

Attachment F:  
Informed Consent- Questionnaire Data Collection

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)  
CENTERS FOR DISEASE CONTROL AND PREVENTION  
U.S. PUBLIC HEALTH SERVICE  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been invited to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

I. DESCRIPTION

1. Title: *Interventions to Reduce Shoulder MSDs in Overhead Assembly*

2. Sponsor and Project Officers:

This study is being done by the National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, Cincinnati, Ohio, 45226. The Project Officer is Brian D. Lowe, Ph.D.

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0964).

### 3. Purpose and Benefits:

You are invited to participate in a study investigating the prevention of soreness, discomfort, and symptoms of the arm and shoulder from overhead work in auto manufacturing. The purpose of this study is to evaluate the benefits of countermeasures to arm discomfort from overhead work. You have been invited to participate because you work on one of the chassis assembly lines at TMMK and your job involves overhead assembly work. Only team members working in the chassis assembly departments will be eligible to participate. The study is expected to last 10 months.

We want to find out about the effectiveness of workplace controls in reducing shoulder soreness, discomfort, and pain among team members in chassis assembly. To determine this, we are asking you to participate in a questionnaire-based health assessment described in

detail below. Since we want to be able to look at changes over time, we will be conducting the study over a 10-month study period. We are asking you to complete questionnaires at one month intervals during the study period.

Although there may be no immediate and direct benefits to you from being in the study, the information gained from the study may help to improve current understanding of how to best prevent shoulder injuries from repetitive overhead work. The information may also help to improve the design of tools, equipment, and practices to reduce shoulder disorders.

## II. CONDITIONS OF THE STUDY

1. If you volunteer to participate you will be asked to:

**<Exercise Treatment Group - this portion of text pertains only to participants randomly assigned to this group.>**

Participate in a shoulder exercise program. After an initial three-month period of responding to monthly questionnaires (described below) you will be asked to participate in a shoulder exercise program. You will first be screened for readiness to participate in the shoulder exercise program by way of a short health questionnaire. If you have no existing medical conditions that would put you at risk from exercise you will be eligible to participate. The exercise program will consist of a series of strengthening and stretching movements to improve the function of your shoulder. The exercises would be performed daily during your work shift and you will be given the opportunity to participate in the exercise program on paid time. You will be asked to participate in the program for seven months. TMMK fitness staff will lead and provide oversight for this program. Compliance with the exercise program is important to evaluate the program effectiveness. It is important that you make an effort to get the most benefit from this

program. If the exercises are causing you to have discomfort, beyond a temporary feeling of mild soreness associated with exercise, you should alert the study team and stop performing the exercises. Mild muscle soreness in the first week or two while your body begins adapting to the program is normal.

A shoulder functional capacity evaluation (FCE) will be conducted before you begin the exercise program and again after four months of participation. This evaluation will consist of a series of flexibility, strength, and endurance tests of your shoulder relevant to overhead work. The results will determine whether you made improvements in functional capacity as a result of the exercise program. The FCE will require a session with a TMMK staff fitness professional certified in athletic training. The TMMK staff member will have oversight of the FCE, and your individual FCE results will be known to TMMK and NIOSH. You may choose to receive copies of your individual results.

**<Tool Support Treatment Group - this portion of text pertains only to participants randomly assigned to this group.>**

Use a new tool support arm at your workstation. After an initial three-month period of responding to monthly questionnaires (described below) you will be asked to use a tool support arm. The tool support arm will be installed at your workstation in Chassis Assembly. This support arm is spring tensioned so that it can be “tuned” to support the weight of the torque tool you use in assembly work. You will receive training on its use. You will be asked to use the support arm for the intervention period of 7 months. The tool support arm is intended to reduce the load on your shoulder by supporting the mass of the torque tool. It will not change other aspects of your job.

**<Tool Support and Exercise Treatment Group - this portion of text pertains only to participants randomly assigned to this group.>**

Participate in a shoulder exercise program and use a new tool support arm at your workstation. After an initial three-month period of responding to monthly questionnaires (described below) you will be asked to participate in a shoulder exercise program and use a new tool support arm. You will first be screened for readiness to participate in the shoulder exercise program by way of a short health questionnaire. If you have no existing medical conditions that would put you at risk from exercise you will be eligible to participate. The exercise program will consist of a series of strengthening and stretching movements to improve the function of your shoulder. The exercises would be performed daily during your work shift and you will be given the opportunity to participate in the exercise program on paid time. You will be asked to participate in the

program for seven months. TMMK fitness staff will lead and provide oversight for this program. Compliance with the exercise program is important to evaluate the program effectiveness. It is important that you make an effort to get the most benefit from this program. If the exercises are causing you to have discomfort, beyond a temporary feeling of mild soreness associated with exercise, you should alert the study team and stop performing the exercises. Mild muscle soreness in the first week or two while your body begins adapting to the program is normal.

A shoulder functional capacity evaluation (FCE) will be conducted before you begin the exercise program and again after four months of participation. This evaluation will consist of a series of flexibility, strength, and endurance tests of your shoulder relevant to overhead work. The results will determine whether you made improvements in functional capacity as a result of the exercise program. The FCE will require a session with a TMMK staff fitness professional certified in athletic training. The TMMK staff member will have oversight of the FCE, and your individual FCE results will be known to TMMK and NIOSH. You may choose to receive copies of your individual results.

Use a new tool support arm at your workstation. A new tool support arm will be installed at your workstation in Chassis Assembly. This support arm is spring tensioned so that it can be “tuned” to support the weight of the torque tool you use in assembly work. You will receive training on its use. You will use the support arm for the intervention period of 7 months. The tool support arm is intended to reduce the load on your shoulder by supporting the mass of the torque tool. It will not change other aspects of your job.

**<This portion of text pertains to all participants.>**

Complete monthly questionnaires about arm soreness, discomfort, symptoms, work environment, and non-occupational physical activity. You will be asked to complete questionnaires once per month for a ten-month study period. This will be for seven months following an initial three month baseline period. The monthly questionnaires will ask about arm soreness, discomfort, and other physical symptoms that you may have. They will take approximately 14 minutes to complete. You can do this during your work hours. At three points in time during the ten-month study period you will also be asked to complete a questionnaire about your job and work environment. This questionnaire is longer and will take approximately 25-30 minutes to complete. ALL questionnaire data will be confidential. You will be assigned a random study ID number and Toyota management will not have access to a link between your identity and this ID number. Only the NIOSH study investigators will have this link and the information will be confidential and stored at a NIOSH office facility. When you complete the questionnaires they will be returned with your study ID number on them and not your

name. You will be able to put them in a safe locked box and they will be collected by a NIOSH researcher. The responses you provide to the questions will never be associated with your name or any other information which might reveal your identity. You will complete the questionnaires in hard copy (pencil and paper) format.

In addition to questions about physical symptoms you will be asked questions about your work environment, supervisor, and co-workers to see if anything about your work, or how you feel about your work, changes during the study period. This study is primarily interested in how your body feels physically. But, how you feel physically can be affected by many factors. It is important to note that all of your responses to questions in the work environment survey will be completely confidential. Toyota management will not be given access to individual questionnaires or identifiers that would link questionnaire responses to specific team members participating in the study. NIOSH will only present summaries of the questionnaire results to Toyota management.

2. Your participation in this study is completely voluntary and you may withdraw at any time. If you withdraw from participation in the study, NIOSH will ask why you chose to withdraw. No further contact with NIOSH investigators would occur.
3. No compensation will be provided to you by NIOSH for participation in the study. All study activities will take place during your work shift on paid time. There will be no consequences to you if you choose not to participate in this NIOSH study.
4. Injury or illness resulting from participation in this study is unlikely and the experimental conditions and procedures are not associated with any known increased risk of injury. If an injury or illness results, medical care is not provided, other than emergency treatment. If you are injured through negligence of a NIOSH employee you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Claims Office: (202) 233-0233, General Law Division of the Office of General Council (OGC). If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If an injury should occur to you as the result of your participation, you also should contact either:

Brian Lowe, Ph.D., Project Officer  
National Institute for Occupational Safety and Health  
4676 Columbia Parkway, C-24  
Cincinnati, OH 45226  
(513) 533-8161

Mark Toraason, Ph.D., Chairperson, NIOSH HSRB  
National Institute for Occupational Safety and Health  
4676 Columbia Parkway, C-11  
Cincinnati, OH 45226  
(513) 533-8207

5. All study data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. All questionnaire forms will be identified with a participant ID number randomly assigned to you. This number, rather than your name, will be used on all questionnaire forms. The only link between your participant ID number and your identity will be held by the Project Officer, Brian Lowe, in a locked file cabinet at the NIOSH facility in Cincinnati, Ohio. If you have any concerns about this study, you should contact the NIOSH Project officer, Brian Lowe (513) 533-8161.
6. There are no known alternative procedures for addressing the study questions.
7. NIOSH may ask to record your photographic image while you are working. This use would only be for illustrating the layout of your workspace, the tools you use in your work, and the postures involved. Use of any photographic or video image in any NIOSH publication or information product would need to be approved by Toyota management before it is released. NIOSH would not use your image, even with Toyota management approval, unless you allowed this use. You will be asked to sign a photo/video release waiver, granting NIOSH the right to use your photographic/video image. You may decline to sign the release and still be eligible to participate in the study.

If you have questions about this study, contact Brian Lowe at the email address and phone number listed above. If you have questions about your rights as a member of this study, contact Mark Toraason at the address and phone number above.

### III. USE OF INFORMATION

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control and Prevention (CDC), a government agency in the Department of Health and Human Services. NIOSH collects this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep such information, including results from this study because of three laws passed by Congress. These laws are:

1. The Public Health Service Act (42 U.S.C 241)

2. The Occupational Safety and Health Act (29 U.S.C. 669)

3. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. Personally identifiable information and company information will be protected to the extent allowed by law. There are conditions under the Privacy Act when NIOSH could be authorized to release this information to outside sources. These conditions under which we might release this information are listed in Appendix A (the Privacy Act).

#### IV. SIGNATURES

I have read this consent form and I agree to participate in this study.

PARTICIPANT \_\_\_\_\_

(Signature)

Name (first and last name printed) \_\_\_\_\_ Today's

Date: \_\_\_\_\_

Email Address \_\_\_\_\_

Address:

Street \_\_\_\_\_

Phone (    ) \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_

Zip \_\_\_\_\_

I, the NIOSH representative or their agent (contractor), have accurately described this study to the participant:

REPRESENTATIVE: \_\_\_\_\_ Date: \_\_\_\_\_

(Signature)

## **Informed Consent Form**

### **Appendix A**

The Information you provide will become part of the CDC Privacy Act System, 09-20-0147, “Occupational Health Epidemiological Studies and EEOICPA Program Records” and may be disclosed to

- Appropriate state or local health departments to report communicable diseases;
- A State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for confidentiality;
- Private contractors assisting NIOSH;
- Collaborating researchers under certain circumstances to conduct further investigations;
- One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;
- The Department of Justice or the Department of Labor in the event of litigation;
- Congressional offices assisting an individual in locating his or her records;

You may request an accounting of the disclosures made by NIOSH.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.