Informed Consent Form (ICD)

Official Title: Integrating Behavioral Economics and Self-Determination Theory to Advance Patient Engagement to Change Diabetes Risk

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Integrating Behavioral Economics and Self-Determination Theory to Advance Patient Engagement to Change Diabetes Risk (BEST Change)

Company or agency sponsoring the study: National Institute of Diabetes and Digestive and Kidney Diseases

Principal Investigator: Jeffrey Kullgren, MD, MPH, MS, Department of Internal Medicine, University of Michigan

Study Coordinator: Eli Carter, MPH, Department of Internal Medicine, University of Michigan

1.1 Key Study Information

You may be eligible to take part in this research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study if you have any questions or concerns. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as an outcome for preventing diabetes. This research will examine four different programs that are designed to encourage people who are higher risk of developing diabetes to take action to reduce their risk.

The text messages (and for some, financial incentives) encourage study participants to take action one of two ways: enrollment and participation in the Diabetes Prevention Program (DPP), or use of a

medication called metformin. These two approaches have been proven in studies to help prevent or delay diabetes. You will not be required to enroll in the DPP nor take metformin.

This study will test the effects of 4 different programs on changes in hemoglobin A1c (a blood test that measures average sugar levels in the blood over the last 3 months) and weight over 1 year.

Your health-related information, including your weight, A1c test results, answers to survey questions, and information on prescription fills for metformin and enrollment and participation in a DPP, will be collected for this research study.

This study involves a process called randomization. This means that the program you are assigned to is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance, to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study program you will be assigned to.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. There are no risks in this study that are beyond the risks of standard care. One of these risks may be no improvement in your current elevated risk for developing diabetes. More detailed information will be provided later in this document.

This study may offer some benefit to you by providing practical information about prediabetes and proven ways to prevent or delay diabetes. It may also boost your motivation to take steps to prevent or delay diabetes. The results of the study may benefit others by helping us better understand what best motivates people to take action to prevent or delay diabetes. More information will be provided later in this document.

We expect the amount of time you will actively participate in the study will be 12 months. It is possible that we may contact you after 12 months to collection more information, if you agree to this. If you decide to be in the study, you give us permission to obtain certain information from your Michigan Medicine electronic health record for dates starting a year before your enrollment through two years after enrollment.

You can decide not to be in this study. Alternatives to joining this study include talking with your health care provider about steps you can take to prevent diabetes and making lifestyle changes, such as getting more exercise and losing weight if you are overweight or obese. If you participate in the study, you will be encouraged to participate in a DPP or take the medication metformin, but you do not have to do either, regardless of which study program you are randomly assigned to. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The estimated 84 million US adults with prediabetes can significantly reduce their risk of developing type 2 diabetes by participating in a DPP or taking a medication called metformin. Although both the DPP and metformin are effective and widely available, few people who could benefit use them. This study is testing 4 different programs to encourage people at risk for diabetes to either participate in a DPP or take metformin. All four programs include sending informative and possibly motivating texts 3-7 days per week. One program uses texts that are sometimes linked to your questionnaire responses, and another program uses texts that are not linked. The other two programs include the text messages (linked or not) *plus* the opportunity to earn money if the participant participates in a DPP or takes metformin. The study will compare how these 4 programs affect A1c (a blood test that measures average sugar levels in the blood over the last 3 months), and weight after 6, 12, and possibly 24 months.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Adults who have U-M Premier Care, Community Blue PPO, or Comprehensive Major Medical health insurance (either because they are U-M employees or dependents of U-M employees) and whose primary care provider is part of Michigan Medicine may be eligible to participate. In addition, participants must:

- be at least 18 years old
- have a recent A1c test result of 5.7 to 6.4%
- have a body mass index (BMI) of at least 25 (at least 23 for people of Asian descent)
- plan to live the local area for the next year
- never have been diagnosed with diabetes (except gestational diabetes, during pregnancy)
- not have enrolled in Medicare nor plan to enroll in the next 12 months
- not expect to change health insurance in the next 12 months to something other than U-M Premier Care, Community Blue PPO, or Comprehensive Major Medical
- not have participated in pilot testing or pretesting for this study
- never have participated in a DPP
- not currently be taking the medication metformin
- be open to possibly taking metformin
- be willing and able to receive texts 3-7 days per week for one year
- have regular access to either a smart phone or tablet that connects to the internet
- not be enrolled in another study examining how a diet, program, or drug might: promote physical exercise, healthy eating habits, or weight loss; lower blood pressure; or lower blood sugar
- not have a diagnosis of dependence on alcohol or opioids
- not have serious psychiatric diagnoses such as severe depression, bipolar disorder, or schizophrenia

- not have undergone intensive cancer treatment in the last 6 months nor plan to do so in the near future
- not have received treatment for an eating disorder in the last 12 months
- not be pregnant or plan to get pregnant in the next year
- not had an organ transplant or weight loss surgery in the last six months
- not had stroke, heart attack, heart surgery, or hospitalization for congestive heart failure in the past 3 months
- not have any other serious health issues or personal concerns that could prevent completion of the study

3.2 How many people are expected to take part in this study?

380 people are expected to participate, all at the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Checking Eligibility
If you sign this consent form, study staff will review your electronic health record (EHR) to confirm that you are preliminarily eligible. You will then be asked to go to any MLab to get a blood sample drawn for an A1c test. The study will order and pay for the test, and the result will be added to your EHR. The A1c test will tell us the average amount of sugar in your blood over the last 3 months, and it will tell us whether you are at elevated risk of developing diabetes. This is also referred to as having prediabetes. In order to be in this study, your A1c test result must be in the prediabetes range of 5.7 to 6.4%. Test results typically are posted in your health record in 1-2 days. We will send you a text message with your A1c test result and if it is in the eligible range, or too high or too low to participate in this study.

Information required for the study
In order to pay you incentives throughout the year, you will be asked to verify your contact information and provide your social security number in the secure online platform. You must complete this step in order to be paid. After your first assessment is complete, you will be mailed a ClinCard with $50 loaded onto it. This is like a gift card that we can add money to throughout the year.

You will also need to provide your MagellanRx member ID. We need this in order to know if you fill prescriptions for the drug metformin. You will receive instructions about where to find this number.

Assessments
If your A1c is in the eligible (i.e., prediabetes) range, you will be asked to complete an online survey that takes about 20 minutes to complete. Next, we will have a digital body weight scale shipped to you. You will weigh yourself and send a photograph of your weight on the scale's readout to the research study team at enrollment, 6 months, and 12 months. We'll provide instructions on when and how to do this.

We will ask you to complete assessments halfway through your time in the study (i.e., at 6 months), and then again at the end (i.e., at 12 months). The assessments involve 3 parts:

1) an online survey in the secure study web platform (Way to Health) that will take about 20 minutes
2) going to any MLab to give a blood sample to have your A1c tested. We will text you your A1c value.
3) weighing yourself using the gray Doran body scale we will ship to you as part of your enrollment in the research study and sending us a photograph of your weight on the scale's readout (if you enroll in the Omada DPP, you will get a second scale to be used just for that program)

We may contact you 24 months after your first visit to ask you to complete some of the assessment parts described above.

Randomization

After you complete your initial set of survey, A1c test, and weight measurements, the Way to Health (W2H) online system will randomly assign you to 1 of 4 possible programs. You have a 25% chance to be assigned to any program. The 4 programs are:

A. receive texts about preventing diabetes
B. receive texts about preventing diabetes that are sometimes linked to your questionnaire responses
C. receive the texts described in Program A *plus* the chance to earn money each month for participating in the DPP or taking metformin
D. receive the texts described in Program B *plus* the chance to earn money each month for participating in the DPP or taking metformin

Text messages

If you are assigned to Programs C or D, you may need to wait a few weeks before your program begins, and you will receive more information about this via text message shortly after you have been randomized. Most texts will be sent at a time of day that you will choose in a later enrollment step. Everyone will receive texts over the first 2 weeks of their program that provide basic information about being at higher risk for diabetes and ways to prevent or delay it. You will receive 1 to 3 texts per day for these first 2 weeks. After the first 2 weeks, the frequency of texts will decrease to 3 to 6 days per week for 2 of the programs. For the other 2 programs, the number and frequency of texts will initially vary based on your responses; after this initial period (which is self-paced and can range from a day to a month), text messages will typically be sent 5 days per week, but occasionally up to 7 days per week. These later texts will describe ways to prevent diabetes and possible reasons you may want to do so. Once per month, you'll receive a text on whether you have participated in a DPP or filled a prescription for metformin, and as well as monthly reminders about your insurance coverage for the DPP and metformin. Some texts may ask you to answer a few questions, and your answers may prompt follow-up texts. In some cases, more than one text message might be sent on a single day. You will receive a small number of email communications related to enrollment and the assessments at 6 and 12 months.

Financial information

Half of all participants will be assigned to a program that includes the opportunity to earn money each month that you participate in a year-long online DPP or take metformin. Through your U-M Premier Care, Community Blue PPO, or Comprehensive Major Medical insurance,, the cost of participating in the

DPP is fully covered, and the monthly co-pay for metformin is typically $5 or less. If you are assigned to a program that includes the opportunity to earn money each month, you will receive more information about how the payments work before your program begins.

Information about you
In order to track your enrollment and participation in a DPP, the researchers have data sharing agreements with Omada Health, the company that offers an online DPP that your U-M health insurance will pay for. The Omada Health DPP, called Omada for Prevention, will be described in more detail after you are assigned your study program. Each month, researchers will receive information from Omada Health about your DPP enrollment and participation. Omada will send to the researchers the following: the number of lessons you have completed, the number of days your body weight was measured, the number of days your physical activity was tracked, and the number of days your meals or snacks was tracked. The researchers will also receive your body weight when you begin the DPP, percent weight lost each week, and dates when you have lost 5% and 10% of your body weight. Similarly, researchers will also receive monthly information on any prescription fills for metformin from the University of Michigan's Prescription Drug Plan team.

Researchers will access your medical record to confirm your eligibility in the study, to collect data such as A1c test results, health care utilization, diagnoses, and treatments, and to provide quarterly updates to your primary care provider on your participation in this study, your A1c values, participation in a DPP, use of metformin.

4.2 How much of my time will be needed to take part in this study?
At 3 to 4 time points, you will be asked to:

- complete an online survey (about 20 minutes)
- go to an MLab to give a blood sample for an A1c test (about 10-60 minutes, depending on wait time at the lab)
- Weigh yourself at home (about 2 minutes)

To complete the above tasks, the total maximum expected time would be 6 hours over the year.

Over the year of study participation, you will receive text messages 3-7 days per week. If you participate in the DPP, that program will also communicate with you via messaging in its app. We estimate you will spend about 5 minutes per week reading and sometimes responding to the texts. Over the course of the year, the total expected time for the text message element of the study will be 4 hours, 20 minutes (5 minutes/week times 52 weeks).

In sum, the maximum time that would be needed for you to take part in this study is 12.5 hours over one to two years.

4.3 When will my participation in the study be over?
You will receive texts over 12 months, and you will complete study surveys and assessments over at least 12 and up to 24 months. In addition to the time above, we will collect information from your

medical records in the year preceding your participation and for another year after the 12 months of your program ends.

After the study is complete, the University of Michigan may decide to offer a program of text messages plus financial incentives to its employees and their dependents who are insured under U-M Premier Care, Community Blue PPO, or Comprehensive Major Medical, but you may not be eligible for the program if you already received it as part of this study.

4.4 What will happen with my information used in this study?
With appropriate permissions, your collected information may be shared in a de-identified form with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- You may experience discomfort when responding to survey questions or texts about your health and the challenges associated with managing your health.
- The main risks of blood tests are discomfort and bruising at the site where the needle goes in.
- There is a small chance of infection with any blood draw.

The researchers will try to minimize these risks by:

- You can skip any survey questions that you feel uncomfortable answering, with the exception of 2 that ask you to choose your top 3 values and your top 3 strengths from lists. These are required because they may play an important role in the program you will receive.
- You may discontinue any study activity if it makes you feel uncomfortable.
- Blood testing complications usually are minor and go away shortly after the tests are done. The trained laboratory staff will use a sterile needle and will clean your skin with alcohol where the needle goes in. The needle may sting a little and may leave a bruise. Some people may feel dizzy or faint. If you do, you may lie down during the blood draw. The trained lab staff will give you first aid if you need it.
- To avoid extra blood tests, when possible we will use the results of blood tests you have recently had as part of your clinical care.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.** While it is unlikely you will have an injury as a result of the study, if you are injured from being in this study, any necessary medical care will not be paid by the study. Costs would be charged to you or your insurance company.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. You may learn more about, and possibly become more motivated to reduce, your risk for diabetes.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
You will continue to receive your health care as usual. There are other ways that you can reduce your risk for diabetes. You do not need to be in this study in order to enroll in the DPP. In addition, you can speak with your health care provider about ways to reduce your risk for diabetes, and they may prescribe metformin for you and/or suggest ways to make lifestyle changes to reduce your risk.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you are participating in the Omada Program or taking metformin and choose to leave the study, these strategies will continue unless you choose to end them. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information.”

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
We do not know of any harm that this could cause for you.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

Permission for Future Contact

At some time in the future, we may want to contact you again to ask additional questions. (Note: You can still participate in the study, even if you do not want to be contacted in the future.) Please select one:

I agree that the researchers may contact me again in the future. _____

I do not agree to have researchers contact me again in the future. _____

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. Whenever ordered for the study, an A1c test will be paid for by the study. The digital body weight scale will also be shipped to you at no cost. It is yours to keep at no cost.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Health care provider appointment to discuss taking metformin, if you choose to do so
- Cost of metformin (co-pay is usually $5 or less per month)
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Everyone participating in the study will have the opportunity to earn $50 each time they complete the following 3 activities at the start of the study, 6 months later, and 12 months later:

- An online survey
- An A1c test from a blood sample at any MLab

- A body weight measurement using the scale you will receive from the study team

If each of these 3 activities are completed at each of the 3 timepoints, you would earn $150. In addition, you may be asked to complete these 3 tasks a fourth time (24 months after the start of the study), in which case you could earn a total of $200.

To measure your body weight, the study team will send you a digital scale. The scale will be yours to keep at no additional cost to you.

In addition, you have a 50% chance of being randomly assigned to receive both text messages and the opportunity to receive $50 in the first month and then between $50 (most likely) and $250 (least likely) each of the subsequent 11 months if you either participate in a DPP or take metformin.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a direct financial interest in the outcome of this study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?

We will do our best to make sure that the personal information we collect about you is kept private and secure.

Any hard copy information about you (for example, notes taken by research staff if you talk by phone) will be kept in secure, locked files. The majority of your information will be kept in secured, password-protected files at the University of Michigan and in the W2H online platform at the University of Pennsylvania. The University of Michigan is using W2H because it is a secure, scalable vehicle that was specially designed for conducting studies like this one. It automates most of enrollment, email and text messaging, delivery of financial incentives, and online surveys. For a complete list of W2H data protections and associated policies and procedures, please visit https://policy.waytohealth.org.

Your information will be transmitted and stored using very secure systems. The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential. All of these personnel have completed research and confidentiality training. Your SSN will only be shared with the US government if a W-9 form is submitted for tax purposes and will never be disclosed to any other partnering organizations.

Your survey responses will not be made a part of your regular medical record. However, the A1c tests ordered by the study and their results will become part of your regular medical record. In addition, 5 times over the year, the study will enter a note into your electronic chart that will update your primary care team about your participation in the study, your enrollment and participation in a DPP, and any prescription fills for metformin.

In order to track your enrollment and participation in a DPP, the researchers have a data sharing agreement with the online DPP that your health insurance pays for: Omada Health, Inc. Omada will provide the researchers with your name, date of birth, health insurance member ID, and data on DPP enrollment, participation, and body weights of study participants using a secure encrypted file sharing system. The participation data will include the number of lessons completed, days body weight was measured, days physical activity was tracked, and days meals or snacks were tracked. We will also receive your body weight when you begin the DPP, percent weight lost each week, and dates when you have lost 5% and 10% of your body weight.

For information on prescription fills for metformin, the researchers will receive data from the University of Michigan's Prescription Drug Plan team. Each month, researchers will upload a file containing the Prescription Drug Plan member ID, names and birth dates of people enrolled in this study to a secure, encrypted file sharing program at the University of Michigan. The Prescription Drug Plan team will use the list to provide the researchers with prescription fills for metformin among study participants using the same secure encrypted file sharing program.

Once your personal information is disclosed to others outside the Universities of Michigan and Pennsylvania, it may no longer be covered by federal privacy protection regulations. You can review the privacy policies of these companies here:

- Greenphire ClinCards (to coordinate your study payments): https://greenphire.com/privacy-policy/
- Twilio Cloud Communications (to send you text messages): http://www.twilio.com/legal/privacy
- Medline (to have a body scale shipped to you): https://www.medline.com/pages/privacy/
- Qualtrics (may be used to collect your answers to questions during screening and in a potential fourth survey): http://www.qualtrics.com/privacy-statement/
- Omada Health, Inc (online Diabetes Prevention Program covered by University of Michigan employee benefits): Terms of Use, Privacy Policy, and HIPAA Notice of Privacy Practices, or on https//omadahealth.com/bestchange

This study 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; laws require that we report child and elder abuse and neglect, harm to self, and harm to others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

This trial is registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and others involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Health plan/health insurance records, including prescription fills of metformin, obtained from the U-M Prescription Drug Plan team
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers
- Information collected during participation in a DPP, obtained from Omada Health, as described above under Question 9.1

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but it would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but they will keep it secure until it is destroyed. If you withdraw from the study but do not cancel your permission to use your PHI, the researchers will continue to use data already collected prior to withdrawal, but they won't collect any further data after withdrawal. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your protected health information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, see http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Jeff Kullgren
Mailing Address: 2800 Plymouth Rd, 16-3, Ann Arbor, MI 48109-2800
Telephone: 734-845-3613

Study Coordinator: Eli Carter
Mailing Address: 2800 Plymouth Rd, 16-4, Ann Arbor, MI 48109-2800
Telephone: 734-232-0795

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

- This consent form will be saved to your online dashboard in W2H. From there, you can access and print copies of this consent form whenever you like.
- In addition to the copy you may download, your electronic signature will be stored securely, and the signed consent form may be entered into your regular University of Michigan medical record.

12. SIGNATURES

I understand the information on this form. I have had the opportunity to discuss this study, its risks and potential benefits, and my other choices with study staff. By agreeing to participate, I authorize the University of Michigan Health System and, if I enroll in the DPP, Omada Health, Inc. to disclose to the study team the health information about me described above. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I am able to download this form at the time I sign it and later, from my online dashboard. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Please select your choice and then click the NEXT button on the right to continue.

- ○ I agree with the paragraph above and want to participate
- ○ I do not want to participate

Please sign in the box below: