Study ID: STUDY-22-01404
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STUDY INFORMATION:

Study Title: PGx App Validation Study

Study site(s): Icahn School of Medicine at Mount Sinai

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

A pharmacogenetic (PGx) test investigates how your genes affect your response to medications. It determines whether a medication could be an effective treatment or whether it may cause side effects. The information helps healthcare teams to select the best treatment. PGx testing is currently not routinely used in healthcare because there are limited trained staff to educate patients about their PGx results. In this research study, we are testing a mobile app, PharMe, to share PGx results.

The purpose of this research study is to compare patients' understanding of their pharmacogenetic (PGx) test results shared through a mobile app vs. pharmacist-led counseling.

If you choose to take part, you will be asked to download the study app, ehive, on your Android or Apple smartphone and complete surveys. If eligible to participate, you will receive an at-home saliva collection kit for PGx testing. You will be randomly (by chance, like flipping a coin) assigned to receive your test results in one of 2 interventions - receiving PGx test results through a mobile application (PharMe) or receiving results through pharmacist-led counseling. Your understanding of the results will be evaluated through surveys 24-hour, 1 month and 3 months after the PharMe app activation or post-counseling. Each survey will take approximately 10 mins to complete.

You will be compensated for your participation.

If you choose to take part, the main risk to you is loss of private information.

You will not benefit directly from taking part in this research. PGx test results will be shared with you during the study and will be uploaded to your medical records.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are 18 years of age or older, you own an Android or Apple Smartphone (a smartphone will not be provided by the study), and you are currently on at least one medication meeting the pharmacogenetic test criteria (including but not limited to clopidogrel, codeine, tramadol, paroxetine, escitalopram, citalopram, omeprazole, pantoprazole, atorvastatin, simvastatin, rosuvastatin, warfarin, and voriconazole). Contact the study team at ehivepgx@mssm.edu if you are unsure your medication meets the study criteria.

Do not participate in this research study if you are unable to read and understand English, unable or unwilling to provide a saliva sample for PGx testing, have conducted PGx testing in the past, have a history of liver, kidney or small bowel transplant or are currently pregnant.

Your participation in this research study is expected to last for 3 months after the review of your PGx test results. There are 200 people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai. Funds for conducting this research study are provided by Hasso Plattner Institute at Mount Sinai.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved. This study is remote, meaning there are no in-person study visits required.

- You will download the study app, ehive, on your smartphone
- You will complete an eligibility questionnaire on ehive
- You will complete the consent process on ehive
- You will collect and ship a saliva sample for PGx testing
- You will download PGx results delivery app, PharMe on your smartphone and review your results (If assigned to receive results by PharMe)
  OR
  Attend a virtual pharmacist-led counseling session to review your results (If assigned to counseling)
- You will complete surveys on ehive at the beginning of the study, and after reviewing your PGx results at 24-hour, 1 month and 3 months.

You will receive notifications and reminders through the study app and by email to complete study procedures. App notifications can be turned off by disabling them on ehive. If there are any issues obtaining the data from your surveys or the ehive app, a research coordinator may reach out to you to assist in troubleshooting the issue. Since this study is completely remote, research coordinators may reach out to you to check in on how the study is going. This may occur once a week or not at all. You can contact the study team with questions by emailing ehivepgx@mssm.edu.

Screening and enrollment:
To participate in this study, you will download the ehive app on your Android or Apple smartphone and complete an eligibility questionnaire to ensure you qualify to participate. If you are eligible, you will complete the consent process on the app and electronically sign the document to enroll. The study team contact information is in the contacts section of the app. You can pause the consent process at any time and contact the study team for additional information. The signed consent document will be available on the app to view and download.

Study Day 1:
On study day 1, you will complete questionnaires on the ehive app about your demographic information, health literacy and knowledge about PGx. This will take approximately 10 mins. The research coordinator will contact you by email using the study mailbox (ehivepgx@mssm.edu) to confirm your address and a PGx sample collection kit will be shipped to you.

PGx Sample Collection:
The PGx test shipment will include sample collection supplies, instructions, and a pre-paid return envelope. You will collect PGx samples by swabbing your cheek along the lower gum on both sides of the mouth. You will collect 2 such swabs and send them for analysis to the study lab, AccessDx, using the provided pre-paid shipping supplies. PGx results will be available in 2-4 weeks.

Randomization
After your PGx results are available, you will be randomly assigned to receive your results through one of 2 interventions - a PGx results delivery app (PharMe) or a pharmacist-led counseling session. You will be notified of your assignment through the ehive app.

If you are assigned to PharMe, a QR code will be sent to your email to download the PharMe app. Your PGx results and a description of the findings will be available on PharMe for self-paced review. Study team contact information will be available on the app if you have questions or need additional information about your results.

If you are randomized to the counseling session, you will be contacted by study staff to schedule a virtual appointment with a pharmacist to discuss your results.

No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to. It will be by chance, like flipping a coin. You will have an equal chance of being given each study.

Follow-up surveys
You will complete follow-up surveys on ehive to assess your understanding of your results 24 hours, 1 month and 3 months after you download the PharMe app or after completing a pharmacist-led counseling session depending on the intervention assigned to you.

If you are randomized to the PharMe group, you will receive an additional PharMe app usability survey. The surveys will be delivered through the ehive app. Also, at the end of your participation, you will be offered a pharmacist-led counseling session to review your PGx results.

If you were assigned to the pharmacist-led counseling group, you will be offered to review your results on the PharMe app at the end of the study and complete the PharMe app usability survey. This is optional.

Genetic Testing
Pharmacogenetic (PGx) testing can identify a potential genetic basis for the way you respond to medications, thereby allowing clinicians to reduce the risk of unwanted side effects and select appropriate medications. The PGx test offered by the study will return results for 17 genes which will inform the decisions for 154 medications. Your test results will be available in 2–4 weeks after the saliva sample is received at the lab. Results will be uploaded to your medical record for your physician.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If “Yes”, please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone

USE OF YOUR DATA AND/OR SAMPLES:

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), and study data, may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed, and it will be replaced with a code. Researchers are not planning on giving you the details

of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you do not want any future research to be done with your data, even with your identity removed, please do not sign this consent form or take part in the study.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things: Download the ehive app, collect and ship saliva samples for PGx testing, download the PharMe app or attend pharmacist-led counseling per study assignment, complete surveys on ehive.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this study will not cost you anything extra. The cost of the genetic test will be paid by the study and will not be billed to you or your insurance. If you agree to take part in this study, you will be paid up to $100 for your time and effort. You will receive an electronic gift card via email at the following timepoints: 24-hour survey - $35, 1 month survey - $35, 3-month survey - $30. Payments will be made only for the completed timepoints.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. Results from the PGx testing will be shared with you and made available in your medical records for your physician. Data collected from this study will be used to support development of the PGx results delivery app for possible future benefits to others.

POSSIBLE RISKS AND DISCOMFORTS:

The study involves no more than minimal risk. The possible risks related to participating in the study include:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database.
- The saliva sample collection may be uncomfortable.
- Some survey questions may be uncomfortable. You have an option to skip any task/question.
- Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that

such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.

- Privacy Risks - Your name and other information that could directly identify you (such as an address, date of birth, or social security number) will never be placed into a database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future. Since the database contains genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.
- Insurance Risks - There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to

be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at ehivepgx@mssm.edu.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?
As part of this study, the research team at the hospital(s) involved in the research will collect your: Name, address, telephone number, date of birth, date of diagnosis, e-mail address, medical records number.

During the study, the researchers will gather information by:

- Reviewing your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, questionnaires and interviews explained in the description section of this consent.
- Reviewing genetic tests.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).

- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: AccessDx

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI? Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff.
The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or

shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

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

Study ID: STUDY-22-01404
Form Version Date: 07 Mar 2024

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time