Patient and Family Consent Forms

Title: Recommendations and Alerting for Delirium Alleviation in Real-Time (RADAR)

PI: Phillip Vlisides, MD

NCT: NCT04007523

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Patient Consent Form

Document Approval Date: 4/11/2022

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Recommendations and Alerting for Delirium Alleviation in Real-Time (RADAR)

Company or agency sponsoring the study:

Michigan Medicine, Department of Anesthesiology

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Phillip Vlisides, MD, Department of Anesthesiology

Project Manager: Amy McKinney, MA, Department of Anesthesiology

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 child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying the idea that social and behavioral support may reduce the incidence and impact of confusion in older adults and may improve the postoperative environment for recovery.

This study involves a process called randomization. The study divides participants into 1 of 4 different groups, based on chance (like the roll of a die), to compare different treatments or procedures. The study group is not chosen by you or the researcher, but by a program specifically designed for this purpose. If you decide to be in the study, you and your family member/caregiver will know which group you are assigned to but the study team will not know.

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 being inconvenienced by a pager alert, or by visits from the study team. This study may offer some benefit to you now or others in the future by improving the post-operative environment for neurological and clinical recovery. More detailed information will be provided later in this document.

We expect the amount of time you will participate in the study will be for up to three days after surgery. Then, we will mail you a follow-up survey 30 days after surgery to ask about your health and well-being.

You can decide not to be in this study. Participating in this study is completely voluntary. 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 below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Many patients experience confusion after surgery. This is especially true for older patients. Unfortunately, we still do not completely understand why confusion happens. The purpose of this study is to evaluate if post-operative social and behavioral support may reduce the incidence and impact of confusion in older adults.

Note: Your clinical care, post-surgery will not change regardless of whether or not you choose to participate in this study. You will still receive whatever supportive care (such as pain medicine) you require.

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?

Eligible patients:

Adults, age 70 and older requiring general anesthesia for major non-cardiac, non-intracranial neurologic, and non-major vascular surgery, with an anticipated length of hospital stay at least 72 hours.

Eligible patients must also have at least one family member or caretaker available on each of the first three post-operative days. If possible, we would like to have the same family member or caretaker available each day.

Ineligible patients:

Patients meeting any of the following criteria will be excluded:

1. Severe cognitive impairment (precluding the ability to perform confusion assessments)
2. Non-English speaking patients and/or family member or caretakers.

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

A total of 60 patients are expected to take part in this study, all here at the Michigan Medicine.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

After enrollment in the study, we will ask you a few questions about your medical history, including depression and anxiety, if you have any pain, and how well you sleep at night. We will check for baseline signs of confusion. We will swab your hands and nares (nose) to check for multidrug-resistant organisms.

Either on the day of surgery, or on the first morning after surgery, our study team will visit you and your family member/caretaker. For subjects assigned to the Family Based Paging System or Combined System will receive additional information and will temporally be assigned a hospital pager. More information is provided below. You will be randomized to one of four groups, and there is no charge to you or your health plan for assignment to any of these groups:

Standard Care:

As an existing program, the Hospital Elder Life Program (HELP) at Michigan Medicine aims to assist elderly patients remain as independent as possible during their hospital stay. HELP volunteers work with patients to promote and monitor patient orientation, cognitive stimulation, relaxation/sleep, mobility, feeding/eating, and hearing or vision needs where functional deficits require assistance. This program is open to all eligible inpatients within the University of Michigan Hospital.

HELP visits are determined at the discretion of the HELP team, determined by age and other confusion risk factors.

HELP-Based Paging System:

For subjects assigned to the HELP-based support system, a single page will be sent to the on-call HELP staff during the first postoperative morning as the team begins ward rounds. The page will request an enhanced treatment protocol, which includes HELP visitations three times daily.

Therapeutic treatment will be administered during each visit per program existing protocols, which generally includes cognitive engagement, mealtime assistance, mobility and range of motion exercises, and assistance with visual and hearing aids. During the evening visit, a sleep protocol will be implemented, HELP officials offer sleep and relaxation exercises, relaxation massages, and warm milk and/or tea.

These therapeutic treatments may offer direct benefits to participants.

Family-Based Paging System:

For subjects assigned to the family-based system, family members (or caretakers) will receive pre-operative education on delirium (including an educational video), a folder with an informational flyer, and a daily checklist of activities to perform that might help reduce delirium risk. These activities entail daily assistance with visual and hearing aids, handwashing, drinking/mealtime assistance, re-orientation to time and place, and cognitive stimulation activities. These therapeutic activities may offer direct benefits to participants.

Family members (or associated friends/caretakers) will also receive training in how to assess for confusion. Lastly, family members will also receive a pager, and automated pages will be sent twice daily with reminders to perform these activities.

Completion of activities will then be logged daily in conjunction with members of the research team.

Combined Systems (HELP-Based Paging System and Family-Based Paging System):

Subjects assigned to this group will receive enhanced HELP visits (see description above), as well as family-paging alerts to remind family members/caretaker to assist their family member (subjects). These participants may benefit from either or both therapies.

If you have any questions related to the above information, please contact the study team.

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

Pre-operative in-person clinic visit (if applicable), or, Day of surgery: approximately 15 minutes to learn about the study, sign the consent form, and perform our baseline assessments.

Either the day of surgery, or the first morning after surgery : you will be assigned to one of four groups. If you are assigned to the Family-Based Paging System group or the Combined Systems (HELP-Based Paging System and Family-Based Paging System), a member of the research team will meet with your family member and/or caregiver to go over the study requirements. This may occur while you are having surgery and will not add time to your surgery. We may assign you to your group the morning after your surgery. This may take up to a half hour of your family member and/or caretaker's time.

Days 1-3 after surgery: you will be visited by a member of the research study team each day, twice daily to ask about your pain levels and confusion symptoms; this may take up to 15 minutes. Your hands and nares (nose) will be swabbed to check for multidrug-resistant organisms. In addition, we will swab the following high-touch surface areas in your hospital room including: bed control buttons/bed rail, call button/TV remote control, tray table, hospital telephone (inside and out), and toilet seat/commode. Swabbing should take less than 5 minutes. The third day will take an additional 5 minutes to assess for depression and anxiety symptoms.

Research activities may take up to an hour and a half per day depending upon which group you are assigned to. Subjects who are assigned to be visited by HELP team members will meet with them up to three times per day. You may also be asked to perform activities with your family member and/or caretaker.

Day 30 after surgery: Your participation will be over 30 days after your surgery upon completion of the mailed survey. It may take up to 10 minutes to complete this survey. A self-addressed stamped envelope will be provided to you so you can return the completed survey to the study team.

4.3 When will my participation in the study be over?

Your participation will officially be over 30 days after your surgery upon completion of the mailed survey. We may review your chart after this period to review data and assess for any changes in your health that may relate to this research study. We may also call you to follow-up on the survey or relay any additional information as needed.

4.4 What will happen with my information used in this study?

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

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 include:

There is a minimal risk of inconvenience of paging-alerts (for family members) and the inconvenience of visits by HELP team members and research study team members.

You may find some of the survey questions annoying or confusing. You are free to skip any questions you do not want to answer.

There is a minimal risk of confidentiality. We will minimize this risk by utilizing an indirect data link, which will not personally identify you. 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.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

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

You may receive personal benefits from participating in this study, including direct therapeutic benefits from the HELP program, and social and behavioral support from family members and/or caretakers. It is possible that you may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

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?

Participating in this study is completely voluntary. You may choose not to participate. In this event, your medical care will proceed as it routinely would otherwise.

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 researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- 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 is no charge to you or your health plan for participating in this research study, no matter what group you are assigned to. The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

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?

No.

8.3 Who could profit or financially benefit from the study results?

No party will profit or financially benefit from these study results.

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 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?

All measures will be taken to protect your privacy. All of your information will be stored on password protected computer files and only members of the research team will have access to this information. In addition, your information will not be linked directly to your name, but rather indirectly by a random number scheme. Only the study team will have access to the key that allows your name to be determined from the random number that was assigned to you. Data retention and storage of this data for future research is a required step for study participation. Also, all members of the research study team are trained and certified in human subject's privacy.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to

report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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 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:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- 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.
- The researchers may need the information to check your test results or look for side effects.
- 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
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- 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 expires at the end of the study, unless you cancel it sooner. 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 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

Principal Investigator: Phillip Vlisides, MD
Mailing Address: 1500 East Medical Center Drive 1H247 University Hospital
Ann Arbor, MI 48109-5048
Telephone: [redacted]

Project Manager: Amy McKinney, MA, CCRC
Mailing Address: 1500 East Medical Center Drive F3848 UH-South
Ann Arbor, MI 48109-5048
Telephone: [redacted]
Email: [redacted]

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: [redacted] (For International Studies, include the appropriate calling codes.)
Fax: [redacted]
e-mail: [redacted]

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?

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 and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent 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 Dr. Vlisides' designee. 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): _____

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): _____

Title: Recommendations and Alerting for Delirium Alleviation in Real-Time (RADAR)

PI: Phillip Vlisides, MD

NCT: NCT04007523

Family Consent Form

Document Approval Date: 4/11/2022

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

FAMILY

NAME OF STUDY AND RESEARCHERS

Title of Project: Recommendations and Alerting for Delirium Alleviation in Real-Time (RADAR)

Principal Investigator: Phillip Vlisides, MD, Department of Anesthesiology

GENERAL INFORMATION

We're doing a study to learn more about confusion in patients age 70 and older after surgery. To facilitate this, your family member/friend would like to participate in this study to see if one of four interactions can eliminate or minimize the effects of post-operative confusion.

Either on the day of surgery, or the first morning after surgery, our study team will visit you and your family member/friend. Enrolled subjects will be randomized (like the roll of a die) to 1 of 4 groups. Family members/friends of subjects who are assigned to the Family Based Paging System or Combined System will receive additional information and will temporally be assigned a hospital pager during their participation in this project.

Standard Care:

As an existing program, the Hospital Elder Life Program (HELP) at Michigan Medicine aims to assist elderly patients remain as independent as possible during their hospital stay. HELP volunteers work with patients to promote and monitor patient orientation, cognitive stimulation, relaxation/sleep, mobility, feeding/eating, and hearing or vision needs where functional deficits require assistance. This program is open to all eligible inpatients within the University of Michigan Hospital. HELP visits are determined at the discretion of the HELP team, determined by age and other confusion risk factors.

There are no extra activities to be completed by family members/friend for this group.

HELP-Based Paging System:

For subjects assigned to the HELP-based support system, a single page will be sent to the on-call HELP staff during the first postoperative morning as the team begins ward rounds. The page will request HELP visitations three times daily. Therapeutic treatment will be administered during each visit per program existing protocols, which generally includes cognitive engagement, mealtime assistance, mobility and range of motion exercises, and assistance with visual and hearing aids. During the evening visit, a sleep protocol will be implemented, HELP officials offer sleep and relaxation exercises, relaxation massages, and warm milk and/or tea.

There are no extra activities to be completed by family members/friend for this group.

Family-Based Paging System:

For subjects assigned to the family-based system, family members (or caretakers) will receive pre-operative education on delirium (including an educational video), a folder with an informational flyer, and a daily checklist of activities to perform that might help reduce delirium risk. These activities entail daily assistance with visual and hearing aids, handwashing, drinking/mealtime assistance, re-orientation to time and place, and cognitive stimulation activities.

Family members (or associated friends/caretakers) will also receive training in how to assess for confusion. Lastly, family members will also receive a pager, and automated pages will be sent twice daily with reminders to perform these activities.

Completion of activities will then be logged daily in conjunction with members of the research team.

Combined Systems (HELP-Based Paging System and Family-Based Paging System):

Subjects assigned to this group will receive enhanced HELP visits (see description above), as well as family-paging alerts to remind family members/caretaker to assist their family member (subjects).

Surveys:

To get information on your feelings regarding this project, we'd like you to complete a Family Confusion Assessment Method (FAM-CAM) survey regarding your friend or family member's thinking and concentration. We will ask you to complete this 11 question survey each day for up to three days following your friend or family member's surgery. We expect it to take less than 5 minutes to complete the survey.

On the third day after surgery, you will be asked to complete one additional family survey that asks about your experience participating in the post-operative care of your friend or family member. This 14 question survey will take less than 5 minutes to complete and it will only be given to you one time.

Finally, we will mail one last FAM-CAM to you after 30 days of your friend or family member's surgery to see how you think they have been thinking and concentrating since their surgery. Again, we expect this will take less than 5 minutes, and it will be mailed to you with a self-addressed, stamped envelope for an easy return. In order to mail this form to you, you will be asked to provide your mailing address and basic demographic information for research study purposes.

Answering these surveys is voluntary. You don't have to answer it if you'd rather not. You can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. Choosing not to answer our survey won't affect the medical care your friend or family member might receive at the University of Michigan Health System.

It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

To keep your information confidential, we will We'll label your survey with a code, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who answered our survey, no one outside our study team will be able to figure out who answered the survey or which people gave which answers. We plan to publish what we learn from this study, but we won't include any personal information that could reveal who answered the survey.

Answering our surveys won't benefit you directly. We hope what we learn will help other people in the future.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

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.

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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to

report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial may be available on www.ClinicalTrials.gov. 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.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

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. 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 below (under Contact Information).

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Demographic information
- Personal identifiers

It's possible that the researchers or others will need access to information about you during or after this study. For example:

- The University of Michigan or a government agency 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, learn more about side effects, or analyze the results of the study.

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.

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

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 see http://www.med.umich.edu/hipaa/npp.htm. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Phillip Vlisides, MD **Mailing Address:** 1500 East Medical Center Dr, 1H247 University Hospital Ann Arbor, MI 48109-5048 **Telephone:** [redacted]	**Project Manager:** Amy McKinney, MA **Mailing Address:** 1500 East Medical Center Dr, F3842 UH-South, Ann Arbor, MI 48109-5048 **Telephone:** [redacted] **Email:** [redacted]

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
[redacted]
E-mail: [redacted]

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.

SIGNATURES

Consent 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 Dr. Vlisides' designee. 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.

Print Legal Name: _____

Signature: _____

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

Principal Investigator or Designee

I have provided this participant with information about this study that I believe to be accurate and complete. The participant 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): _____