Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: Navigating Initiation of Mental Health Treatment for Black Youth with Suicide Risk

Version Date: April 26, 2024

Consent Name: Intervention

Principal Investigator: Rhonda Boyd, PhD Telephone: (215) 590-3945

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

The purpose of this research is to learn more about how a patient navigation program will help Black youth with suicidal thoughts and behaviors start mental health treatment. A patient navigator is a person who will assist youth and families begin mental health treatment by providing information and helping to address barriers to mental health treatment.

Study Overview

You are being asked to take part in this research study because you are between the ages of 6 to 18, have had suicidal thoughts or behaviors or self-harm in the last year, and have identified your race as Black. Your participation will include one 30 to 60 minute session with the patient navigator to review treatment referrals and discuss your needs. There will also be ongoing communication through your preferred method of communication (e.g., phone call, text, email) for up to 2 months or until you have successfully established mental health care. If you are 10 years or older, you will also complete measures. This will involve: one 30–60-minute initial baseline interview and two follow up interviews at 2 months and at 6 months.

The main risks of this study are from the study measures. These include breach of confidentiality and embarrassment.

There may be direct benefits to you by participating in this study. You may feel better after starting mental health treatment. The knowledge gained from this research will help to inform a patient navigation program that will help Black youth who report suicidal thoughts or behaviors.

Participation in this study is voluntary. If you do not choose to take part in this study, you can discuss other options with your doctor.

If you are interested in learning more about the study, please continue to read below.

How many people will take part?

About 50 African American/Black youth and/or 50 parents will take part in this study.

What are the study procedures?

The study involves answering questions about yourself and the use of and beliefs about mental health services. Some of the procedures in this study will be repeated. After the first 30-to-60-minute initial session with the patient navigator, procedures will include agreed-upon routine check-ins to help facilitate your pathway to mental health care.

Questionnaires/Surveys: You will be asked to complete questionnaires about demographics, your attitudes/beliefs about therapy, your mood and feelings, suicidal thoughts, and use of mental health services.

Randomization: You will be randomly assigned (like the flip of a coin or drawing lots) to one of two groups: the Patient Navigation Plus group or the regular Patient Navigator group. You will have a 50% chance of being assigned to either group.

Patient Navigation Plus: If you are in this group, you will participate in an interview to identify your current needs, problem solve barriers to go to mental health treatment, gather information about mental health, and help with mental health referrals. You will also receive check-ins and reminders about mental health referrals from your patient navigator.

Regular Patient Navigation: If you are in this group, you will receive assistance with mental health referrals and check-ins and reminders about mental health referrals from your patient navigator.

Follow-up Reminders: We will send you study-related reminders throughout the study. These may be by phone call, letters, text message, and/or email. We will contact you by your preferred method.

Medical Record Review: We will review your medical records throughout the study to collect information about your medical history, current health, insurance, diagnoses, treatments, medications, and results of clinical tests.

It is not known which group is better to help Black youth start mental health treatment. The group you are assigned to may prove less effective.

Visit Schedule

The table below describes the purpose and duration of each study visit. All the visits can be done in person, by email or by telephone.

Visit	Purpose	Main Procedures	Duration
Visit 1 *Enrollment + First Study Visit*	Screening	Questionnaires/Surveys	45 minutes
Visit 2 *2 months after Visit 1*	Follow-up	Questionnaires/Surveys about suicidal thoughts, mental health service use, and satisfaction with Patient Navigation program	30 minutes
Visit 3 *6 months after Visit 1*	End of Study		30 minutes

Will I receive any results from the tests (procedures) done as part of this study?

You will not receive any results from the study surveys.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

The main risks of taking part in this study are discussed below.

Risks associated with completing the questionnaires/surveys:

You may feel uneasy about answering some questions that may seem personal. You do not need to answer questions that make you feel uncomfortable. You can stop at any time.

Risks of patient navigation intervention:

Assisting you to start mental health treatment may make you and/or your family uncomfortable. You have the right to refuse to answer any questions or not receive any information.

Risks associated with Breach of Confidentiality:

As with any study that collects data, there is the possibility of breach of confidentiality. Every precaution will be taken to protect your personal information to ensure confidentiality. This risk is minimized by using secure files, storing data on secure computers, and not having your name or a study identifier associated with any data you provide.

Are there any benefits to taking part in this study?

You might benefit if you feel better after starting mental health treatment. We cannot guarantee or promise that you will receive any direct benefit by participating in this study. However, your participation could help us improve the patient navigation program for other families. In the future, this may help other youth to access mental health treatment.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, procedures, interviews, and surveys. Information related to your child's medical care at CHOP will go in their medical record. Medical records are available to CHOP staff. Staff will view your child's records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP/Penn;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Groups monitoring the safety of this study (e.g., Data & Safety Monitoring Board);
- The National Institutes of Health (NIH) who is sponsoring the research study

Public health authorities are required by law to receive information for the prevention or control of disease, injury or disability. If you have consented to this study and another study at CHOP/Penn, data may be shared between studies. We may contact you in the future to update your information or to see if you'd like to participate in future research. You may ask us to remove you from our contact list at any time.

By law, CHOP/Penn is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP/Penn to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institutes of Health (NIH) may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To rescind your permission, it is preferred that you inform the investigator in writing.

Dr. Rhonda Boyd
The Children's Hospital of Philadelphia
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In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you if you are taking part in this study.

Will you be paid to take part in this study?

Baseline	2- month follow up	6-month follow up
$25 each for youth and caregivers	$25 each for youth and caregivers	$50 each for youth and caregivers

- If the interview is in person, each family will be reimbursed up to $45 for travel and parking.
- If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, call the study doctor, Dr. Rhonda Boyd at 215-590-3945. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of the main study clinical trial is 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.

Sharing Data with the National Institutes of Health (NIH)

Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH's goal is to maximize the benefits that come from the research.

The NIH repository stores genetic information and phenotypic data from many studies. The NIH then shares that information with researchers. We will send the information about you and the other participants to a repository at the NIH. The information will be deidentified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual.

The NIH intends to share the collected information with other researchers for future research. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise not to try to re-identify anyone.

Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH, but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it's possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.

Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future.

Controlled or Unrestricted Access

The data about you will either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access is publicly available to anyone (e.g., The 1000 Genomes Project).

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Your identifiable and non-identifiable information will be stored for future research purposes indefinitely. Results of the analysis of data you have provided may be shared with other researchers for any research question and be made available for future use. This information will be de-identified, meaning it will not contain any traditional identifiers (i.e., name, date of birth, address, telephone number). We will not follow up with you to tell you about the specific future research that will be done. We will not give you any results from these future studies.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to you and/or your child's participation (child who is less than 13 or younger). You are also authorizing the use of your and/or your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Parent/Legal Guardian or Adult Subject Consent

Name of Subject	
Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Youth Consent (14 -17 years of age)

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your participation. You are also authorizing the use of your health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.

Name of Subject	
Signature of Subject (14 -17 years old)	Date

Child Assent to Take Part in this Research Study (subjects 7-13 years of age)

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she/they could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject(optional) Date