INTERVENTIONS TO REDUCE SHOULDER MSDS IN OVERHEAD ASSEMBLY

Request for Office of Management and Budget (OMB) Review and Approval
for a Federally Sponsored Data Collection

Brian D. Lowe, Ph.D.
Research Industrial Engineer1
Project Officer
blowe@cdc.gov

National Institute for Occupational Safety and Health
Division of Applied Research and Technology
4676 Columbia Parkway, Mail Stop C-24
Cincinnati, Ohio 45226

513-533-8161 (phone)
513-533-8596 (fax)

December 4, 2012
1**Table of Contents**

LIST OF ATTACHMENTS

Attachment A: Occupational Safety and Health Act [29CFR § 671]
Attachment B: 60-Day Federal Register Notice
Attachment B1: Response to 60- Day Federal Register Notice
Attachment C: NIOSH Strategic Goals and Activities
Attachment D: NIOSH – TEMA Memorandum of Understanding
Attachment E: Information Security Plan
Attachment F: Informed Consent- Questionnaire Data Collection
Attachment G1: Physical Activity Readiness Questionnaire (PAR-Q)
Attachment G2: Shoulder Rating Questionnaire (SRQ)
Attachment G3: Disabilities of the Arm Shoulder and Hand (DASH) Questionnaire
Attachment G4: Standardized Nordic Questionnaire for Musculoskeletal Symptoms Instrument
Attachment G5: Work Organization Questionnaire
Attachment H: Consent of Photographic Image Release
Attachment I: Individual Recruitment Flyer
Attachment J: IRB approval for Data Collection
Attachment K: Details of Interventions
Attachment L: Framing a Cost Benefit Analyses

SECTION A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

Background

This is a new information collection request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). This data collection is authorized by Section 20(a) (1) of the Occupational Safety and Health Act (29 U.S.C. 669) (Attachment A). This is a request for one year.

The proposed information collection will address the need to assess the effectiveness and cost-benefit of occupational safety and health (OSH) interventions for musculoskeletal disorders (MSDs) among workers in the Manufacturing (MNF) sector. This need is expressed in a number of NIOSH Strategic Goals (Attachment C). This study will provide current important information on prevention of injury among MNF workers that is not available elsewhere. This project is part of the mission of CDC-NIOSH to conduct rigorous scientific intervention effectiveness research to support the evidenced based prevention of occupational injuries and illnesses.

MSDs currently account for approximately 28% of the total non-fatal injuries and illnesses with days away from work or restricted duty (DAW) in private industry (BLS, 2010). Liberty Mutual has estimated direct workers' compensation costs to industry in the US in 2008 to be $53.4 billion (up from $48.6B in 2006), with $15.2 billion (28%) attributed to MSDs ($13.4B overexertion, $1.8B repetitive motion) (Liberty Mutual 2010 Safety Index).

Musculoskeletal disorders (MSDs) continue to represent a major proportion of injury/ illness incidence and cost in the U.S. Manufacturing (MNF) sector. In 2008, 29% of non-fatal injuries and illnesses involving days away from work (DAW) in the MNF sector involved MSDs and the MNF sector had some of the highest rates of MSD DAW cases. The sub-sector for motor vehicle manufacturing (3361) was among the highest of MNF sub sectors, with MSD DAW rates that were on average 96% higher than the general manufacturing MSD DAW rates from 2003-2007. In automotive manufacturing overhead conveyance of the vehicle chassis is a common practice and requires line employees to handle tools for prolonged periods with elevated arm postures. These postures are believed to be associated with symptoms of upper limb discomfort, fatigue, and impingement syndromes (Fischer et al., 2007). Overhead working posture, independent of the force or load exerted with the hands, may play a large role in the development in these conditions. However, recent work suggests a more significant role of localized shoulder muscle fatigue in contributing to these disorders. Fatigue of the shoulder muscles may result in changes in scapulo-thoracic and glenohumeral kinematics that affect risk for shoulder impingement syndromes (Ebaugh et. al., 2006; Chopp et al., 2010).

The Manufacturing sector (MNF) is facing a number of changes including an overall decline in jobs, an aging workforce, and changes in organizational management systems. Studies have indicated that the average age of industrial workers is increasing and that older workers may differ from younger workers in work capacity, injury risk, severity of injuries, and speed of recovery (Kenny et. al., 2008; Gall et. al., 2004; Restrepo et. al., 2006). As the average age of the industrial population increases and newer systems of work organization (such as lean manufacturing) are changing the nature of labor-intensive work, prevention of MSDs will be more critical to protecting older workers and maintaining productivity.

Studies indicate that overexertion MSDs are primarily caused by physical risk factors associated with manual material handling (MMH), including high task repetition, excessive biomechanical loading on body joints, and awkward body postures (Kumar 2001). It has also been indicated that combined exposure to multiple risk factors (versus single physical risk factors) produce the most adverse health effects (Marras 2000). For example, repetitive and heavy manual lifting in awkward postures have been found to be major risk factors for low back disorders in many studies (Waters et al., 1993; Waters et al., 1998; Marras et al., 1995; Westgaard et al., 1996; NIOSH 1997; Gagono et al., 2000). Although it is proposed that primary prevention interventions designed to reduce the multiple risk factors involved in MMH (high force, awkward postures, task repetition) will reduce future overexertion MSDs, relatively few controlled experimental studies have been conducted to test this hypothesis. Most MSD intervention effectiveness studies have been quasi-experimental (e.g. pre- and post- intervention studies without control groups or randomization). Those studies that have focused on the effectiveness of MSD engineering controls alone have tended to focus on short term risk factors as outcomes rather than MSD symptoms/cases and have been mixed in quality and findings (van der Molen et al 2005). Several recent literature reviews (Bigos et al. 2009; van Duijvenbode et al 2009; Sahar et al 2009; Tveito et al 2004) found few high-quality studies to support the efficacy of engineering ergonomic interventions designed to reduce low back pain.

Rigorous experimental research is needed to define the effectiveness and cost-benefit of interventions for controlling incidence and costs of musculoskeletal disorders. A partnership between NIOSH and Toyota Motor Engineering & Manufacturing North America, Inc. (TEMA) provides a timely opportunity to conduct such research in a relevant, efficient, and impactful manner. TEMA and NIOSH have recently developed a formal agreement (Attachment D) to collaborate on a number of goals related to "… conducting research and analysis of effective ergonomic programs and strategies to address aging workforce trends, diverse workforce demographics, and repetitive motion risk factors". TEMA has many strengths as a potential research partner, including its size, diversity of industry that is largely representative of the larger US industry, geographical proximity of facilities to the NIOSH Cincinnati, OH location, and perhaps most importantly, their active engagement in intervention research.

Privacy Impact Assessment

The study will collect both potentially sensitive data (self-reported MSD symptoms and results from shoulder functional assessments) and personal identifiers (name, address, phone number, employee clock number). The method of handling the information will comply with the Freedom of Information Act and the Privacy Act of 1974. Disclosure under the Privacy Act System is permitted: to private contractors assisting NIOSH; to collaborating researchers under certain limited circumstances to conduct further investigations; to the Department of Justice in the event of litigation; and to a congressional office assisting individuals in obtaining their records. All data collection and records management practices and systems will adhere to all applicable federal, Health and Human Services (HHS), Centers for Disease Control (CDC), and NIOSH IT security policies and procedures [Security Requirements for Federal Information Technology Resources, January 2010; Health and Human Services Acquisition Regulation (HHSAR), Clause 352.239-72]. For example, data will be transcribed from hard copy and stored on encrypted CDs, flash drives, and/or ftp sites according to applicable Federal Information Processing Standards Publications (FIPS PUBS, see http://www.itl.nist.gov/fipspubs). See the Information Security Plan in Attachment E for more information.

Overview of the Data Collection System

Questionnaires will be self-administered in hard copy format. Employee respondents will deposit completed questionnaires in a locked box. A NIOSH researcher will have access to retrieving the questionnaires from this box. NIOSH researchers will primarily conduct the data collection and contractors will be used in support roles for data management. An interview option will be offered as a last resort for those respondents who do not find the hard copy format to be acceptable.

Items of Information to be Collected

Information in identifiable form (IIF) will be collected as part of the informed consent procedure (Attachments F) for this study. This will include: first and last name, street address, email address, and date of birth. Additional information collected is described below. All information will be used to determine whether there are significant differences in reported musculoskeletal symptoms and functional shoulder capacity (pre-/post-intervention scores) when intervention and control groups are compared and covariates are statistically controlled. Individual participant personal information will not be published in any identifiable form and will be protected to the extent allowed by law (Freedom of Information Act and the Privacy Act). The questionnaires are standard tools used to establish the degree of upper extremity symptoms and pain among the participants. The study is designed to determine the usefulness of the prophylactic interventions in preventing MSDs of the upper extremity.

The following information will be collected in questionnaire format (Attachments F, G1-G5):

1: Informed Consent Form – This form explains the study purpose and procedures to the potential study participant and serves as the mechanism by which the individual formalizes his/her consent to voluntarily participate in the study. (5.0 min average time to complete).
Consent of Photographic Image Release – This form gives NIOSH permission from the research participant to use his/her photographic image in resulting information products. (2.0 min average time to complete).

2: Screening Questionnaire

- American College of Sports Medicine Physical Activity Readiness Questionnaire (PAR-Q) (Attachment G1): This is a standard questionnaire to screen for physical readiness to participate in an exercise program. It is designed to identify the small number of adults for whom physical activity may be inappropriate. (2.0 min average time to complete)

3: Primary Physical Symptom Questionnaires (administered to all 125 participants at baseline and every 1 months for 10 months; 15 minutes estimated time for all primary questionnaires combined per data collection):

- Shoulder Rating Questionnaire (SRQ) (Attachment G2): This is a validated non-disease specific questionnaire pertaining to shoulder function and shoulder disability. (4.0* min average time to complete)
- Disabilities of the Arm Shoulder and Hand (DASH) (Attachment G3): This is a validated non-disease specific questionnaire addressing upper extremity pain more broadly in the arm, shoulder, and hand. (6.2* min average time to complete)
- Standardized Nordic Questionnaire for Musculoskeletal Symptoms (Attachment G4): This questionnaire is a widely used body map for the description of discomfort symptoms over the entire body. (4.0* min average time to complete)

*These are completion time averages from published studies.

4: Secondary Questionnaires

- Work Organization and Non-Occupational Physical Activity (Attachment G5): This questionnaire collects information on the work environment and non-physical attributes of the work demands. (222 questions; 26 min average time to complete, administered three times - at the beginning, middle and end of intervention period)

A limited amount of digital video may be collected to document work posture associated with the conventional workplace design and with the articulating tool support device. This video data will not be linked back to any individual participant data. All video data will be kept secure and managed in accordance with the Privacy Act of 1974, Title 5, United States Code, Section 522 (a). Digital video files will be saved on a NIOSH computer network that is only accessible by the principal investigator, study co-investigators, and some supporting staff for the study. TEMA will not have access to the videos. Prior to the video data collection, participants will be asked for permission to have video recorded of them, and uses of the video will be explained to them (Attachment H). Digital video will be saved on the NIOSH network. The principal investigator and study co-investigators may use the video data for designing future interventions or assessing working posture in overhead work.

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

There will be no website content associated with this project. This is not applicable.

A2. Purpose and Use of Information Collection

All information collected will be used to determine the efficacy of two workplace interventions for the reduction of self-reported arm and shoulder symptoms and pain attributable to overhead work in automotive assembly. Results of the study (in de-identified and aggregated form) will be disseminated in the scientific literature and in educational materials developed by NIOSH (website, publications). The privacy of all data collected will be protected to the extent legally possible, as covered by the Privacy Act of 1974, Title 5, United States Code, Section 522 (a). Individual participant personal information will not be published in any identifiable form.

The data collection for this intervention study is part of a multi-phase project between NIOSH and TEMA that has received NIOSH intramural funding from Fiscal Year 2013 through Fiscal Year 2015. The project was awarded federal funds through the NIOSH National Occupational Research Agenda (NORA) competition for intramural research. TEMA is also providing substantial funding for the costs of the tool support interventions.

The data collection is justified because few prospective controlled trials for the effectiveness of interventions for musculoskeletal disorder (MSD) prevention have been conducted. There is a clear need to conduct rigorous experimental research to further define the effectiveness and return-on-investment of interventions for preventing musculoskeletal disorders. The project design will allow the cost-benefit of two intervention strategies to be calculated and enable evidence-based practices to be shared

with the greatest audience possible. Such data has practical utility to the federal government, state government, and private stakeholders.

For example, the federal Occupational and Safety and Health Administration (OSHA) is seeking input about the relevance of MSD-focused safety and health regulations. Recently, OSHA announced intention to restore a record keeping regulation to document MSDs on OSHA 300 logs (US Federal Register, 2010a). OSHA has also proposed a regulation for an injury/illness prevention program that could include the framework for MSD control (US Federal Register, 2010b). OSHA is in the process of soliciting input for both potential standards. The possibility of regulation increases the imperative that additional MSD intervention research be conducted to identify evidence-based practices. OSHA is also required to submit cost-benefit analyses for the implementation of proposed regulations. Without rigorous studies on the effectiveness of primary prevention approaches in general, and MSD interventions specifically, such analyses can be difficult.

CDC-NIOSH will also use this data to develop guidance for conducting economic analyses of OSH interventions. A major part of OSH project planning is to conduct a cost-benefit analysis for future intervention projects. This study will provide a necessary piece of information that is often lacking for such analyses, which is the range of expected effectiveness (in terms of reduced injury/illness incidence, severity, and cost) for particular types of MSD interventions. Compiling such information will allow companies to make more accurate projections for savings.

Organizations seek to evaluate the effectiveness and cost-benefit of MSD prevention program elements using the most scientifically rigorous methods possible. For this reason, TEMA is eager to collaborate with NIOSH on this project and has contributed substantial financial resources to support the proposed prospective intervention study. The goal is to validate evidence based practices and make these widely available to the greatest audience possible. The results of the current study are relevant to TEMA and other private companies in the Manufacturing sector that must control musculoskeletal disorders associated with overhead work. If a rigorous experimental study can determine the level of effectiveness and cost-benefit of interventions, other organizations may utilize this data to determine whether these interventions should be adopted.

The findings from this project will be transferred to stakeholders and OSH practitioners in the private sector using several channels:

NIOSH (website, publications, and personnel)

- A NIOSH publication is anticipated, in the form of a “Workplace Solution” document. This format conveys information about successful interventions to a wide audience in a less technical format.

MNF trade organizations (website, publications, and personnel)

- Links to the same dissemination products will also be provided directly to several trade organizations. Aspects of the studies will also be submitted for publication in trade journals.

Peer reviewed journals

- At least three manuscripts are planned for publication in the peer reviewed literature. Main audiences for these types of journals are fellow researchers, but also OSH practitioners, and stakeholders.

Privacy Impact Assessment Information

Information in identifiable form (IIF) will be collected as part of the informed consent procedure for this study (Attachments F). This includes: first and last name, street address, phone number, email address, and date of birth. Individual information will not be collected on the other questionnaire instruments, which will be linked to study participants only with a unique numeric identifier (created by NIOSH) to track the responses of the participant over the course of the study. Individual participant personal information will not be published in any identifiable form and will be protected to the extent allowed by law (Freedom of Information Act and the Privacy Act). Information will be maintained until the conclusion of the study in 2015. The IIF data will only be used by NIOSH researchers for the purposes outlined below.

IIF Being Collected	**Purposes**
First and last name of individual participant	The participant's first and last name (in combination with their birth date) will be used to link to a unique identifier (created by NIOSH) to track the responses of the participant over the course of the study.
Street address of individual participant (optional)	The street address will also be used to send a hard copy of final study results if requested by the individual.
Date of birth	The participant's date of birth (in combination with their first and last name) will be used to link to a unique identifier (created by NIOSH) to track the responses of the participant over the course of the study. The date of birth will also be compared to a self-reported "age in years" that will be used as a covariate in analyses.

A3. Use of Improved Information Technology and Burden Reduction

This data collection does not involve the use of automated, electronic, mechanical or other technological collection techniques or other forms of information technology. Therefore, none of the responses will involve information technology. Electronic data collection procedures are not being used as they would impose a greater burden on this particular study sample. In order to reduce burden to the employees, data collection will occur at the workplace. Computers are not accessible at these locations to employ to collect data. It would be simpler for the employees to fill out a paper and pencil survey as opposed to an online survey. With hard copy format questionnaires can be completed on the work shift at any location at any time. Questionnaires will not contain any identifiers (coded with a study ID number) and will be deposited in a secure drop box.

A4. Efforts to Identify Duplication and Use of Similar Information

NIOSH has searched the scientific literature, contacted colleagues throughout the occupational safety and health community, and contacted professional, labor and industry organizations representing MNF workers. NIOSH is unaware of any prior MSD intervention effectiveness studies, specific to preventing shoulder injuries attributable to overhead assembly work, conducted as a prospective study design, with a control group and group randomization. Studies of preventive exercise as an intervention to work related musculoskeletal symptoms, pain, and injury have been conducted (e.g. Sjögren et al., 2005; Blangsted et al., 2008; Camargo et al, 2009; Zebis et al., 2011). However, in these studies physical exercise interventions were conducted as the sole preventive strategy and were not conducted in parallel with a work design intervention to allow a relative comparison of the efficacy of the two approaches. The unique nature of the present study design will allow the combined effect of both interventions to be evaluated and compared in their efficacy and cost-benefit.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in the data collection. The data collection will be conducted in collaboration with Toyota Motors, which in 2011 had 317,000 employees.

A6. Consequences of Information Collected Less Frequently

Respondents will be asked to respond to the data collection once per month at three intervals during the pre-intervention baseline observations and once per month during a

four-month intervention period. Three post-intervention observations will then be made at one month intervals, after the four month intervention period, for a total of 10 monthly observations. Physical symptoms will be reported by way of questionnaire administration using the questionnaire instruments described in section A1. The data being collected will include self-reported shoulder function, upper extremity pain symptoms, and body part discomfort (Attachments G1- G5). The frequency of this data collection is justified based on several factors:

- A shortcoming of previous studies is the single measurement of baseline and post-intervention symptoms. Collecting multiple measurements prior to the introduction of the intervention strengthens the study by avoiding regression to the mean effects. Collecting measurements less frequently (i.e. quarterly as opposed to monthly) at multiple intervals pre- and post-intervention would increase the total study duration. Keeping the study duration the same (10 months) and collecting the information less frequently would yield fewer observations and a less stable estimate of pre- and post-intervention symptoms.
- Musculoskeletal exposures, symptoms, and pain and discomfort can vary over time (McGorry et al., 2011) and less frequent data collection would not be sensitive to episodes of pain that resolve more rapidly.
- Problems with recall may affect longer intervals between symptom reporting by questionnaire.

Well-designed studies of shoulder preventive exercise have collected symptom reports at multiple intervals and have done so much more frequently than quarterly (for example, Sjogren et al, 2005 queries symotoms at 5 week intervals). The planned frequency of data collection in the proposed study is believed to be justified, and reducing this frequency would sacrifice the ability to avoid mean regression effects and attain the sensitivity needed for an intervention effectiveness study of the highest quality. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Information collection will occur more frequently than quarterly for the reason described in section A.6. There are no special circumstances associated with this data collection activity. This request fully complies with regulation 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A: A 60-day publication period in the *Federal Register* (July 11, 2012 vol. 77, No. 133, pages 40889 - 40890 (see Attachment B). Public comments were received (see

Attachment B1).

B: NIOSH has consulted with numerous individuals and organizations outside the agency regarding the availability and usefulness of the proposed data collection. The following chronology documents these contacts:

July, 2009

The National Institute for Occupational Safety and Health (NIOSH) and Toyota Motor Engineering & Manufacturing North America, Inc. (TEMA) Department of Environmental and Safety Engineering sign a Memorandum of Understanding and establish a Partnership to use their collaborative efforts and expertise to advance the protection of workers, promote best practices, and encourage employers to develop and utilize safety and health management programs and effective prevention strategies and technologies. The project objectives were discussed with senior management at TEMA (Mr. Kevin Butt, General Manager, Toyota Motor Engineering & Manufacturing North America, Inc.).

May, 2010

The project concept was presented at the National Occupational Research Agenda (NORA) Manufacturing Sector Council Meeting. This sector council is made up of industry leaders in the Manufacturing Sector. The sector council is charged with shaping research priorities with respect to a national research agenda for occupational safety and health in the Manufacturing Sector. Sector council members showed support for the project.

June, 2011

The MSD intervention study was peer-reviewed as part of the NIOSH National Occupational Research Agenda (NORA) competitive process for intramural research. This peer review was equivalent to a study section review of an NIH grant application. The project received a highly competitive score and was chosen for funding by NIOSH in FY2013. The review panel members for the NORA Fiscal Year 2012 process is listed below.

2012 NIOSH NORA Peer Review Intervention/Measurement/Training/Evaluation		
Randal Keller, Ph.D., C.I.H. Scientific Review Officer SRA International, Inc. Health and Civil Services Sector **Scientific Review Officer**	Bryan Hardin, Ph.D., A.T.S. Assistant Surgeon General (Retired) Veritox RCF Expertise: Environmental Health Sciences **Chairperson**	Phillip Bishop, Ed.D. Fulbright Senior Specialist University of Alabama Department of Kinesiology **Scientist Reviewer**
Lezah Brown-Ellington, Ph.D., MSPH Assistant Professor Illinois State University Health Sciences Department **Scientist Reviewer**	David DeJoy, Ph.D. Professor Emeritus University of Georgia, College of Public Health Department of Health Promotion and Behavior **Scientist Reviewer**	Laura Geer, Ph.D., MHS Assistant Professor SUNY Downstate School of Public Health Dept of Environmental and Occupational Health Sciences **Scientist Reviewer**
David Hostler, Ph.D., CSCS Research Associate Professor of Emergency Medicine University of Pittsburgh Department of Emergency Medicine **Scientist Reviewer**	Virginia Howard, Ph.D. Associate Professor of Epidemiology University of Alabama at Birmingham Department of Epidemiology **Scientist Reviewer**	Steven Johnson, Ph.D., P.E., C.P.E. Professor of Industrial Engineering University of Arkansas Engineering Center **Scientist Reviewer**
W. Monroe Keyserling, Ph.D. Associate Director The University of Michigan Center for Occupational Health and Safety Engineering **Scientist Reviewer**	Kristen Kucera, MSPH, Ph.D. Epidemiologist, Assistant Professor Duke University Department of Community and Family Medicine **Scientist Reviewer**	Lina Lander, Sc.D. Assistant Professor University of Nebraska Medical Center Department of Epidemiology **Scientist Reviewer**
Grace Sembajwe, DSc., MSc. Research Associate Harvard School of Public Health Department of Environmental Health **Scientist Reviewer**	Tracey Wortham, Ph.D. Associate Professor Murray State University Department of Occupational Safety & Health **Scientist Reviewer**	

A9. Explanation of Any Payment or Gift to Respondents

No direct payments or gifts will be provided for respondents. All questionnaire administration will take place during employee's normal work shift hours while the employee is on paid time.

A10. Assurance of Confidentiality Provided to Respondents

The only information in identifiable form (IIF) that is being collected is for the purposes of informed consent. Each participant that enrolls in the study will be subsequently identified with only a random study identification number on all other information collection forms (see Attachment J for IRB approval).

Several controls (safeguards) will be put into place to minimize the possibility of unauthorized access, use, or dissemination of the information being collected. Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule (see http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy449.htm**)**.

Privacy Impact Assessment Information

A. This submission has been reviewed by CDC's Information Collection Review Office, who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0118, "Study at Work Sites Where Agents Suspected of Being Occupational Hazards Exist".

B. Access to individual data will be limited to authorized NIOSH researchers and contractors. Physical controls: NIOSH facilities have 24-hour security guards, and key card ID badges must be used to enter the buildings. The data will be collected in hardcopy form and these hard copies will be stored in locked rooms or cabinets. The hard copy data will be manually transcribed into a database in electronic format. Technical controls: all electronic data will be stored on secure servers that are protected with firewalls and passwords. Any contractor charged with data collection, preparation, or management tasks to be performed away from a NIOSH facility will be required to follow equivalent procedures.

The process for handling security incidents is defined in the system's Information Security Plan (Attachment E). Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate

C. Respondents will be required to sign a written informed consent form (Attachment F). The forms describe how respondents are informed about the intended uses of the information collection and plans for sharing the information.

D. Respondents will be informed that their participation is voluntary, and that they may discontinue participation at any time. They will also be advised that they will not lose any benefits to which they are otherwise entitled if they chose not to participate. The Privacy Act does apply and the informed consent form (Attachments F) address the effect on the respondent of not responding to the data collection request, the intended uses of the data, with whom information will be shared, and the legal authority for the data collection.

A11. Justification for Sensitive Questions

The questionnaire instruments contain questions that relate directly to upper extremity musculoskeletal symptoms of discomfort and/or pain and musculoskeletal function. There are no questions pertaining to sexual behavior that would clearly be considered sensitive. The questionnaires are standard instruments for obtaining information on musculoskeletal symptoms, pain, and disorders.

A12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden to Respondents

No direct costs will accrue to respondents. A maximum of 125 individuals will participate in the intervention study data collection. This is based on an estimate of 25-30 individuals in each of four treatment conditions. The hour-burden estimates include the time for reviewing the simple instructions and responding to the questions. The questions are applicable to the respondent's own perception of musculoskeletal well-being so there is no need for searching existing data sources, gathering and maintaining needed data, or completing and reviewing the collection of information. All hour-burden estimates were derived based on actual statistics reported in published studies for completion time of these questionnaire instruments, or, in the case of the informed consent form and work organization questionnaire, from prior CDC-NIOSH studies that utilized these or extremely similar forms.

Table A.12-1. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
Employees	Informed Consent Form	125	1	5/60	10
	Consent of Photographic Image Release	125	1	2/60	4
	Physical Activity Readiness (PAR-Q)	125	1	2/60	4
	Shoulder Rating Questionnaire (SRQ)	125	10	4/60	83
	Disabilities of the Arm Shoulder and Hand (DASH)	125	10	6 /60	125
	Standardized Nordic Questionnaire for Musculoskeletal Symptoms Instrument	125	10	4/60	83
	Work Organization Questionnaire	125	3	26/60	163
Total					472

B. Annualized Cost to Respondents

There is no cost to respondents as the questionnaires will be administered during working hours. The total estimated annualized cost to Toyota is $12,272, as summarized in Table A.12-2. The hourly wage rate of $26 is averaged for the personnel (team members) who will be eligible for participation in the study.

.

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden (in hours)	Average Hourly Wage Rate	Total Respondent Costs
Employees	Informed Consent Form	10	$26	$260
	Consent of Photographic Image Release	4	$26	$104
	Physical Activity Readiness (PAR-Q)	4	$26	$104
	Shoulder Rating Questionnaire (SRQ)	83	$26	$2,158
	Disabilities of the Arm Shoulder and Hand (DASH)	125	$26	$3,250
	Standardized Nordic Questionnaire for Musculoskeletal Symptoms Instrument	83	$26	$2,158
	Work Organization Questionnaire	163	$26	$4,238
Total				$12,272

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or maintenance costs to respondents.

A14. Annualized Cost to the Government

Total costs include work performed over the course of three years by CDC research personnel at partial levels of effort (1 research industrial engineer, 1 safety engineer, 1 industrial hygienist, and 1 statistician) and contracted administrative personnel, including tasks such as: (1) development of survey materials; (2) development of sampling frame and sample selection; (3) survey conduct; (4) sample tracking; (5) data receipt and processing; and (6) data entry and delivery. Estimated annualized costs to the Federal Government for the survey period are presented in Table A.14-1 below.

Table A.14-1. Estimated Annualized Cost to the Federal Government

	FY2013	FY2014	FY2015		TOTAL PROJECT	Annualized Cost
CDC Personnel Salaries and Benefits [a]	162,284	165,530	168,841		496,655	165,552
Travel	3,600	7,200	4,200		15,000	5,000
Contractual	5,000	10,000	18,560		33,560	11,187
Supplies	68,680	29,360	3,000		101,040	33,680
OTHER						
				TOTAL	646,255	215,418

[a] Includes a 3% personnel cost of living salary increase per year

A15. Explanation for Program Changes or Adjustments

None. This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

Statistical Analysis of the Data

Data collection will be completed over a 10-12 month period, followed by statistical analysis and dissemination of data. A full description of the statistical protocol is provided in Part B1 and B2 of this ICR. Results will be made available through publication in scientific journals and notices in trade publications. NIOSH dissemination strategies will be adopted and are anticipated to include a web-based topic page and a

NIOSH numbered publication in the format of a workplace solution. Other digital media dissemination approaches will be adopted.

Project Time Schedule

Table A.16-1. Project Time Schedule

Activity	Time Schedule (Months After OMB Approval)
Procurement of articulating tool support arm devices (tool support intervention)	Prior to OMB approval
Finalize preventive exercise protocol (exercise intervention)	0
Finalize survey data collection system.	Within 1 months after OMB approval
Random assignment of treatment conditions to line and work shift (cluster randomization)	Within 1 months OMB approval
Recruitment of study participants, participant informed consent and enrollment.	Within 1 months after OMB approval
First of three monthly baseline symptom surveys	Within 1 months after OMB approval
Second of three monthly baseline symptom surveys	Within 2 months after OMB approval
Third of three monthly baseline symptom surveys	Within 3 months after OMB approval
Baseline work organization survey	Within 3 months after OMB approval
baseline FCE for shoulder	Within 3 months after OMB approval
Installation of 25 tool support intervention devices – begin intervention period	Within 4 months after OMB approval
Month 1 intervention period symptom survey	Within 4 months after OMB approval
Month 2 intervention period symptom survey	Within 5 months after OMB approval
Mid-intervention period work organization survey	Within 5-6 months after OMB approval
Month 3 intervention period symptom survey	Within 6 months after OMB approval
Month 4 intervention period symptom survey	Within 7 months after OMB approval
First of three monthly post-intervention symptom surveys	Within 8 months after OMB approval
Post-intervention work organization survey	Within 9 months after OMB approval
Post-intervention FCE for shoulder	Within 10 months after OMB approval
Second of three monthly post-intervention symptom surveys	Within 9 months after OMB approval
Third of three monthly post-intervention symptom surveys	Within 10 months after OMB approval
Complete analysis determining effectiveness of interventions.	Within 24 months after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

There is no request for an expiration date display exemption.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions being sought to the certification statement.