	Human Research Protection Program Institutional Review Board **Consent to Participate in a Research Project and Authorization to to use and Disclose Protected Health Information (PHI)**	

STUDY TITLE: Strategies to Improve Well-Being and Diabetes Management

PROTOCOL NUMBER or Research Summary Date: IRBnet #: 2074997

CONSENT VERSION DATE: 5.13.24

HOSPITAL OR INSTITUTION: MaineHealth Institute for Research

INVESTIGATOR: Elizabeth Scharnetzki, PhD

PARTICIPANT'S NAME (printed):_____

Part I: Key Information About this Research Study

You are being asked to volunteer in a research study.
Your participation in this study is completely voluntary. Even if you do agree to participate now, you may leave the study at any time without penalty and without giving a reason. Whether or not you decide to participate will have no impact on your current or future care you receive at MaineHealth. Withdrawal or refusing to be in the study will not affect your relationship with MaineHealth in any way.

Why is this study being done?
The purpose of the study is to test a strategy psychologists developed for coping with the stress, stigma and emotions that are sometimes associated with stressful situations. We are interested in understanding if this will improve the process of managing Type 2 Diabetes. With your help, we hope to improve patient's experiences.

Why are you being asked to be in this research study? You are being asked to take part in this study because you are a patient at Maine Medical Partners Endocrinology and Diabetes Center; you have been diagnosed with type 2 diabetes and you currently use a continuous glucose monitor (Dexcom, Free Libre).

How many people will take part in this study? This study will include up to 300 people. All participants will be patients of Maine Medical Partners Endocrinology and Diabetes Center.

What will you be asked to do and how long will it take? If you chose to participate, the study and your total time commitment will be 1 year. Participation involves three primary activities:

1) You will be asked to complete several surveys at different time points throughout the year. Should you choose to participate, the first survey will be sent to you shortly after we completion of this consent process. The other surveys you will be asked to complete will be sent after your 3-month check-up visits with your endocrinologist (no more than 5 surveys across the year). We anticipate that each survey will take no more than 20 minutes.

2) You will be asked to complete a series of brief writing exercises over the next year. This exercise was designed by psychologists and has been shown to boost confidence and people feel more resilient in stressful times. We are hoping to test the efficacy and impact of this exercise for people managing diabetes. Before each of your 3-month check ups at the MMP Endocrinology and Diabetes clinic, you will receive a prompt from the study team with the instructions for the exercise. The writing exercise should take no more than 10 minutes each time you complete it; you will be prompted to complete the exercise 4 times over the course of the year.

3) You will be asked to wear your continuous glucose monitor (CGM) as you normally do. With your permission and agreement to participate, we will collect and aggregate this data, but it will be kept private and secure.

In addition to these activities, if you choose to participate, we will also ask to collect a few pieces of information from your medical records (i.e., year you received your type 2 diabetes diagnosis, HbA1c, height and weight).

Across the study, we will connect your responses, CGM data and surveys using only a randomly assigned study ID number. Your name and contact information will be stored separately from from your responses and study data.

What are the risks or discomforts that are possible from being in this study?
The risk for participating in this research study is minimal; however, breach of confidentiality is a potential risk. You are free to only answer questions that you want to answer. All of your data will be kept private and secure in databases that only the research study team will have access to. Across the study, we will connect your responses and surveys using only a randomly assigned study ID number. This all identifiable information (such as contact information) will be stored separately from all study data. Our findings will be shared with the science and local communities, however, they will only be reported at the group-level, so nothing can be tied to you as an individual.

Additionally, taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to withdraw from participation in this study at any time.

What benefits to you are possible if you participate in this study?
The writing exercise that we are testing in this study has been shown for some people to boost confidence and resiliency stressful times; this could be a potential benefit to participating in this study. Iinformation from this study may also benefit other people now or in the future by adding to our knowledge and understanding of strategies for manaing diabetes..

Will being in this study cost you anything?
There is no cost to participate in this study.

Will you be paid for being in this study?
As a thank you for your time, you will receive a $150 gift card. Upon completion of the study, members of the research study team will reach out to you using the preferred contact information you provide to collect your mailing information. All contact information will be stored separately from your study responses, and all contact and identifiable information will be destroyed after gift cards have been sent.

Part II. Additional Information and Details

WHAT ABOUT CONFIDENTIALITY?

At MaineHealth, we will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, the sponsor of the study (and those who work for them), MaineHealth's Institutional Review Board, applicable Institutional officials, and certain federal offices, including the Office for Human Research Protections (OHRP), and, where applicable, the Food and Drug Administration (FDA). However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

In a lawsuit, a judge can make us give him the information we collected about you.

You will be assigned a random 4-digit number at the start of the study. You will use the study ID to complete the all surveys and writing exercises. At the top of each electronic form, you will be prompted to enter your number. Your name and contact information will be stored separately from all study data.

This research is covered by a Certificate of Confidentiality from *NIH*. 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 NIH 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.

IF I AM BEING COMPENSATED FOR BEING IN THIS STUDY (*do not include this section if there is no compensation)*

Please check the appropriate box:

__ You are a U.S. Citizen or Resident Alien. If you are paid $600 or more a year from MaineHealth, your social security number and amount paid will be reported to those in charge of taxes (IRS) and you may have to pay taxes on this money.

___ If you do not wish to be paid for your participation in this study, please initial here: ____

HOW CAN I WITHDRAW FROM THIS STUDY?
You can always choose to stop participating in this study. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate. If you wish to withdraw from the study, please contact Elizabth Scharnetzki at Elizabeth.Scharnetzki@mainehealth.org

For the information collected prior to your withdrawal:

The information will continue to be part of the data and included in the final analysis for this research. No new information will be collected. If you choose not to participate any information provided (for example, contact information) will be destroyed via permanent deletion upon completion of study publication.

HOW WILL MY INFORMATION BE SHARED?

Information obtained during this study may become the property of MaineHealth. When your involvement with the study ends the information you provided will be stripped of identifiers so that no link can be made to your identity and may be used for other research purposes, including research conducted by other investigators. Because there will be no identifiers associated with the information/samples additional consent from you will not be sought.

We receive money from the National Institutes of Health (NIH) to do this study (Centers of Biomedical Research Excellence support). NIH requires that we have a plan in place to share information we gain in this study. We anticipate publishing the findings of this research and publishers often require that we have a plan in place to share the information we collect during this study. All of your data will be kept private and secure in REDcap databases that only the research study team will have access to. Across the study, we will connect your responses and surveys using only a randomly assigned study ID number. This all identifiable information (such as contact information) will be stored separately from all study data. Our findings will be shared with the science and local communities through scientific publications and professional conference presentations. To ensure study findings are reproduceable, per best practice, statistical code for our analyses will be made available on open science platforms (e.g., Open Science Framework), and deidentified, aggregated data may be available upon request by members of the scientific community. All findings will be reported at the group-level, so nothing can be tied to you as an individual.

Sharing research data helps to translate research results into knowledge, products, and procedures that improve human health. If you provide permission now to share your anonymized information with the database noted below, you may withdraw your permission later without any penalty or loss of benefit. The information will be withdrawn from the database. However, if the information has already been shared with other researchers that information will not be able to be deleted.

Permission for the research team to obtain and use your patient health information

---

How will the privacy of my patient health information be protected?

There are state and federal privacy laws that protect the use and sharing of your patient health information. By signing this form, you provide your permission, called your "authorization," for the use and sharing of patient health information protected by the Privacy Rule. Authorization includes allowing:

- Your health care providers to share your health information for this research study
- The research team to use and share your health information for this research study.

Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at MaineHealth. Specifically, this will include: *medical record number (MRN), verification of Type 2 diabetes diagnosis, year of diabetes diagnosis, heigh, weight, continuous glucose monitor data, HbA1c information.* This may also include any new health information about you that comes from the research tests or procedures described in this consent form. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

The research team and people within MaineHealth who oversee and help administer research may see, use or share your information as needed for the research.

People outside of MaineHealth may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and share your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and share your information only as described in this form; however, people outside MaineHealth who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and sharing of your information has no time limit. You may revoke (cancel) your permission to use and share your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. Send your request to:

Elizabeth Scharnetzki, PhD
1Riverfront Plaza, 4th Floor, Westbrook, ME 04092
Phone: (805) 340-9716
elizabeth.scharnetzki@mainehealth.org

If you do cancel your authorization to use and share your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we shared before you wrote to the Principal Investigator to cancel your authorization.

Your decision to not sign this authorization will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If any information contained in this consent form is not clear, please contact Elizabeth Scharnetzki (their contact information is provided below). You may print out this consent form

to think about or discuss with family or friends before making your decision. If you have had all your questions answered and understand your involvement in this study, you can click the button on the bottom of this page, and you will be directed to the research study. If you have any questions, complaints, or concerns about your participation in this research, contact:

Elizabeth Scharnetzki, PhD
1Riverfront Plaza, 4th Floor, Westbrook, ME 04092
Phone: (805) 340-9716
elizabeth.scharnetzki@mainehealth.org

The researcher named above is the best person to email for questions about your participation in this study. For questions about your rights as a research participant, or to provide input, contact the MaineHealth Institutional Review Board (which is a group of people who review the research to protect your rights) at (207) 661-4474. Alternatively, you may provide comments or ask questions in the Human Research Protection Program Feedback section on our website at https://mhir.org/?page_id=1373 .

MaineHealth Institutional Review Board
1Riverfront Plaza, 4th Floor, Westbrook, ME 04092
Phone: (207) 661-4474
Email: mmc_irb@mainehealth.org

Contact this number for general questions, concerns or complaints about research.

ACKNOWLEDGEMENT

I have read, or have had read to me, the above information before signing this consent form. I agree to take part in this research study. I also give permission to use or share my personal health information for the purpose of this research. I have had the chance to ask questions. I have received answers that fully satisfy those questions.

☐ I consent to having my data collected and analyzed.
☐ I understand the information in this consent form.

_____ _____
Signature of Participant Date/Time

_____
Printed Name of Participant

Study representative statement
I have fully explained in terms understandable to the subject all of the following: the purpose of this research, the study procedures, the possible risks and discomforts and the possible benefits. I have answered all of the subjects and his/her authorized representative(s) question to the best of my ability. I will inform the subject of any changes in the procedure or the risks and benefits if any should occur during or after the course of the study.

_____ _____
Signature of the Person Obtaining Consent Date/Time

_____
Printed Name of the Person Obtaining Consent

A signed copy of this consent form must be given to each subject entering the study.