SPARC Trial Informed Consent and HIPAA

04/23/2021

You are being asked to participate in the SPARC Trial. Your participation is voluntary. The following will introduce you to the study in greater depth. Thank you for considering participation in this important work. (*Repeat in Spanish*)

Select if you would like to read this form in English

Select if you would like to read this form in Spanish (*Spanish)*.

St. Luke's Health System IRB
IRB NUMBER: 2019-0026
IRB APPROVAL DATE: 04/23/2021

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[*This form will be displayed in the correct language based on the responses above]*

The SPARC Trial

Comparing the Effectiveness of Safety Planning Intervention Plus Follow-Up from a Suicide Prevention Hotline (SPI+) versus Safety Planning Intervention Plus Caring Contacts (SP+CC) among Adults and Adolescents Screening Positive for Suicide in Emergency Departments and Primary Care Clinics

Principal Investigator:
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Research Scientist, Applied Research Division
St. Luke's Health System

Idaho Suicide Prevention Hotline (24/7): (208) 398-4357

Introduction to the Study

You, or your child, are being asked to join a research study. If you are a parent of a child, who is being asked to participate in the study, the word "you" or "your" used throughout this form refers to your child. If you are an adult being asked to participate in the study, the word "you" or "your" refers to you. Children and teenagers, ages 12-17 years, will also be asked to provide their permission to participate.

You are being asked to join a research study because during your visit there were some signs that you may be at risk for suicide. This form asks if you would like to be part of this research. Ask as many questions as you need to about the study. You will have as much time as you need to make your choice. As you think about being in this study you should know:

- Taking part in this research study is your choice. You can choose to not be in the study. Your decision to not be in this study will not affect your medical care. You may still be referred and receive support from the Idaho Suicide Prevention Hotline without participation in this study.
- The goal of this study is to determine which of two follow-up interventions are most helpful to people at risk for suicide.
- This study involves filling out surveys four times over one year.
- About 1,380 participants ages 12 and up will be in this study.
- This study may involve receiving text messages and/or email messages and phone calls. If you do not have your own phone, you will need access to a phone. If you share a phone or email account, it will be important that you receive the messages and complete all surveys yourself.
- There are some risks with being in this study. Some questions may make you feel uneasy. You may stop taking part at any time. Your information will be kept private but there is a small risk that some information may be released. Care will be taken to keep your data secure.

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- If you do participate in this study, you will help us learn more about ways to improve care for people with suicide risk. You will also receive Amazon eGift cards as compensation for your time.

If you think that you want to be in this study, you should read the rest of this form to learn more. If you decide to not sign this form, you will not be able to take part in this study.

What will I have to do in the study? You will be randomly placed in one of two groups. No one will be able to choose or change which group you are assigned to. The treatments used in both groups are recommended by experts**.**

[*For Group 1:] You will receive at least one phone call from the Idaho Suicide Prevention Hotline to check in and provide support. The Hotline will call you within 72 hours.*

[For Group 2:] You will receive a phone call and caring messages from the Idaho Suicide Prevention Hotline. The Hotline will call you within 72 hours.

You will be asked to complete surveys about your:

- background, including:
  - housing,
  - gender identity,
  - sexual orientation,
  - education,
  - income,
  - religion, and
  - drug and alcohol use;
- quality of life;
- loneliness
- suicide risk; and/or
- how well you like the contact from the Idaho Suicide Prevention Hotline

You will be asked to complete surveys at two weeks, 6 months, and 12 months. You will be asked to provide various forms of contact information so the study team can follow-up with you.

The surveys will be completed online by a link sent to you through email or text, or by phone call with study staff who can enter your information in the online form for you. You will be able to choose the follow-up method that you prefer. If you agree to participate in the study, the first survey (baseline) will be completed today after signing the consent form.

Researchers will also review data in your St. Luke's health record such as your safety plan, insurance claims data, number of mental health visits you attend, and medications, and Emergency Department visits. Researchers may also access an electronic system, Emergency Department Information Exchange (EDIE) that collects number, location, and diagnosis for emergency and hospital visits outside of St. Luke's.

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Schedule of Events				
	Baseline Visit	2 Week Satisfaction Survey	6 Month Outcome Survey	12 Month Outcome Survey
Consent Signed	x			
Baseline Survey	x			
Satisfaction Survey		x		x
Outcomes Survey			x	x
Compensation (Amazon Gift Card)	$35	$10	$40	$40

If researchers learn during the study that one type of follow-up support from the Idaho Suicide Prevention Hotline is better than the other, study staff will notify you, and you will be switched to the better option. The researchers may also remove you from the study if they are unable to contact you, if they feel it is in your best interest to be withdrawn from the study, or if your circumstances change and you are no longer eligible to participate.

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.

Are there any benefits to joining the study?

There may not be any direct benefits to you for taking part in this research. If you take part, you will help us learn more about improved ways to care for people at risk for suicide.

Will it cost anything to participate?

There is no cost to participate in this study. Wireless carriers may charge you fees for receiving calls and texts related to your participation in this study. The study will not pay for these charges.

Will you get paid for joining the study?

You will be paid for the time you spend on this study. The table above shows when and how much you will be paid. Compensation will be in the form of an electronic Amazon gift card that will be sent to you after you complete the surveys at each timepoint.

What are the risks if I decide to join the study?

There are some known risks to participating in this study. There may be other risks which are not known at this time. The study team will notify you if any new, unforeseen risks arise beyond what is discussed below.

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This study does not protect you from suicide, nor does it put you at greater risk of suicide.

Potential loss of privacy is a known risk to this research. If you share a phone or email with someone else, there is a chance that they will have access to messages intended for you. If you are a minor, your texts or emails may be accessible by your parents or legal guardian.

Also, some questions may make you feel uneasy. You may stop taking part in the research at any time.

If you think you have an injury or illness because you took part in this study, contact the study staff right away at 208-381-8468 and/or St. Luke's Health System IRB at 208-381-1406. If you ever have thoughts of harming yourself, please call 911 or the Idaho Suicide Prevention Hotline at (208) 398-4357. If you get an unexpected injury or illness that St. Luke's determines is because you took part in this study, you will get emergency medical care at no cost. An unexpected injury or illness is one not talked about in the consent form or talked about by the doctor or the study staff. An injury or illness cannot be unexpected if it is caused by a disease or a problem you already have. An attempted suicide or completed suicide is not a study related injury. You do not give up any of your legal rights if you sign this consent form.

You may decide to stop being in the research study at any time by contacting the study staff at sparc@slhs.org. There is no penalty or loss of benefits that you would normally receive if you choose to stop participating or if you choose to not participate at all in the study. If you decide to withdraw from the study, the information already collected will be kept as part of the research.

How will my information be protected?

St. Luke's has an electronic health record system so providers and staff can access your records on a need to know basis. Your record will include studies you take part in. People who view your medical record may see that you participated in this study. The study is using a secure system called REDCap to capture the survey information. Information that directly identifies you will be kept confidential. Results that are published or discussed will not use your name or identify you in any way. Information collected as part of this research project may be shared with other researchers. Any data shared outside of this research team will be anonymous and will not identify you in any way. Information will be stored in REDCap or another secure data base for up to 10 years and will then be destroyed according to St. Luke's Health System policies.

Authorization to release PHI

Health information that we gather about you is personal. St. Luke's researchers are required by a law called the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to keep your **protected health information** (PHI) private. All reasonable efforts will be made to protect the confidentiality of your PHI.

What is protected health information?

- **Protected health information** is health information combined with information that identifies you.
- **Health information** is any information that relates to the past, present, or future physical or mental health or condition of an individual or the provision of health care to an individual.
  - **Information that identifies individuals** includes name, date of birth, dates of service, address, or

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medical record numbers.

What protected health information may be accessed, used, created, and/or released?

If you sign this form, you give permission for the release of the PHI needed to complete the research study. The PHI will be accessed, created, used, and released as described in this authorization. Information may include:

- Present medical records such as clinical documentation or physician notes
- Records about your hospital and clinic visits, including visit dates, location, and diagnosis from EDIE (Emergency Department Information Exchange)
- Information that identifies you such as your name, address, health plan number, birth date, email address, and your phone number

Why will this information be accessed, used, created, and/or released to others?

- To do the research,
- To study the results,
- To ensure your safety, and
- To make sure that the research was properly performed.

Who will my protected health information be released to?

The researchers may release your PHI to the following entities or agents associated with or responsible for monitoring this research:

- Research staff and representatives of the Patient Centered Outcomes Research Institute (PCORI)
- St. Luke's Health System Institutional Review Board and/or St. Luke's Health System employees and contractors, and researchers at partner organizations, including the Idaho Suicide Prevention Hotline, and the University of Washington.
- If you are a minor, survey results related to suicide risk may be released to parents or a legally authorized representative.

There is a chance your PHI may be re-disclosed (re-released) by the entities or agents receiving it listed above. That information may no longer be protected by the HIPAA Privacy Rule. However, other laws that keep your information private may apply.

Will I be able to access my research information?

You have the right to see a copy of the health information collected from you in the course of the research study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation. Research data including survey responses will be kept confidential between the research team and the participant (including minor participants) unless your survey responses indicate you may be at significant risk for suicide.

If I choose not to sign this form, may I still be in the study?

If you do not sign this form, you will not be able to be in the research study, but you will still be able to receive medical care from St. Luke's Health System and you can still use the standard services offered by the Idaho Suicide Prevention Hotline.

How long will my permission be valid?

Unless you revoke (take back) your permission, this form will expire 10 years after the study closes.

May I revoke (take back) my permission?

You may take back your permission for the study at any time, but it must be done in writing and sent to:

Principal Investigator Anna Radin, DrPH, MPH
sparc@slhs.org

If you take back your permission for the study, then you may not continue to participate in the study.

When you take back your permission, no new PHI will be used, created, and/or released after that date. Information that has already been gathered may still be used or given to others for the purposes of this research.

What if I have questions?

You have a right to receive a copy of this form after you have signed it. If after you have signed this form you have any study-related questions, please contact the Principal Investigator at sparc@slhs.org. If you have questions about your rights as a research participant, you may contact the St. Luke's Health System Institutional Review Board at 208-381-1406.

If you ever have thoughts of harming yourself, please call 911 or the Idaho Suicide Prevention Hotline at (208) 398-4357.

Have all of your questions about participating in this study been answered?

- Yes
- No

If "no", please talk with the Research Coordinator about any remaining questions you may have. **Informed Consent Statement and Authorization**

I have read or had read to me all the information in this consent form. I have been given the chance to discuss it and ask my questions. All my questions have been answered to my satisfaction. I voluntarily consent to take part in this study. I understand that I will receive a copy of this form.

By signing this form, I have not given up any of my legal rights that I otherwise would have as a subject in a research study.

By signing this form, I agree to the use, creation, and/or release of my PHI as explained in this form.

Signing this form electronically is the same as signing a paper document. A copy of this signed document will be emailed to the address you provided. You may keep this copy for your records.

Do you consent to participate in this study?

- Yes
- No

- *If no: You have opted not to participate in this research study. This will in no way affect the care you receive at St. Luke's. Thank you for your time today!*

  [instructions on how to return tablet to clinic/ED staff may be included here]

Adult Study Participants only
Please provide your full name below:
First Name: _____
Last Name: _____

For Parents or Legally-Authorized Representatives of Minor Study Participants only
Please provide the full name of the **parent or legally authorized representative** of the minor below:
First Name: _____
Last Name: _____
Relationship of the parent or legally authorized representative to the minor: _____

[SIGNATURE BLOCK with date and time]

For Minor Study Participants only:

Assent for Minor Participants (Age 12-17) *Please complete if the study participant is 12-17 years of age.*
This research has been explained to me. I understand what will happen while I am in this research study. I have asked the questions about the study that I wanted to ask, and they have been answered. If I change my mind about being a part of this study, I know I can talk to my parents or email study staff at sparc@slhs.org to quit the study. I understand that no one will be angry with me if I decide not to be in in this research. I know if my survey responses indicate I may be at significant risk for suicide, the researchers may contact my parents or guardians with or without my permission. I also understand that even if I decide not to participate in the study, I will not be treated any differently. I agree to be in this research study.

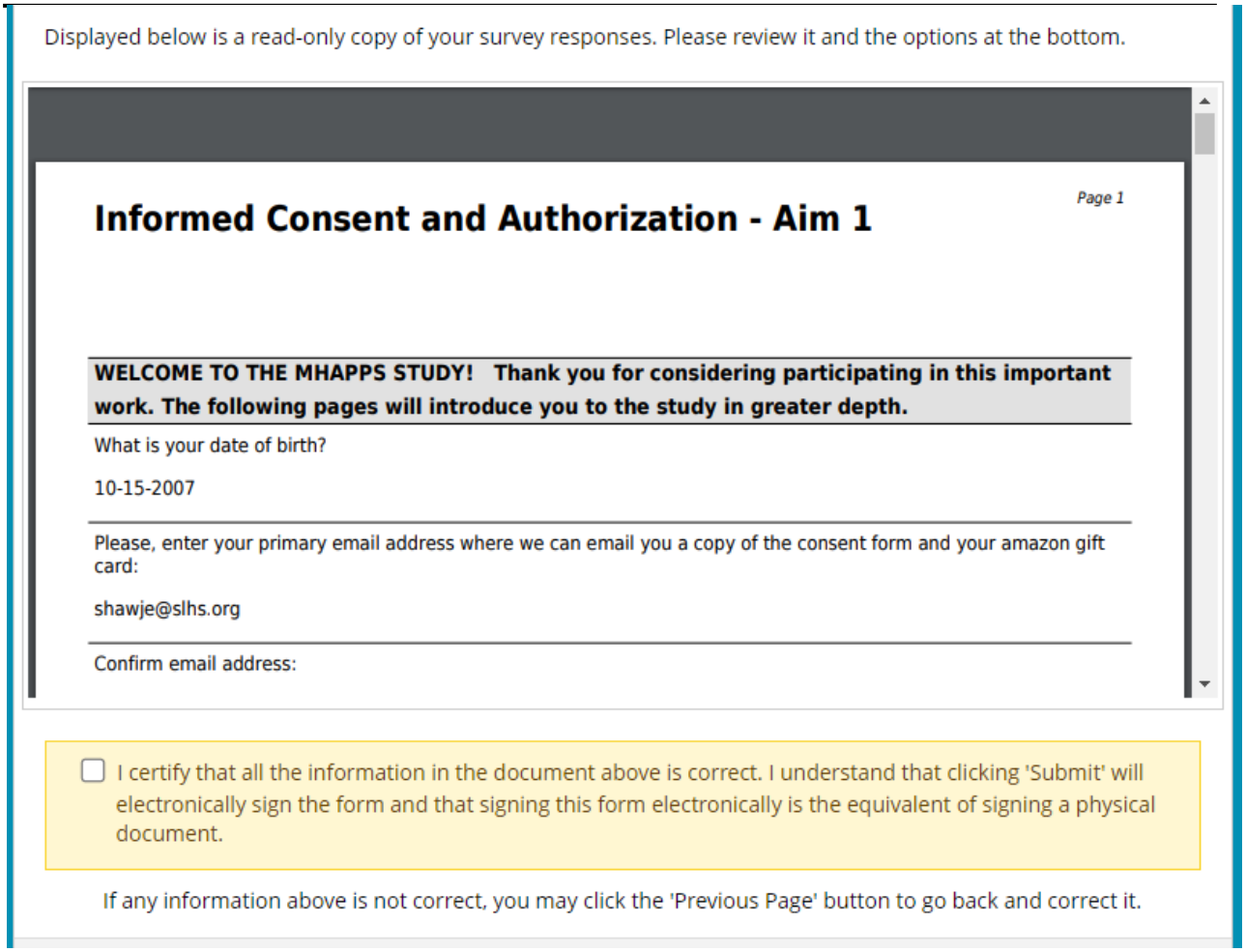
Do you agree to be in this study?
Please provide your full name below:
First Name: _____
Last Name: _____

[SIGNATURE BLOCK with date and time]

_____

Email address:

[*After submitting a signed, completed ICF, this is an example of the type of certification that will appear (actual version will vary slightly and say SPARC instead of MHAPPS)]*



Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

Page 1

Informed Consent and Authorization - Aim 1

WELCOME TO THE MHAPPS STUDY! Thank you for considering participating in this important work. The following pages will introduce you to the study in greater depth.

What is your date of birth?

10-15-2007

Please, enter your primary email address where we can email you a copy of the consent form and your amazon gift card:

shawje@slhs.org

Confirm email address:

☐ I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

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