54, pp. 12133-34 (Attachment 2). No comments were received.

The Mine Safety and Health Administration (MSHA) was contacted regarding this information collection. An MSHA representative was asked to review the planned data collection and provide any feedback necessary. The MSHA representative generated an email with the following information:

- Ask the miners if they have any ideas on equipment or aids other than or in addition to the pads to aid them in preventing knee/leg injury or discomfort.
  e.g. matting nearby or attached to equipment, knee braces in addition to pads, shin protection
- Get the history of knee injury or knee occupational illness of the miners in the program.
  e.g. are there more problems with **infection** due to chafing, abrasion, cuts etc. than muscular/skeletal issues or are the problems evenly distributed.
- Ask miners, when they get knee infections how do they take care of them? Are there antibiotic/antiseptic creams/lotions etc. that help them or do they require medical attention, or do they have to miss work or change jobs to heal?
- Do the miners use any creams, lotions, salves, vasoline, etc. to reduce friction and prevent chafing, abrasion while wearing pads?
- What materials/clothes can be used to reduce friction of knee against the pad or clothing?

Additionally, the MSHA representative provided comments directly on the forms. These comments included the suggestion of additional questions as well as wording changes. All changes suggested by the MSHA representative were implanted into the data collection forms.

9. Explanation of Any Payment or Gift to Respondents

The respondents will receive a payment of $25 in the form of a gift card to either Lowes or The Home Depot (depending on which store is located in the surrounding area) for each interview they complete regarding the kneepads (i.e. the section foreman will not receive a payment for the monthly phone calls as these are expected to take only 10 minutes; the section foremen would be paid for their participation in the rest of the study). The $25 gift card will be supplied for the interviews conducted during Phase I testing as well as for the interviews during Phase II. Additionally, the respondents will be allowed to keep any kneel-assist devices (prototypes and control) they were given throughout the study as these devices cannot be given to any other individuals for health purposes (sweat and bacteria will be present once they are worn). Respondents for Phase I would have the opportunity to receive a total of $75 worth of gift cards (baseline, one month, focus group) each time a new prototype is evaluated. Recall, Phase I testing will continue until prototypes that are likely to be successful during Phase II of the study are fabricated. Respondents participating in Phase II would have the opportunity to earn a total of $125 worth of gift cards if they complete all interviews (baseline, and then 1, 3, and 6 months following the control and prototypes).

Several longitudinal studies within NIOSH have successfully retained respondents by providing them with a payment or a gift. At the National Personal Protective Technology Laboratory (NPPTL), several recent studies are ongoing where a payment is provided for each visit by the respondent. For their respirator certification tests, the personal can

participate as many times as they would like (typically ranges from once to 50 times per year). Visits can last from 10 minutes to 4 hours. The typical payment thus ranges from $75-$200 for each visit. NPPTL also tests fire fight ensembles. Each respondent must attend 22 visits and receives $30/hour in payment with the duration of each visit ranging from 1 to 4 hours. Another study involves cooling garments. This involves 8 visits lasting 1 to 4 hours with respondents receiving $30/hour. Finally, another division within NIOSH is having fisherman test different flotation devices. At the conclusion of the study, the fisherman gets to keep the device to which they were assigned. These devices can be worth a couple hundred dollars each. Each of the above described studies has been successful in retaining respondents via these methods of payment or by using gifts.

10. Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

It will be necessary to link the multiple responses of each respondent. Therefore, each participating mine will be asked to assign a number to each participating subject. NIOSH will never see this list. Prior to data collection, mine management will inform the subjects of their unique identifier. At the beginning of the interview, they will be asked to give that number to NIOSH researchers. At no time will NIOSH have access to the list of names that assigns the number. Thus, NIOSH will be unable to match the responses to any one person. Therefore, the Privacy Act does not apply to this data collection.

Additionally, the respondents will sign a consent form and a photo release form. These consent forms will inform the respondents that the study is voluntary and that they may leave the study at any time. On these forms will appear their name, age, signature, and address. However, this information would not be linkable to the data collected. Therefore, the Privacy Act does not apply this information. These forms will also be secured/locked in the principle investigator's office. The consent forms (Attachment 3 and 4) was approved (Attachment 5) by the NIOSH Human Subjects Review Board.

11. Justification for Sensitive Questions

The questionnaire pertains only to the respondents' opinions regarding kneel-assist devices and does not contain any questions regarding health status, lifestyle, sexual practices or other potentially sensitive issues.

12. Estimates of Annualized Burden Hours and Costs

For all but the focus group form, estimates for the burden hours were determined by having NIOSH technicians, that were formerly mine workers, respond to the questions in an interview format. The average time taken to complete the entire form was used to estimate the burden. For the focus group questions, a one hour time limit was established since limiting focus groups to 45 minute to 1 hour is a common practice as it has shown good success for experts in the communications field. A NIOSH employee that was a communications expert reviewed the questions to ensure that she felt 1 hour was a reasonable

discussion time. Additionally, this communications expert also has agreed to assist work with the members of our team so that we can become acceptable discussion leaders for a focus group. The burden cost was determined to be a flat rate regardless of how long the forms took to complete. This was done for budgetary purposes and so that the reimbursement could be provided to the mine worker immediately after the interview.

A. Estimated Annualized Burden Hours

Please note that the study consists of two phases. In Phase I of the study, mine workers will be asked a series of questions to ascertain whether or not the prototype kneel-assist device is likely to be successful in a full study (Phase II). For Phase I, the section foreman will be asked basic environmental questions about the mine and baseline data will be collected for each mine worker that captures their basic demographics (age, sex, etc.). After using the prototype kneel-assist device for one month, they will be asked to provide their feedback regarding several key performance areas (e.g. durability, ease of movement). Additionally, after the one month evaluation time has passed, the participating mine workers will be gathered for a focus group style of questioning in order to gain additional information. Phase I of the study will continue until a prototype kneel-assist device has been generated. Thus, while the burden table below shows the burden associated with the implementation of one prototype that is fully successful, in reality, it may require two or three generations. Ideally, the mine workers interviewed for Phase I will remain constant throughout all versions of the prototype. The mine workers will be compensated each time they participate. Once a successful prototype has been developed, Phase II of the study will begin. Phase II will last a total of 12 months with 7 different interviews (baseline; 1, 3, and 6 months following usage of the control and prototype kneel-assist device). Additionally, the section foreman will again have to provide information regarding the mining environment. It should be noted that the mine workers participating in Phase I of the study may not participate in Phase II.

	Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Phase I	Section Foreman	Phase I Section Foreman Form	1	1	10/60	0.5
	Mine Workers	Phase I Baseline Form	9	1	20/60	3
	Mine Workers	Phase I 1month form	9	1	30/60	4.5
	Mine Workers	Phase I Focus Group Questions	9	1	1	9
Phase II	Section Foreman	Phase II Section Foreman Form	6	12	10/60	12
	Mine Workers	Phase II Baseline Form	54	1	20/60	18
	Mine Workers	Phase II 1, 3, and 6 months forms	54	6	25/60	135
				Total		182

B. Estimated Annualized Burden Costs

	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Reimbursement per Response	Total Respondent Cost
Phase I	Section Foreman	1	1	$0	$0
	Mine Workers - baseline	9	1	$25	$225
	Mine Workers – one month	9	1	$25	$225
	Mine Workers – focus group	9	1	$25	$225
Phase II	Section Foreman (different from Phase I section foreman)	6	12	$0	$0
	Mine Workers – baseline (different from Phase I mine workers)	54	1	$25	$1,350
	Mine Workers - 1, 3, and 6 months after control and prototype (different from Phase I mine workers)	54	6	$25	$8,100
				Total	**$10,125**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

The interviews have no capital, operating, or maintenance costs for the respondents or their employers. The only cost to the respondents is the time required to complete the interviews/questionnaires.

14. Annualized Cost to the Government

During this study, the control kneel-assist devices will be provided to the mine workers (Phase I and Phase II). This is at an estimated cost of $10,000. The prototype kneel-assist devices will be provided by The Rooster Group, a study collaborator that has entered into a Research Collaboration Agreement with NIOSH. Thus, the prototypes will be provided at no cost to the government. The reimbursement of $25 per interview will cost the government $10,125 (see burden cost table above in section 12B). When the study has been completed, the results will be published. Printing costs are estimated at $4,000 based on the cost of several Information Circulars that have recently been published by NIOSH. The actual interview process will consume 182 hours of NIOSH researchers' time. Salaries for members of the NIOSH team range from approximately $40,000 to $115,000 a year. This yields an hourly wage of approximately $20 to $60. Using an average hourly wage of $40, the interview process would cost $7,268. Travel will also be necessary for this study as the interviewers will conduct the interview at the participating mines. In order to reduce costs,

mines in the Pennsylvania and West Virginia area will be targeted. The estimated travel expenses are $20,000. The data analysis and publication process should require approximately 200 hours. Thus, this would cost approximately $8,000. The total cost to the government would be $55,393.

15. Explanation for Program Changes or Adjustments

This is a new information collection submission.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Phase	**Time Schedule**
Training of interviewers and recruitment of cooperating mines and mine workers	1-2 months after OMB approval
Conduct Phase I test(s) (1 month duration)	2-3 months after OMB approval
Data analysis – Phase I data	3 months after OMB approval
Interview and monitor subjects during Phase II (12 month duration)	4-16 months after OMB approval
Data analysis – Phase II data	16-18 months after OMB approval
Publication of results	18.24months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There is no reason to preclude display of the OMB expiration date on the questionnaire.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.