Study Protocol Official Title: The Center for Enhancing Triage and Utilization for Depression and Emergent Suicidality (ETUDES) in Pediatric Primary Care-iCHART RCT

NIH Number: MH115838

ICF Date: 1/18/2023

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.**
Associate Professor of Psychiatry
University of Pittsburgh School of Medicine
3811 O'Hara Street
Pittsburgh, PA 15213
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TITLE OF PROJECT: integrated Care to Help At Risk Teens (iCHART)

SOURCE OF SUPPORT: National Institute of Mental Health

Description of this research study
We are testing if an intervention called integrated Care to Help At-Risk Teens (iCHART) is effective in supporting children's treatment with their mental health clinician or pediatric provider. iCHART is a suite of tools to guide the pediatric provider in assessing common mental health issues to make more targeted treatment recommendations, launching an automated texting intervention to increase treatment engagement, and generating a safety plan that is loaded on children's smartphones.

This study is part of a larger set of research activities within the Center for Enhancing Treatment and Utilization for Depression and Emergent Suicidality (ETUDES Center). You and your child are already enrolled in the ETUDES Center Pediatric Primary Care Study and will continue to complete ongoing questionnaires and interviews. Your child may also be eligible for additional studies in the ETUDES Center.

By signing this consent, you are agreeing for your child to participate in the iCHART study. The details of the procedures are listed below:

What will the study involve?
The iCHART Study is a randomized control trial. If you and your child choose to participate, your child will be randomly assigned, that is by chance (like by flipping a coin) to receive the iCHART intervention or treatment as usual (TAU). The iCHART intervention will determine if it is effective in treatment of depression and suicidality, compared to regular or treatment as usual. Those assigned to the iCHART intervention group will receive the three components of the intervention (listed below).

In the intervention and treatment as usual group, your doctor may develop a safety plan of which you may also receive a copy and refer your child to mental health treatment. Please note that the research team will not act as your child's treatment team and will not know the content of the discussions between your child and the doctor. Your child is still able to access any services they need with a mental health clinician.

The iCHART Intervention

The iCHART intervention includes 3 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:** The final component will provide text messages 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.**

Other research activities available through the ETUDES Center:

- If your child participates in the iCHART intervention, you and your child may be asked if you're interested in sharing your experiences with using the intervention. This will take place in the form of an interview, which will be recorded, and a separate consent discussion and payment will occur at the time of this interview. Not all participants in iCHART will be asked to complete the final iCHART interview.
- Your child may be eligible for future studies through the ETUDES Center where we collect social media data and/or information from your child's phone to determine if we can predict mood and suicidal behavior.

If your child participates in one of these studies, we will share the data from this study with those investigators to help with their analyses.

Will your child benefit from participating in this study?
Your child will be randomly assigned to one of two interventions. For participants who are randomized to receive iCHART, there may be some benefit to their mental health. However, we cannot guarantee that your child will benefit directly from participating in this study. 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 study?
Because the study is enrolling individuals with suicidal thoughts and behaviors, there is always a risk of worsening suicidal thoughts and behaviors. Should this occur, the research team will contact you and your child's provider to let them know and refer your child to your doctor or mental health therapist for evaluation and treatment.

There is potential for a breach in confidentiality if your answers were somehow to become available to non-study personnel. As such, transmissions like texting a crisis line or calling a crisis line on your personal device may be unknowingly and/or unintentionally intercepted by third parties. We may use text messaging through a study staff phone to schedule appointments for focus groups and interviews. No personal information other than scheduling will be asked of you/your child through texting. Any information passed through text messaging is not encrypted and can be accessed by an outside party. Someone not associated with the research study may see the messages on your phone.
Feel free to let research staff know if you/your child are not comfortable receiving texts at any time.

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 study.

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. 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 study:

- Authorized representatives of the study 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 study.
- If investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, 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 at Children's Hospital of Philadelphia (CHOP) will obtain copies of consent forms and documentation of verbal consent, which includes identifying information such as names, for all participants recruited from CHOP affiliated primary care practices.
- Information collected from this study may be shared with sites participating in this multi-site 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.

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 study participation ends.

Researchers and the teams working for them will be able to see some information about your child from this research study. Information about your child, including how you respond to questions about your child, will be shared with the Children's Hospital of Philadelphia (CHOP). The Children's Hospital of Philadelphia Institutional Review Board may have access to your study information. CHOP is our research partner in developing the iCHART intervention.

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 study. You and your child be paid for completing the assessments in the ETUDES Center Pediatric Primary Care Study. You will not receive additional payment for participating in iCHART or receiving treatment as usual.

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 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 study 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 your ability to receive treatment from any provider.

The PI may decide to remove your child from this 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 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.

HIPAA Authorization for Disclosure of Protected Health Information (PHI)
This research study will involve the recording of past, current and/or future identifiable medical information from your hospital and/or other outpatient records. The information that will be recorded includes information such as: your child's diagnosis, medications, age, medical and psychiatric history, results of mental health screeners, risk factors for suicidality, and service utilization. This authorization is valid for an indefinite period of time.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team for the purposes described.

As part of this research study, some information that we obtain from your child will be placed into your child's medical records held at UPMC, including mandated reporting results of child abuse or neglect report, and notes that enhance communication between research staff and treatment providers related to managing suicidality.

May I have access to my child's medical information that results from my child's participation in this research study?
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your child's participation in this research study) contained within your child's medical records filed with your child's health care provider. You will not have access to information generated by this research which is not part of your child's medical record.

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 study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

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 412-246-5629 or georgeba2@upmc.edu or Amy Anderson at 412-586-9851 or amy.anderson2@chp.edu.

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PARENTAL PERMISSION

VOLUNTARY CONSENT: The above information has been explained to me and my current questions have been answered. To indicate my agreement to participate in this research study, and to allow the use and disclosure of my child's 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.

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

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

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?

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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: integrated Care to Help At Risk Teens (iCHART)

SOURCE OF SUPPORT: National Institute of Mental Health

Description of this research study
This research is being conducted to test if an intervention called integrated Care to Help At-Risk Teens (iCHART) is effective in supporting your treatment with their mental health clinician or pediatric provider. iCHART is a suite of tools to guide the pediatric provider in assessing common mental health issues, making treatment recommendations, launching an automated texting intervention to increase treatment engagement, and generating a safety plan that is loaded on your smartphone.

This study is part of a larger set of research activities within the Center for Enhancing Treatment and Utilization for Depression and Emergent Suicidality (ETUDES Center). You are already enrolled in the ETUDES Center Pediatric Primary Care Study and will continue to complete ongoing questionnaires and interviews. You may also be eligible for additional studies in the ETUDES Center.

By signing this consent, you are agreeing to participate in the iCHART study. The details of the procedures are listed below:

- The iCHART Study is a randomized control trial. If you choose to participate, you will be randomly assigned, that is by chance (like by flipping a coin) to receive the iCHART intervention or treatment as usual (TAU). The iCHART intervention will determine if it is effective in treatment of depression and suicidality, compared to regular or treatment as usual. Those assigned to the iCHART intervention group will receive the three components of the intervention (listed below).

- In the intervention and treatment as usual group, your doctor may develop a safety plan of which you may also receive a copy and refer you to mental health treatment. Please note that the research team will not act as your treatment team and will not know the content of the discussions between you and the doctor. You are still able to access any services you need with a mental health clinician.

The iCHART Intervention

The iCHART intervention includes 3 components:

A. **Safety Planning App:** The app will guide the doctor in helping you use skill building to reduce suicidal risk and offers a personalized safety plan. The safety plan is a set of instructions or activities you can use to cope when you begin to experience low mood or suicidal thoughts. How you use the app will be shown on a dashboard that your provider may view at any time and can be used to communicate your progress with your doctor.

B. **Mental Health Screener:** The 2nd component, which may occur at a later time or at today's visit is a questionnaire we can send to you to complete additional questions about mental health, your treatment preferences, and readiness to engage in treatment.

C. **Text Messages:** The final component will provide text messages to you to aid in engaging in treatment and the safety plan.

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CHILD ASSENT

The above information has been explained to me and all my current questions have been answered. To indicate my agreement to participate in this research study:

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

I Agree

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

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?

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Western Psychiatric Hospital

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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, BFT 318
Pittsburgh, PA 15213
(412) 246-6166

TITLE OF PROJECT: integrated Care to Help At Risk Teens (iCHART)

SOURCE OF SUPPORT: National Institute of Mental Health

- I understand that I am currently participating in the integrated Care to Help At Risk Teens (iCHART) RCT. 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 registry.
- I understand that I am encouraged to ask questions, voice concerns, or complaints about any aspect of iCHART RCT during the course of the study 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 'Yes' box(es) and by completing the fields below.

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?

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Consent to Participate in a Research Study

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In the intervention and treatment as usual group, your doctor may develop a safety plan of which you may also receive a copy and seek mental health treatment. Please note that the research team will not act as your treatment team and will not know the content of the discussions between you and the doctor. You are still able to access any services you need with a mental health clinician.

The iCHART Intervention
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There is potential for a breach in confidentiality if your answers were somehow to become available to non-study personnel. As such, transmissions like texting a crisis line or calling a crisis line on your personal device may be unknowingly and/or unintentionally intercepted by third parties. We may use text messaging through a study staff phone to schedule appointments for focus groups and interviews. No personal information other than scheduling will be asked of you through texting. Any information passed through text messaging is not encrypted and can be accessed by an outside party. Someone not associated with the research study may see the messages on your phone. Feel free to let research staff know if you are not comfortable receiving texts at any time.

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The information we receive from you will be labeled with a code number that we assign and not with anything that directly identifies you. Any hard copy notes will be kept in locked research offices in locked storage cabinets to which only research study staff has access. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

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- Authorized representatives of the study 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 study.
- If investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, 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 addressing billing and operational issues.
- Research staff at Children's Hospital of Philadelphia (CHOP) will obtain copies of consent forms and documentation of verbal consent, which includes identifying information such as names, for all participants recruited from CHOP affiliated primary care practices.
- Information collected from this study may be shared with sites participating in this multi-site study and other investigators; however, this information will be shared in a de-identified manner (i.e., without identifiers).
- Your 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.

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A. *If child abuse or neglect is suspected or reported, the research team is obligated to follow mandatory state reporting laws.*
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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.

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Researchers and the teams working for them will be able to see some information about you from this research study. Information about you will be shared with the Children's Hospital of Philadelphia (CHOP) and will be de-identified. De-identified means that the information you share will be associated with an identification number, not your name. The Children's Hospital of Philadelphia Institutional Review Board may have access to your study-derived de-identified information. CHOP is our research partner in developing the iCHART intervention.

Are there costs associated with participation? Will my I be paid?
Neither you nor your insurance provider will be charged for participation in this research study. You will be paid for completing the assessments in the ETUDES Center Pediatric Primary Care Study. You will not receive additional payment for participating in iCHART or receiving treatment as usual.

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 study voluntary?
Yes, your participation in this research study is completely voluntary. Also, you can, at any time, choose to withdraw from this research study. Whether or not you provide your consent for participation in this research study 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 your ability to receive treatment from any provider.

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

Any identifiable research information obtained as part of this 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.

HIPAA Authorization for Disclosure of Protected Health Information (PHI)
This research study will involve the recording of past, current and/or future identifiable medical information from your hospital and/or other outpatient records. The information that will be recorded includes information such as: your diagnosis, medications, age, medical and psychiatric history, results of mental health screeners, risk factors for suicidality, and service utilization. This authorization is valid for an indefinite period of time.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team for the purposes described.

As part of this research study, some information that we obtain from you will be placed into your medical records held at UPMC, including mandated reporting results of child abuse or neglect report, and notes that enhance communication between research staff and treatment providers related to managing suicidality.

May I have access to my medical information that results from my participation in this research study?
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider. You will not have access to information generated by this research which is not part of your medical record.

Who will have access to my identifiable information related to my participation in this research study?
Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your 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 412-246-5629 or georgeba2@upmc.edu or Amy Anderson at 412-586-9851 or amy.anderson2@chp.edu.

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VOLUNTARY CONSENT: The above information has been explained to me and all my current questions have been answered. To indicate my agreement to participate in this research study, and to allow 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.

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

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

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

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?

Signature Field (if survey software includes it)