UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Integrating the Youth Nominated Support Team (YST) with CBT for Black Youth with Acute Suicide Risk

Company or agency sponsoring the study: National Institute of Mental Health (NIMH)

Names, degrees, and affiliations of the principal investigator: Cynthia Ewell Foster, Ph.D., University of Michigan

Principal Investigator: Cynthia Ewell Foster, Ph.D.

Children's Hospital of Michigan Co-Investigator:
Curt Stankovic, MD, MBA
Pediatric Emergency Department
Children's Hospital of Michigan (CHM)
3901 Beaubien St., Detroit MI 48201
(313) 745 - 5260

MiSide Co-Investigator:
Marquita Felder, LMSW
Children, Youth and Families Counseling
MiSide
5716 Michigan Ave #3000, Detroit, MI 48210
(313) 963 - 2266

1.1 Key Study Information

You and your child may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child'. 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, this study will require that your child receive follow-up care at MiSide. 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.

This research is studying a two-component intervention, Cognitive Behavioral Therapy for Suicide Prevention plus the Youth-Nominated Support Team (CBT-SP + eYST) in adolescents to learn about how it can be helpful to adolescents who come to the emergency department and have had thoughts of suicide or have attempted suicide. Youth will nominate up to four adults who will provide support to them over the next 3 months. We will also ask you to complete a survey today, in 6 weeks, and again in 14 weeks.

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 discomfort when talking about stressful or painful situations, thoughts, and feelings. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by learning if a program is helpful to adolescents who have had thoughts of suicide or have attempted suicide. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 14 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: The purpose of this study is to find out if the combination of two psychosocial interventions, Cognitive Behavioral Therapy for Suicide Prevention and the Youth-Nominated Support Team (CBT-SP + eYST), can help adolescents who come to the emergency department and who have had thoughts of suicide or have attempted suicide. As a part of the intervention, you will be asked to pick caring adults in your life who can stay in touch with you after you leave the emergency department. We will talk with these caring adults about your challenges and how they can be most helpful to you over the next 3 months. You will also be linked to a clinician at MiSide to receive mental health care for your suicide-related concerns.

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?

Adolescents between the ages of 12 and 17 who identify as Black and are eligible for care at MiSide can take part in this study if they are coming to the emergency department because of suicidal thoughts or because they have made a suicide attempt. Adolescents that have psychotic symptoms, severe agitation, and those with severe cognitive impairments are not able to participate. Participants must also be English-speaking and be accompanied by a parent or legal guardian.

3.2 How many people are expected to take part in this study?
6 youth and their parents/guardians are expected to participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Adolescents
We will ask you and your parent/legal guardian to answer a set of surveys about your feelings and actions today in the emergency department. In 6 weeks and 14 weeks, we will ask you to answer a similar set of surveys as well as some additional questions about how you are feeling and what you have been doing. We will ask you what it is like to take part in this study. Your survey responses will not be shared with anyone outside of the study team.

There are two components to being in this study. You will receive evidence-based mental health care as well as the Youth Nominated Support Team (YST) Intervention.

As part of the YST program, we will ask you to pick up to four adults who you trust and would like to have contact with over the next 3 months. These can be adults in your family, school, or community. They can also be adults that live in your community or anywhere across the country. With permission from your parent or legal guardian, the adults that you choose will be invited to join the study. You and your guardian can decide whether you want to tell them about the study or whether you want the study team to reach out to them and tell them about the study. They will meet with our study team in person or through a secure video platform or a phone call to learn more about some of the difficulties that you may be having and how they can help to support you. We will give these adults general information about adolescent mental health concerns, including depression, and suicide risk. We will also share what we know about what has been recommended for your care. Our study staff will talk with your support team about how they can be there for you and encourage you as you work towards making healthy choices. These adults will be asked to stay in contact with you on a weekly basis for up to three months, encourage you to stay in your treatment and support your healthy behaviors. Our study team will provide education sessions with each support person which will be audio and/or video recorded for quality control. None of the interactions between you and the caring adult will be monitored in any way. Our research team will plan to communicate with your support persons approximately once weekly for three months.

Our team will help you and your parent/guardian call the MiSide access line today while you are in the emergency department. MiSide is a Detroit Wayne County Integrated Health Network Provider; they will confirm that you are eligible for services there and you will be assigned to a MISide clinician and

scheduled for an intake appointment within 14 days. This clinician will be able to provide specialized evidence-based mental health care called Cognitive Behavioral Therapy for Suicide Prevention and will also coordinate with your YST support team. You will be eligible for a minimum of 12 sessions of psychotherapy supervised by experts at the University of Michigan. Each session lasts approximately one hour and can be completed either in person or via a secure telehealth platform. Most youth attend sessions on a weekly basis and therapists typically like to be in contact with parents as well. MiSide clinicians will audio and/or video record the sessions to ensure they are providing the best care possible. Only staff connected to the study would view these recordings and they will be deleted as soon as feedback is given to the clinician.

Parent/Guardian
You will be asked to complete a brief survey today and again in 14 weeks about your child's thoughts, behaviors, moods, and any other mental health services that your child may have received. For your child to take part in the research, you must agree that they can take part. You will have the opportunity to agree or disagree with your child's selection of support people.

4.2 How much of my time will be needed to take part in this study?
The initial survey, which you will complete today while waiting in the emergency department will take 30-40 minutes. The online survey at 6 weeks will be completed by youth only and is expected to take about 10-15 minutes. The survey that we ask both parents and youth to complete in 14 weeks will take about 30 minutes. Youth will be contacted once a week by their support team. Both parents and youth will be involved with the CBT-SP sessions. Both parents and youth will receive surveys via email and text message, with up to 2 reminders per survey.

4.3 When will my participation in the study be over?
Your participation in the study will end in 14 weeks, but this does not mean you would need to end your care at MiSide at that time if it is going well for you/your child. We may collect information from your medical records for another year after your participation.

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?
You may get bored, tired, or upset with the survey questions. You can take a break or stop answering questions at any time. You can also stop participation at any time.

You don't have to be in this study if you don't want to. Nobody will be mad or upset if you don't want to be in the research study. You can say okay to take part in the study now and change your mind later.

Just tell the doctor or your parent/guardian if you want to stop at any time. Your doctor will still take care of you if you don't want to be in the study.

Additionally, there may be a risk of loss to 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.

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 have adverse events, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any adverse events 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 benefit from having a careful assessment of suicide/self-harm risk as well as careful risk monitoring that is beyond what is typical in usual care. You will also receive high quality mental health care supervised by experts and will receive YST which is a promising support intervention for youth. If you report concerning levels of suicidal thoughts or behaviors, you will be contacted by a clinician as soon as possible to ensure that you are safe. Your participation may also help us improve our understanding of programs for teens that may benefit from mental health and related services. We are specifically interested in making sure these treatments work well for Black youth.

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 research project is voluntary. You do not have to participate, and you can stop at any time.

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, and you will not lose any benefits to which you are otherwise 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?
There is no penalty if you decide to leave the study before it is finished.

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?
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 10.1.

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?
After you complete the initial surveys and nominate the support persons, you and your parent/guardian will each receive a $15 gift card. In addition, you will receive a $25 gift card after completing the 6-week

follow up survey. You and your parent/guardian will each receive a $35 gift card after completing the 14-week follow up surveys.

8.3 Who could profit or financially benefit from the study results?
In the interest of transparency, we would like you to know that Dr. King is an advisor to and holds equity in Oui Therapeutics, a company providing the online software platform for this project. She is not likely to benefit financially from the results of this research.

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?
To keep your information confidential, we will use a subject ID number to label all of the data. Your name will not be recorded on the surveys. A list linking your ID number with your name will be kept in a location separate from the data and only available to core members of the research team. Any contact information you provide to us will only be used to complete the follow-up portion of this study. Your contact information will not be shared with anyone outside of the research team. If you tell us or we learn something that makes us believe that you or others have been or may be physically harmed, we may be required to report that information to the appropriate agencies.

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 National Institute of Mental Health (NIMH) 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 of child abuse and neglect or harm to self or others.

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. We are also asking your permission to get other information about you from your medical record like demographics and information about your MiSide visits.

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.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information

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.
- 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.
- 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.

We would also like your permission to keep some of your data collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different. You can take part in the main study even if you decide not to let us keep your data for future research.

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: Cynthia Ewell Foster, Ph.D.
Mailing Address: 4250 Plymouth Rd, Ann Arbor, MI 48109
Telephone: 734-764 0231
Email: cjfoster@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 (For International Studies, include the appropriate calling codes.)
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?

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 Children's Hospital of Michigan and MiSide medical record.)*

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 [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: _____

Parent Email: _____

Signature: _____

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

Sig-B

Consent to audio and/or video recording solely for purposes of this research
This study involves audio and/or video recording. If you do not agree to be recorded, you CANNOT take part in the study.

____ Yes, I agree to be video/audio recorded.

____ Yes, I agree to be audio recorded only.

____ No, I don't agree to be video/audio recorded.

Print Legal Name:
_____

Signature:
_____

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 study team keep my data for future research.

_____ No, I do not agree to let the study team keep my data for future research.

Print Legal Name: _____

Signature: _____

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

Sig-E

Legally Authorized Representative or Parent Permission

Subject Name (Child):_____

Child Email: _____

Parent/Legally Authorized Representative:

Printed Legal Name:
_____

Signature: _____

Address: _____

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

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

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): _____