UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Developing text-based support for parents of adolescents after an emergency department visit (TESP)

Company or agency sponsoring the study: National Institute of Mental Health (NIMH)

Principal Investigator: Ewa Czyz, Ph.D., Department of Psychiatry, University of Michigan

1.1 Key Study Information

You, and/or your child, may be eligible to take part in a research study. Parents, caregivers or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' may refer to 'your child.' This form contains information that will help you decide whether to join the study. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

This research is studying how to support families of adolescents who visit the emergency department (ED) with a mental health, behavioral, or emotional concern. We hope to learn if a supportive text messaging program can benefit parents or caregivers who care for adolescents after ED discharge. From this study, we also hope to learn how to better carry out the text messaging program and how to improve services for families after ED discharge.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include being bored, tired, or upset with the surveys. More information will be provided later in this document.

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

You can decide not to be in this study. Your choice to not join the study will not change your current treatment plan or providers.

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: We are conducting a research study to learn if a new supportive text messaging program can benefit parents/caregivers who care for adolescents who sought ED services for a mental health, behavioral, or emotional concern. It has been designed to supplement or "go with" usual services recommended by ED providers after discharge. From this study, we hope to learn how to better carry out the program and how to improve services for families after ED discharge.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. Your choice will not affect the services you receive in this hospital in any way.

3.1 Who can take part in this study?

Adolescents (ages 13-17) who received services from University of Michigan's Psychiatric Emergency Services (PES) due to a mental health/behavioral/emotional concern and their parents/caregivers. In addition, parents/guardians who have a smartphone are eligible to participate.

3.2 How many people are expected to take part in this study?

We plan to enroll up to 150 parents/caregivers and their adolescents who received PES services.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Parent/caregiver:

At study enrollment

You will be asked to complete a survey asking questions about your thoughts, feelings, mood, and behaviors. We will also ask questions about your child's behaviors. The survey will take approximately 20 minutes.

After study enrollment

You will be asked to complete 2 brief (~1-2 minutes) surveys each day for 6 weeks. An online link to the brief survey will be sent to your phone in a text message. In addition, you will be asked to complete two online surveys (~10-15 minutes) sent to you by email or by text message approximately 2 and 6 weeks after enrollment. Finally, we will contact you by telephone approximately 12 weeks after enrollment to complete the last survey (~15 minutes). The surveys are asking questions about your mood, thoughts, providing support to your teen, and your teen's use of any services. We will also ask for your feedback about your experience in the study.

Some parents/caregivers may be randomly selected (similar to flipping a coin) to take part in additional activities

You may be selected to receive 1-3 support text messages per day for 6 weeks after study enrollment. These text messages will include tips and recommendations for caring for adolescents after ED discharge, and may also include tips for parents'/caregivers' own self-care and well-being. Parents/caregivers who are randomly selected to receive these messages will have the option to request stopping the messages at any time if they wish.

Teen:

At study enrollment

You will be asked to complete a survey asking questions about your thoughts, feelings, mood, and behaviors. The survey will take approximately 20 minutes.

After study enrollment

You will be asked to fill out a total of 3 follow-up surveys. First, you will be asked to complete two online surveys (~10 minutes) sent to you by email or by text message approximately 2 and 6 weeks after enrollment. Finally, we will contact you by telephone approximately 12 weeks after enrollment to complete the last survey (~15-20 minutes). The surveys are asking questions about your thoughts, behaviors, and your use of coping strategies.

4.2 How much of my time will be needed to take part in this study?

Parent/caregiver:

You will be asked to fill out an initial survey taking approximately 20 minutes. You will also be asked to fill out two daily surveys for six weeks, each taking 1-2 minutes. Finally, you will be asked to complete a total of 3 follow-up surveys: two online (10-15 minutes each) and one by phone (15 minutes).

Teen:

You will be asked to fill out an initial survey taking approximately 20 minutes. You will also be asked to complete a total of 3 follow-up surveys: two online (10 minutes each) and one by phone (15-20 minutes).

4.3 When will my participation in the study be over?

As described above, we will contact you approximately 12 weeks after study enrollment to complete the last survey, and your participation will be over at that point. In order to do this, we will keep your contact information on file. Your contact information will be maintained by the study team and stored in a password protected data file. It will only be available to the research staff of this study.

4.4 What will happen with my information used in this study?

Your collected information may be shared with the National Institute of Mental Health, the study sponsor. With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

You may get bored, tired, or upset with the survey questions. To help minimize these risks, you may take a break or skip any questions that you do not want to answer. You can also stop participation at any time. There may also be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
Please let the research staff know of any problems you (or your child) have during the study. Please also seek medical attention if necessary at any point during the study**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, your participation may help us improve our understanding of services and programs for families and teens who seek emergency department services for a mental health, emotional, behavior, or related concerns.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Your participation in this study is completely voluntary. Your choice will not affect the services you receive in this hospital in any way. If you decide not to participate in this study, this decision will not change your current treatment plan or treatment providers.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty or harm to you, and you will not lose any benefits to which you are otherwise entitled.
If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, you may inform one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no potential harm to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Parent/caregiver:
You may receive **up to $248** as a thank you for your time and participation in this study.

You will receive $10 for completing the initial survey, $20 for completing each of the two online surveys at 2 and 6 weeks after enrollment, and $30 for completing the last survey over the phone at 12 weeks. You will also receive up to $168 for completing the brief daily surveys for 6 weeks, depending on how many surveys you decide to complete ($2 for completing each survey x 2 surveys per day x 42 days). Compensation will be distributed after each study activity is completed.

Teen:
You may receive **up to $70** as a thank you for your time and participation in this study.

You will receive $10 for completing the initial survey, $15 for completing each of the two online surveys at 2 and 6 weeks after enrollment, and $30 for completing the last survey over the phone at 12 weeks. Compensation will be distributed after each study activity is completed.

8.3 Who could profit or financially benefit from the study results?
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
To keep your information confidential, your research information will not be made a part of your regular medical record. Your research information will be stored in a locked cabinet in a secure University of Michigan facility and using secure electronic records that will be password-protected. Research data (responses to questionnaires/surveys) will be labeled only with a study ID, not your name. Research records will be kept in separate research files that do not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The surveys are designed and administered using the Qualtrics Research Suite. Qualtrics is the preferred online survey tool of the University of Michigan Health System. For more information, Qualtrics security and privacy statements can be found at www.qualtrics.com/security-statement and www.qualtrics.com/privacy-statement.

To maintain your privacy, your answers to the surveys will be kept confidential. It is important to understand that research staff are obligated to share information, as necessary, to protect individuals from serious harm. If you tell us that you or others may be at risk for serious harm, we might provide you with resources and/or might have to take steps to get help. Getting help can include notifying parents/caregivers, doctors, or appropriate authorities. 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, documents, or biospecimens 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, documents, or biospecimens 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 National Institute of Mental Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 child abuse and neglect, or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you and/or your child for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about your child may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- All records relating to your child's condition, the treatment they have received, and their response to the treatment
- Demographic information

- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.
- If you tell us or we learn something that makes us believe that you or other have been or may be physically harmed, we may be required to report that information to the appropriate agencies.

The results of this study could be published in an article or presented at a conference but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.
Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed below. If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Ewa Czyz, Ph.D. Mailing Address: 4250 Plymouth Rd., Ann Arbor, MI, 48109 Email: ewac@umich.edu	Study Coordinator: Amanda Jiang Mailing Address: 4250 Plymouth Rd., Ann Arbor, MI 48109 Email: amji@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your selection in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with the research team. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed above. I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-A

Assent (13-17 years old) to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with the research team. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed above. I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name (Adolescent): _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-E

Legally Authorized Representative or Parent Permission

Subject Name (Adolescent's Name): _____

Parent/Legally Authorized Representative:

Printed Legal Name: _____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data.

_____ Yes, I agree to let the study team keep my data for future research.

_____ No, I do not agree to let the study team keep my data for future research.

Print Legal Name (Parent): _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Acceptable method of contact for participant:

Parent/guardian
phone #: _____ (home / work / cell)
phone #: _____ (home / work / cell)
e-mail address: _____
mailing address: _____
_____

Adolescent
phone #: _____ (home / work / cell)
e-mail address: _____
mailing address (if different): _____
_____

(Optional) Please name up to two personal contacts whom we have permission to contact should we lose touch with you throughout the time you are participating in the study.

Name: _____ Relationship to participant: _____

Phone #: _____ Email address: _____

Name: _____ Relationship to participant: _____

Phone #: _____ Email address: _____