Informed Consent Forms

Official Title: Optimizing Suicide Prevention Strategies for Pediatric Primary Care

ClinicalTrials.gov ID (NCT number):

Protocol Date: 6/8/2023

UPMC | University of Pittsburgh Medical Center

Western Psychiatric Hospital

Division of Child and Adolescent Psychiatry

Consent to Participate in a Research Study – Parent Consent

PRINCIPAL INVESTIGATOR: **Stephanie Stepp, Ph.D.**
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TITLE OF PROJECT: PROS-iCHART-cASAP Study

SOURCE OF SUPPORT: National Institute of Mental Health

KEY INFORMATION:

1. Your child is being asked to take part in a research study. Research studies include only people who choose to take part. The study team members will explain the study to you and your child and will answer any questions you might have. You and your child should take your time to make a decision.

2. The purpose of this study is to determine how best to implement and use an intervention the researchers developed for use in your pediatrician's office called integrated Care to Help-At Risk Teens (iCHART) which added a computer version of the As Safe As Possible (ASAP) in your pediatrician's office. Your child will use the intervention through your pediatrician's office.

This study takes place over about 6 months, and involves the following:

- We will ask your child to answer questions about mood and feelings.
- We will ask for permission to access data from the iCHART-cASAP intervention you may have used at your pediatrician's office.

3. Possible risks related to participation include:

- There is a risk that the information we collect could be lost or stolen. However, we have taken many precautions to protect against this outcome, including encrypting your child's data and storing all electronic information on a password protected server.
- There is also risk of suicidal behavior, worsening depression and potential distress as we are directly including those with these symptoms in the study.

4. Your child will not benefit directly from participating in this study. However, the knowledge gained by conducting this study may help others in the future.

Description of this research study

The Center for Enhancing Treatment & Utilization for Depression & Emergent Suicidality (ETUDES Center) is a grant funded by the National Institute of Mental Health (NIMH) to help professionals in pediatric primary care better identify and support youth who may be experiencing depression or risk for suicide by asking teens to use a digital intervention through their pediatrician's office. Our goal is to enroll 60 youth with symptoms of depression and/or risk for suicide.

All youth and caregivers enrolled in this research study will complete ongoing questionnaires over 6 months and may or may not have interacted with the integrated Care to Help At-Risk Teens (iCHART) computerized As Safe As Possible cASAP) intervention at their pediatric primary care office.

By signing this consent, you are agreeing for you and your child to participate in the assessments and allowing research to access the data from your pediatric primary care practice's use of the iCHART-cASAP intervention.

What will the research study involve?

If you and your child choose to participate, we will:

1. Ask you and your child to complete questionnaires about mood and feelings, treatment preferences and barriers at four times over a period of 6 months. At each time, you will be asked to complete some forms online and some by phone. We estimate that these evaluations will take 45 to 90 minutes to complete.
2. Ask for permission to access the data you produced from the iCHART-cASAP intervention

Assessment Questions

Participants will be asked to complete assessments with our research team at four times over a period of 6 months. At each time, you will be asked to complete some forms online and some by phone and/or HIPAA compliant video conferencing platform. We estimate that these evaluations will take 45 to 90 minutes to complete. The first assessment will occur after you/your child have agreed to participate in this research. The next assessments will take place 1 month, 3 months, and 6 months, after the initial call. During the assessments, we will ask about your child's physical, emotional, social, behavioral, and academic functioning.

iCHART-cASAP intervention at your pediatric primary care practice

At a recent pediatric primary care appointment, your practice was testing a tool called the integrated Care to Help-At Risk Teens (iCHART) added on to a computerized version of an intervention to teach adolescents coping skills called As Safe As Possible (cASAP). Each practice participating in this study will start by referring adolescents to participate in research study visits after screening positive for depressive and/or suicidal symptoms on a tool called Screening Wizard within the iCHART portal. At some point, each participating practice will be randomly assigned a date to administer the full iCHART-cASAP intervention to participants who are screening positive for depressive or suicidal symptoms. The full intervention is described

below. The research staff are approaching those who have interacted with iCHART-cASAP to provide permission to access the data and summary information included in the practice's iCHART portal and enroll in this study.

iCHART-cASAP is made up of four components:

A. Safety Planning App: The 1st component is an app that will guide a provider or member of the research team in helping your child use skill building to reduce suicidal risk and offers a personalized safety plan. The safety plan is a set of instructions or activities your child can use to cope when they begin to experience identified warning signs of low mood or suicidal thoughts. How your child uses this app will be shown on a dashboard that your provider may view at any time and use to track your child's progress. With the app safety plan, your child will be able to log into the app at any time with a pin code. If a pin code is lost, a text will be sent with the pin. The content of the safety plan will be available, even when the phone or device does not have access to Wi-Fi/data. We ask that you consult with your child's provider before removing access to their phone while they are using the app. While staff do not monitor the app 24 hours a day, your child could use the app to connect with a crisis line in your county in an emergency. The contact information for crisis services will be populated in advance on the app, with your child's provider, and a member of the research team. Additionally, a provider or member of the research team will show your child how to use the app and answer questions.
B. Mental Health Screener: The 2nd component is a questionnaire about your child's mental health, treatment preferences, and readiness to engage in treatment. The questionnaire is texted to you and your child to complete independently, when convenient. Responses are summarized in a brief report returned to your provider to help them identify most appropriate next steps in care for your child. This report will be placed in your child's medical record. Item level data may also be uploaded into the medical record.
C. Text Messages: Text messages may be sent to your child to encourage your child to use the safety planning app and to engage in treatment. Your child will receive text messages when they report signs of distress in the app and/or do not interact with the app for multiple days. Your child may receive text messages on their text capable phone, for about 2 weeks once this component is launched. Your child can continue to use this after the 2 weeks if they feel it will be helpful. The messages will give them information about mental health treatment for depression and ask True/False, Yes/No, or multiple-choice questions. This text message intervention is not managed by a live person in real time. The intervention is not meant to aid in the actual scheduling of appointments. You should both understand that we will not be able to respond to any immediate or emergency concern that is sent to our phone number, nor any text message outside the scope of the questions we ask.
D. cASAP: The computerized As Safe As Possible intervention aims to teach skills to learn to tolerate distress, focus on positive emotions to feel better, deal with anxiety, worry or other difficulty emotions, learning to get unstuck from negative loops of feelings, thoughts, and behaviors, and support reaching out to people in your child's life that are there for you when you need help.

Will your child benefit from participating in this research study?
Your child will not directly benefit from participating in this research. The information we get from those who participate, may help researchers find better ways to help young people who are going through hard times in their lives.

What are the risks associated with this research study?
The interviews and questionnaires may potentially cause psychological distress. There is a risk of feeling embarrassed by providing responses about mental health questions. There is a risk of feeling tired or inconvenienced. Trained and experienced research staff will conduct the interviews. If your child becomes upset, the interviewer can assist.

There is potential for a breach in confidentiality if you and your child's answers were somehow to become available to non-study personnel. We cannot guarantee that scheduling information will not be accessed or that your child will not download content on a phone that you do not wish them to have. We ask that you minimize this risk by (1) protecting your phone with a password, pin code, or other feature that allows locking of the phone and (2) immediately erasing messages after responding to our queries.

Feel free to let research staff know if you/your child are not comfortable receiving texts about scheduling at any time. There is no compensation for texting or other phone plan charges that may occur as a result of participation in this study

Although every reasonable effort has been taken, confidentiality during internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this research.

How will my child's information be protected & will it be shared?
The information we receive from you and your child will be labeled with a code number that we assign and not with anything that directly identifies either of you. All recordings will be coded by participant identification number, date, study name, and initials of interviewer. Digital records will be kept on secure servers behind UPMC and/or the University of Pittsburgh's firewall. Any hard copy notes will be kept in locked research offices in locked storage cabinets to which only research study staff has access. Your child will not be identified by name in any publication of research results unless you and your child sign a separate form giving your permission (release).

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to your participation in this research:

- Authorized representatives of the research sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research.
- If investigators learn that you, or someone with whom you are involved, is in serious danger or potentially being harmed, they will need to inform the appropriate agencies, as required by Pennsylvania law.

- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable information to provide services and address billing and operational issues.
- Research staff with the American Academy of Pediatrics Pediatric Research in Office Settings (PROS) network will obtain copies of consent forms and documentation of verbal consent, which includes identifying information such as names, for all participants recruited from PROS affiliated primary care practices.
- Information collected from this research may be shared with sites participating in this multi-site research study and other investigators; however, this information will not include identifiers like your name but may include zip codes and dates.
- Your limited data will be uploaded along with all other study data to the National Data Archive (NDA), which is a requirement for the National Institute of Mental Health in funding this study.
- A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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 research assessments and interviews are confidential, however here are times when our research staff cannot keep certain information secret that you or your child tells us. These instances include:

A. *If child abuse or neglect is suspected or reported, the research team is obligated to follow mandatory state reporting laws.*
B. *When our research staff assess your child for depression and suicidal risk, we may uncover the presence of a method, plan, or intent for suicide. We will review or develop a safety plan with your child and review concerns that came from the assessment with you and your child's treatment provider. We will also follow up with you and your child to determine if your child is engaged in care to ensure safety and provide referral recommendations if necessary.*

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 or documents 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 or documents 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 NIMH. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about your child's 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.

Research records will be maintained for at least 7 years following final reporting or publication of a project. For projects involving children, records will be maintained for 5 years past the age of majority (age 23 per PA State Law) after research participation ends.

Researchers and the teams working for them will be able to see some information about your child from this research. Information about your child, including how you respond to questions about your child, will be shared with the PROS Network. The PROS Network Institutional Review Board may have access to your study information. The PROS Network is our research partner.

Are there costs associated with participation? Will my child be paid?
Neither you nor your insurance provider will be charged for participation in this research. To thank you and your child for your time and efforts you will be paid for the research activities. See the chart below for payments per activity:

Baseline	Month 1 Follow Up	Month 3 Follow Up	Month 6 Follow Up	Total
$20	$25	$30	$35	$110

Payment will be mailed to your address to be shared with your child for your joint participation. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Who will pay if I am injured as a result of participating in this research study?
If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

Is my participation in this research study voluntary?
Yes, you and your child's participation in this research study is completely voluntary. Also, you/your child can, at any time, choose to withdraw from this research study. Whether or not you/your child provide your consent for participation in this research will have no effect on your current or future relationship with the University of Pittsburgh, your current or future care or treatment at UPMC or affiliated care provider, your current or future relationship with a health

care insurance provider or PROS network provider, or your ability to receive treatment from any provider.

The PI may decide to remove your child from this research study if your child's health or safety may be at risk, if your child has not been following study instructions, or because of a study administrative decision by the PI. Your child's data up until the point of formal withdrawal will be retained and stripped of identifiers.

Any identifiable research information obtained as part of this research study prior to the date that you withdrew your consent will remain. To formally withdraw your consent for your participation in this research study, you should provide a written and dated letter of this decision to the principal investigator of this research study:

Dr. Stephanie Stepp, at the following address: 3811 O'Hara St Pittsburgh, PA 15213.

Who will have access to my child's identifiable information related to my child's participation in this research study?

Your child's medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the research study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the research study.

We will protect your privacy and the confidentiality of your child's records, as described in this document, but cannot guarantee the confidentiality of your child's research records, including information obtained from your child's medical records, once your child's personal information is disclosed to others outside UPMC or the University.

If you have any questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office, 1.866.212.2668.

If you have any questions for the research staff, please reach out to Brandie George-Milford at 412-204-6247 or georgeba2@upmc.edu or Lexus Griffin at griffnl3@upmc.edu.

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PARENTAL PERMISSION

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any part of this research study at any time. Any future questions will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be answered by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. A copy of this consent form will be given to me/my child.

I agree (check box to move forward in software)

Child First Name: _____
Child Last Name: _____
Child's Birthdate: _____

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

Full Name: _____ ___ _____(first, middle initial, last name)

Birthdate: ____ / _____ / _____ (mm/dd/year)

Relationship to child: _____

Signature Field (if survey software includes it)

Answer to ONE of 3 questions from drop-down box:

What is your mother's maiden name?
In what city were you born?
What high school did you attend?

Click here to print a copy of the consent form to keep for your records.

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and

we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Name of Person Obtaining Consent (Print)_____

Role in Research Study_____

Signature of Person Obtaining
Consent_____ Date_____

Signature line (if available in survey software)

Answer to ONE of 3 questions from drop-down box:

What is your mother's maiden name?
In what city were you born?
What high school did you attend?

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Division of Child and Adolescent Psychiatry

Assent to Participate in a Research Study (12-17 year olds)

PRINCIPAL INVESTIGATOR: **Stephanie Stepp, Ph.D.**
Associate Professor of Psychiatry
University of Pittsburgh School of Medicine
3811 O'Hara Street
Pittsburgh, PA 15213
Office: (412) 383-5051
Cell: (412) 715-5447

TITLE OF PROJECT: PROS-iCHART-cASAP Study

SOURCE OF SUPPORT: National Institute of Mental Health

Description of this research study

The Center for Enhancing Treatment & Utilization for Depression & Emergent Suicidality (ETUDES Center) is a grant funded by the National Institute of Mental Health (NIMH) to help professionals in pediatric primary care better identify and support youth who may be experiencing depression or suicidality. Our goal is to enroll 60 youth with symptoms of depression and/or suicidality.

All youth and caregivers enrolled in this research study will complete ongoing questionnaires over 6 months and may or may not have interacted with the integrated Care to Help At-Risk Teens (iCHART) computerized As Safe As Possible cASAP) intervention at their pediatric primary care office.

By signing this consent, you are agreeing for you and your child to participate in the assessments and allowing research to access the data from your pediatric primary care practice's use of the iCHART-cASAP intervention.

What will the research study involve?

If you and your child choose to participate, we will:

1. Ask you and your child to complete questionnaires about mood and feelings, treatment preferences and barriers at 4 points over a period of 6 months. At each time, you will be asked to complete some forms online and some by phone. We estimate that these evaluations will take 45 to 90 minutes to complete.
2. Ask for permission to access the data you produced from the iCHART-cASAP intervention

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CHILD ASSENT

This research has been explained to me, and I agree to participate.

I agree (check box to move forward in software)

Child First Name: _____
Child Last Name: _____
Child's Birthdate: _____

Signature Field (if survey software includes it)

Answer to ONE of 3 questions from drop-down box:
- What is your mother's maiden name?
- In what city were you born?
- What high school did you attend?

Click here to print a copy of the consent form to keep for your records.

VERIFICATION OF EXPLANATION

I certify that I have carefully explained the purpose and nature of this research to (name of child) in age appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she provided affirmative agreement (i.e., assent) to participate in this research.

Signature of Person Obtaining Assent_____ Date_____

Signature line (if available in survey software)

Answer to ONE of 3 questions from drop-down box:
- What is your mother's maiden name?
- In what city were you born?
- What high school did you attend?

Consent for Continued Participation in a Research Study

PRINCIPAL INVESTIGATOR: **Stephanie Stepp, Ph.D.**
Associate Professor of Psychiatry
University of Pittsburgh School of Medicine
3811 O'Hara Street
Pittsburgh, PA 15213
Office: (412) 383-5051
Cell: (412) 715-5447

TITLE OF PROJECT: PROS-iCHART-cASAP Study

SOURCE OF SUPPORT: National Institute of Mental Health

- I understand that I am currently participating in the PROS Network iCHART-cASAP Study. I further understand that consent for my participation in this study was initially obtained from my authorized representative because I was younger than 18 years of age at the time the initial consent was requested. I have now reached the age to provide direct consent for continued participation in this study.
- I understand that I am encouraged to ask questions, voice concerns, or complaints about any aspect of the study during the course of the research activities, and that such future questions, concerns, or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.
- I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.
- I understand my continued participation does not have an impact on my relationship with or treatment at University of Pittsburgh or University of Pittsburgh Medical Center, or any health insurance provider I may have.
- I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

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VOLUNTARY CONSENT The above information has been explained to me and my current questions have been answered. To indicate my agreement to continue participating in study, and to continue allowing the use and disclosure of my medical record information for the purposes described above, I consent to participate in the study by clicking the 'I agree' box and by completing the fields below.

I Agree (checkbox to move forward in the software)

Full Name: _____ (first, middle initial, last)

Birthdate: ____ / _____ / _____ (mm/dd/year)

Signature line (if available in survey software)

Answer to ONE of 3 questions from drop-down box:
What is your mother's maiden name?
In what city were you born?
What high school did you attend?

CERTIFICATION of INFORMED CONSENT
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Name of Person Obtaining Consent (Print)_____

Role in Research Study_____

Signature of Person Obtaining
Consent_____ Date_____

Signature line (if available in survey software)

Answer to ONE of 3 questions from drop-down box:
What is your mother's maiden name?
In what city were you born?
What high school did you attend?