NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	i-Matter: Investigating an mHealth texting tool for embedding patient-reported data into diabetes management (Phase 2) S18-01044
Principal Investigator:	Antoinette Schoenthaler, EdD, FACH Department of Population Health NYU School of Medicine 180 Madison Ave. 7th Floor, New York, NY 10016 646-501-3434
Emergency Contact:	Jocelyn Cruz, MPH 646-501-3474

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

This study seeks to refine and test a technology-based patient-reported outcome (PRO) system called the Modern Journal System [MJS] DIABETES. MJS DIABETES is designed to include patients’ perspective of their disease and functional status into the management of type 2 diabetes in primary care practices.

3. How long will I be in the study? How many other people will be in the study?

This study has two phases that will be completed over the course of 5 years. **Phase 1** consists of the following: (1) focus groups to adapt MJS DIABETES to the needs of providers and patients with type 2 diabetes; (2) a workshop to integrate MJS DIABETES into the electronic health record system, the primary care practice and the lives of patients with type 2 diabetes; and (3) evaluate the usability of MJS DIABETES in order to optimize the tool’s performance and workflow integration. **Phase 2** consists of a practice-based randomized controlled trial designed to test the effect of MJS DIABETES versus usual care on reducing HbA1c levels, and changes in how well patients comply with their self-care behaviors, knowledge about

their diabetes, how sure they can manage their diabetes, and the quality of communication with their provider.

You are being asked to participate in **Phase 2** of this study because you are a patient with a diagnosis of type 2 diabetes receiving care at the NYU Langone Health (NYULH) Network of Family Health Centers (FHC) or Faculty Group Practices (FGPs). We expect to recruit up to 282 patient participants from the NYULH Network of FHCs and/or FGPs to participate in Phase 2 of the study.

4. What will I be asked to do in the study?

Below is a description of this phase of the study. This includes information about the goal of this phase of the study, and the research procedures.

Phase 2: The goal of phase 2 is to conduct a practice-based trial to evaluate how well a mobile phone intervention called MJS DIABETES works to reduce HbA1c levels in a sample of 282 patients with uncontrolled type 2 diabetes. We will also test the effect of MJS DIABETES on how well patients comply with their self-care behaviors, knowledge about their diabetes, how sure they can manage their diabetes, and the quality of communication with their provider. Patients that participated in Phase 1 are not eligible for Phase 2.

All study participants will complete:
- Screening: 10 minutes
- Consent/Baseline: 45 minutes
- Follow-up visits at 3, 6, 9: 30 minutes each visit
- Final study visit at 12 months: 60 minutes

If you agree to participate, then your first study visit will be today. During this visit, you will be asked to read the consent form, ask questions and sign the consent form. After signing the consent form, you will be asked questions your type 2 diabetes. If you have uncontrolled type 2 diabetes (defined as HbA1c >7%) and are willing to send and receive text messages, then you will be asked to continue with the study baseline visit.

At the baseline visit, you will be asked questions about yourself, questions about your diabetes and how you manage it, about any other medical conditions you may have, and about your conversations with your primary care provider. After completing these questions, you will be assigned, by chance, to one of two study groups: Group A or Group B. You have a 50% chance of being in either group.

If you are in Group A:
- You will receive standard treatment for your type 2 diabetes by your primary care provider.

If you are in Group B:
- You will receive and respond to about four daily text messages about your sleep quality, diet, your physical activity and taking your medication for 12 months.
- In addition, once each week, you will receive one text message asking if you have taken your diabetes medications.

- In addition to the text message questions, you will receive feedback about your responses and motivational messages.
- After the first 4 weeks, and every 4 weeks thereafter, you will receive a printed journal report that visualizes your responses to the text message questions and the medication taken question.
- During the course of the study, with your permission, we will audiotape a clinic visit with your primary care provider to understand how you use the text messages and journal report.
- At the end of the 12 months, you will also be asked to complete an exit interview to tell us about your experience in the study. This visit can be also conducted using the NYU Webex telephone conferencing system. Thus, you will have the option to complete it remotely via a Webex telephone conference call.

With your permission, we will audio record the clinic visit and the exit interview. The information collected from the focus group and feedback sessions will be labeled with a code number only. No names or other identifying information will be used or transcribed from the conversation during the analysis.

Do you give permission to audiotape the clinic visit and exit interview in Phase 2 (Please initial the appropriate answer)?
Yes _____ No_____

If you agree, you will be asked to sign a separate consent form to give permission to audiotape focus group and feedback sessions.

For both groups:

- You will receive phone calls from our study staff every 3 months.
- You will be asked to complete a final follow up visit at 12 months, which will take approximately 60 minutes and will be a repeat of all the initial visit measures.

5. Chart Review: With your permission, study staff will review your medical chart at baseline and 12 months. Information gathered from your medical chart will include: Information about your diabetes such as clinic HbA1c readings, duration of diabetes, evidence of target organ damage, changes in diagnosis, medical comorbidity, and your diabetes medications prescribed and their dosages. In addition, we will collect information on how often you visited the doctor and reasons for visits and use of other medications that are known to affect type 2 diabetes. The information collected from your chart will be labeled with a code number only. No names will be used. What are the possible risks or discomforts?

Though we expect the level of risk due to this intervention to be minimal, potential risks to the patient may include the following:

Risk of Study

Discomfort: Participants may feel uncomfortable answering some of the study questions. All participants will have the option to refuse to answer any questions they wish. There is also a minimal risk that being taped may make participants uncomfortable. However, Dr. Schoenthaler is taking many steps to ensure that they do not feel uncomfortable during the audiotaped sessions by being clear about the intent of the taped session. In addition, no names will be transcribed from the tapes to ensure that there is no

identifiable information during the coding process and included in the report. All tapes will be stored in a safe and secure place that only study personnel will be able to access.

Discomfort with Text Messages: You may not like receiving text messages once the study begins or feel uncomfortable with the content in the message. The research assistant will review the types of messages you will receive prior to beginning the study. You may choose to stop the messages either for a brief period or for the duration of the study and have the opportunity to stop receiving any message that may make you uncomfortable.

Violation of privacy: There is a potential risk to the participants concerning possible violation of the privacy, since text messages as well as audio-recordings of clinic visits and exit interviews will be used as a source of data. To mitigate these issues, we will enact the following safeguards: (1) all data will be de-identified and stored in a safe and secure place that only study personnel will be able to access; (2) all recorded sessions will be conducted in a private room in the FHC or FGP; and (3) we will encrypt all sensitive user data that is collected within the MJS platform. In addition, no personally identifying information will be collected through the MJS platform. We will also assist participants in setting up safeguards on their phone (e.g., setting up screen passwords) to ensure that no information is shared. If a participant is uncomfortable using their personal mobile phone, we will loan the individual a mobile phone for the duration of the study.

Because your survey responses and text messages will be used as a source of data for this study, there is a potential risk of a violation of your privacy. Text messages will be sent to your mobile phone that could identify you, if your phone is unguarded, as someone with a goal to increase a health behavior such as eating healthier. You are acknowledging that you are responsible for the message once it is received on your phone as well as the content of any text message you send via the SMS text message system. If you happen to misplace your phone, if someone views your text messages, or if it was stolen, the study team will not assume responsibility for the content that they had kept or stored on their phone. The text messages you receive will not identify you as someone who is taking part in a study and you have the option to choose your behavioral goal (e.g. physical activity). By enrolling in the study you are giving permission to a text messaging company, Mobile Health Interventions, to transmit your data using web-service and wireless communication companies to your mobile phone and a secure, password-protected database. Mobile Health Interventions cannot assure the security of information you provide while it is being transmitted over the internet or via wireless communication companies. The research assistant will also be sending the text messages from a computer with an Internet connection. Secure transmission of text messages via the Internet cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, or destroyed.

The research team is taking many steps to ensure that your private information is kept safe. All study visits will be conducted in a dedicated room at the respective site. Additionally, all data will be stored in a safe and secure place that only study personnel will be able to access. To reduce any potential violation of privacy through the transmission of text messages, the following additional safeguards will be put in place:

1. Text messages will not identify you as having a specific disease but rather focus on increasing cardiac health and improving overall behavioral health goals (such as taking medications, eating a diet low in saturated fat, increasing physical activity, or quitting smoking).
2. Text messages will not include personal identifying information such as your name.
3. You have the right to postpone your messages for 24 hours by replying STOP to any message.
4. While you are responsible for handling the content of the messages that are received and stored on your phone, as well any content you send, the messages are entered through a secure web-site and all

messages and the data you provide will be stored in a secure password-protected database on a computer that only research staff participating in the project will have authorization to access.

Physical risk: The physical risks of the studies are minimal and the potential risks have been outlined above. The clinical care of any given patient will be entirely handled by the patient's physician, and study participants will be made aware of this at the consent visit. Similarly, any medical problem that arises during study visits will be referred to the patient's clinician. As part of the process involved in obtaining written informed consent, all participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation. Furthermore, that such an action will in no way affect their treatment or future interactions with their health care provider. To ensure confidentiality, data will be associated with an individual participant only by an assigned identification number, the code for which will be kept in a locked drawer. Since traditional text messages may be viewed by a third party if seen on an individual's phone, we will follow the confidentiality practices of other messaging studies on sensitive topics to ensure maximum privacy. Specifically, participants will be instructed to change message settings to alert individuals that an SMS message has been received but do NOT display or preview any of the messages. This ensures that a third party cannot passively see the message on a participant's phone because no information is provided. Also, subjects will be advised to add a security code to their phone in which one must enter the security code to view a message. The potential benefits for subjects include improvements in medical compliance, lifestyle, cardiovascular risk factors, cardiovascular events and overall health.

Anxiety: There is a potential risk that participants may feel anxious during the audiotaped encounters. To mitigate this issue, participants will be reminded that the tapes are only for research purposes and will not influence their relationship with the FHC and/or FGP or their primary care provider. Moreover, participants will be reassured that the tapes will be saved in a secure and confidential database that only the study staff will have access to, and that have the right to ask that the tapes be deleted if they feel sensitive information was discussed during the encounter that they do not want the research team to hear. Patients will also be informed that they do not need to answer any questions that they are not comfortable with.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

There are no direct benefits to the participants in this study. However, results of this project may help to identify a method to improve care of patients with type 2 diabetes by improving patient-provider communication about patient-reported outcomes. Using technology to develop scalable and disseminable intervention models can help support patients with type 2 diabetes by improving adherence to self-care behaviors, reducing their cardiovascular risk profile, increasing their role as active participants in the management of their health, and potentially improving their diabetes control.

8. What other choices do I have if I do not participate?

The decision to participate in this study is up to you. You do not have to participate. Your decision will not affect your relationship with your FHC or FGP.

9. Will I be paid for being in this study?

Phase 2 Compensation: You will be paid $80 for your participation over the course of the 12 months. This is divided up as follows:

- **Baseline visit**: $20
- **3 month follow up visit:** $10
- **6 month follow up visit:** $10
- **9 month follow up visit:** $10
- **12 month follow up visit:** $30

10. Will I have to pay for anything?

There is no cost to you to participate in this study. The study is being sponsored by a grant from the Agency for Healthcare Research and Quality, and Merck & Co., Inc.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by the principal investigator or the study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. If you do

decide to stop participating, we ask that you contact Dr. Schoenthaler and let her know that you are withdrawing from the study. Dr. Schoenthaler's mailing address is 227 East 30th Street, Room 634, New York NY,10016. You will be told how to withdraw from the study.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

14. HIPAA Authorization.

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: The Agency for Healthcare Research and Quality, and Merck & Co., Inc.
- Rip Road Inc, the technology company developing the MJS DIABETES tool

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

_____
Subject Initials

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research

studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

17. Financial Disclosure

The NYU Langone Health maintains a financial disclosure process by which researchers must disclose any personal financial interest that may be related to the research. This study involves tools manufactured by Rip Road. One or more of the investigators involved in this study has or has had a financial relationship with Rip Road for work or an activity that is not part of this study. This may include consulting, advisory boards, equity, or writing reports. If you would like more information, please ask the researchers, the study coordinator, or the CIMU at 212-404-4079.

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

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Research Subject Audio Use Consent Form:

Title of Study:	i-Matter: Investigating an mHealth texting tool for embedding patient-reported data into diabetes management (Phase 2) S18-01044
Principal Investigator:	Antoinette Schoenthaler, EdD, FAACH Department of Population Health NYU School of Medicine 180 Madison Ave. 7th Floor, New York, NY 10016 646-501-3434
Emergency Contact:	Jocelyn Cruz, MPH 646-501-3474

Use of Study Audio/Video Recordings:

Each study session, including the clinic visit and the exit interviews, will be audio-taped. These recordings will be labeled only with a code number, which will be kept in the Investigator's files. The tapes will be completed to document how patients used MJS DIABETES with their providers and their experience using the tool at the end of phase 2. All recordings will be conducted in a private dedicated room at the primary care clinic.

If you agree to participate in this study, your signature on this consent form gives the researchers permission to make and retain the audio recordings for this study. You have the right to review the recordings and to request that all or any portion of the recording be erased.

When you sign this form, you are agreeing to consent for the use of the A/V recordings for study purposes only. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date