Digital Youth-Nominated Support Team (YST) Program

NCT05900700

Date of IRB Approval: September 18, 2024

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CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

---------- IRB OFFICE USE ONLY ----------

Study ID: HUM00221931 / Amendment ID: Ame00137231

Approval Date: 10/20/2022

Document Finalized: 9/14/2023 12:27 PM

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Study ID: HUM00221931 / Amendment ID: Ame00134685

Approval Date: 10/20/2022

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Digital Youth-Nominated Support Team (YST) Program

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

Principal Investigator: Alejandra Arango, PhD, Department of Psychiatry, University of Michigan

1.1 Key Study Information

You and your parent/guardian 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.

This research is studying the use of a new website to learn ways we can improve the website and to learn how well the website helps youth. Researchers want to understand what teens and parents/guardians think about the website. You will be asked to use the website and participate in three surveys over 12-14 weeks (about 3 months). You will be asked to use the website to pick adults ("support adults") who you trust care about you and your mental health to be a part of this study. Your parent/guardian will review and have the opportunity to approve the adults that you nominate. The study team will talk with these support adults about your challenges and how they can be most helpful to you in the coming months.

For parents/guardians, you will also be asked to use the website and participate in two assessments over 12 to 14 weeks (about 3 months) after your child is discharged from the hospital. You will also be asked to review and approve of adults your child nominates to be part of their support team.

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. Loss of confidentiality is a potential risk, as well. 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 improving the website for future use with youth. More information will be provided later in this document.

You can decide not to be in this study. Your parent/guardian cannot be in the study if you do not participate. If you choose not to participate, you will still receive the routine treatment program provided at this hospital.

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 get feedback from users about a website to learn ways we can improve the website. Another purpose of this study is to learn how well the website helps youth. The website is designed to help youth build their social support network. The website under study is called eYST. eYST is the digital version of The Youth-Nominated Support Team (YST), a social support program for youth at risk for suicide, which aims to strengthen each youth's supportive network of adults. The website being studied is based on an in-person social support program shown to be helpful to teens. eYST is an experimental software, which means that it is being tested and is not yet shown to be effective.

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?

Youth 13 to 17 years of age who are hospitalized are eligible to participate in this study (with parental permission) if they: 1) understand written and spoken English, 2) have attempted suicide or have had thoughts about suicide and a plan to harm themselves, and 3) own a smartphone or mobile phone.

The parents/guardians and support adults of youth participants are also eligible to participate if they: 1) are 18+ years of age, 2) understand written and spoken English, 3) own a smartphone or mobile phones; and 4) (parents/guardians) have a child participating in the study or (support adults) were nominated by youth participating in the study.

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

We intend to enroll approximately 20 youth participants, 20 parents/guardians, and up to 80 (four per youth) support adults.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Youth:

If you agree to be in this study, you and your parent/guardian will sign this form.

1. After this form has been signed, you will meet with a member of our staff.
    a. The staff member will ask you some questions and you will fill out surveys asking about yourself (e.g., emotions, thoughts, behaviors).
    b. You and your parent/guardian will gain access to the eYST website.

    The eYST website is an experimental software and not part of standard care.

2. You will then use the website to nominate caring adults and your parent/guardian will review and approve the adults you nominate. Then, the study team will invite your approved nominations to participate in this research study.

3. Research staff will meet with the approved support adults that are able to participate and share information about how things have been going for you (e.g., diagnosis, treatment recommendations). Supportive adults will then reach out to you to connect with you over the coming months.

Parent/Guardian: If you agree to participate, you will meet with a member of our staff. The staff member will ask you some questions about yourself and your child's health and wellbeing.

1. You will complete the first part of the eYST website with the study clinician. This includes a brief introduction to the website. You will then review and approve the support adults that your child nominates as caring adults who your child trusts cares about them and their mental health. After your approval and your consent to share your youth's health information, the study team will invite the approved nominated support adults to also participate in this research study as your child's support adults.

Youth and Parent/Guardian:

1. You will receive an online survey in 4 weeks and have a video/phone call with a member of our study team in 12 weeks. Both you and your parent/guardian must be on the same video/phone call to complete the 12-week follow up call. If the two of you are NOT together, the call will be rescheduled. The video/phone call will last about 60 minutes.

   You, your parent/guardian, and your support adults will have access to the eYST website throughout your study participation.

2. The study team will access the youth's medical record to review/verify medication use and psychiatric history and to support risk management in the event of suicide risk. Your parent/guardian will be asked to permit the use and disclosure of your health information for research at the end of this form.

3. It is important that you understand that the 12 week follow up call is the only time we will learn about how things are going for you. Be aware that the website is not an emergency phone service. You must use your routine phone functionality on your phone in order to call 911 or other crises support services. The information you put into the website is not monitored by study staff, so the only way we will know if you are experiencing suicidal thoughts is if you tell the study clinician.

4. Finally, our study team will use the eYST website data (such as number of logins and duration of logins) to analyze your use of the website throughout the study.

4.2 How much of my time will be needed to take part in this study?
Your participation in this research will last about 12 weeks (3 months) to 14 weeks.

4.3 When will my participation in the study be over?
Your study participation will end approximately 12 weeks (3 months) to 14 weeks after discharge, at which time you will no longer have access to the eYST website.

4.4 What will happen with my information used in this study?
Collected information may be shared with Oui Therapeutics, Inc, the website manufacturer.

With appropriate permissions, 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 most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. You do not have to answer any questions you do not want to answer. Study staff will work with your treatment team on the unit and share information with them that is discussed during any study meetings. Therefore, it is possible that information that is shared with the study team may be used by your treatment team.

Please know that great care is taken to maintain participant's privacy and keep the information you provide as part of this research study confidential, but complete protection cannot be guaranteed. There are a few situations where we are mandated to break confidentiality for the safety and protection of you and others including: 1) if we learn of abuse or neglect to a child, older person, or disabled person; and 2) if we learn that there is an imminent risk of harm to yourself or someone else. The use and disclosure of your protected health information is further described below. There is a small risk that your research records could be lost or otherwise compromised.

The researchers will try to minimize these risks by ensuring all research staff members have been trained in data protection and confidentiality, and access to data will be restricted to only approved members of the study staff.

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 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 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?
The alternative to study participation is to not participate. If you choose not to participate, you will still receive the routine treatment programming provided at this hospital.

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 harm to you is expected 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.

- 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 are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
Adolescents:
You will receive a $25 gift card for completing the first study session today, a $25 gift card for completing the study session (survey) at 4 weeks, and a $35 gift card for completing the study session (video/phone call) at 12 weeks. The total payment amount is $85 if you complete all study sessions.

Parent/Guardian:
You will receive a $25 gift card after you complete the 4-week assessment and a $35 gift card after you complete the 3-month study assessment.

8.3 Who could profit or financially benefit from the study results?
Oui Therapeutics, Inc is the manufacturer of the website eYST and may benefit from the outcome of the study and any commercial profits will not be shared with you.

Dr. Cheryl King, a study co-investigator, has equity and has served as a paid consultant for Oui Therapeutics, Inc. Oui Therapeutics, Inc is the manufacturer of the eYST website being studied. This means that Dr. King could gain financially from this study. Several measures have been taken to ensure that Dr. King's financial interests don't interfere with the integrity of this study.

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

9. CONFIDENTIALITY OF SUBJECT RECORDS 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.

9.1 How will the researchers protect my information?
Researchers will protect all the information about you and your part in this study, just as is done for all patients at Michigan Medicine. Your records will be maintained in accordance with applicable state and

federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described below.

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 such as 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.

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.

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. **Parent/Guardian's medical records will not be reviewed.**

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)
- 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.
- Representatives of the website manufacturer, Oui Therapeutics, Inc may have access to data .

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule (e.g., study funders, NIH), your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Your name, e-mail address, and/or phone number along with other information collected and/or created during your study participation via the eYST website will be kept on servers for the period which we are required to keep.

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: Alejandra Arango
Mailing Address: 4250 Plymouth, Ann Arbor, MI 48105
Email: arango@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
Fax: 734-763-1234
Email: 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 University of Michigan medical record.)*

You will receive a copy of the signed and dated informed consent.

12. SIGNATURES

Sig-A

Youth 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: _____

Signature: _____

Date of Signature (mm/dd/yy):

Sig-A

Parent/Guardian 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-E

Legally Authorized Representative or Parent Permission

Subject Name:

_____

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

Parent/Guardian Consent to Share Private Health Information with Approved Support Persons
This project involves study staff sharing your youth's information, including diagnosis and treatment recommendations, as well as information on their recent psychiatric inpatient stay with approved support persons who consent to participate. You will have an opportunity to approve all youth nominations.

_____ Yes, I agree to let the study team share my child's health information with approved nominated support persons.

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: _____