Study Title: Mobile Technology for Reducing and Preventing Adolescent Suicide

NCT04896593

Document Date: 5.24.2021

Hartford HealthCare

Informed Consent for Research

6816

Principal Investigator: David F. Tolin, Ph.D.
Anxiety Disorders Center, Institute of Living
860-545-7685

KEY INFORMATION FOR
"MOBILE TECHNOLOGY FOR REDUCING AND PREVENTING ADOLESCENT SUICIDE"

We are asking you to choose whether or not to volunteer for a research study about reducing and preventing adolescent suicide. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to to evaluate the feasibility and usability of a software application (app), [redacted], intended to reduce the frequency of suicidal thinking and suicide attempts when used together with regular treatment. The app being studied is based on face-to-face cognitive behavioral therapy (CBT) procedures shown to be effective in clinical trials of suicidal patients.

You have been asked to participate in the research study, Mobile Technology for Reducing and Preventing Adolescent Suicide. [redacted]

You will complete a study eligibility assessment to determine whether or not the study is a good fit. Adolescents who meet all study eligibility requirements will meet with a clinical psychologist while they are still in the hospital to download the [redacted] app to their phone, review how the app works, and complete the first part of the treatment. As long as COVID-19 safety procedures are in place, you will be asked to wear a mask during all in-person assessment and treatment sessions. If you are unwilling to wear a mask for the entire duration of all in-person sessions, you will not be able to take part in this study.

[redacted]

The clinical psychologist will call both you and your parent/guardian to ask questions about you symptoms (including symptoms of suicidal thoughts and behaviors), any changes to your treatment, and to get feedback about using the app, [redacted]

[redacted]

IRB Use Only.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. Although the app is designed to decrease suicidal behaviors, there is no guarantee that you will personally benefit from taking part in this study. We hope the information learned from this study will benefit other people experiencing suicidal thoughts in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Most risks and side effects are part of regular medical care and exist even if you do not join the study. The most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. Study meetings and app use will involve discussing or thinking about emotionally difficult topics that can sometimes increase a person's distress in the short term. Although this study is designed to reduce suicidal behaviors, participants with a history of suicidal thoughts and behaviors are at risk for experiencing these symptoms in the future whether or not they participate in the study. Participants who attempt suicide are at risk for death by suicide whether or not they participate in the study. Although the study will protect confidentiality, loss of confidentiality is a potential risk of study participation.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You do not have to take part in the study if you do not wish to. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is David Tolin, Ph.D. from the Hartford HealthCare Department of Psychiatry. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:

David Tolin, Ph.D.,
Anxiety Disorders Center
Institute of Living
Hartford, CT 06106
david.tolin@hhchealth.org
860-545-7685

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact representatives from the Hartford HealthCare Human Research Protection Program (HHC HRPP) between the business hours of 8am and 5pm EST, Monday-Friday at 860-972-2893.

INFORMED CONSENT FORM FOR
"MOBILE TECHNOLOGY FOR REDUCING AND PREVENTING ADOLESCENT SUICIDE"

Principal Investigator: David F. Tolin, Ph.D.
Anxiety Disorders Center, Institute of Living
860-545-7685

This research is funded by The National Institute of Mental Health and Oui, Therapeutics. The National Institute of Mental Health and Oui, Therapeutics are paying Hartford HealthCare and Dr. David Tolin to conduct this research.

The Hartford HealthCare Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

You are being invited to participate in this study because you are being treated in the hospital and have either attempted suicide in the past or recently reported thoughts about killing yourself. Oui, Therapeutics has developed a mobile app called [redacted] that is designed to prevent adolescent suicide when used in addition to regular treatment. [redacted]

The purpose of this study is to gather feedback from users of the app in order to learn ways we can improve features of the app to make it more user-friendly. Another purpose of this study is to learn how well [redacted] helps users to prevent suicidal behaviors. All participants in this study will receive the [redacted] app in addition to their standard treatment and all participants (and a parent or guardian) will participate in [redacted] clinical assessments [redacted]. Study staff will request your consent to contact your mental health provider to keep them informed of your progress in the study. We intend to enroll approximately 20 participants (ages 13-17) and a parent/guardian for this study.

A.2. What procedures are involved with participation in this research study?

1. You will complete a study eligibility assessment to determine whether or not the study is a good match for you. A trained study staff member will ask you and your parent/guardian questions about your medical history and symptoms. These assessments will take about 1 hour for you and 30 minutes for your parent/guardian.

2. Participants who meet all study eligibility requirements will meet with a clinical psychologist while they are still in the hospital. The clinical psychologist will provide directions for you to download the [redacted] app to their phone and will also review how the [redacted] app works. No personal information is required to download the app, although you will have the option to share this information (e.g., phone number) with Oui, Therapeutics if you choose to do so. The [redacted] app contains 12 modules, each instructing a different type of suicide prevention skill. [redacted]

3. [redacted]

4. [redacted]

5. Be aware that the [redacted] app is not an emergency phone service. You must use the routine phone functionality on your smart phone in order to call 911 or other crises support services. <u>The information you put into the app is not monitored, so the only way we will know if you are experiencing suicidal thoughts is if you tell the study clinician.</u>

6. All study meetings will be audiotaped and may be reviewed by one of the study investigators so that we can be sure that the study procedures were done correctly. Access to the audiofiles will be limited to IRB-approved study staff. Files will be maintained for 6 years following study closure at which time they will be permanently deleted. The principal investigator (David Tolin, Ph.D.) and other staff associated with this

project will have access to and will monitor the security of the recordings. If you are unwilling to be audiotaped, you will not be able to take part in this study.

7. As long as COVID-19 safety procedures are in place, you will be asked to wear a mask during all in-person assessment and treatment sessions. If you are unwilling to wear a mask for the entire duration of all in-person sessions, you will not be able to take part in this study.

A.2. Where will participation take place?

[redacted]

A.3. How long will participation last?

[redacted]

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

The most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. Study meetings and app use will involve discussing or thinking about emotionally difficult topics that can sometimes increase a person's distress in the short term. These periods of increased distress tend to be very brief, but they could increase a desire for suicide for short periods of time. Study staff will be consulting with your treatment team on the unit and sharing information with them that is discussed during any study meetings. It is therefore possible that information that is shared during the course of the study may be used by the inpatient treatment team to guide decisions about your discharge from the hospital.

A risk in patients who have suicidal thoughts is suicide attempt. Approximately half of patients who have made a suicide attempt in past make another suicide attempt, and patients who have made multiple prior attempts are at the highest risk. The goal of this study is to develop interventions to prevent future suicide attempts. The risk of suicide attempt tends to decline over time, and when this suicide prevention program is provided in person in an adult outpatient setting for 12 sessions patients are about 60% less likely to make a suicide attempt compared to patients who do not receive this treatment. This improvement in risk lasts for up to 2 years after treatment. However, the suicide prevention treatment provided in an outpatient setting does not help everyone, and 15-30% of patients will continue to experience significant emotional distress and will make future suicide attempts during or shortly after treatment. How well this treatment works within an adolescent population and when provided via mobile application, is not yet known.

A much less common, but serious risk is death by suicide. Fewer than 2% of patients in outpatient treatment die by suicide. The risk of death by suicide is higher among patients with a history of suicide attempts, especially those who have made multiple suicide attempts. Patients who make a suicide attempt while participating in this study are at the greatest risk for dying by suicide.

As part of this study we will be in contact with you at various checkpoints for 16 weeks after you leave the hospital to monitor your symptoms. If we discover that you are having symptoms of suicidal thoughts and/or behaviors we will do an assessment to determine the best way to help you. Depending on our assessment we may provide you with referrals for follow-up care or emergency services. If we assess that you are in imminent danger of committing suicide we may contact your parent/guardian, treatment providers, and/or the police to ensure your safety and wellness.

Please know that great care is taken to maintain participants' privacy and keep the information you provide as part of this research program confidential. There are a few situations where we are mandated to break confidentiality for the safety and protection of you and others including: 1) if we learn of abuse or neglect to a child, older person, or disabled person; and 2) if we learn that there is an imminent risk of harm to yourself or someone else. The use and disclosure of your protected health information is further described in the study authorization form. There is a small risk that your research records could be lost or otherwise compromised. To reduce this risk, all research staff members have been trained in data protection and confidentiality, and access to data will be restricted to only approved members of the study staff.

C. There are possible benefits to you or others to be expected from your participation in this research.

There may be no direct benefit to you for participating in this study. You will continue to receive routine treatment as usual. You will also receive access to a mobile application, [redacted], for suicide prevention at no charge. This study intervention may help reduce your symptoms although there is no guarantee that you will receive any therapeutic benefit.

D. There are alternatives to participation in this study that you should consider.

You may choose not to participate in this study. If you choose not to participate, you will still receive the routine treatment programming provided at this hospital.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
the research, research-related treatments, or a research related injury	David Tolin, Ph.D.	(860) 545-7685
your rights as a research participant	An IRB Representative	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

After you have been discharged, if at any point you feel unsafe you can get help by calling the National Suicide Prevention Lifeline at 1-800-273-TALK (8255), 911, or by going to your nearest emergency room.

F. Your participation in the research is voluntary.

You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Hartford Hospital. However, if you withdraw your consent you will not be able to continue using the app.

Your participation in this study may be stopped without your consent at any time and for any reason by the study staff, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you or your parent/guardian do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to complete a final study assessment for your safety.

G. [redacted]

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford Hospital will protect all the information about you and your part in this study, just as is done for all patients at Hartford Hospital. Study records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described below and in the study's authorization form.

This study has received a Certificate of Confidentiality from the National Institute of Mental Health to safeguard the privacy of research study participants by protecting identifiable research information from forced disclosure. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Coded data (that is data that is only known by a study code number) will be shared with the study sponsor, Oui, Therapeutics. Oui, Therapeutics will also obtain information directly from the app about app use including the number of log ins and number of modules completed.

Records of your participation in this study will be held confidential to the extent permitted by the applicable laws and regulations, and consistent with the Health Insurance Portability and Accountability Act ("HIPAA") Authorization that you will be asked to sign.

The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA), as well as governmental agencies in other countries where the study product may be considered for approval and the Ethics Committee/Institutional Review Board (IRB) will be able to inspect and copy confidential study specific records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed.

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission. The results of this research project may be presented at meetings or in publications; however, you will not be

identified in these presentations and/ or publications.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov.This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can look up this study at any time using the following NCT number: NCT04896593.

Contact Preferences

While we will make every effort to protect your privacy, we also realize the importance of being able to contact you about your participation in this research study. This can sometimes mean exchanging information by phone, text, or email. We'd like you to tell us what way is best for reaching you and what information is permitted to be exchanged.

Please indicate below your preferred method(s) to be contacted **by initialing next to all that apply**:
Can we contact you by:

Home phone (if you do not have a home phone please initial "No"

_____ No (initial) _____Yes (_____) _____-_____ (initial)

Is it ok to leave voice mail appointment reminders on your home phone?

_____ No (initial) _____Yes (initial)

Cell Phone

_____ No (initial) _____Yes (_____) _____-_____ (initial)

Is it ok to leave voice mail appointment reminders on your cell phone?

_____ No (initial) _____Yes (initial)

Is it ok to send text messages about your appointment and other information related to this research project to your cell?
We do not reimburse for standard texting/messaging fees that may occur.

_____ No (initial) _____Yes (initial)

Email
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- To contact you to schedule or remind you about the phone calls as part of your research participation.
- Other information related to this research project.

Only the research team will have access to your email communications. We will only communicate by encrypted email from a work e-mail address to send you the information listed above. This email account is accessible to the research staff and is typically checked daily. E-mail should be used for routine, non-emergency communications only. In cases where you are in crisis and require emergency services call 911 or go to your nearest emergency room.

Risks: You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address.
- To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study, make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your appointment reminders and protected health information via email?

_____ No (initial) _____Yes (initial)

Participant email address (please print and use all capital letters):

_____

You can withdraw permission at any time. Please contact the research staff if you change your mind or if your contact information changes.

David Tolin, Ph.D.
200 Retreat Ave
Hartford, CT 06106
Phone: (860) 545-7685

You will receive a copy of this document to keep. By signing below, it means you have read this document. By initialing, you are giving the research staff permission to contact you through the approved method.

Participant's Signature	**Printed Name**	**Date**

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, your child will receive help in the following way:

If you have medical insurance, Hartford Hospital will collect fees for medical treatment at Hartford Hospital from their insurance company. If they are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford Hospital will cover these expenses.

There is no plan for Hartford Hospital to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

J. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, **Mobile Technology for Reducing and Preventing Adolescent Suicide**, and that you consent to the performance of the procedures listed above.

Participant's Signature	Printed Name	Date

Person Obtaining Participant's Signature	Printed Name	Date

Witness signature	Printed Name	*Date*

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

Hartford HealthCare

Informed Consent for Research

6816

Principal Investigator: David F. Tolin, Ph.D.
Anxiety Disorders Center, Institute of Living
860-545-7685

KEY INFORMATION FOR "MOBILE TECHNOLOGY FOR REDUCING AND PREVENTING ADOLESCENT SUICIDE"

We are asking you to choose whether or not to volunteer yourself and your child for a research study about reducing and preventing adolescent suicide. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to to evaluate the feasibility and usability of a software application (app), [redacted], intended to reduce the frequency of suicidal thinking and suicide attempts when used together with regular treatment. The app being studied is based on face-to-face cognitive behavioral therapy (CBT) procedures shown to be effective in clinical trials of suicidal patients.

Your child has been asked to participate in the research study, Mobile Technology for Reducing and Preventing Adolescent Suicide. This research study is expected to last for about 12 months.

Your child will complete a study eligibility assessment to determine whether or not the study is a good fit. Adolescents who meet all study eligibility requirements will meet with a clinical psychologist while they are still in the hospital to download the [redacted] app to their phone, review how the app works, and complete the first part of the treatment. If we are unable to meet with your child for this session while they are in the hospital they can still participate in the study if they can come back to the Institute of Living to complete this session with study staff within two days after their discharge. As long as COVID-19 safety procedures are in place, your child will be asked to wear a mask during all in-person assessment and treatment sessions. If your child is unwilling to wear a mask for the entire duration of all in-person sessions, they will not be able to take part in this study.

[redacted]

The clinical psychologist will call both you and your child to ask questions about your child's symptoms (including symptoms of suicidal thoughts and behaviors), any changes to your child's treatment, and to get feedback about using the app[redacted]

IRB Use Only.

[redacted]

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. Although the app is designed to decrease suicidal behaviors, there is no guarantee that you or your child will personally benefit from taking part in this study. We hope the information learned from this study will benefit other people experiencing suicidal thoughts in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Most risks and side effects are part of regular medical care and exist even if you do not join the study. The most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. Study meetings and app use will involve your child discussing or thinking about emotionally difficult topics that can sometimes increase a person's distress in the short term. Although this study is designed to reduce suicidal behaviors, participants with a history of suicidal thoughts and behaviors are at risk for experiencing these symptoms in the future whether or not they participate in the study. Participants who attempt suicide are at risk for death by suicide whether or not they participate in the study. Although the study will protect confidentiality, loss of confidentiality is a potential risk of study participation.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You do not have to take part in the study if you do not wish to. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is David Tolin, Ph.D. from the Hartford HealthCare Department of Psychiatry. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:

David Tolin, Ph.D.,
Anxiety Disorders Center
Institute of Living
Hartford, CT 06106
david.tolin@hhchealth.org
860-545-7685

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact representatives from the Hartford HealthCare Human Research Protection Program (HHC HRPP) between the business hours of 8am and 5pm EST, Monday-Friday at 860-972-2893.

INFORMED CONSENT FORM FOR
"MOBILE TECHNOLOGY FOR REDUCING AND PREVENTING ADOLESCENT SUICIDE"

Principal Investigator: David F. Tolin, Ph.D.
Anxiety Disorders Center, Institute of Living
860-545-7685

This research is funded by The National Institute of Mental Health and Oui, Therapeutics. The National Institute of Mental Health and Oui, Therapeutics are paying Hartford HealthCare and Dr. David Tolin to conduct this research.

The Hartford HealthCare Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself and your child. You must then decide if you want your child to be in the study.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

Your child is being invited to participate in this study because they are being treated in the hospital and have either attempted suicide in the past or recently reported thoughts about killing themselves. Oui, Therapeutics has developed a mobile app called [redacted] that is designed to prevent adolescent suicide when used in addition to regular treatment. The app being studied is based on face-to-face cognitive behavioral therapy (CBT) procedures shown to be effective in clinical trials of suicidal patients. CBT is a type of psychological therapy which focuses on how your thoughts, beliefs and attitudes affect your feelings and behavior, and teaches you coping skills for dealing with different problems. [redacted] is experimental software, which means that it is being tested and is not approved by the United States Food and Drug Administration (FDA).

The purpose of this study is to gather feedback from users of the app in order to learn ways we can improve features of the app to make it more user-friendly. Another purpose of this study is to learn how well [redacted] helps users to prevent suicidal behaviors. All participants in this study will receive the [redacted] app in addition to their standard treatment and all participants (and a parent or guardian) will participate in [redacted] clinical assessments [redacted] Study staff will request your consent to contact your child's mental health provider to keep them informed of your child's progress in the study. We intend to enroll approximately 20 participants (ages 13-17) and a parent/guardian for this study.

A.2. What procedures are involved with participation in this research study?

1. Your child will complete a study eligibility assessment to determine whether or not the study is a good match for them. A trained study staff member will ask you and your child questions about your child's medical history and symptoms. These assessments will take about 30 minutes for you and 1 hour for your child.

2. Participants who meet all study eligibility requirements will meet with a clinical psychologist in-person while they are still in the hospital or within two days after their discharge. If your child does not already have their phone at the hospital you will need to drop off your child's phone at the Institute of Living so that your child will have access to their phone. The clinical psychologist will provide directions for your child to download the [redacted] app to their phone and will also review how the [redacted] app works. No personal information is required to download the app, although your child will have the option to share this information (e.g., e-mail address) with Oui, Therapeutics if they choose to do so. If your child uses their e-mail address with the app it will allow your child to change their own passwords. If they choose not to use their e-mail address they can contact study staff for assistance to change their password. Please discuss these options with your child so they can make an informed decision about whether or not to share their e-mail address. [redacted]
The clinical psychologist will also complete the first module of the program with your child during the in-person session. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

6. All study meetings will be audiotaped and may be reviewed by one of the study investigators so that we can be sure that the study procedures were done correctly. Access to the audiofiles will be limited to IRB-approved study staff. Files will be maintained for 6 years following study closure at which time they will be permanently deleted. The principal investigator (David Tolin, Ph.D.) and other staff associated with this project will have access to and will monitor the security of the recordings. If you or your child is unwilling to be audiotaped, you will not be able to take part in this study.

7. As long as COVID-19 safety procedures are in place, your child will be asked to wear a mask during all in-person assessment and treatment sessions. If your child is unwilling to wear a mask for the entire duration of all in-person sessions, they will not be able to take part in this study.

A.2. Where will participation take place?

[redacted]

A.3. How long will participation last?

[redacted]

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

The most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. Study meetings and app use will involve your child discussing or thinking about emotionally difficult topics that can sometimes increase a person's distress in the short term. These periods of increased distress tend to be very brief, but they could increase a desire for suicide for short periods of time. Study staff will be consulting with your child's treatment team on the unit and sharing information with them that is discussed during any study meetings. It is therefore possible that information that is shared during the course of the study may be used by the inpatient treatment team to guide decisions about your child's discharge from the hospital.

A risk in patients who have suicidal thoughts is suicide attempt. Approximately half of patients who have made a suicide attempt in past make another suicide attempt, and patients who have made multiple prior attempts are at the highest risk. The goal of this study is to develop interventions to prevent future suicide attempts. The risk of suicide attempt tends to decline over time, and when this suicide prevention program is provided in person in an adult outpatient setting for [redacted] sessions patients are about 60% less likely to make a suicide attempt compared to patients who do not receive this treatment. This improvement in risk lasts for up to 2 years after treatment. However, the suicide prevention treatment provided in an outpatient setting does not help everyone, and 15-30% of patients will continue to experience significant emotional distress and will make future suicide attempts

during or shortly after treatment. How well this treatment works within an adolescent population and when provided via mobile application, is not yet known.

A much less common, but serious risk is death by suicide. Fewer than 2% of patients in outpatient treatment die by suicide. The risk of death by suicide is higher among patients with a history of suicide attempts, especially those who have made multiple suicide attempts. Patients who make a suicide attempt while participating in this study are at the greatest risk for dying by suicide.
As part of this study we will be in contact with your child at various checkpoints for 16 weeks after they leave the hospital to monitor their symptoms. If we discover that they are having symptoms of suicidal thoughts and/or behaviors we will do an assessment to determine the best way to help them. Depending on our assessment we may provide you with referrals for follow-up care or emergency services. If we assess that they are in imminent danger of committing suicide we may contact you, treatment providers, and/or the police to ensure their safety and wellness.

Please know that great care is taken to maintain participants' privacy and keep the information you and your child provide as part of this research program confidential. There are a few situations where we are mandated to break confidentiality for the safety and protection of you and others including: 1) if we learn of abuse or neglect to a child, older person, or disabled person; and 2) if we learn that there is an imminent risk of harm to yourself or someone else. The use and disclosure of your protected health information is further described in the study authorization form. There is a small risk that your research records could be lost or otherwise compromised. To reduce this risk, all research staff members have been trained in data protection and confidentiality, and access to data will be restricted to only approved members of the study staff.

C. There are possible benefits to you or others to be expected from your participation in this research.

There may be no direct benefit to you or your child for participating in this study. Your child will continue to receive routine treatment as usual. Your child will also receive access to a mobile application, [redacted], for suicide prevention at no charge. This study intervention may help reduce your child's symptoms although there is no guarantee that your child will receive any therapeutic benefit.

D. There are alternatives to participation in this study that you should consider.

You may choose for your child not to participate in this study. If you choose not to participate, your child will still receive the routine treatment programming provided at this hospital.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #

the research, research-related treatments, or a research related injury	David Tolin, Ph.D.	(860) 545-7685
your rights as a research participant	An IRB Representative	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

After your child has been discharged, if at any point you believe your child is unsafe you can get help by calling the National Suicide Prevention Lifeline at 1-800-273-TALK (8255), 911, or by going to your nearest emergency room.

F. Your participation in the research is voluntary.

You or your child may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Hartford Hospital. However, if you withdraw your consent your child will not be able to continue using the app.

You and your child's participation in this study may be stopped without your consent at any time and for any reason by the study staff, the sponsor, the FDA and other regulatory authorities. Reasons you/your child may be withdrawn from the study include it is determined to be in your child's best interest, you or your child do not follow the study instructions, the study is stopped, or for other administrative reasons. If your child leaves the study early, they may be asked to complete a final study assessment for your child's safety.

G. [redacted]

[redacted]

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford Hospital will protect all the information about you and your child and their part in this study, just as is done for all patients at Hartford Hospital. Study records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about them may be used or disclosed for purposes of this research project as described below and in the study's authorization form.

This study has received a Certificate of Confidentiality from the National Institute of Mental Health to safeguard the privacy of research study participants by protecting identifiable research information from forced disclosure. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information

Coded data (that is data that is only known by a study code number) will be shared with the study sponsor, Oui, Therapeutics. Oui, Therapeutics will also obtain information directly from the app about app use including the number of log ins and number of modules completed.

Records of your participation in this study will be held confidential to the extent permitted by the applicable laws and regulations, and consistent with the Health Insurance Portability and Accountability Act ("HIPAA") Authorization that you will be asked to sign.

The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA), as well as governmental agencies in other countries where

the study product may be considered for approval and the Ethics Committee/Institutional Review Board (IRB) will be able to inspect and copy confidential study specific records which identify you/your child by name. Therefore, absolute confidentiality cannot be guaranteed.

If the results of this study are published or presented at meetings, you will not be identified. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission. The results of this research project may be presented at meetings or in publications; however, your child will not be identified in these presentations and/ or publications.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can look up this study at any time using the following NCT number: NCT04896593.

Contact Preferences

While we will make every effort to protect your privacy, we also realize the importance of being able to contact you about your participation in this research study. This can sometimes mean exchanging information by phone, text, or email. We'd like you to tell us what way is best for reaching you and what information is permitted to be exchanged. We will also be requesting contact information for family members or friends who may be able to contact you or provide us with your contact information in the event that we are not able to reach you by the methods you provide below. Because this study involves getting in touch with you multiple times over several months, providing us with your contact information is required for study participation. Providing contact information for your family or friends in case we cannot reach you directly is requested, but is not required to participate in the study.

Please indicate below your preferred method(s) to be contacted **by initialing next to all that apply**:
Can we contact you by:

Home phone (if you do not have a home phone please initial "No"

_____ No (initial) _____Yes (_____) _____-_____ (initial)

Is it ok to leave voice mail appointment reminders on your home phone?

_____ No (initial) _____Yes (initial)

Cell Phone

_____ No (initial) _____Yes (_____) _____-_____ (initial)

Is it ok to leave voice mail appointment reminders on your cell phone?

_____ No _____Yes

(initial) (initial)

Is it ok to send text messages about your/your child's study participation to your cell? We do not reimburse for standard texting/messaging fees that may occur.

_____ No _____Yes
(initial) (initial)

Email

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- To contact you to schedule or remind you about the study assessment phone calls as part of your/your child's research participation.
- Other information related to this research project.

Only the research team will have access to your email communications. We will only communicate by encrypted email from a work e-mail account to send you the information listed above.This email account is accessible to the research staff and is typically checked daily. E-mail should be used for routine, non-emergency communications only. In cases where you or your child is in crisis and requires emergency services call 911 or go to your nearest emergency room.

Risks: You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address.
- To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study, make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your appointment reminders and protected health information via email?

_____ No _____Yes
(initial) (initial)

Participant email address (please print and use all capital letters):

_____

You can withdraw permission at any time. Please contact the research staff if you change your mind or if your contact information changes.

David Tolin, Ph.D.
200 Retreat Ave
Hartford, CT 06106
Phone: 860-545-7685

You will receive a copy of this document to keep. By signing below, it means you have read this document. By initialing, you are giving the research staff permission to contact you through the approved method.

_____

Participant's Signature **Printed Name** **Date**

I. What happens if your child is injured as a direct result of your participation in this research project?

In the event that your child is injured as a direct result of taking part in this research, your child will receive help in the following way:

If your child has medical insurance, Hartford Hospital will collect fees for medical treatment at Hartford Hospital from their insurance company. If they are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford Hospital will cover these expenses.

There is no plan for Hartford Hospital to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

J. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, and acknowledge that you have the independent legal authority to voluntarily agree for your child to participate in this research, **Mobile Technology for Reducing and Preventing Adolescent Suicide**, and that you consent to the performance of the procedures listed above.

_____

Name of Child

_____

Parent or Guardian's Signature (circle whether parent or guardian) Date

_____

Parent or Guardian's Printed Name

_____

Person Obtaining Participant's Signature Printed name Date

_____

Witness signature *Printed name* *Date*

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

Hartford HealthCare

Children's Assent for Research Participation

Title of Study: **Mobile Technology for Reducing and Preventing Adolescent Suicide**

Principal Investigator: David Tolin, Ph.D.
Anxiety Disorders Center, Institute of Living
Research Site Address: 200 Retreat Avenue
Hartford, CT 06106
Telephone: (860) 545-7685

These are some things we want you to know about research studies:
Research studies include only those people who want to be in the study. You are being asked to take part in this study because you are receiving treatment and you have expressed suicidal symptoms at some point in the past.

Your parent/guardian needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent/guardian gives their permission. You don't have to receive treatment in order to participate in this study, and you don't have to participate in this study in order to receive treatment.

When your study doctor or a study staff member talks with you about this form, please ask that person to explain any words or information that you do not clearly understand.

Why is this study being done?
The purpose of this study is to get feedback from users of an app designed to help prevent suicidal behaviors in order to learn ways that we can improve the app. Another purpose of this study is to learn how well the app helps to prevent suicidal behaviors.

This is what will happen if you are in the study - what you will be asked to do:
If you agree to be in this study, you will be asked to sign this form and your parent/guardian will be asked to sign a separate permission form agreeing to let you be in this study.

After the forms have been signed, you will meet with a member of our staff. The staff member will ask you some questions about your health and suicidal feelings and behaviors. You will also meet with a study clinician who will help you to download the app onto your phone and show you how it works. As long as COVID-19 safety procedures are in place, you will be asked to wear a mask during all in-person study meetings. If you decide not to wear a mask for the entire duration of all in-person sessions, you will not be able to take part in this study.

[redacted]

[redacted]. Your parent or guardian will also complete an interview with the study clinician to learn more about what other treatments you have received. You will have access to the app for the time that you are participating in this study.

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

How long will I be in this study?

[redacted]

Will the study hurt me?

The most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. Study meetings will involve discussions of difficult topics. Using the app will involve thinking about difficult topics. The researchers will keep your information private to the extent possible, but complete protection cannot be guaranteed.

New findings

If the study doctor finds out important things that might change your mind about being in this study, you will be given information about it as soon as possible.

Will the study help me?

There may be no direct benefit to you for participating in this research study. You will receive a mobile app for suicide prevention in addition to treatment as usual, although there is no guarantee that you will feel the mobile app helped you.

Will I get any money or gifts for being in this research study?

[redacted]

How will my privacy be protected?

- Study records will be locked up so only those who work on the study can get them in order to do their study duties. It is possible that agencies responsible for overseeing the research will look at records in the future. These agencies may include the Hartford HealthCare

Drug Administration, or governmental agencies in other countries where the study product may be considered for approval.

- When data are shared or if the results of this study are made public, no one will know that you were in the study. You will only be known by a secret number.
- You will be able to share your e-mail address to use with the app if you choose to do so. Sharing your e-mail address will allow you to manage your password on your own. If you chose not to use your personal e-mail address you can contact the study staff for assistance with managing your password. Please be sure to discuss this decision with your parent or guardian if you have any questions or concerns.
- By signing this form you are saying it is ok for the study clinician to speak with your parent/guardian and with the mental health provider you work with after you leave the hospital. This is necessary so that we can let them know if we have concerns about your safety so that they can take steps to support you and keep you safe.

You will be given a copy of this form.

You may ask questions about this study at any time.
You can decide not to be in this study, or after entering the study you can decide that you want to be taken out of it. You can talk this over with your parents or guardian before you decide.

For questions about the study or if you have complaints, concerns or suggestions about the study, contact Dr. Tolin at (860) 545-7685.

Signature of Child	Date
Signature of Person Obtaining Assent	Date