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

INTERVENTIONS TO REDUCE SHOULDER MSDS IN OVERHEAD ASSEMBLY
0920-0964 REINSTATEMENT

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- Goal of the study: Test the effectiveness of an engineering and an administrative control for preventing new, and reducing existing, shoulder musculoskeletal symptoms as a result of repetitive overhead work.
- Intended use of the resulting data: Test the hypothesis that a tool support intervention and an exercise program intervention is more effective than traditional work practices.
- Methods to be used to collect: Prospective randomized control trial with randomization by group level. Musculoskeletal discomfort questionnaire administered
- The subpopulation to be studied: Automotive assembly workers
- How data will be analyzed: General Linear Model with intervention treatment condition and time as independent variables.

SECTION A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

Background

This is a reinstatement requesting two years of approval to an 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). The original ICR (0920-0964) expired on April 30, 2015.

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.

A2. Purpose and Use of Information Collection

This reinstatement is necessary because there were significant delays in implementing the tooling intervention in the intended work processes. These delays were to a large degree due to business conditions and were outside of the control of the investigators. As a result, the study achieved approximately 50% of the original sample size approved by OMB in the original ICR request. The reinstatement is necessary to extend the duration of the ICR so that additional participants can be enrolled and data collection can be continued.

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.

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* (June 5, 2015 vol. 80, No. 108, pp.32131) (See Att B) No public comments were received.

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.

October, 2014 - May, 2015

Ongoing discussions of project objectives and need for extension were held with senior management at TEMA (Toyota Motor Engineering & Manufacturing North America, Inc.) in addition to safety specialists, line supervisors, and employees at Toyota Motors Manufacturing Kentucky (TMMK).

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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act applies to this data collection activity. The applicable System of Records Notice is 09-20-0118, "Study at Work Sites Where Agents Suspected of Being Occupational Hazards Exist."

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**)**.

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.

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

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.

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. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval
IRB approval has been granted to the study protocol for this ICR. The approved IRB protocol is in Attachment J.

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 be considered sensitive. The questionnaires are standard instruments for obtaining information on musculoskeletal symptoms, pain, and disorders. No social security numbers will be collected.

A12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden to Respondents

No direct costs will accrue to respondents. Approximately 125 individuals (two year approval) 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. The estimated annualized burden hours needed to complete the study is 238.

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	63	1	5/60	5
	Consent of Photographic Image Release	63	1	2/60	2
	Physical Activity Readiness (PAR-Q)	63	1	2/60	2
	Shoulder Rating Questionnaire (SRQ)	63	10	4/60	42
	Disabilities of the Arm Shoulder and Hand (DASH)	63	10	6 /60	63
	Standardized Nordic Questionnaire for Musculoskeletal Symptoms Instrument	63	10	4/60	42
	Work Organization Questionnaire	63	3	26/60	82
Total					238

B. Annualized Cost to Respondents

There is no cost to respondents as the questionnaires will be administered during working hours. The total estimated 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.
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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	5	$26	$130
	Consent of Photographic Image Release	2	$26	$52
	Physical Activity Readiness (PAR-Q)	2	$26	$52
	Shoulder Rating Questionnaire (SRQ)	42	$26	$1092
	Disabilities of the Arm Shoulder and Hand (DASH)	63	$26	$1638
	Standardized Nordic Questionnaire for Musculoskeletal Symptoms Instrument	42	$26	$1092
	Work Organization Questionnaire	82	$26	$2132
Total				$6136

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 two years by CDC research personnel at partial levels of effort (1 research industrial engineer, 1 safety engineer, 1 industrial hygienist, and 1 statistician), including tasks such as: (1) development of sampling frame and sample selection; (2) survey conduct; (3) sample tracking; (4) data receipt and processing; and (5) data entry and delivery. Estimated annualized costs to the Federal Government for the survey period are presented in Table A.14-1 below. This was calculated by distributing the estimated total costs over the two years (FY2016 and FY2017). The total cost average for the two years is $173,041.00 making the annualized cost to the federal government $86,520.50.

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

	FY2016	FY2017	TOTAL PROJECT	Annualized Cost
CDC Personnel Salaries and Benefits [a]	84,420.50	84,420.50	168,841	84,420.50
Travel	2,100	2,100	4,200	2,100
Contractual				
Supplies				
OTHER				
TOTAL	86,520.5	86,520.5	173,041	86,520.5

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

A15. Explanation for Program Changes or Adjustments

This is a reinstatement. There is a reduction in the original number of respondents and burden hours as the study was not completed during the previous approval period.

A16. Plans for Tabulation and Publication and Project Time Schedule

Statistical Analysis of the Data

Data collection *for an individual participant* will be completed over a 10 month period. However, we are requesting a two year reinstatement to account for the time horizon necessary to recruit participants. We have encountered unforeseeable delays due to conditions in the industry with which we are partnering. This past experience leads us to allow for a 6 to 12 month period for full recruitment of participants.

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)
Finalize preventive exercise protocol (exercise intervention)	0
Random assignment of treatment conditions to line and work shift (cluster randomization)	Within 12 months after OMB approval
Recruitment of study participants, participant informed consent and enrollment.	Within 12 months after OMB approval
First of three monthly baseline symptom surveys	Within 13 months after OMB approval
Second of three monthly baseline symptom surveys	Within 14 months after OMB approval
Third of three monthly baseline symptom surveys	Within 15 months after OMB approval
Installation of tool support intervention devices – begin intervention period	Within 15 months after OMB approval
Month 1 intervention period symptom survey	Within 16 months after OMB approval
Month 2 intervention period symptom survey	Within 17 months after OMB approval
Month 3 intervention period symptom survey	Within 18 months after OMB approval
Month 4 intervention period symptom survey	Within 19 months after OMB approval
Complete analysis determining effectiveness of interventions.	Within 22 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to this certification statement.