



TITLE: Implementation of an Electronic Care Plan for People with Multiple Chronic Conditions (eCarePlan v2)

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WHO IS PAYING FOR THE STUDY?: Department of Health and Human Services Agency for Healthcare Research and Quality (AHRQ)

WHY IS THIS STUDY BEING DONE?

You have been invited to be in this research study because you have multiple chronic health conditions. The purpose of this study is to support the development and testing of a care planner application that is designed to support care coordination, communication, and collaboration for care team members across all settings, including the home.

We are asking you to allow us to place a copy of some elements of your personal health information in a research data store that exists outside the official electronic health record. This copy of your personal health information will be stored for the duration of the study will not be used and/or shared for future research, and will be destroyed after the study is complete.

WHAT PROCEDURES ARE INVOLVED IN THIS STUDY?:

You will be given access to a new medical software application that will store your health information, and present it to you for review. We will ask you to fill out a web-based survey where you will review the application and answer basic questions about the accuracy of your health information, as well as the functionality and usefulness of the application.

The health information to be obtained and stored will include diagnoses, procedures, prescription medications, care providers, and personal health goals. The stored information will not be shared with anyone outside of the research team. It will not be analyzed for anything other than your perception of its completeness and accuracy.

If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact the research team at the following email address: cmp@ohsu.edu

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

You will not directly benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY?

You may freely choose not to participate in this study.

WILL I RECEIVE RESULTS FROM THIS STUDY?

You will not receive results from this study.

If you are interested in staying informed about the progress being made on the development of the application, and continuing to contribute to the development process, we may ask for your permission to contact you again in the future.

WHO WILL SEE MY PERSONAL INFORMATION?

In this study, we will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will do our best to keep your information confidential by following standard security protocols. The physical systems that host the research data store are managed by OHSU's Advanced Computing Center (ACC) in their restricted facility. This means, it is only accessible from within OHSU's network by specific individuals. In addition, the research data store shall reside on an entirely separate server, which is not accessible from the Internet at all.

We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) at OHSU, the funder of the study, or the Office of Human Research Protection (agencies that oversee research). If your information goes outside of OHSU, it might not be protected under federal law from being used or further shared.

If you decide at any point that you no longer want to participate, and you would like your personal health information removed from the research data store, you can request this by contacting:

Gina DeNoble, MS
Research Project Coordinator
Department of Medical Informatics and Clinical Epidemiology
Oregon Health & Sciences University
cmp@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that it already has been based on your authorization.

You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you choose not to participate, or if you decide to stop at any time, it will not affect your ability to receive health care at OHSU or insurance coverage.

WILL ANY OF MY INFORMATION FROM THIS STUDY BE USED FOR COMMERCIAL PROFIT?

Information, including any photographs, videotapes, or audiotapes, about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?:

It will not cost you anything to participate in this study. You will receive \$25 for participating, it will be delivered as a prepaid debit card. You will need to provide your social security number in order to receive the compensation card.

WHERE CAN I GET MORE INFORMATION?:

This research is being overseen by an Institutional Review Board (“IRB”). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by 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 more information or provide input about this research

You may also submit a report to the OHSU Integrity Hotline online at <https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html> or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join, or you withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

WHAT IF I AM AN OHSU EMPLOYEE OR STUDENT?

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator’s department, or your grade in any course. If you would like to report a concern with regard to participation of OHSU students or employees in OHSU research, please call the OHSU Integrity Hotline at 1-877-733-8313 (toll free and anonymous).

HOW DO I TELL YOU IF I WANT TO TAKE PART IN THIS STUDY?

All participants will be asked to follow a secure link that will be sent via email to complete the consent process, asynchronously, using a web-based platform called REDCap. This asynchronous, virtual consent process will provide all the information listed in this form, and will ask you to indicate your agreement to participate by clicking ‘YES’ or ‘NO’. Each participant will be able to download a PDF copy of the information sheet with your ‘YES’ or ‘NO’ indication included.