IRB Protocol# 2000031753
NCT05180721

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY

Study Title:
A Multi-level Intervention to Increase Access and Use of Patient Portals for Diabetes Management in Community Health Centers (MAP)

Principal Investigator (the person who is responsible for this research):
Robin Whittemore

Research Study Summary:
- We are asking you to join a research study.
- The purpose of this research study is to design a program about patient portals for patients with diabetes at community health centers.
- The study activity is a focus group or interview. You will be asked to hear about plans for the program and tell the researchers your opinion about it.
- Your involvement will require approximately one and a half hours.
- There may be some risks from participating in this study. Your personal information could be shared by accident.
- The study may have benefits to you. You may enjoy the conversation.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your healthcare provider.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because you are an adult with type 2 diabetes who receives medical care at a community health center. We are looking for approximately 10 participants to be part of this research study.

Who is paying for the study?
The National Institutes of Health is paying for this study.

What is the study about?
The purpose of this research study is to design a program to help patients with diabetes at community health centers. The program will be to increase their use of web-based patient portals. “My Chart” is an example of a patient portal. The program will also be to improve their diabetes control. You are not being asked to complete the program, only to tell us your opinions about how we should design it. Eventually the program will be provided to other adults with type 2 diabetes.

What are you asking me to do and how long will it take?
You will be asked to have a conversation about how you take care of your diabetes and what you know about patient portals. You will be asked about reasons you might use patient portals

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and reasons you might not use them. You will be asked your opinions about a future program to increase the use of patient portals.

You may be asked to have the conversation with a small group of other patients if it is safe to do so. If a group conversation is unsafe because of COVID, then the researcher may talk to you one-on-one in person, or over the phone, or on Zoom videoconferencing.

A person hired for the study will lead the conversation. The discussions will be audiotaped and a typed report will be written about everything that was said at the discussion, word for word, in both Spanish and English. A research assistant will also take detailed notes during the meeting.

We anticipate that your involvement will require 1.5 hours. You will receive a 20.00 gift card. Refreshments will be provided at group meetings.

Are there any risks from participating in this research?
There are no physical risks associated with this study. However there is the possible risk of loss of confidentiality.

How can the study possibly benefit me or others?
You may benefit from taking part in this study. You may enjoy the conversation. You may learn about patient portals. We hope that our results will improve healthcare for other people with diabetes in the future.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs may include transportation and your time coming to the study visit.

Will I be paid for participation?
You will be paid a $20.00 gift card for taking part in this study. You will be paid after you have completed the conversation. According to the rules of the Internal Revenue Service (IRS), payments for taking part in a study may be considered taxable income.

How will you keep my data safe and private?
All of your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we have to share it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

The study will follow HIPAA regulations. We take several precautions to protect your confidentiality. You will be given a unique study identification number that will be used on all study forms and data files. Your personal information will be separated from the study data. The code linking a participant to their code number will be maintained in a separate file on a secure server at Yale (eg. Secure Box). All paper data will be scanned and saved in a file on the secure server. We will not keep any paper copies of data. All identifying information will be destroyed at the earliest possible time following completion of the study.

If the discussion is in a group, then every member will be asked and reminded to keep all information they hear during the focus group confidential. We will keep your information

confidential. We ask that all focus group members not repeat any information shared during the focus group to others. However, we have no control over what happens outside of the group. Therefore, please, be aware of what you share in the group and do not share anything you hear from others outside of the group. You may tell others that you were in a focus group and the general topic of the discussion but actual names and stories of other participants should not be repeated.

After the focus group meeting and the interview, the audio recording will be written down word for word. Any names used during the discussion will be replaced with a general reference (Person A, Person B, etc.). The recordings and the written transcript will be stored on a secure computer. The research team will only access it to identify the main ideas and viewpoints. The main idea and viewpoints will be summarized across all focus groups and interviews in the study and a report will be written. No names or identifying information will be used in any reports or presentations based on the focus groups/interviews. The recordings and transcripts will be destroyed after the study is completed.

Some data from this study will be kept indefinitely. Although the data will be kept, it will never be stored with any information that could be linked back to you. During analysis, any study information will always be identified in aggregate so there is never any potential of you being identified as an individual.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission. We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

It is possible that identifiers might be removed from your private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

Research study records
Records about phone calls made as part of this study
Records about your study visits

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

- Health care providers who provide services to you in connection with this study.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to **Robin Whittemore Ph.D, APRN** Yale School of Nursing PO BOX 27399 New Haven, CT 06516-7399

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Certificate of Confidentiality from the National Institutes of Health.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institute of Minority Health and Health Disparities which is funding this study. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other

person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

What are alternative procedures?
An alternative option to participate in this study is to not participate in this study.

What if I want to refuse or end participation before the study is over?
Taking part in this study is voluntary and is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time and discontinue your participation. Whatever choice you make will not have any effect on your relationship with your healthcare provider or the community health center where you get your medical care.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Robin Whittemore at 203-737-2351.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial 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. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Documentation of Informed Consent

Your signature below indicates that you read and understand this consent form and the information presented and that you agree to be in this study.

We will give you a copy of this consent form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date