Please Note: To complete the consent process, you must advance to the end of this form to add your name and signature where indicated.

Consent to Take Part in a Human Research Study

TITLE:	Implementation and Evaluation of the Pathway Platform: A Digitally Enabled Care Pathway to Improve Depression Key Performance Indicators and Patient Outcomes in Primary Care Clinics
PROTOCOL NO.:	20.043E
SPONSOR(S):	Advocate Aurora Health Care
INVESTIGATOR:	David Kemp, MD
SITE:	Advocate Christ Medical Center 4440 West 95th St Oak Lawn, Illinois 60453
STUDY-RELATED PHONE NUMBERS:	Advocate Aurora Research Institute at Advocate Christ Medical Center (708) 684-4695

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have depression and are receiving a treatment for your depression from your doctor.

This consent form provides information on the study and risks involved in this research study. Please read this form carefully so that you can decide if you want to take part in the study. Participation in this study is completely voluntary.

What should I know about a research study?

- Someone will explain this 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.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, call (708) 684-9751 to speak with the Advocate Research Institute at Christ Medical Center

This research has been reviewed, approved and will be monitored by the Advocate Aurora Health Institutional Review Board ("IRB") . An IRB is a committee, independent of Takeda Pharmaceuticals and the investigators, that reviews and oversees research studies to protect the rights and safety of participants. You may talk to them at 414-219-7744 or email IRBOffice@aah.org if:

- 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 subject.
- You want to get information or provide input about this research.

Why is this research being done?
This study is being conducted to understand the use of a mobile app (titled *Pathway)* to help patients like yourself track depression symptoms, medications, side effects, and goals in addition to the usual care with your doctor. We will compare the effect of the app over 6 months and examine whether the app can increase engagement between patients and their doctor and help in the management of illnesses as patients start a new treatment for depression. We hope that using an app to facilitate management of depression symptoms, medication use, and side effects will help patients and their providers understand their response to medications and lead to better response and improvements in depression.

How long will the research last?
We expect that you will actively participate in this research study for a minimum of 6 months. You will be given the option to continue using the app at that time. If you chose to continue, the app will remain active and continue to prompt your input until the study is completed in January, 2023 If you chose not to continue using the app after 6 months, you will stop receiving reminders and the app will become inactive. Either way, your participation in the study will end with a series of questionnaires that you will complete within the app.

How many people will be studied?
We expect up to 200 patients and up to 20 clinics will participate in this research study.

What happens if I say yes, I want to be in this research?

- You will be asked to download the Pathway app to your cell phone.
- The app will provide the ability to track your daily medication use and side effects as well as depression symptoms, cognitive function, and quality of life every two

weeks. The app will also ask you a set of more detailed research questions about your healthcare and depression at the beginning, after 3 months and then every 6 months until the end of the study. Each set of questions should take no more than 5 minutes to complete and you will be able to use other features, such as short education modules and tracking goals that you have set with your care team.

- We will collect information from your electronic medical record and information entered into the app for the purposes of this study.
- Your identity, contact information, app usage information and your responses to questionnaires that are within the app will be shared with the company that developed the app, Fora Health, for the purposes of the study.
- The data that is collected from your phone will be made available to your Advocate Aurora Health Care clinical team.
- If you do not complete the research questions at the beginning and at the 6 month interval of the study, a member of the research team will call you.
- Toward the end of the study, we may contact you to see if you are interested in participating in an interview, in order to gather feedback on the participant experience during the study. This interview is completely voluntary, and this is separate from your participation in the above-mentioned study. You may choose not to participate in this interview at any time, and this will not impact your participation in the above-mentioned study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Log into your patient portal account
- Download the Pathway app
- Complete the questionnaires within the app
- Continue with your routine health care

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you. Your participation is voluntary. Your decision whether or not to participate will not affect your current or future relationship with Advocate Aurora Health Care.

What happens if I am injured because of the research?

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party.

No funds have been set aside by Advocate Aurora Health Care as compensation for research related injury or associated costs. You do not waive any of your legal rights by signing this consent form.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you are thinking about leaving the research study, contact the research team, who will assist you with ending your participation and your access to the app will be turned off.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect future data from your routine medical care. If you agree, these data will be handled the same as research data.

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

We do not anticipate any harm to you if you choose to participate. There is a possibility that the app may be frustrating to use or that increased use of your phone or notifications are inconvenient, and this may cause you stress.

The most important non-medical risk involved in your participation in this study is the unintended disclosure of your protected health information (PHI). PHI includes any health information that is collected about you, including medical history and information collected throughout the study. Although very unlikely, the possible loss of the privacy of your PHI could happen. If the privacy of your PHI was lost, it could cause you stress, anxiety, embarrassment or other problems that could come from people or entities knowing your PHI who you don't want to have this information. The portions of this form following the heading, "HIPAA Authorization to Use and Disclose Your Personal Health Information," explain in more detail how your PHI will be handled and used.

Will there be any costs to me if I participate?

Taking part in this research study may lead to added costs to you in terms of data usage on your cell phone.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, Patients with depression and their treating provider may benefit from the use of a mobile health app to assist in disease management.

Will I be compensated for participating in this study?

Upon completion of the initial 6 month participation period, you will be compensated $75 for your time and effort.

What happens to the information collected for the research?

- Information collected through the app will become a permanent part of your medical record. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB, other representatives of this organization, and Takeda Pharmaceuticals, Inc., the funder of this study. The developer of the app, Fora Health, will collect the data you enter into the app and transfer these data into

the Advocate Aurora Health Care electronic medical record to be viewable to your care team. Additionally, a final analytic dataset with no individual identifying information (deidentified) will be shared with the study collaborator Takeda for future analytic use.

What else do I need to know?

- Information from the app does not replace any care, appointments, or communication you have with your doctor. You should contact your doctor directly if you have any suicidal thoughts or concerns regarding your health, or call 911 in an emergency situation.
- This research is being funded by Takeda Pharmaceuticals, Inc**.**
- Information collected in the app will be provided to the research team and to your doctor to help guide your treatment.
- Your responses in the app will not be monitored in real time or shared with your doctor other than in summary reports to accompany your routine clinical visits.
- The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: One of the investigators responsible for the study, has a financial relationship with Takeda, the company that is sponsoring this research. This investigator does not receive any payments directly from Takeda for his work on this studv. You have the right to discuss this information with the research team before deciding whether or not to participate in this study.

What if I am an Advocate Aurora Health Care employee?

Your participation in this research is not a part of your Advocate Health Care duties and declining to participate will not affect your employment with AHC, or the benefits, privileges, or opportunities associated with your employment at AHC. You will not be offered or receive any special consideration if you participate in this research.

HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Note: In this authorization document, "you" and "your data" refer to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

Federal law provides additional protections of your medical records and related health information. That law is the *Health Insurance Portability and Accountability Act* (HIPAA). This study's HIPAA statement is provided below. You are providing your authorization if you sign this form and the accompanying consent or permission form to participate in the study.

Who will see my protected health information?

Who may have access to my information:	***Purpose:***
Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor	To oversee the study and make sure the information is correct.
Advocate Aurora Health consultants and employees, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.

By signing this form, you are authorizing access to and sharing of personally identifiable health information. This includes direct access to your medical records at Advocate Aurora Health.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself; reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

How will my information be used for this study?
This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study;
- to review the study, and to check the safety and results of the study;
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial;
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care;
- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

How will my information be kept confidential?
We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form you were given. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves Advocate Aurora Health we cannot control how it is used, and the law may not require outside organizations to protect the privacy of your information.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after

everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

The authorization to use and share your information has no end date.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

You will receive a signed and dated copy of this form for your records.

Signature Block for Capable Adult

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

Signature of subject	Date
Printed name of subject	

Invitation Message to Access e-Consent Form

Dear <Patient Name>,

Thank you for your interest in learning more about our Pathway Platform Mobile App Study. Participation is completely voluntary and by clicking the link below, you will be taken to a consent form for your review. It includes information on the study and your participation. After reviewing the consent, if you decide to join simply complete and sign the consent.

Click here to view consent form

If you have questions at any point, please reach out to me or the research team at (708) 684-4695 or CMC-Researchinnovation@advocatehealth.com. If you do not complete the consent to participate, a study team member may reach out to you to confirm your interest and eligibility.

Thank you,

Dr. David Kemp and the Pathway Study Team