NCT #: NCT07215117

Brief Title: Engineering Whole Health into Hospital Care – University of Michigan

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 (UM Site)

Date Approved: 04/25/2025

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Engineering Whole Health into Hospital Care to Improve Wellness: The Inpatient Whole Health Bundle

Company or agency sponsoring the study: Agency for Healthcare Research & Quality (AHRQ)
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Sanjay Saint, MD, MPH, Department of Internal Medicine, University of Michigan

Study Coordinator: Karen E. Fowler, MPH, Center for Clinical Management Research, VA Ann Arbor Healthcare System

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

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.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include a risk to your confidentiality. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by developing future programs to improve hospitalized patient wellness. More information will be provided later in this document.

We expect that you will be receiving study interventions for the length of this hospital stay. The study follow-up survey will be completed in approximately 2-3 weeks.

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

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

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Adult hospitalized patients on specific medical units at the University of Michigan Health System. You must be able to speak English and able to provide your own consent to participate.

3.2 How many people are expected to take part in this study?

We expect up to 150 people to participate in the study intervention. In addition, we are asking up to 150 people who are not in the intervention to complete a survey. This will allow us to compare satisfaction between those who participate in the intervention and those who do not.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this 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: music, headphones, white noise audio, mobile device chargers, and convenience items such as eye masks, candles, toothbrushes, and toothpaste. The study team will also keep track of which items 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.

4.2 How much of my time will be needed to take part in this study?
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.

4.3 When will my participation in the study be over? Your participation in this study will be over after you complete the study survey after you are discharged.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are:

- There may be a risk to your privacy.
- Some people get uncomfortable when asked questions.

The researchers will try to minimize these risks by:

- You can end your participation in the study at any time.
- Your participation in this study will be kept confidential. Refusal to take part in this study will in no way influence your employment, ratings, or subsequent recommendations.
- You can skip any survey question you do not want to answer.

Additionally, there may be a risk involving loss of confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research, including those marked "[Not research]" in section 4.1, above. Risks associated with your regular medical treatment should be discussed with your regular doctor.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
This study does not involve any medical treatments or procedures. There are no physical risks associated with this study. However, please notify the study team immediately if you experience any ill effects associated with this study.

5.3 If I take part in this study, can I also participate in other studies?
Yes. This study does not involve any treatments or physical risks. Participation in this study will not limit your ability to participate in other research studies.

5.4 How could I benefit if I take part in this study? How could others benefit?
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.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
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.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researchers believe that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive a $10 gift card for completing the study survey.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study.

9. CONFIDENTIALITY OF PARTICIPANT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your participation will occur at Michigan Medicine. To protect your confidentiality your name will not be recorded on any of our study notes or on your study survey. We will label all study documents with a unique study identification number. Only study staff will have access to the file that links you to your study identification number. Your study data will be stored either in a locked filing cabinet or electronically on a secure server that only the study team can access.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner and for quality improvement purposes.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Analyze the results of the study
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission does not expire, unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Sanjay Saint, MD, MPH
Principal Investigator Contact:	University of Michigan Department of Internal Medicine 2800 Plymouth Road Building 16, Room 430 Ann Arbor, MI 48109 (734) 615-8341
Study Coordinator:	Karen E. Fowler, MPH
Study Coordinator:	2800 Plymouth Road Building 16, Room 305E Ann Arbor, MI 48109 (734) 845-3611 Email: kefowler@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of the signed and dated informed consent document.

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

12.1 What is meant by the storage, future research use, and sharing of study participants' medical information taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information to use in future research. These future research uses take different basic forms, which are described below. The medical information may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

For purposes of this research study, your collected private information may be shared with the study sponsor, the Agency for Healthcare Research & Quality, its collaborators, and associated research partners.

With appropriate institutional and regulatory permissions, your collected private information could be used for future research with other researchers and companies, including those in other countries, with or without your consent.

In addition, after identifiers are removed from your private information, the information could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries without your additional informed consent.

In each of the situations described above, you may later change your mind and withdraw your consent to the storage, use and sharing of your information even if you give your consent now, provided that the information can still be identified as yours and has not already been used or shared. Keep in mind, however, that any information that has already been used or shared with other researchers cannot be recovered or deleted.

This study receives funding from the Agency for Healthcare Research and Quality (AHRQ). AHRQ requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back.

Researchers who wish to access your information must obtain permission to access your information. Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information.

To protect your confidentiality, we will remove all details from your information that could identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you.

You do not have to agree to storage and sharing of your information if you do not wish to. You may take part in this study even if you do not want us to share your information with other researchers. You will indicate your choice regarding storage and sharing of your information in a signature box near the end of this document.

13. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the researchers keep my data for future research (signature required below).

_____ No, I do not agree to let the researchers keep my specimens for future research (no signature).

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____