A Multi-Site, Non-Intervention Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings
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START: A Multi-Site, Non-Intervention Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings

Investigator:

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Contact Info:

513-636-4124

Funding: **Patient-Centered Outcomes Research Institute (PCORI)**

Key Information:

The following is a short summary of this study to help you decide if you want to participate in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. **When we say "you" in this form, we mean you or your child**; "we" means the study doctor and other staff.

Reason for the study:

The main reason for this research study is to address the need of improving the treatment and management for adolescent suicidality. We are evaluating outcomes for different treatments for suicidal thoughts and behaviors, including inpatient, telehealth Crisis Intervention Services (CIS), and in person Outpatient Crisis Intervention Clinics (OCIC). With the results from our proposed study, we may be able to reduce the family and clinician uncertainty about the best treatment setting for adolescents who experience suicidal thoughts.

Procedures:

This study will be an observational design and the research will be done through collection of information from your medical record and your/your family's completion of questionnaires. Your participation in this study will not affect the care you receive clinically. Upon enrollment and after completion of treatment, you will also be asked to

complete short surveys and questionnaires every 2 weeks up to 26 week period. All surveys and questionnaires will be administered through an online web service. If there are questions related to answers or completion of surveys or otherwise based on clinical judgement, you may be contacted by phone or through in person interview. An Electronic Health Record (EHR) review will also be used to follow your progress post treatment.

We expect that you will be in this research study for up to 180 Days.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate: The section below describes the most common and most serious side effect that researchers know about.

Loss of confidentiality (minimal risk of occurring)

- The likelihood of personal health information (PHI) being disclosed to unintended recipients is of **minimal** risk of occurring and secured systems have been in place for each treatment and location that will ensure the protection of any information from any unauthorized releases. In order to further enhance our data security measures, we are limiting access to the data to our Data management team located at Cincinnati Children's Hospital.

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

- *Increased level of safety monitoring to decrease risk of repeat behavior.*
- *Participants may derive a sense of accomplishment from participation in research*

Benefits to others

- *We will learn about which factors influence outcomes within each treatment group.*
- *We will learn about barriers to treatment*
- *Reduce uncertainty about the best treatment setting for adolescents with suicidality.*

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. You can receive the care listed above even if you do not participate in the study.

Cost to Participate:

You and your insurance company will be charged for the healthcare services that you would ordinarily be responsible to pay. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. Our research study will not cover any of the costs for treatment.

Payment:

If you agree to take part in this research study, we will pay your child $20 every 2 weeks for up to 6 months for their time and effort for study participation. Payments will be given upon completion of both patient and guardian surveys every 2 weeks. The caregiver will not be reimbursed but your child will be reimbursed for your time and effort while you are in this research study. Your child will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you (your child) a handout that will explain how to use the card. Because your child is being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your (your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. If you do not have or do not wish to use your child's social security number, you may use your (parent's) social security number. If you choose to use the parent social security number, the child will continue to be the identified study participant. The W-9 form will be given to the Cincinnati Children's business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries	**Dr. Drew Barzman**	Phone: 513-636-4124

❓ Who to talk to…	❓ You can call …	❓ At …
• Any research concerns or complaints		
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Jennifer Combs** **Alex Osborn,**	Phone: 513-803-0007 513-803-0822 XXX
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Total number of participants:

We expect about 100 **participants** at Cincinnati Children's Hospital will be in this research study out of 244 people in the entire study nationally.

Detailed Procedures

If you agree to participate in this study, we will collect information about you and your care from your medical records. We will also ask you to complete questionnaires every two weeks. These questionnaires can be shared with you through the internet or in paper format. The study team will discuss these options with you and provide the questionnaires in your preferred format.

If you answer positively to questions related to suicide risk, an automated message will be sent to your guardian identifying the possible safety concern. Study staff will follow up with you within 24 hours to answer any questions you might have.

The message will read: "This is a message from the PreSTART study. Your child has identified suicide ideation on study surveys. Please follow your identified safety plan and follow up with

child's clinician. Study staff will contact you within 24 hours. If you need immediate consultation, please contact PIRC at 513-636-4124."

The 2 questions that will prompt an automated message are:

- "I have been having thoughts about how I might kill myself"
- "I have a plan to kill myself"

The chart below details the procedures you can expect throughout your time in this study.

	Visit Week (study activities occur every two weeks)												
	1	2	4	6	8	10	12	14	16	18	20	22	24
Demographics About You	X												
Severity of Suicidal Ideation	X	X	X	X	X	X	X	X	X	X	X	X	X
Suicidal Events	x	X	X	X	X	X	X	X	X	X	X	X	X
Substance Use	X	X	x	X	X	X	X	X	X	X	X	X	X
Treatment Satisfaction		x											
Satisfaction with Life	X	X	X	X	x	X	X	X	X	X	X	X	X
COVID-19 Thoughts		X											
Emotional Response	X						x						

Description of Questionnaires

Demographics About You – This questionnaire will ask you general questions about yourself; including your date of birth, your sex and gender identity and information about your household. There will be one form for you and your guardian.

Severity of Suicidal Ideation – These questionnaires will ask you how you have been feeling and if you have thought about harming yourself. The questionnaires being used

are the Concise Health Risk Tracking-Self Report (CHRT-SR) and the Columbia-Suicide Severity Rating Scale (C-SSRS). You should complete these yourself.

Suicidal Events – This questionnaire will ask about your recent suicidal thoughts, suicidal attempts and any care you have received regarding your suicidality. This questionnaire will be completed by your parent/guardian.

Substance Abuse – This questionnaire will ask you about your recent suicidal thoughts, suicidal attempts, any care you have received regarding your suicidality and any drug and/or alcohol use.

Treatment Satisfaction – This questionnaire will ask you how you feel about the treatment you have been receiving for your suicidal thoughts or attempts. This form will be completed by you and your parent/guardian independently.

Satisfaction with Life – These questionnaires will ask you and your parent how you are feeling about your life, environment and outlook of the future. The questionnaires are known as the Patient-Reported Outcome Measurement Information System (PROMIS). You and your parent/guardian will each complete one of these questionnaires independently.

COVID-19 Thoughts – This questionnaire will ask you and your guardian how you have are feeling about your life and how the COVID-19 pandemic may be affecting your life and mood. You and your parent/guardian will each complete one of these questionnaires independently.

Emotional Response – This questionnaire uses pictures to determine your current feelings and is called the Self-Assessment Manikin (SAM). You should complete this form yourself.

Study Withdrawal:

You can leave the research at any time; it will not be held against you. Quality of care will not be impacted by your choice not to participate. You will continue to receive appropriate standard of care, including inpatient services or appropriate outpatient services.

Change of Treatment:

Upon the signing of this form, parents/guardians give our research team consent to gather data on the patient for the 180 days of the study period, even if they change or do not show for treatment. If, after your evaluation, you decide to change your treatment from the treatment you discussed with your clinician, we will keep you in the study and follow you for up to 180 days. Additionally, we will continue to gather data

on patients that either leave inpatient treatment against medical advice or do not show up for OCIC or CIS treatment. Data will be carefully gathered by research coordinators from the patients Electronic Health Records.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Consistent with the Federal guidelines, all patients and guardians will be informed of the federally mandated reporting laws for child abuse and neglect, verbally and in the written consent form. Therefore, if abuse or neglect is suspected the Department of Human Services could be called. Risks associated with this include embarrassment, legal consequences, and removal of the child from home.

Data collected for or generated from this study could be shared and used for future research. Data may be shared with other collaborators at Cincinnati Children's Hospital and possibly with outside collaborators, who may be at another institution or for-profit company.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

All future researchers will be given the least amount of information needed to meet the goals of their research project. Researchers that use these samples and information must agree to never try to re-identify a participant from a coded dataset. Researchers will only be allowed to use the provided samples and information for approved research purposes. Any researchers planning to do research with information that may identify you will need to have extra review and approval by an Institutional Review Board (IRB). An IRB is a group of scientists and non-scientists who look at research projects like these and make sure research participants' rights and welfare are protected.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital and XXXXX will need to use and share your PHI as part of this study. This PHI will come from:

- Your medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will never expire.

Will your child's other medical care be impacted?

By signing this document, you / your child agree to participate in this research study and give permission to Cincinnati Children's and - to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent Date

_____ _____
Signature of Parent or Legally Authorized Representative* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent Date