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.

1.1 Key Study Information

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study. Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project. If you decide to join the study, you will be asked to sign this form before you can start study-related activities.

This research is studying a two-component intervention, Cognitive Behavioral Therapy for Suicide Prevention plus the Youth-Nominated Support Team (CBT-SP + eYST) in small numbers of adolescents to learn about how it can be helpful to youth 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. You are being asked to participate in this study because you were nominated as a caring adult by a youth who visited the emergency department. We will prepare you for this role. Specifically, if you agree to take part in the study, we will ask you to attend an education session to learn about the youth's difficulties, their treatment plan, ideas for supporting their follow-through with treatment and healthy behavior choices, suicide risk factors, and the availability of emergency services. This education session will be audio and/or video recorded to make sure that the intervention is done correctly. You will also be asked to view educational videos on the eYST website and to have contact with the youth each week for three months to provide support for them. In addition, the intervention specialist will contact you each week for 3 months to discuss any questions or concerns that you may have. You will also be asked to complete a brief survey about yourself at the start of the study and a brief survey to give feedback at the end of 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 3 months.

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. We will recruit 6 adolescents between 12 and 17 years old, their parent/guardian. Each youth will nominate 3-4 support persons for a maximum of 24 support persons in the study.

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. Youth are always informed that there are many reasons why a nominated support person may not be able to participate. If you choose not to participate in this study, the study team will inform the youth about this and will work with you and the youth to communicate the decision to preserve your ongoing relationship. You may continue to have a relationship with the youth who nominated you as a YST Support Person whether or not you chose to participate in the study.

3.1 Who can take part in this study?
Support Persons must be over 18, English speaking, and approved by the parent/legal guardian to participate in the study.

3.2 How many people are expected to take part in this study?
Up to 24 Support Persons are expected to participate, with each youth having up to four Support People assigned to them.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
You were nominated to be a YST Support Person. As a S upport P erson, you will be asked to have contact with the youth who nominated you each week for up to three months to offer emotional support, support the youth's involvement in recommended treatments, and support the youth's healthy behaviors. We will prepare you for this role. Specifically, if you agree to participate , we will ask you to watch educational videos on the eYST website and attend an education session (approximately 1-hour) in person or via Zoom, a private video conferencing or telehealth service, or by phone. This

education session will be audio and/or video recorded to make sure that the intervention is done correctly. During your education session,you will meet your assigned intervention specialist, learn about the youth's difficulties, treatment plan, receive ideas for supporting the youth's follow-through with treatment and healthy behavior choices, and learn about suicide risk factors, and the availability of emergency services. Your role will be to listen and encourage the youth to make good choices and follow-through with recommended treatments. You are not expected to be a mental health professional. Your role as a YST Support Person will be reviewed with you in more depth during your education session with your assigned intervention specialist. As a YST Support Person, you will have weekly check-ins with your intervention specialist every week for the 3 months of the study. During these calls, you will have an opportunity to discuss any questions or concerns you may have about the youth and how best to support them. We will also ask you to complete two brief surveys in this study. The first survey will ask about your demographic information and relation to the youth who nominated you. The second survey will ask about your experience as a YST Support Person in the study.

4.2 How much of my time will be needed to take part in this study?
The education session will last approximately 1 hour. Viewing the educational videos on the eYST website are estimated to take up to 60 minutes. The weekly calls with the intervention specialist will take between 5 and 20 minutes each, depending on the number of questions you may have. The two surveys should take less than 5 minutes each to complete. We will send the surveys to you 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 research activities will end in 3 months but you may stay involved with the youth beyond that time. Many youth nominate individuals with whom they have an ongoing relationship, like a family member, mentor, or neighbor.

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

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 a general inconvenience of your time required to complete the requirements of this study. The researchers will try to minimize these risks by ensuring all necessary study requirements are completed efficiently.

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.

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, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any issues you experience during this study.

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 not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. You may also benefit by learning about mental health and suicide prevention and from the satisfaction of being a helping adult to a youth in need.

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. Youth are always informed that there are many reasons why a nominated Support Person may not be able to participate. If you choose not to participate in this study, the study team will inform the youth about this and will work with you and the youth to communicate the decision to preserve your ongoing relationship. You may continue to have a relationship with the youth who nominated you as a YST Support Person whether or not you chose to participate in the study.

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 or to your relationship with the youth who nominated you to be a YST Support Person, 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. You may continue to have a relationship with the youth who nominated you as a YST Support Person.

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?
For Support Persons, there are no costs for this study.

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.

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?
Your participation will occur at MiSide. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

Your research information will be stored electronically in encrypted, password-protected computers. It will also be stored on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards. Only members of the study team will have access to your study information. 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 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
    - Learn more about side effects
    - 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.

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 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 left the study 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 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.
- Other (specify):_____

12. SIGNATURES

Sig-A

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

Print Legal Name: _____

Signature: _____

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

Sig-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 do not agree to be video/audio recorded.

Print Legal Name: _____

Signature: _____

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

Sig-D

Consent 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 information for future research.

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

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):

_____