Consent to Participate in Research

Title of Research Study: Phenotyping **A**dherence **T**hrough **T**echnology-**E**nabled **R**eports and **N**avigation: The PATTERN Study

IRB Study Number: STU00217555

Investigator: Allison Pack, PhD MPH

Supported By: This research is supported by The National Institute of Aging, through the Northwestern University's Claude D. Pepper Center

Financial Interest Disclosure:

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: In addition to the grant Dr. Pack received from Merck to conduct this research, she also has received grants through Northwestern University from, Pfizer, the Gordon and Betty Moore Foundation, the RRF Foundation for Aging, Lundbeck, Gilead and Eli Lilly. Dr. Pack has also received consulting fees from Gilead.

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.

- The purpose of this study is to test various ways technology can be used to help patients learn how to take and manage their medications, identify any challenges, and easily report any concerns back to their primary care team. That way, the team can link them to appropriate resources.

- You will be asked to participate in one phone interview for the study. You will also have opportunity to complete an online questionnaire about your medication use.

- We expect that you will be in this research study for 6 months.

- There is no physical risk from taking part in this study. There is a small potential for loss of private information; however, there are procedures in place to minimize this risk. The questions may make you feel uncomfortable or remind you of unpleasant aspects of your condition. You may skip any question you do not want to answer.

- The main benefit of being in this study include a better understanding of how to take and manage your medications and identify any challenges.

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 are an adult, aged 65 or older, with a diagnosis of multiple chronic conditions. You need to be prescribed 8 or more medications that you are primarily responsible for taking. You also receive medical care at the participating Northwestern Medicine primary care practice in which you plan on attending a primary care visit.

How many people will be studied?
We expect about 80 people will participate in this phase of our research study. Overall, there will be 110 people in total.

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.
- You do not have to answer any question you do not want to answer.

What happens if I say "Yes, I want to be in this research"?
If you participate in this research study, you will be randomized to be in 1 of 2 groups. Randomization means you will be randomly assigned to a group based on chance, like flipping a coin. Neither you nor the study team will choose what group you get. You will have an equal 1 in 2 chance of being in each group. The groups are:

1. Usual care group. Patients in the usual care group will receive the normal standard of care.

2. PATTERN group. Patients randomized to the PATTERN group will receive tools to help simplify your role in managing complex, multi-drug regimens and monitor use over time. This approach includes the following component:

    - **Online Questionnaire.** You may be asked to complete an online questionnaire about your medications and any concerns or problems that you may have taking your medicines.
    - **Care Notifications:** Any concerns will be flagged to your doctor or nurse, and they may contact you to follow up.

Interviews

Regardless of which of the groups you are assigned to, you will be asked to complete one interview over the phone.

The interview will be about 2-4 weeks after a primary care visit you attended and it will take no more than 30 minutes to complete. During this interview, you will be asked questions about your health, the medications you take, how you understand health information, and a few other basic background questions. We'll ask you about how you are taking your medicines, as well as some questions about your satisfaction with any materials you may have received (online questionnaire). With your permission, we will audio-record a portion of this interview so we can better remember what you said.

Medical Record Review

In addition to the interview, we will also collect some health information from your medical record. We will collect information about your prescription medicines, chronic conditions, and clinical values. We will get this information directly from your clinic, so you won't need to do anything. Signing this form today will let us access your record for the purposes of this study only.

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, possible benefits include better understanding of how to take and manage your medications and identify any challenges.

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

Psychological risks: The questions make may you feel uncomfortable or remind you of unpleasant aspects of your condition. You may skip any question you do not want to answer.

Privacy risks: This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

You can leave the research at any time, and it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can ensure that you will not be contacted again regarding the research study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

How will the researchers protect my information?

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.

There are some important things that you need to know. 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 and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the National Institutes of Health (NIH), US Department of Health and Human Services (DHHS) and US Office for the Protection of Human Research Protections (OHRP).

After the study is finished, a dataset that does not contain any identifying information will be kept indefinitely for future analysis. Only authorized research personnel will have access to these data.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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 study for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

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 or code 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.

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 $50 total for your time and effort. You will be compensated within a few weeks of when you complete the phone interview by a physical Visa prepaid card or a virtual prepaid card.

Please note that if you prefer to receive a physical prepaid gift card, there are additional instructions should you wish to use the gift card to withdraw cash from an ATM, at a restaurant or a gas station. These instructions will be mailed to you with the gift card. You will incur fees if the card is not used in 12 months or more.

You will still receive this compensation even if you choose to end the interview early.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study tools

During this study you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The National Institute on Aging, who is sponsoring the study, and that company's contractors and partners.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

At the end of the research study, when all analyses have been completed, all protected health information (PHI) will be deleted.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Allison Pack, PhD MPH
General Internal Medicine
750 N Lake Shore Dr. 10th Floor
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any tests or procedures done may be included in your medical records and may be seen by your insurance company.

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Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 503-3117.

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.
- 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 contact me in the future to see whether I am interested in participating in other research studies by the Center for Applied Health Research on Aging (CAHRA).
_____	_____	For the purpose of better recalling my responses, the researcher may audio-record a section of the interview.

Consent:

Your signature documents your permission to take part in this research and for disclosure and use of personal health information from your medical record for purposes of this study. Once completed, you will get an automatic email with the signed version of this consent. If you want a paper copy of this consent for your records, you can print it from the screen.

By clicking 'I agree', I certify that I give my consent freely to participate in this study.

I agree
I disagree

_____ _____

First Name Last Name

_____ _____

Electronic Signature Date of Birth

_____ _____

Consent to Participate in Research

Consent Date

Study ID (to be added by RC)

_____
First Name of Person Obtaining Consent

_____
Last Name of Person Obtaining Consent

_____
Electronic Signature of Person Obtaining Consent

_____
Date