UNIVERSITY of ROCHESTER

INFORMATION SHEET
Feasibility Study of the My Health Coach App for Adults with Fetal Alcohol Spectrum Disorder
Principal Investigators: Christie Petrenko, Ph.D. & Cristiano Tapparello, Ph.D.

Who is conducting this study?

This form describes a research study being conducted by Drs. Christie Petrenko and Cristiano Tapparello. They are researchers at the University of Rochester in Rochester, NY, USA. Dr. Petrenko is a psychologist. She has been working with people with fetal alcohol spectrum disorders (FASD) since 2003. Dr. Tapparello is in computer engineering.

We are also partnering with members of the Adult Leadership Collaborative of FASD Change Makers to run this study. We value their motto: "Nothing about us without us."

What is this study about?

We developed an app for adults with FASD called My Health Coach. We want to see if adults with FASD like this app. We also want to know it helps with daily tasks and quality of life.

What will happen if you do this study?

Here is what will happen if you choose to do this study:

- **Step 1 – see if you are eligible**. You will first complete a short online survey. This is to check that you meet the criteria to be in the study.
- **Step 2 – first round of surveys**. We will ask you to do some surveys. You can do these online by yourself or on Zoom with one of our research staff. The surveys ask about your quality of life, daily activities, and barriers to getting healthcare. They surveys may take about 30 minutes to complete. You will earn $25 for doing these surveys.
- **Step 3 – try out the app**. You will install the app on your phone and try it out for 6 weeks. You can use the app as much as you like.
- **Step 4 – second round of surveys**. We will ask you to complete another round of surveys. This will let us see if anything changed after using the app. You will earn $25 for doing these surveys.
- **Step 5 – interview**. We will ask you to complete an interview on Zoom with one of our research staff. In this interview, we will ask you what you thought about the app and being in the study. This information will help us make the app better and studies easier to participate in. We will record these interviews so we can remember what you said. We will delete these recordings after the study is over. You will earn $25 for doing this interview.

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We may communicate with you by email if you provide your email address. The app requires WiFi or a cellular data plan for some features.

How long will this study take?
This study will last about 2 months.

How many people can do this study?
Up to 48 people with FASD can do this study.

What are the possible risks or discomforts if you do this study?
You might get bored or feel uncomfortable completing surveys or interviews. You can choose to skip questions you do not want to answer. You can also take breaks. You can also decide how much to use the app. You can also decide to not participate anymore.

There are also additional risks to privacy and confidentiality through the app. We will protect against these risks by using state-of-the art authentication and encryption algorithms between the app and the Cloud.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. You can search this website at any time.

What are the possible benefits from being in this study?
There is no guarantee you will not benefit personally from being in this research study. It is possible you will find the app helps with daily activities or quality of life.

What if you don't want to do the study?
You can choose to not participate or stop participating at any time.

Will you get any money or gifts for being in this study?
You will get a reloadable gift card at the start of the study if you are eligible. You will be paid according to the following schedule:

Timepoint	Amount
Completing surveys at the start of the study	$25 loaded on gift card
Completing surveys again at 6 weeks	$25 loaded on gift card
Completing an interview	$25 loaded on gift card

You will not be paid for completing screening surveys or for using the app.

How will the researchers keep your information private?
The University of Rochester makes every effort to keep your information private. Your name and other identifying information will not be released in public about this study. We will keep your information and survey and interview responses on secure computer servers. All data collected in the app will be protected with state-of-the-art encryption.

In order to collect study information, we have to get your permission to use and give out your personal health information. To conduct the study, we will use the answers you provide in online surveys, the study interview, and responses in the app. We will not access your medical records or any other information you do not give to us as part of the study. Your permission to use your health information for this study will not expire unless to tell us you want to cancel it. We will keep the information we collect about you indefinitely. If you cancel your permission, you will be removed from the study.

Sometimes, researchers need to share information that may identify you with people who work for the University. If this does happen, we will make efforts to protect your information. Results of the research may be presented at meetings or in publications, but your name will not be used.

Will this information be used by anyone else in the future?
Data from this study will also be submitted to the National Institute on Alcohol Abuse and Alcoholism Database ($NIAAA_{DA}$) at the National Institutes of Health (NIH). $NIAAA_{DA}$ is a large database where de-identified study data from many NIAAA studies is stored and managed. De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a unique code number called a GUID. A GUID (globally unique identification) is created by entering some information you provide into a secure database. GUIDs can be used to connect your information to other research studies without identifying you. Sharing your de-identified study data helps researchers learn new and important things about FASD more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the $NIAAA_{DA}$. Other researchers across the world can then request your de-identified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with $NIAAA_{DA}$. The study data provided to $NIAAA_{DA}$ may help researchers around the world learn more about

FASD. NIAAA will also report to Congress and on its website about the different studies using $NIAAA_{DA}$ data. You will not be contacted directly about the study data you contributed to $NIAAA_{DA}$.

You may decide now or later that you do not want your study data to be added to the $NIAAA_{DA}$. You can still participate in this research study even if you decide that you do not want your data to be added to the $NIAAA_{DA}$. If you know now that you do not want your data in the $NIAAA_{DA}$, please tell the study researcher. If you decide any time after today that you do not want your data to be added to the $NIAAA_{DA}$, call or email the study staff who conducted this study, and they will tell $NIAAA_{DA}$ to stop sharing your study data. Once your data is part of the $NIAAA_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about $NIAAA_{DA}$, this is available on-line at https://nda.nih.gov/niaaa.

Because the project is being done with other researchers around the world as part of the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD), data collected in this study will also be sent electronically to a central location and could be used by other researchers in CIFASD. Only deidentified data will be shared with CIFASD.

Who is funding this study?

The University of Rochester is receiving payment from the National Institute of Alcohol Abuse and Alcoholism for conducting this research study.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

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 consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of

Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

What if you have questions about this study?
For more information or questions about this research you may call Christie Petrenko at (001) 585-275-2991, or email: christie_petrenko@urmc.rochester.edu.

What if you have questions about your rights as a research subject?
Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (001) 585-276-0005 or (001) 877-449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

REMEMBER!
Taking part in this study is your choice. You can choose not to do the study, and no one will be mad at you. You can also choose to stop at any time.