

INFORMED CONSENT DOCUMENT INFORMED CONSENT DOCUMENT

Project Title: **Be Engaged: Help Integrate Protection/Promotion (Be Hipp)**

Research Team: **Linda Snetselaar, PHD, RD; Lois Ahrens, RD; Donna Hollinger, RD, MS; Karen Smith, RD, MS; Dru Mueller, RD, MS; Ilona Lichty, RD; Bill Barker, BA, Linda Merlino, MS, Samantha Hench, MS; Cassidy Branch, MA; Kim Merchant, BA, MA; Jennifer Woolston RD, Kerri Bland, BS, RD**

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are an adult of age 18 years or older and employed at Shive-Hattery, Inc. in a job category that may increase your risk for upper extremity and back injury.

The purpose of this research study is to examine a holistic approach to health by combining health protection (ergonomics) with health promotion (wellness).

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 280 people will take part in this study conducted by investigators at the University of Iowa. Out of the 280 employees enrolled, 140 will be randomly assigned (like flipping a coin) to the Intervention Arm and attend group sessions while 140 will be assigned to the Control Arm and receive quarterly newsletters.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately three years. If you are assigned to the Intervention Arm, you will be asked to attend twelve monthly sessions each year that will take 30 minutes each. You will be asked to come to a clinic visit at the beginning of the study and once per year for three years. This visit will take 45-60 minutes.

If you are assigned to the Control Arm, you will be asked to come to a clinic visit at the beginning of the study and once per year for three years. This visit will take 45-60 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

After giving your consent to participate, you will be asked to fill out a questionnaire on-line and have your height and weight measured. You are free to skip any questions that you would prefer not to answer. The on-line questionnaire will ask about the following items:

- General demographic questions about you (e.g. birth date, gender, address), personal health (diabetes, hypothyroidism, rheumatoid arthritis, prior upper extremity and spine disorders), and history of injury or trauma to the upper extremities and spine.
- Questions about physical activity, nutrition, stress and mental health, alcohol and tobacco use, health knowledge and attitudes, medical history, biometrics (e.g. blood pressure and blood glucose), and readiness to change health habits.
- Your views of your physical and mental health.
- Questions about musculoskeletal symptoms such as wrist pain that you had to see a physician for.
- Questions about psychological demands, scope of decision making, social support, physical demands, and job security.

We will ask you to fill out the questionnaire and have height and weight measures done at the beginning of your participation and annually for three years. This visit will take approximately 45-60 minutes.

The study team will provide your name to the Shive-Hattery Human Resource office who will give us your absentee and worker's compensation records for the year. This will be done at the beginning of the study and annually for three years. A comparison will be done to evaluate the effectiveness of the intervention. As with all study records, this information will be kept confidential within the study team.

If you are randomly assigned to the Intervention Arm:

You will participate in a health protection/promotion program which involves attending twelve half-hour group sessions per year. During these sessions you will discuss "barriers to change"; and receive encouragement to explore areas of **interest to you**. These areas may include work station design, stress reduction, social support, smoking cessation, healthful eating practices, and physical activity. The group sessions will take place mid day at Shive-Hattery and lunch will be provided.

Photographs

One aspect of this study intervention may involve making a photograph of your work station. This would be done by you with a study provided digital camera. The photograph would be used in group sessions as an example of a work station and how it might be improved to reduce stress and injury. The photos would be kept by the study counselor and destroyed at study end.

You can still be in the study without having photographs taken.

I agree to have my work place photographed?

Yes No

If you are randomly assigned to the Control Arm:

You will receive quarterly newsletters about health protection and health promotion.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience the risk indicated below from being in this study. In addition to this, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The study questionnaires will ask about your health, which may make you uncomfortable.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because there may be increased understanding of how to effectively integrate health promotion and health protection activities in the workplace.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You may need to provide your address if a check will be mailed to you. You will receive \$25.00 per year for completing the study questionnaire and having height and weight measures taken at study entry and annually for three years for a total of \$100.00 for the entire study.

WHO IS FUNDING THIS STUDY?

The National Institute for Occupational Safety and Health is funding this research study. This means that the University of Iowa is receiving payments from the National Institute for Occupational Safety and Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institute for Occupational Safety and Health for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Preventive Intervention Center investigators,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will keep all data in locked files or in password-protected computer files to which only research study personnel will have access. The information that we collect from you will be identified by a study ID code. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires Shive-Hattery to obtain your permission for the research team to access or create “protected health information” about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once Shive-Hattery has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under “Confidentiality.”

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards, and support staff. You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes Shive-Hattery to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be

given access to your health care records by contacting Shive-Hattery. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Linda Snetselaar PHD, RD Department of Community and Behavioral Health, College of Public Health, 200 Hawkins Drive, E225A GH Iowa City, Iowa 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to come for a final visit to complete the study questionnaire and height and weight measures.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Linda Snetselaar (319) 384-5011, Lois Ahrens, (319) 384-5044, Kim Merchant, (319) 384-5059, Donna Hollinger, (319) 384-5072, or Karen Smith, (319) 384-5036. If you experience a research-related injury, please contact:
Linda Snetselaar (319) 384-5011.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 340 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, <http://research.uiowa.edu/hso>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 200705717
APPROVAL DATE: 09/17/09
EXPIRATION DATE: 03/23/10

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 03/23/10.

(Signature of Subject)

(Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)