

Consent to Participate in Research

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Title of Research Study: Technology-Enabled Prevention Services for At-Risk Youth

Principal Investigator: [REDACTED]

Supported By: This research is supported by Northwestern University and the National Institute of Mental Health.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- This study is part of a series of studies aimed at designing a smartphone application (app) to help adolescents understand and deal more effectively with stress and anxiety.
- The purpose of this study is to learn more about teen stress and anxiety and how they deal with that stress and anxiety.
- You will be asked to complete two design exercises with a member of the research staff.
- We expect that each session will take about 75 minutes.
- Your participation does not involve any significant risks. You may feel emotional discomfort talking about stress and anxiety.
- You are not likely to have any direct benefit from being in this research study. One potential benefit is that the knowledge gained from this study may help the design of resources to help adolescents with stress and anxiety.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are a teen that visits the [REDACTED] Public Library.

How many people will be in this study?

We expect about 10 people will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- You do not have to be in this study if you do not want to.
- It is up to you if you want to participate.
- You can choose not to take part and change your mind later if you want.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

What happens if I say, “Yes, I want to be in this research”?

If you agree to join this study, you will participate in two design sessions with a member of the research staff. The design sessions will be guided activities, where the interviewer will lead you through a pen-and-paper exercise and an exercise using a smartphone.

You will be asked to complete these sessions in person at the [REDACTED] Public Library. We will ask to video record the session as a requirement of your participation. These recordings will allow researchers to go back and review the sessions and information to inform the development of the technology.

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Is there any way being in this study could be bad for me?

There is nothing bad that will happen to you, although you may feel uncomfortable with some of the questions I ask about emotions, like stress and anxiety. You can skip any questions you do not want to answer and you can stop at any time.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can choose to participate or not to participate. If you do not want to be in this study or leave the study at any point, your decision will not affect your relationship with Northwestern University or the [REDACTED] Public Library. You may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. In other words, you can leave the research at any time and it will not be held against you. Your permission of the use of your information will never expire unless you change your mind. Even if you end your permission, the researcher may use your personal information that was collected prior to you stopping permission.

How will the researchers protect my information?

If you choose to be a part of the study, all of your responses will be kept private. That means that your personal information, like your name and email, will be removed from the information you share in the design exercises. We call this de-identifying the data because your file will only have your answers from the design exercises and not any of your personal information. We will take your de-identified answers and combine them with other teens' answers who also took part in the design exercises. Once all those answers are together, we are able to analyze the data, this can include looking to see how the answers are the same and how they are different. This bigger file with all the answers from the teens who took part in the study may be shared with our study sponsor. Recordings of sessions will be deleted once analyzed and/or transcribed; transcribing is where the words from the audio recordings are made into readable text and saved in an electronic file. You will have the choice to be a part of activities where we share the results of the study, such as presentations at conferences.

The servers where the data will be stored are controlled and monitored by the NUIT Research Data Center. The data center has *controlled access, and the server is on secure data networks behind managed firewalls. The server is also monitored for service interruptions. Only people who are on NU networks can log in and look at the data, and it is encrypted so that only the staff on our team have access to the data.* Study records that can identify you are kept private through use of a number we assign to each participant. All information will be kept on a password protected computer that can only be used by the research team.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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.

Identifiable information that could still be disclosed beyond the research team: 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

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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.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.
- Collaborating researchers at other institutions who are involved with this study.
- The research team may give information to appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to hurt yourself or others, or for public health reasons.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research project for study recordkeeping and potential use in future research projects. Identifiers will be removed from your identifiable private information and could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee anonymity of your personal data. The results of this study could be shared in articles and presentations, but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations, only as applicable.

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

If you agree to take part in this research study, we will pay you \$25 for your time and effort in each session (\$50 total). You will be paid at the end of the session, and you will be paid in cash. The study number for this project is: [REDACTED]

Here is who you can talk to:

If you have questions, concerns, or complaints, you can talk to the Principal Investigator, [REDACTED]
[REDACTED] This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

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- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your permission to participate in these optional activities by verbally saying “I agree” or “I disagree” for each activity:

I agree I disagree

_____ _____
 The researcher may use audio or video recordings from this study in scholarly presentations or publications when showing your face or your voice might serve to help other professionals understand the research. I may be identifiable as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

_____ _____
 The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

Signature for Adult 18 or older:

Your signature documents your permission to take part in this research.

 Signature of participant Date/Time

 Printed name of participant

 Signature of person obtaining assent Date/Time

 Printed name of person obtaining assent