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Wake Forest School of Medicine

Department of Family and Community Medicine

PARENT SUPPORT AND RESOURCE PROGRAM

Informed Consent Form to Participate in Research, Parent

Stephanie Daniel, Ph.D., Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to give educational information and support to parents/legal guardians (referred to in this document as "parents") after their adolescent is discharged from the hospital, and to see if this education and support is helpful to them. You are invited to be in this study because you are the parent of an adolescent who is currently hospitalized for suicidal thoughts and past or current suicidal behavior.

Participation in this study will involve adolescents completing a questionnaire before discharge about their thoughts, feelings, and behaviors. Study staff will randomly divide parents into **two groups**. Prior to discharge, we will give **Group 1** information about teenagers discharged from the hospital after suicidal thoughts or behavior, but we will give no more information or support after that.

Prior to discharge, we will give **Group 2** information about teenagers discharged from the hospital after suicidal thoughts or behavior. This information as well as additional support will continue for 3 months after discharge. We will send text messages with educational information about what to expect after discharge and how they can best support their adolescent. We will also call these parents on the phone once each week to provide support to them and help them solve any problems they have or help them connect to treatment. Parents in this group can also call or text us if needed.

In addition, we will interview parents in **both groups** three times over the next six months. Parents will be asked how they are doing, how their adolescent is doing, and how treatment is going. We will not be interviewing your adolescent or other family members, only you.

All research studies involve some risks. A risk to this study that you should be aware of is that your private information might be seen by people who do not have permission to see it. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include not participating in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Stephanie Daniel, Ph.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is: [redacted] or [redacted] .

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted] .

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are the parent/legal guardian (referred to in this document as "parent") of an adolescent who is currently hospitalized for suicidal thoughts and past or current suicidal behavior. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to give educational information and support to parents after their adolescent is discharged from the hospital, and to see if this education and support is helpful to them. This research will help us improve our ability to meet the needs of families in the future when there is a family member who is hospitalized due to suicidal thoughts or behavior.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 50 parents whose adolescents are hospitalized at Wake Forest Baptist Medical Center will participate in this study, as well as the 50 hospitalized adolescents.

WHAT IS INVOLVED IN THE STUDY?

Study staff will ask adolescents to complete a questionnaire before discharge about their thoughts, feelings, and behaviors. This will take 10-20 minutes. After that, adolescents will have no direct involvement in the study.

Parents will be randomly divided (50/50 chance) into **two groups**. Prior to discharge, we will give **Group 1** information about teenagers discharged from the hospital after suicidal thoughts or behavior, but we will give no more information or support after that.

Prior to discharge, we will give **Group 2** information about teenagers discharged from the hospital after suicidal thoughts or behavior. This information as well as additional support will continue for three months after discharge. We will send text messages with educational information about what to expect after discharge and how they can best support their adolescent. Text messages sent to parents will include weblinks to additional resources. In addition, parents can text keywords (for example, "coping" or "worried") to us to access specific information of interest. We will also send a few "polls" inviting your responses. Most of these text messages are automated and not from project staff.

We will schedule brief phone calls (generally 10-30 minutes) with parents in **Group 2** once each week to provide support to them and help them solve any problems they have or help them connect to treatment. Parents can also call or text us during business hours if needed.

In addition, we will interview parents in **both groups** three times over the next six months: before or immediately after discharge, three months after discharge, and six months after

discharge. The interviews will include assessment questionnaires that most parents will be able to complete in 1-2 hours. The first interview will occur in person, and parents can complete the questionnaires using an iPad (although if necessary the interview can occur by phone). The 3- and 6-month interviews will occur by phone, and parents can complete the questionnaires online. Parents will be asked how they are doing, how their adolescent is doing, and how treatment is going. We will not be interviewing your adolescent or other family members, only you. At the six month interview, study staff will conduct an exit interview with you (typically less than 30 minutes) to find out which parts of the program were helpful.

This study is meant to add to the usual treatment that your adolescent or family will receive from mental health providers in the community, not take the place of it. As such, we will encourage you to follow through with any mental health treatment recommendations made by the Wake Forest Baptist Medical Center staff. With your or your adolescent's signed authorization, we will coordinate with your adolescent's mental health provider(s) and request treatment records.

We will audio-record the phone calls that we make to parents in **Group 2** and during the exit interviews for **both groups**. This is being done to put parents' words to paper, make sure that we are giving support in the right way, and to find out whether the study was helpful to them. You understand that you may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audio recording before it is used. You should also understand that you will not be able to inspect, review, or approve the audio recordings before they are used in this study.

Please choose one of the following regarding the use and disclosure of the audio recordings used in this research study:

_____ I would like the audio recordings of me to be destroyed once their use in this study is finished.

____ The audio recordings of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an Institutional Review Board (IRB), a group of people who review the research to protect my rights. I understand that I will not be able to inspect, review or approve their future use.

Parents in **both groups** will be asked for the names and contact information of three people who would know how to contact them. These people are contacted only if you move, change phone numbers, or lose contact with this study. If we contact one of these people, all that we will tell them is that you are in a study at Wake Forest Baptist Medical Center about support for parents.

How Long Will I Be in the Study?

You will be in the study up to approximately six months after your adolescent is discharged from the hospital. Parents in **Group 2** can stop receiving text messages at any time by texting the keyword *STOP*, or parents in **either group** can stop participating at any time.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects include:

The primary risk in this study is the discomfort that parents may feel in talking about their emotional well-being or the suicidal thoughts or behavior or other emotional or behavioral problems of their children. Potential risks also include that parents may not benefit from the study, or may have worsened distress after discharge despite the study. The frequency of these risks is considered *uncommon*. All research staff in this study are master's or doctoral level mental health professionals who have training in working with individuals who may be distressed or have mental health needs.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about your emotional well-being and your adolescent's suicidal thoughts or behavior or other emotional or behavioral problems. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities. For example, this may include learning that you or your adolescent is in serious danger of hurting oneself or someone else, or that a youth is a victim of unreported physical or sexual abuse, as defined by the statutes of North Carolina.

Other people who have access to your phone could see the texts that you receive as part of this study (if you are in **Group 2**). We recommend that you use phone security measures such as screen patterns, numeric PINs, or passwords to lock your screen from others if you wish to keep your participation in this study private.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. The benefits of participating in this study may be receiving support and educational information about at-risk teenagers after your adolescent is discharged from the hospital. This may lead to decreased distress and an increased sense of effectiveness as a parent. We hope the information learned from this study will also benefit other parents and hospitalized teenagers in the future.

What Other Choices Are There?

Instead of being in this study, you have the option of not participating in this study. Whether you choose to participate in this study or not, you will still receive treatment as usual (TAU). TAU

typically involves a discharge planning session by hospital staff with you and your adolescent to discuss safety monitoring and referrals for mental health services following discharge. The primary risk of TAU is the discomfort that parents or adolescents may feel in talking about their emotional well-being or the suicidal thoughts or behavior or other emotional or behavioral problems of their children. Potential risks also include that the parent(s) or adolescent may not benefit from TAU, or may have worsened distress after TAU. The primary benefit of TAU is that it may help you to improve your adolescent's safety and to arrange mental health treatment for your adolescent after discharge.

WHAT ARE THE COSTS?

All study costs will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required.

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 National Institutes of Health (which is funding this project) that is needed for auditing or program evaluation. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of imminent risk of harm to self, imminent risk of harm to someone else, or previously unreported child abuse.

Audio recordings will be stored on our password-protected, secure computer network. Audio recordings will be identified by a participant code number rather than name. The audio recordings will be kept for ten years after the study is finished. At that time, your research information will either be destroyed or de-identified.

By agreeing to participate in this study, you give study staff permission to share your name, phone number, and email address (if you are in **Group 2**) with a mobile phone application ("app") called **iPlum**. This information is required for iPlum to create a second, deidentified phone number for you (this number will work on your current cell phone). We will share this second phone number with **TextIt**, a commercial texting service that will send automated text messages to you and will automatically respond to you when you text keywords. We are using this 2-step method because iPlum will provide greater protection for your information. By using the iPlum number, TextIt will not see your personal phone number. iPlum has guaranteed to protect your information according to the Health Insurance Portability and Accountability Act (HIPAA). All texts through iPlum will be encrypted, which is more secure than standard texts. Study staff will also communicate with you by phone and text through the iPlum app.

By agreeing to participate in this study, you agree to download and install the iPlum app to your cell phone and give the app permission to send you notifications. Your phone may require a password to download an app. The app will ask for permission to access your microphone (for phone calls) and contact list. The permissions for access to your microphone and contact list are optional, and the app will work without these permissions. Study staff can assist you in setting up iPlum on your phone, if you prefer. Once your study participation has finished, you can delete the iPlum app from your phone.

All texts from TextIt will come from one phone number, and texts and phone calls from study staff will come from other phone numbers. You will be given a wallet card showing you these numbers. You agree to text only keywords and individual question responses to the TextIt number, not any other information. All other texts should go to study staff only, not TextIt.

Over the course of the study, we will review the frequency and types of phone calls and texts from parents to study staff so that we can summarize the concerns of parents. We will also record the responses from parents to individual questions that we text, keyword requests that parents text to the study's electronic application, and weblink clicks. This is done so that we can understand which aspects of the study are most helpful. Weblink clicks will be tracked by an app called **short.cm**, which has guaranteed to protect your information according to HIPAA laws.

As mentioned above, the three interviews with study staff (before discharge, three months after discharge, and six months after discharge) will include assessment questionnaires. Some of these interviews will occur by phone, with parents completing the questionnaires online. For these phone interviews, links to the online questionnaires will be sent to participants using email or iPlum text messaging. These online questionnaires will be sent from a secure web application called **REDCap** (short for "Research Electronic Data Capture"). Wake Forest School of Medicine (WFSM) stores REDCap data on WFSM servers and is required to keep your

information confidential.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

Will You Be Paid for Participating?

You will receive an electronic or paper version of a $30 gift card to a major retailer (such as Walmart) after completion of each of three interviews, for a total of $90.

Who is Sponsoring this Study?

This study is being sponsored by the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the program being studied.

What Happens if You Experience an Injury or Illness as a Result of Participating in this Study?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy

the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Stephanie Daniel, Ph.D., at [redacted] or [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we collect from you and/or information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: name of you and your adolescent, parental contact information, adolescent discharge date from psychiatric hospitalization, IP addresses of devices that access study weblinks, and audio recordings.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor (National Institutes of Health); representatives of the sponsor assisting with the research; investigators at other sites (e.g., Duke University) who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If

disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there is recorded media which is identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least ten years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Stephanie Daniel, Principal Investigator, that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Stephanie Daniel, Ph.D.
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required

by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled, and will not affect your present or future care at any of the participating universities or hospitals including Wake Forest Baptist Medical Center. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first. The investigators also have the right to stop your participation in the study at any time. This could be because you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Stephanie Daniel, at [redacted] or [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Wake Forest Baptist Health *Notice of Privacy Practices*, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____

Date: _____ Time:_____ am pm

Subject cell phone # or email to be used for this study: _____

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____

Date: _____ Time:_____ am pm