NCT #: NCT06354920

Brief Title: M-Well Bonding Bundle to Improve Patient-Physician Relationships

Official Title: Engineering Whole Health into Hospital Care to Improve Wellness: Bonding Bundle

Informed Consent Document: Engineering Whole Health into Hospital Care to Improve Wellness: Bonding Bundle (Physician Consent UM Site)

Date Approved: 05/31/2024

CONSENT TO BE PART OF A RESEARCH STUDY

Part 1 of 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at several different locations (multi-site research). The University of Michigan is providing IRB oversight for all sites in this study. This consent form includes two parts. Part 1 (General Information) includes information that applies to all study sites. Part 2 (Site Information) includes information specific to the study site where you are asked to enroll. Both parts of consent form must be provided to you.

Study title:	Engineering Whole Health into Hospital Care to Improve Wellness: Bonding Bundle
Company or agency sponsoring the study:	Agency for Healthcare Research & Quality (AHRQ)

1. KEY INFORMATION ABOUT THIS STUDY

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 or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing a physician's behaviors while visiting with patients may have an impact on the patient-physician relationship. Specifically, we will test an intervention focused on improving relationships between physicians and their hospitalized patients. This study is being conducted at both the University of Michigan Hospital and the LTC Charles S. Kettles VA Medical Center in Ann Arbor, MI.

This study involves a process called randomization. This means that the tasks you are asked to do are not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

For this study, attending physicians will be randomly assigned to either receive the intervention or serve as a control group. If you choose to participate, a study project manager or research assistant will let you know if you are assigned to the intervention or the control group. Participation in this study is voluntary.

All participants in this study - both intervention and control arms- will be asked to do the following:

1) Study staff will shadow you over several days during your work rotation to observe the interaction between you and your patients. Separately, we will obtain permission from each patient to enter their room with you and your team to conduct these observations.
2) You will be asked to complete a brief survey at the end of your work rotation. This survey can be completed electronically or on paper and will take approximately 5 minutes to complete.

Those participants that are randomly assigned to the intervention group will be encouraged to use suggested study elements while they are visiting with their patients that may help improve the patient-physician relationship. Participants in the intervention group can also choose to participate in an optional one-time interview. This interview would be at your convenience at a later date. We would ask questions to get more detailed information about your experiences with the intervention. We will also ask for suggestions to improve physician wellness and the patient-physician relationship.

It is possible you may be assigned to additional study groups over the next year depending on the service schedule. Each clinical rotation, two attending physicians are randomly picked to participate. If you are randomly selected to participate again in the future, you will be asked to be shadowed and to complete the study survey again. No health-related information – from you or your patients – will be collected as part of this study.

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 improving your connection to your hospitalized patients. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 1 or more clinical rotations over the next year. The optional study interview would take 30 to 60 minutes.

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:

A good relationship between patients and their physicians provides the foundation for safe, effective high-quality health care. The purpose of this study is to test an intervention designed to improve the relationship between hospitalized patients and their physicians.

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?

Attending physicians taking care of hospitalized medical patients at the University of Michigan Hospital or the LTC Charles S. Kettles VA Medical Center. Residents are not eligible to participate as a primary subject. You must be able to speak English and able to provide your own consent to participate. We are also collecting data from patients at both hospitals to get their opinions on the patient-physician relationship.

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

In total, up to 130 physicians are expected to participate in this multi-site study.

As part of this study, we will also collect data from hospitalized patients to gather their feedback on the patient-physician relationship. Patient participation will include allowing study observations of patient-physician interactions and completing a study survey. In total, we expect approximately up to 2,500 patients to participate in study observations and up to 1,000 of those patients to complete a study survey.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

As part of this study, 2 attending physicians each service rotation will be randomly assigned to either participate in the intervention or serve as a control. You have a 50/50 chance (like a coin flip) of participating in either the intervention or control arm of this study.

Study observations will be conducted with all study participants (both intervention and control arms). Study staff will shadow you while you are visiting with your hospitalized patients. These observations will usually occur during morning teaching rounds. We will not collect any personal or identifying data on your patients during these observations. We will take notes about specific aspects of the interaction between you and/or your teams and your patients. We will enter patient rooms to make these observations. Before rounds, each patient will be approached by study staff and asked for their permission to enter their room with you and your team. We will only enter the rooms of patients who have given their permission. You can ask the study staff to leave the patient room at any time.

All study participants will also be asked to complete a brief survey at the end of your service rotation. This survey can be completed electronically or on paper.

If you are randomized to participate in the intervention group, you will be asked to use a few suggested elements while interacting with your patients. If you are in the control arm, you are asked to conduct rounds as you normally would.

It is possible you may be asked to participate in this study for more than one service rotation, depending on the service schedule.

Those in the intervention arm may also be asked to participate in an optional one-time interview. We would like to talk to a few physicians more in-depth about their experiences with the intervention. A member of the study team will email you to set up a convenient time for the interview. The one-time interview will take 30-60 minutes and can be conducted over the phone or using meeting software such as Zoom. The interview will be audio recorded so we do not miss anything that you have to say. One or two study team members will conduct this interview. We will ask you a few general questions, but feel free to expand if there is something else you think is important. If during the interview we ask a question you don't want to answer, you don't have to. If at any time you want to stop the interview, that is fine too. Participation is completely voluntary. The audio recording will be transcribed (made into a written copy). All names in the transcript will be deleted. Your answers will be combined with other study participants' answers. This will allow us to compare everyone's answers.

As a subject participating in this research study, you have certain responsibilities that may apply to this study. You will be expected to allow us to shadow you while visiting with patients and to complete the study survey at the end of your service rotation.

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

We will shadow you for approximately 4-5 days during each service rotation that you participate in this study. It will take less than 5 minutes to complete the post-rotation study survey. It is possible you may be asked to participate for more than one rotation over the next year, depending on the service schedule. If you are in the intervention group and are chosen to participate in the study interview, you will be asked to complete a one-time 30 to 60-minute interview.

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 at the end of your service rotation. Each rotation typically lasts approximately 14-16 days. However, you may be asked to participate for additional rotations over the next year depending on the service schedule. You may also be asked to participate in a one-time study interview a few weeks after your work rotation.

4.4 What will happen with my information and/or biospecimens used in this study?

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

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.
- There may be a risk of coercion.
- Some people get uncomfortable when asked questions.
- Some people get uncomfortable when being observed.

The researchers will try to minimize these risks by doing the following:

- 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 or interview question you do not want to answer.
- You can ask the researchers to leave a shadowing session at any time.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 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.

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 treatments or procedures. There are no physical risks associated with this study. However, tell the researchers listed in the Part 2 *Site Information* section 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?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Possible benefits may include an improved relationship with your patients.

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 study team persons listed in the Part 2 *Site Information* section.

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 researcher believes 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?

See Part 2 *Site Information.*

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. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

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. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA).

9.1 How will the researchers protect my information?

Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. 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. The audio recordings from the optional study interview will be deleted once they have been transcribed and verified. Identifiable information will not be shared between the study sites. The linking information will be removed from all study data at the end of the study to protect confidentiality.

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

9.2 What individually identifiable information 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.

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.
- 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
- 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.

END OF PART 1 *GENERAL INFORMATION*

SEE PART 2 *SITE INFORMATION* FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING

CONSENT TO BE PART OF A RESEARCH STUDY

Part 2 of 2: SITE INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

This part of the consent form includes additional information about being a research participant at your enrolling site. Before making your decision to join the study, review both the General study information and this Site information.

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

Site Name: University of Michigan

8(A) FINANCIAL INFORMATION (CONTINUED)

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 is no site-specific information on this topic. See the Part 1 *General Information* section 8.1 for additional information on this topic.

8.2 Will I be paid or given anything for taking part in this study?

No. You will not be paid for taking part in this study as you will be participating during your normal working hours.

9(A) CONFIDENTIALITY OF SUBJECT RECORDS

9.1 How will the researchers protect my information?

See the Part 1 *General Information* section 9.1 for additional information on this topic.

- Paper study documents, such as this consent form and the study survey, will be stored in locked filing cabinets at the University of Michigan North Campus Research Complex.
- Electronic study data will be stored on a secure University of Michigan server that only study staff can access.

All identifiable information collected from University of Michigan participants will be stored on a secure University of Michigan server. De-identified data, such as survey responses or de-identified interview transcripts will be shared with researchers at the VA Ann Arbor Healthcare System. Data analysis of the de-identified study data will occur at the VA Ann Arbor Center for Clinical Management Research. No personal identifying information will be shared between the two study sites.

9.2 What protected information about me could be seen by the researchers or by other people? Why? Who might see it?

See the Part 1 *General Information* section 9.2 for additional information on this topic.

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.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

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

9.4 When does my permission to use my information expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting 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

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 or treatments
- Talk about study-related costs to you or your health plan
- 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

Site Principal Investigator:	Sanjay Saint, MD, MPH
Site Principal Investigator Contact:	University of Michigan Department of Internal Medicine 2800 Plymouth Road Building 16, Room 430 Ann Arbor, MI 48109 (734) 615-8341

Site Study Coordinator:	Karen E. Fowler, MPH
Site Study Coordinator Contact *(if applicable)*:	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 responsible for the review of the study:

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

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 this 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. 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 _____.

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-B

Consent/Assent to video/audio recording/photography solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

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): _____