

**NCT #: NCT06405347**

**Brief Title: The M-Well Inpatient Whole Health Bundle**

**Official Title: Engineering Whole Health into Hospital Care to Improve Wellness: The Inpatient Whole Health Bundle**

**Informed Consent Document: Engineering Whole Health into Hospital Care to Improve Wellness: The Inpatient Whole Health Bundle (VA Site)**

**Date Approved: 03/14/2024**

# Department of Veterans Affairs Research Consent Form

VAAHS Research IRB  
Approved 03/14/2024



Title of Study:	Engineering Whole Health into Hospital Care to Improve Wellness: The Inpatient Whole Health Bundle	
Principal Investigator:	Nathan Houchens, MD	VAMC: <b>VA Ann Arbor Healthcare System</b>
Participant Name:		Date:

## KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Agency for Healthcare Research and Quality. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

### WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to test an intervention focused on improving patients' wellness and satisfaction with their hospital stay. As part of this study, patients hospitalized on specific hospital units will be asked to participate in the study intervention. If you choose to participate, a study team member will offer you a menu of items that may help improve your wellness and satisfaction with your hospital stay. You can choose to use or not use any of the items on the menu. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

By doing this study, we hope to learn if the items offered will help improve patients' satisfaction with their hospital stay. Your participation in this research will last for approximately 2-3-weeks. You can participate in the intervention for as long as you are in the hospital. You will be asked to complete a study survey after you are discharged. This survey will be mailed to you about a week after you are discharged from the hospital. It will take approximately 10 minutes to complete this survey.

### WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may or may not personally benefit by taking part in this study. But by taking part, you could help us improve hospitalized patients' wellness and satisfaction with their care. *For a complete description of benefits, refer to the Detailed Information section of this consent.*

### WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

As with all research studies, there is a risk of loss of confidentiality of your research data. However, we will take steps to protect you from these risks. *For a complete description of risks, refer to the Detailed Consent and/or Appendix.*

### DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

### WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Nathan Houchens, MD at the VA Ann Arbor Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [Nathanho@med.umich.edu](mailto:Nathanho@med.umich.edu) or (734) 845-5922. You can also contact the project manager, Karen Fowler at [Karen.Fowler@va.gov](mailto:Karen.Fowler@va.gov) or (734) 845-3611.

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## DETAILED INFORMATION ABOUT THE STUDY

### WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research, we hope to learn if an intervention will improve hospitalized patient's satisfaction with their care.

### HOW LONG WILL I BE IN THE STUDY?

We plan to enroll up to 600 Veterans in the study intervention. Your individual participation in the project will take approximately 2-3 weeks. You can participate in the intervention for as long as you are in the hospital. You will be asked to complete a study survey after you are discharged. This survey will be mailed to you about a week after you are discharged from the hospital. It will take approximately 10 minutes to complete this survey. This entire research study is expected to take approximately 2 years to complete.

### WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to take part in this study, a study team member will visit your room to offer a menu of items to help improve your wellness and satisfaction with your care.

The menu will include items such as: meditation videos, music, white noise audio, electronic tablets (like iPads if available), mobile device chargers, massage therapy, aromatherapy, whole health assessment, an opportunity to share your personal story with your providers, and convenience items such as eye masks, candles, toothbrushes, and toothpaste.

The study team will also keep track of which items or services you use and keep this information in our records.

You will be asked to complete a study survey after you are discharged. This survey will be mailed to the address on file in your medical record. It will take approximately 10 minutes to complete this survey. The survey will ask you to rate your satisfaction with various aspects of your hospital stay, included some of the items offered as part of this study.

### WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

As part of this study, you will be offered a menu of items to use during your hospital stay. You may choose to use as many or as few of the items as you would like. You will also be asked to complete a study survey to provide your feedback on your satisfaction with your hospital stay.

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## WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any study has possible risks and discomforts. The activities, items, or services in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- There is a risk that some of the intervention items or services may not be helpful or may cause physical harm. The use of aromatherapy may cause an allergic reaction or other physical harm. The use of massage therapy may also cause physical harm. We will take steps to minimize these physical risks. The aromatherapy and massage services will be given by a trained therapist who will follow standard procedures.
- Another risk is potential loss of confidentiality if the research data was breached. This risk is unlikely, and we will take steps to prevent this.
  - Your name and other identifying information will be kept in a separate limited access file from your study data.
  - Your study data will be stored on a secure VA server that only the study team can access.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

## WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include increased wellness or satisfaction with your care.

## HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Paper study documents, such as this consent form and the study survey, will be stored in locked filing cabinets at the VA Ann Arbor Healthcare System Center for Clinical Management Research offices.
- Electronic study data will be stored on a secure VA server that only study staff can access

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board (IRB), our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

Your information collected as part of the research will not be used or distributed for future research studies.

Some of the items offered will require us to put documentation in the medical record, such as massage

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therapy. Therefore, we may include information about your study participation in your medical record, depending on the items you choose.

## Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO; Sponsors; Contractors, Affiliates as appropriate) the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Study Team receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Nathan Houchens, MD and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

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## WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

## WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will receive a \$10 gift card if you mail back a completed study survey. The \$10 gift card will be mailed to you once your completed survey is received.

## WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: Latoya Kuhn at (734) 845-5561.

## DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. If you don't want to take part, there is no penalty or loss of benefits to which you are otherwise entitled. You may discontinue taking part in this study at any time without any penalty or loss of benefits. You may withdraw from the study *and still receive the same standard of care that you would otherwise have received*. If you leave the study early, the study team may continue to review the data already collected for the study but will not collect any more information.

## WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, complaints, or concerns about the study, you can contact members of the study team: Nathan Houchens, MD (Principal Investigator) can be contacted at [Nathanho@med.umich.edu](mailto:Nathanho@med.umich.edu) or (734) 845-5922. Project manager Karen Fowler may be contacted at [Karen.Fowler@va.gov](mailto:Karen.Fowler@va.gov) or (734) 845-3611.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Ann Arbor Healthcare System Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Ann Arbor VA Research Office at (734) 845-3440 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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## FUTURE USE OF DATA AND RE-CONTACT

Your de-identified data will be stored at the VA Center for Clinical Management Research, with access limited to approved study staff. There will be no way to identify you or link you to this data. Your data without any identifiers could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

## AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms \_\_\_\_\_ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

**I agree to participate in this research study as has been explained in this form.**

_____	_____	_____
Participant's Name (Printed)	Participant's Signature	Today's Date

**Person Obtaining Informed Consent:**

_____	_____	_____
Study Team Member Name (Printed)	Study Team Member's Signature	Today's Date