Consent to Participate in Research

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 developing a smartphone application (app) to help adolescents understand and deal more effeictively with stress and anxiety.
- The purpose of this study is to evaluate the usability of a digital coaching dashboard connected to the teen smartphone app for anxiety and stress currently under development.
- You will be asked to complete an interview with a member of the research staff, complete tasks on the digital coaching dashboard, and answer questionnaires about your experience using the app.
- We expect that the session will take about 60 mintues.
- 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 inform 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 work with youth at 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.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- 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"?

You will participate in a semi-structured interview with a member of the research staff in which you will review the coaching dashboard connected to the app currently under development and complete tasks using the dashboard. After completing tasks, you will be asked about your perceptions of an experience with the dashboard.

Consent to Participate in Research

You will be asked to complete this interview in person at the [redacted] Public Library. We will ask to video record the session as a requirement of your participation so that the study team may later transcribe the session. These recordings will allow researchers to go back and review the sessions and information to inform the development of the technology.

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

Your participation does not involve any significant risks. You may feel emotional discomfort talking about helping youth manage mental health. If you find any questions to be distressing, you do not have to answer and have the option of stopping.

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 decide 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 can leave the research at any time and it will not be held against you. Your authorization 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 decide to participate, all of your responses will be kept confidential. All identifying information will be removed from the data collected, which will include qualitative data and survey responses. A de-identified data file will be prepared from the survey data of all respondents and used for analysis and may be shared with the study sponsor. Recordings of usability testing sessions will be deleted once analyzed and/or transcribed and transcription texts will be deidentified. No names, addresses, or other identifying information will be recorded in this data file. For reporting purposes, your answers will be combined with the answers from the other respondents and will appear only as aggregated information. Participants will have the opportunity to engage in dissemination activities at their discretion.

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. Access to the data is only allowed from NU networks and is encrypted so that only the staff on our team have access to the data.

Study records that can identify you are kept confidential through use of a participant identification number. All information will be kept on a password protected computer only accessible 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 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 harm 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. 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. 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] 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:

- Your questions, concerns, or complaints are not being answered by the research team.

Consent to Participate in Research

- 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 willingness to participate in these optional activities by placing your initials next to 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

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent