CONSENT TO PARTICIPATE IN RESEARCH STUDY & HIPAA AUTHORIZATION

TECH-E Study Consent/Assent & HIPAA Authorization Form

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STUDY INFORMATION

The present study is called **Technology and Emotions or TECH-E**.

SOURCE OF SUPPORT: National Institutes of Mental Health
NuRelm, a small technology company, is assisting in the development of technologies and analysis for the study. NuRelm will have access to identifiable data to help with any tech problems users may face and to manage the application.

This document is written for both the parent/guardian of an adolescent who has symptoms of depression. Whenever the word “you” or “your” is used, it is referring to the adolescent. Parent also refers to legal guardian.

KEY INFORMATION

We are looking for teens and parents to participate in a 6-month research study. This study only includes subjects that choose to participate.

- The purpose of the study is to determine if an application on a mobile device can help adolescents manage mood symptoms.
- This study may involve downloading applications to the adolescent’s phone. The applications will collect non-sensitive cellphone data and store it on a secure cloud server. Teens will be required to have a cellphone and a data plan to participate in the research study.
- Adolescents will be asked to take weekly surveys. Parents will also take 3 surveys.
- Some infrequent risks involve breach of confidentiality.
- There are no direct benefits to participating in this study. However, participating in this study will allow researchers to understand if the application is helpful for adolescents to manage their mood.
- If you are interested, please read further to learn more about the study.

- ***Introduction***

You are being asked to participate in a research study for adolescents who have symptoms of depression and their parents. Research helps us learn new information and helps us to improve the way we deliver healthcare. Please read through the information provided. Ask any questions you might have before consenting/assenting to be a participant in the study. **Taking part in this study is voluntary**. You may choose to not participate or to leave the study at any time. Your decision to leave the study will not result in any penalty or loss of benefits to which you are entitled.

Who is conducting the study?

The study is led by Dr. Ana Radovic, a physician at the Center for Adolescent and Young Adult Health (CAYAH) and a researcher in the field of adolescent mental health. Whether or not you decide to participate in the study will not affect the care that you receive from any UPMC facility, including care from Dr. Radovic if she is a doctor that you see. The primary coordinator for the study is Kayla Odenthal. You may contact Dr. Radovic or Kayla at any time with any questions about the study at sovalab@pitt.edu Contact Information:

Why is this study being done?

The goal of the study is to understand whether patterns of smartphone use are related to symptoms of depression and how another app called MoodRing affects your symptoms. We want to see if technology can help adolescents manage their mental health. Adolescents and parents are being asked to participate because the adolescents have symptoms of depression. Your therapist may also be recruited to participate. See page 3 for the details about that. The app is not approved by the Food and Drug Administration.

How many people will take part?

We are looking for 200 adolescent and parent pairs to participate in this study.

How long will the study last?

24 weeks, which is 6 months

What will happen during the study?

First, each adolescent and their parent/guardian will get a separate link to an online survey which should take around 30 minutes to complete..

The surveys will ask questions about:

1. Demographics, such as name, age, address, race
2. Socio-economic background, which is measures of income, education, occupation
3. Mental health history
4. Mood, well-being, mental health services use
5. Social support
6. Smartphone and internet use
7. Medications

Once both the adolescent and parent have completed this first survey, we will use a computer program to assign each pair to one of two study groups. This computer program will decide which study group the adolescent and parent pair is in. This assignment is by chance, kind of like picking a number from a hat.

In group 1, adolescents will be asked to download two mobile applications, and in group 2, adolescents will be asked to download just one of the mobile applications. Otherwise, everything else will be the same. Everyone should continue to get the routine healthcare they otherwise would be getting, as these applications are not mental health treatment.
Every adolescent will be asked to download a smartphone application called AWARE which runs in the background of their phone. Once you download it, you won't need to open it again except to just make sure that it is running. You will be asked to leave the application on and running in the background at all times. The AWARE smartphone application will passively collect data on smartphone usage.

In group 1, adolescents and parents will receive instructions on how to download a second smartphone mobile application called MoodRing. This app allows the adolescent to enter information about your symptoms and treatment. If you are in group 1 and your clinician was how you were recruited to be in this study, they will also have access to a clinician dashboard website. They will be able to see data collected from the app you use.
For example, the clinician will be able to see what your mood is and how it is changing, how you are sleeping, your activity level, and whether you are using coping strategies. You can also tell us about a clinician you are seeing who you would like to be involved in the study and see your research data. Clinicians are involved in the study only if you are randomly selected to be in group 1.

We will help you set up one or both of the applications and help troubleshoot any technological difficulties you may experience throughout the study.

All adolescent participants will take a very brief weekly online survey. It takes about 3 minutes to complete. This survey will ask about current depression symptoms and will not ask if you have feelings of suicide.

All adolescents and parents will also be asked to take a longer 20-30 minute survey at 3 months and at 6 months. All surveys will be conducted online, with links provided via text message and email.

Longer surveys will ask about:

- demographics, like name, address, birthdate, race
- mental health history,
- adolescent internet and social media use
- use of healthcare
- treatment sought for mental health
- belief in yourself to seek out healthcar

- social support
- symptoms of anxiety and depression
- sleep quality, and how sleep affects you on school days
- your relationship with your parents
- acceptability of the app.

The longer surveys at baseline, 3 months, and 6 months will ask questions about suicidality. If an adolescent endorses suicidality, this information will not be kept confidential from the parent/guardian or the adolescent's clinician. The research team will contact the adolescent to perform a risk assessment and the parent/guardian and clinician will also be notified. We will collect contact information for an emergency contact during the initial survey; this individual will be contacted only if the adolescent and/or parent cannot be reached to perform a safety assessment.

It is important to note that we do not monitor your survey responses in real time. Taking a survey is not a substitute for reaching out directly to your clinician or crisis services in the case of a medical or mental health emergency.

We also ask for parent authorization to access the adolescent's electronic medical records. This will be completed through R3 which is a service of the University of Pittsburgh Department of Biomedical Informatics (DBMI). They regularly work within UPMC only to access clinical data and authorizes additional UPMC data sources for research. If you agree, R3 and our team will access your adolescent's:

- diagnoses
- use of medications
- the course of their mental health treatment.

This information will be used to learn whether our research interventions affect the mental health services an adolescent receives. Our research team may also enter information about the adolescent's imminent safety such as suicidal thoughts with a plan, intent, and/or attempt to the treatment provider. We would only learn of this information during the screening process that you have both already completed, or in the 3 and 6 month surveys.

The parent authorization to allow us to access these medical records will not expire, but may be cancelled at any time. If you choose to cancel this authorization, only information regarding your child's imminent safety will be documented in the child's medical records to the treatment provider. Cancelling authorization does not impact your child's participation in the rest of the study activities. All individuals accessing the electronic medical record data have received the appropriate privacy training to not share your information for any other purpose. Parents and guardians, if you wish to withdraw authorization to use your adolescent's medical records, please submit it in writing to Dr. Radovic.

What information will the application collect? And where will it go?

The application captures data that your phone is already collecting, as anonymously as possible. Examples of the data collected include:

- the noise level around you (but not the content of the noise)
- whether your phone is on or off
- numbers of calls and text messages (but not the content of those calls or text messages)
- information about your location via geocode/GPS (but not specific addresses).
- Other data include activity, phone usage, light levels around the phone, and Bluetooth/Wi-Fi sensors.

The contacts you communicate with, including phone numbers, are encrypted (which means concealing data by converting it into a code) and will remain anonymous.

The data captured will be transferred through a secure connection to:

- an Amazon Web Server
- another researcher we are working with, Dr. Afsaneh Doryab, who is at the University of Virginia (this will occur later on)
- Dr. Radovic's lab at the University of Pittsburgh.

Data will be identified through device ID, but not by your name. The Amazon Web Server does not own your data and cannot access it.

What are the risks of taking part in the study?

We do not expect that you will experience any harm from participating in this study, but there may be some infrequent risks:

Risk:	What we are doing to mitigate this risk:
Breach of confidentiality. This may happen if someone who is not part of the research study obtains private information about you or your child.	1) All survey data is stored on a secure online survey platform called REDCAP and a secure University of Pittsburgh server. 2) We keep your contact information separate from your research data. We may share research data *without any personal identifiers* with other researchers in the future. 3) The data collected from the smartphone device will be tagged with a number and not your personal information, except the location trace which is difficult to figure out. 4) Data collected using the app is uploaded to our servers anytime you have an internet connection, and is not stored on your device once uploaded. 5) We ask that you password protect your smartphone and use a password or PIN to open it. We also ask that you password protect your email. 6) Any communication with us via text message may not be secure. Any private information that you would like to share with us should be done so by phone call rather than text message.

Draining your smartphone battery. Because the app is constantly running, there is a risk that your battery may die more quickly.	The software will monitor your battery strength, and the app will run less if your battery is low. If the battery is very low, the app will pause.
Reduced phone or Wi-Fi network performance and Data usage. The app will add approximately 200 MB of data on top of the data the adolescent typically uses each month.	We recommend that adolescents already have a data plan to participate in the study. You will receive compensation for the study. Also, data will be uploaded over Wi-Fi connection to avoid using too much data.
Feeling upset from some of the survey questions, such as questions about symptoms of depression, anxiety, loneliness, or functioning.	Dr. Radovic and the research team are clinicians with expertise in adolescent depression. If you ever have any questions about symptoms you or your child are experiencing, you may reach out to us at any time. A resource sheet with crisis resources will be provided with this consent form.

What are the benefits of taking part in the study?
The application we are testing may be helpful to adolescents, parents, and clinicians in helping to take care of the mental health of adolescents, but we do not know this, which is why we are doing this study.

Will I be paid for participation?
Both the adolescent and parent will be compensated for participation on a reloadable debit card. Both the adolescent and the parent will receive:

- $20 each for completing the first survey
- $30 each for completing the 3 month survey
- $50 each for completing the 6 month survey.

Adolescents and parents can each receive a potential $100 for participating, or $200 total for both. Participants will only be compensated for completed study measures.
Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a “Form 1099 – Miscellaneous” with the IRS and provide a copy to the taxpayer. We

are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 26% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 74% of the expected payment.

Adolescents and parents will no longer be compensated if they end their participation.

Although we will work to protect your adolescent's privacy as much as possible, if the adolescent or parent discloses, or in the process of data collection we uncover any instances of child abuse/neglect or harm to self or others, by law, we will need to disclose this to state or local authorities for the child's safety.

Certificate of Confidentiality

The official language below might be a bit confusing but in summary, it means that the federal government has given us a special certificate which allows us to refuse to share your research data with legal authorities who may request it, except in special circumstances including if a child is at risk for abuse, neglect, or harm.

The research is currently funded by the National Institute of Mental Health or NIMH. All research under NIMH is protected under a Certificate of Confidentiality due to its sensitive nature. This Certificate means the research team can legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (ex. If there is a court subpoena). The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The certificate cannot be used to resist a demand for information from personnel of the United States Government such as the United States Food and Drug Administration that is used for auditing or evaluation of federally-funded projects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse/neglect or harm to self or others.

IF YOU ARE EXPERIENCING CRISIS

If you feel like you may be at risk for hurting yourself or someone you love, please let someone know. If you have a supportive adult you can trust, let them know. Most counties in the U.S. have a phone number you can call if you are in crisis and the person on the line will help you figure out what to do.

In Pittsburgh, Allegheny County, that number is 1.888.796.8226

If you are NOT in crisis, PUT THIS INFO IN YOUR PHONE JUST IN CASE!
If you live somewhere else, you can call the National Suicide Prevention Lifeline at 1.800.273.8255 and they will connect you with your local crisis center.

Otherwise, you may call 911.

Other resources include:
- Crisischat.org is an online crisis resource from the National Suicide Prevention Lifeline.
- Imalive.org is an online messaging service to help people in crisis.
- Crisis text line: Text "START" to 741-741; this is a texting crisis service.

Sharing data with other researchers or regulatory agencies

Identifiable data may be shared with the National Institutes of Health, UPMC Children's Hospital of Pittsburgh, or the University of Pittsburgh Office of Research Protections and the Food and Drug Administration, all for the purpose of monitoring the conduct of the study. Data that is de-identified, meaning there is no personal information of yours attached to it, may be shared in the future with other researchers. People at the NIH and FDA may look at your private health information to monitor the conduct of the research. They are aware of the need to keep it private, but Pitt cannot guarantee that they will since they are an external organization.

How long are records kept?
Per University of Pittsburgh policy, all research records will be kept for 7 years after final publication of the study. Records for minors will be maintained until the minor is 25 years old.

Can I withdraw from the study?
You may withdraw from this study at any time. It is possible that we will remove you from the study if you do not have a data plan compatible with use of the app. If either the adolescent or the parent withdraws from the study, the other can no longer participate in the study.

We may analyze data you provide to us prior to your withdrawal unless you specifically request we withdraw your data from the study. You may withdraw from the study by contacting our research team at our email, sovalab@pitt.edu, or by phone at (412) 540-5384.

European Travel
If you plan to travel to Europe in the next 6 months for more than 2 weeks at a time, you should let us know immediately. Certain countries have strict privacy regulations that make it not possible for you to participate at this time. These countries are: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom (which includes

England, Scotland, Wales and Northern Ireland), Norway, Iceland, and Lichtenstein. If you plan to travel to these countries, we may withdraw you from the study. If you plan to travel there for 2 weeks or less, please let us know when that will be so we can pause data collection during that time.

We will use the data collected prior to your withdrawing for the research.

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

How will this study affect my health insurance coverage?
Neither you nor your insurance provider will be charged for the costs of services performed only for the purposes of this research study. You will be charged in the usual manner for any services or procedures performed as part of your standard medical care (i.e., care you would receive even if you were not participating in this study).

Consent after 18
Should you turn 18 during the course of your participation, we will reach out to you to obtain your direct consent for continued participation.

Other AWARE Studies
There are other studies currently using the AWARE app. While participating in this study, we ask that you do not participate in other studies that require the AWARE application. If you are wondering if a study you are currently participating in or thinking about participating in uses AWARE, please let us know the name of the study and the contact information and we will find out.

Who should I call with questions or problems?
Dr. Radovic can be reached by calling UPMC Children's Hospital of Pittsburgh at (412) 692-5325 and asking to be connected, or by email at ana.radovic@chp.edu. Kayla and the rest of the research team can be reached at sovalab@pitt.edu.
A copy of this consent will be given to you.

CONSENT TO PARTICIPATE

PARENTAL PERMISSION
The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any part of this research study at any time. Any future questions will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be answered by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. A copy of this consent form will be given to me/my child.

_____

Printed Name of Child-Subject

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for my and his/her participation in this research study and provide my authorization for the use of his/her medical records

Parent's or Guardian's Name (Print) _____

Relationship to Participant (Child) _____

Parent or Guardian Signature_____ Date_____

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Name of Person Obtaining Consent (Print) _____

Role in Research Study _____

_____ _____

Signature of Person Obtaining Consent Date

VERIFICATION OF EXPLANATION

I certify that I have carefully explained the purpose and nature of this research to the child participant in age appropriate language. S/he has had an opportunity to discuss it with me in detail. I have answered all his/her questions and s/he provided affirmative agreement (i.e., assent) to participate in this research.

Signature of Person Obtaining Assent

_____ Date_____

CONSENT FOR CONTINUED RESEARCH PARTICIPATION

I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative since I was unable to provide direct consent at the time that this initial consent was requested. I have now turned age 18 and I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during the course of this study. Future questions, concerns or complaints will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. I agree to participate in this research study and provide my authorization for the use of my medical records.

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

Participant's Signature_____ Date_____

Electronic Consent for REDCap:

CONSENT FOR PARENT AND ADOLESCENT TO PARTICIPATE

I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By typing my full name, date of birth, and mother's maiden name, I consent to participate in this research study and I provide permission for my child to participate in this research study

Do you, the parent, consent for yourself and provide permission your child to participate in the study? (yes/no)

Do you, the adolescent, agree to participate in the study? Yes/No

What is your mother's maiden name?

What is your date of birth?

Type your full name:

Enter Today's Date: