

**COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION
IN A RESEARCH STUDY****YALE UNIVERSITY
MAYO CLINIC
FAIR HAVEN COMMUNITY HEALTH CENTER**

Study Title: QBSafe: a randomized trial of a novel intervention to improve care for people living with type 2 diabetes.

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

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Research Study Summary:

You are being asked to participate in this research study because you have diabetes and you have an appointment with your clinician where you may discuss your diabetes care.

Invitation to Participate and Description of Project

The purpose of this study is to improve conversations about the management of diabetes. Caring for diabetes can be challenging and time consuming. People may not always feel comfortable talking with their clinician about the difficult parts of living with diabetes. We developed a set of conversation cards that can be used during clinic visits. The reason for doing this research is to find out if using the conversation cards during a regular clinic visit is better than having just a regular clinic visit without the conversation cards.

Description of Procedures

The research will involve using a set of conversation cards with your clinician during your visit. Some participants in the research will be given the conversation cards which we are testing. They will use the conversation cards during the visit, but the visit will proceed in the usual way. Some participants will not be given the conversation cards. Instead, they will have their regular visit with the clinician.

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 clinician in any way. You will not lose access to your medical care or give up any legal rights or benefits.

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 have diabetes, a hemoglobin A1c >8% and an upcoming visit with your clinician. We are looking for 156 participants to be part of this research study.

Who is paying for the study?

This study is funded by the National Institute of Health (NIH).

What is the study about?

The purpose of this study is to find out if using a set of conversation cards during a regular clinic visit is better than having just a regular clinic visit without the conversation cards.

What are you asking me to do and how long will it take?

If you agree to take part, your participation in this study will involve the following:

- You will be asked to answer survey questions about your life with diabetes, how diabetes and its treatment interferes with your life, about diabetes distress, treatment burden, quality of life, and low blood sugar reactions prior to your visit with the clinician.
- You will be asked to allow us to record your visit with your clinician today. This may be done by having a study team member present in the room during the appointment to record the visit with a small camera (audio and/or video), or your clinician may record the visit. You, your clinician, and any visitors can turn off the recorder at any time. If there is a physical examination, any study member observing the visit will step out of the room, and the recording device will be either shut off or directed to the ground so that audio but not video is captured.
- Your clinician may use a set of conversation cards we developed during your visit and ask you questions that focus on your quality of life, burden of treatment, and other aspects of living with diabetes.
- You will be asked to complete a brief questionnaire at the end of your appointment.
- About 6 months after the visit, you will be asked to answer additional survey questions.
- About 6 months after the visit, you will be asked to obtain a blood test to measure your hemoglobin A1c (or A1c). This test is done routinely during your diabetes visits, typically every 3 to 6 months.
- Additionally, information about your medical conditions, laboratory results, medications, referrals to specialists, and hospital and emergency visits will be obtained from your electronic health record.

We think that the study will take **2 hours** of your time.

Are there any risks from participating in this research?

The risks to participating in this research study are minimal, which means we do not believe they will be any different than what you would experience at a routine clinical encounter or during your daily life. Sometimes having a conversation observed or recorded can be distressing. If you wish to no longer be observed or recorded, you may ask the study team member observing to exit the room, turn the camera to the ground, or turn off the recording device. Since we will be collecting information about you, there is also the possible risk of loss of confidentiality.

How can the study possibly benefit me or others?

Although you may not directly benefit from participating in this research study, there is a potential benefit to people in the future as a result of the information gathered in this research study.

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 spent during the clinic visits.

Will I be paid for participation?

You will be paid for taking part in this study. We will offer you small tokens of appreciation for participation which will include \$25 gift cards during the first clinic visit upon completion of the survey, and an additional \$25 for the 6-month visit upon completion of the survey. 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?

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 Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as the research data you contributed.

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.

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, including the audio-video recordings of your visit and the questionnaires.
- The entire research record and any medical records held by Fair Haven Community Health Center and the Yale New Haven Hospital system between 2011 to most recent records.
- Records about phone calls made as part of this research.
- Records about your study visit

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.
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Principal Investigator of the study.
- Co-Investigators and other investigators at Yale and at Mayo Clinic.
- Study Coordinator and Members of the Research Team.
- 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 Dr. Kasia Lipska, PO BOX 208020, Department of Internal Medicine at the Yale University, New Haven, CT 06520.

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.

What if I want to refuse or end participation before the study is over?

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 clinicians at Fair Haven or at Yale New Haven Hospital.

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 at **203-500-3053**.

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.

If you have questions about the Psychology Subject Pool, you may contact the coordinator at (203) 432-4518, or psychsubject.pool@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.

Authorization and Documentation of 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 form.

_____ Participant Printed Name	_____ Participant Signature	_____ Date
_____ Person Obtaining Consent Printed Name	_____ Person Obtaining Consent Signature	_____ Date